CLOSED, EGT, MEDREQ, STAYED

# U.S. District Court
## Southern District of Florida (Ft. Lauderdale)
## CIVIL DOCKET FOR CASE #: 0:07-cv-61800-FAM

Sanofi-Aventis et al v. Apotex, Inc. et al
Assigned to: Chief Judge Federico A. Moreno
Referred to: Magistrate Judge Edwin G. Torres
Cause: 35:0271 Patent Infringement

Date Filed: 12/10/2007
Date Terminated: 04/29/2008
Jury Demand: Defendant
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Sanofi-Aventis** represented by **Alfred John Saikali**
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332
305-358-5171
Fax: 305-358-7470
Email: asaikali@shb.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Alexis Gorton**
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
212-446-4800
Email: agorton@kirkland.com
*ATTORNEY TO BE NOTICED*

**Gerald J. Flattmann, Jr.**
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
212-446-4800
Email: gflattmann@kirkland.com
*ATTORNEY TO BE NOTICED*

**John M. Desmarais**
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
212-446-4800
Fax: 446-4900

Email: jdesmarais@kirkland.com
*ATTORNEY TO BE NOTICED*

**William T. Vuk**
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
212-446-4800
Email: wvuk@kirkland.com
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Sanofi-Aventis, U.S. LLC** represented by **Alfred John Saikali**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Alexis Gorton**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Gerald J. Flattmann, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**John M. Desmarais**
(See above for address)
*ATTORNEY TO BE NOTICED*

**William T. Vuk**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Apotex, Inc.** represented by **Jennifer Rae Coberly**
Zuckerman Spaeder Taylor & Evans
201 S Biscayne Boulevard
Suite 900
Miami, FL 33131
305-358-5000
Fax: 579-9749
Email: jcoberly@zuckerman.com
*TERMINATED: 04/09/2008*
*LEAD ATTORNEY*

**Stephen Jay Bronis**
Carlton Fields, P.A.
100 SE 2nd Street

Suite 4000
Miami, FL 33131
305-530-0050
Fax: 305-530-0055
Email: sbronis@carltonfields.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James P. White**
Welsh & Katz
120 S Riverside Plaza
22nd Floor
Chicago, IL 60606
312-655-1500
Fax: 312-655-1501
Email: jpwhite@welshkatz.com
*ATTORNEY TO BE NOTICED*

**Laurel White Marc-Charles**
Richard & Richard
825 Brickell Bay Drive
Suite 1748 Tower III
Miami, FL 33131-2961
305-374-6688
Fax: 374-0384
Email: Laurel@richardandrichard.com
*ATTORNEY TO BE NOTICED*

**Phillip D. Segrest, Jr.**
Welsh & Katz
120 S Riverside Plaza
22nd Floor
Chicago, IL 60606
312-655-1500
Fax: 312-655-1501
Email: pdsegrest@welshkatz.com
*ATTORNEY TO BE NOTICED*

**Robert Burton Breisblatt**
Katten Muchin Rosenman LLP
525 West Monroe Street
Chicago, IL 60661-3693
312-902-5200
Fax: 312-902-1061
Email:
Robert.Breisblatt@kattenlaw.com
*TERMINATED: 05/02/2008*
*ATTORNEY TO BE NOTICED*

**Sherry L. Rollo**

Welsh & Katz
120 S Riverside Plaza
22nd Floor
Chicago, IL 60606
312-655-1500
Fax: 312-655-1501
Email: srollo@welshkatz.com
*ATTORNEY TO BE NOTICED*

**Steven E. Feldman**
Welsh & Katz
120 S Riverside Plaza
22nd Floor
Chicago, IL 60606
312-655-1500
Fax: 312-655-1501
Email: sefeldman@welshkatz.com
*ATTORNEY TO BE NOTICED*

**Walter J. Tache**
Carlton Fields
4000 International Place
100 S.E. Second Street
Miami, FL 33131-2114
305-530-0050
Fax: 530-0055
Email: wtache@carltonfields.com
*TERMINATED: 04/09/2008*
*ATTORNEY TO BE NOTICED*

**Defendant**

**Apotex Corp.** represented by

**Jennifer Rae Coberly**
(See above for address)
*TERMINATED: 04/09/2008*
*LEAD ATTORNEY*

**Stephen Jay Bronis**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James P. White**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Laurel White Marc-Charles**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Phillip D. Segrest, Jr.**

(See above for address)
*ATTORNEY TO BE NOTICED*

**Robert Burton Breisblatt**
(See above for address)
*TERMINATED: 05/02/2008*
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**Sherry L. Rollo**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Steven E. Feldman**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Walter J. Tache**
(See above for address)
*TERMINATED: 04/09/2008*
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Apotex, Inc.** represented by **Jennifer Rae Coberly**
(See above for address)
*TERMINATED: 04/09/2008*
*LEAD ATTORNEY*

**Laurel White Marc-Charles**
(See above for address)
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**Walter J. Tache**
(See above for address)
*TERMINATED: 04/09/2008*
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Alexis Gorton**
(See above for address)

*ATTORNEY TO BE NOTICED*

**Alfred John Saikali**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Gerald J. Flattmann, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**John M. Desmarais**
(See above for address)
*ATTORNEY TO BE NOTICED*

**William T. Vuk**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis, U.S. LLC** represented by **Alfred John Saikali**
(See above for address)
*LEAD ATTORNEY*
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**Alexis Gorton**
(See above for address)
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*TERMINATED: 04/09/2008*
*ATTORNEY TO BE NOTICED*

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**Apotex Corp.** represented by **Jennifer Rae Coberly**
(See above for address)
*TERMINATED: 04/09/2008*
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(See above for address)
*TERMINATED: 04/09/2008*
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Alfred John Saikali**
(See above for address)
*LEAD ATTORNEY*
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(See above for address)
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**Gerald J. Flattmann, Jr.**
(See above for address)
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(See above for address)
*ATTORNEY TO BE NOTICED*

**William T. Vuk**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis, U.S. LLC** represented by **Alfred John Saikali**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Alexis Gorton**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Gerald J. Flattmann, Jr.**
(See above for address)

*ATTORNEY TO BE NOTICED*

**John M. Desmarais**
(See above for address)
*ATTORNEY TO BE NOTICED*

**William T. Vuk**
(See above for address)
*ATTORNEY TO BE NOTICED*

| Date Filed | # | Docket Text |
|---|---|---|
| 12/10/2007 | 1 | COMPLAINT against Apotex, Inc., Apotex Corp. Filing fee $ 350. Receipt#: 971492, filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (dj) (Entered: 12/11/2007) |
| 12/28/2007 | 2 | ANSWER to Complaint with Jury Demand, COUNTERCLAIM *and Affirmative Defenses* against all plaintiffs by Apotex, Inc., Apotex Corp.. (Coberly, Jennifer) (Entered: 12/28/2007) |
| 01/02/2008 | 3 | ANSWER to Complaint with Jury Demand, Amended COUNTERCLAIM against all plaintiffs by Apotex, Inc., Apotex Corp.. (Coberly, Jennifer) (Entered: 01/02/2008) |
| 01/03/2008 | 4 | SCHEDULING ORDER; ORDER REFERRING CASE to Mediation. 15 days to appoint mediator. Jury Trial set for 5/27/2008 09:00 AM in Miami Division before Chief Judge Federico A. Moreno.Signed by Judge Federico A. Moreno on 1/3/2008.(lc1) (Entered: 01/03/2008) |
| 01/04/2008 | | Pursuant to 4 , Set/Reset Scheduling Order Deadlines: Calendar Call set for 5/20/2008 02:00 PM in Miami Division before Chief Judge Federico A. Moreno. Amended Pleadings due by 1/31/2008. Discovery due by 3/27/2008. Joinder of Parties due by 1/31/2008. Mediation Deadline 4/28/2008. Motions due by 4/28/2008. Pretrial Stipulation due by 5/13/2008. (dg) (Entered: 01/04/2008) |
| 01/08/2008 | 5 | Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis. Responses due by 1/23/2008 (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 01/08/2008) |
| 01/08/2008 | 6 | AFFIDAVIT signed by : William Vuk. re 5 Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis. (Attachments: # 1 Exhibit 1# 2 Exhibit 2# 3 Exhibit 3# 4 Exhibit 4# 5 Exhibit 5# 6 Exhibit 6# 7 Exhibit 7# 8 Exhibit 8# 9 Exhibit 9# 10 Exhibit 10# 11 Exhibit 11# 12 Exhibit 12# 13 Exhibit 13# 14 Exhibit 14# 15 Exhibit 15# 16 Exhibit 16# 17 Exhibit 17# 18 Exhibit 18# 19 Exhibit 19)(Saikali, Alfred) (Entered: 01/08/2008) |
| 01/08/2008 | 7 | Plaintiff's MOTION for Hearing re 5 Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis. (Saikali, Alfred) (Entered: 01/08/2008) |

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| 01/08/2008 | 8 | Plaintiff's MOTION to Stay *Certain Deadlines and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis. Responses due by 1/23/2008 (Attachments: # 1 Text of Proposed Order Proposed Order) (Saikali, Alfred) (Entered: 01/08/2008) |
| 01/09/2008 | 9 | NOTICE of Instruction to Filer: re 5 Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* filed by Sanofi-Aventis, ERROR: Motion with Multiple Reliefs Filed as One Relief; Instruction to Filer: In the future please select all applicable Reliefs (You can select multiple reliefs by using the Ctrl key). This is for *FUTURE* reference only, it is not necessary to refile this document. (gp) (Entered: 01/09/2008) |
| 01/09/2008 | 10 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing for Gerald J. Flattmann, Jr., Filing Fee $75, Receipt #972917. (cw) (Entered: 01/10/2008) |
| 01/15/2008 | 11 | AFFIDAVIT signed by : William Vuk. *in Support of Plaintiffs' Motion to Continue Pretrial Deadlines and Trial* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit Exhibit 1# 2 Exhibit Exhibit 2# 3 Exhibit Exhibit 3# 4 Exhibit Exhibit 4)(Saikali, Alfred) (Entered: 01/15/2008) |
| 01/15/2008 | 12 | Plaintiff's MOTION to Continue *Pretrial Deadlines and Trial and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 1/30/2008 (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 01/15/2008) |
| 01/15/2008 | 13 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings for Steven E. Feldman, Filing Fee $75, Receipt #973233. (cw) (Entered: 01/16/2008) |
| 01/15/2008 | 14 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing for Alexis Gorton, Filing Fee $75, Receipt #973247. (cw) (Entered: 01/16/2008) |
| 01/15/2008 | 15 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings for Sherry L. Rollo, Filing Fee $75, Receipt #973233. (cw) (Entered: 01/16/2008) |
| 01/15/2008 | 16 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing for William T. Vuk, Filing Fee $75, Receipt #973246. (cw) (Entered: 01/16/2008) |
| 01/17/2008 | 17 | ORDER granting 10 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings for Gerald J. Flattmann, Jr. Signed by Judge Federico A. Moreno on 1/17/2008. (lc1) (Entered: 01/17/2008) |
| 01/17/2008 | 18 | *Plaintiffs'* ANSWER to Counterclaim *(Amended) of Apotex Inc. and* |

| | | |
|---|---|---|
| | | *Apotex Corp.* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC.(Saikali, Alfred) (Entered: 01/17/2008) |
| 01/18/2008 | 19 | ENDORSED ORDER granting 15 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings. This is a paperless order. Signed by Judge Federico A. Moreno on 1/18/2008. (lc1) (Entered: 01/18/2008) |
| 01/18/2008 | 20 | ENDORSED ORDER granting 14 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings. This is a paperless order. Signed by Judge Federico A. Moreno on 1/18/2008. (lc1) (Entered: 01/18/2008) |
| 01/18/2008 | 21 | ENDORSED ORDER granting 13 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings. This is a paperless order. Signed by Judge Federico A. Moreno on 1/18/2008. (lc1) (Entered: 01/18/2008) |
| 01/18/2008 | 22 | ENDORSED ORDER granting 16 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings. Signed by Judge Federico A. Moreno on 1/18/2008. (lc1) (Entered: 01/18/2008) |
| 01/22/2008 | 23 | ORDER granting 12 Motion to Continue and Revising Pretrial Deadlines. The trial is continued from May 27, 2008 to October 6, 2008. The calendar call is continued to Tuesday, September 30, 2008. Signed by Judge Federico A. Moreno on 1/22/2008. (lc1) (Entered: 01/22/2008) |
| 01/22/2008 | | Set Deadlines/Hearings per Order at DE 23 : Discovery due by 8/6/2008. Pretrial Stipulation due by 9/23/2008. Calendar Call set for 9/30/2008 02:00 PM before Chief Judge Federico A. Moreno. Jury Trial set for 10/6/2008 09:00 AM before Chief Judge Federico A. Moreno. (bb) (Entered: 01/24/2008) |
| 01/24/2008 | 24 | NOTICE /the parties have exchanged proposed mediators by Sanofi-Aventis (tb) (Entered: 01/25/2008) |
| 01/25/2008 | 25 | MOTION for Protective Order *and Incorporated Memorandum of Law* by Apotex, Inc., Apotex Corp.. (Attachments: # 1 Text of Proposed Order)(Coberly, Jennifer) (Entered: 01/25/2008) |
| 01/28/2008 | 26 | MEMORANDUM in Opposition re 5 Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* filed by Apotex, Inc., Apotex Corp.. (Attachments: # 1 Exhibit # 2 Exhibit # 3 Exhibit # 4 Exhibit)(Coberly, Jennifer) (Entered: 01/28/2008) |
| 01/31/2008 | 27 | ORDER REFERRING MOTION to Magistrate Judge Andrea M. Simonton 25 MOTION for Protective Order *and Incorporated Memorandum of Law* filed by Apotex, Inc.,, Apotex Corp., Signed by Judge Federico A. Moreno on 1/31/2008.(lc1) (Entered: 01/31/2008) |
| 01/31/2008 | 28 | ORDER of Correction re 27 Order Referring Motion.Signed by Judge Federico A. Moreno on 1/31/2008.(lc1) (Entered: 01/31/2008) |

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|---|---|---|
| 01/31/2008 | 29 | Defendant's MOTION for Extension of Time to File *Joint Scheduling Report* by Apotex, Inc., Apotex Corp.. (Attachments: # 1 Exhibit Apotex Scheduling Report)(Tache, Walter) (Entered: 01/31/2008) |
| 01/31/2008 | 30 | Plaintiff's MOTION for Leave to File *Scheduling Report and Proposed Scheduling Order* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit 1# 2 Exhibit 2# 3 Text of Proposed Order 3)(Saikali, Alfred) (Entered: 02/01/2008) |
| 02/07/2008 | 31 | AFFIDAVIT signed by : Alexis Gorton. *in Support of Plaintiffs' Emergency Motion to Stay Pending JPML Decision* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit 1# 2 Exhibit 2# 3 Exhibit 3# 4 Exhibit 4# 5 Exhibit 5# 6 Exhibit 6# 7 Exhibit 7# 8 Exhibit 8# 9 Exhibit 9# 10 Exhibit 10# 11 Exhibit 11# 12 Exhibit 12# 13 Exhibit 13)(Saikali, Alfred) (Entered: 02/07/2008) |
| 02/07/2008 | 32 | Emergency MOTION to Stay re 31 Affidavit, *Pending JPML Decision and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 2/22/2008 (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 02/07/2008) |
| 02/07/2008 | 33 | Plaintiff's MOTION for Hearing re 32 Emergency MOTION to Stay re 31 Affidavit, *Pending JPML Decision and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/07/2008) |
| 02/07/2008 | 34 | REPLY to Response to Motion re 5 Plaintiff's MOTION to Stay *and Transfer and Supporting Memorandum of Law* filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/07/2008) |
| 02/07/2008 | 35 | AFFIDAVIT signed by : Alexis Gorton. re 34 Reply to Response to Motion, *in Support of Motion to Transfer or Stay* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit 20# 2 Exhibit 21# 3 Exhibit 22# 4 Exhibit 23)(Saikali, Alfred) (Entered: 02/07/2008) |
| 02/07/2008 | 38 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing for John M. Desmarais, Filing Fee $75, Receipt #974606. (cw) (Entered: 02/11/2008) |
| 02/08/2008 | 36 | ORDER denying as moot 29 Motion for Extension of Time to File, denying as moot 30 Motion for Leave to File. Signed by Judge Federico A. Moreno on 02/08/2008. (lc1) (Entered: 02/08/2008) |
| 02/08/2008 | 37 | NOTICE of Instruction to Filer: re 32 Emergency MOTION to Stay re 31 |

| | | |
|---|---|---|
| | | Affidavit, *Pending JPML Decision and Supporting Memorandum of Law* filed by Sanofi-Aventis, U.S. LLC, Sanofi-Aventis. Regarding Emergency Motions/Requests for Emergency Hearing. Pursuant to 5F in the Administrative Procedures, because the matters require the immediate attention of the Judge, the Original Emergency Motion and a Copy for the Judge must be filed in conventional paper format in the division where the Judge is chambered. This is for *FUTURE* reference only, it is not necessary to refile this document. (gp) (Entered: 02/08/2008) |
| 02/11/2008 | 39 | MEMORANDUM in Opposition re 25 MOTION for Protective Order *and Incorporated Memorandum of Law* filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/11/2008) |
| 02/11/2008 | 40 | AFFIDAVIT signed by : Alexis Gorton. re 39 Memorandum in Opposition, *To Defendants' Motion for Protective Order* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit Exhibit 1# 2 Exhibit Exhibit 2# 3 Exhibit Exhibit 3# 4 Exhibit Exhibit 4# 5 Exhibit Exhibit 5# 6 Exhibit Exhibit 6)(Saikali, Alfred) (Entered: 02/11/2008) |
| 02/13/2008 | 41 | RESPONSE in Opposition re 32 Emergency MOTION to Stay re 31 Affidavit, *Pending JPML Decision and Supporting Memorandum of Law* filed by Apotex Corp., Apotex, Inc.. (Coberly, Jennifer) Modified on 2/14/2008 (ls). [Filers modified by Clerk] (Entered: 02/13/2008) |
| 02/14/2008 | 42 | ORDER granting 38 Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings. Signed by Judge Federico A. Moreno on 02/14/2008. (lc1) (Entered: 02/14/2008) |
| 02/14/2008 | 43 | REPLY to Response to Motion re 32 Emergency MOTION to Stay re 31 Affidavit, *Pending JPML Decision and Supporting Memorandum of Law* filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/14/2008) |
| 02/14/2008 | 44 | Plaintiff's MOTION for Protective Order *and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Text of Proposed Order)(Saikali, Alfred) (Entered: 02/14/2008) |
| 02/14/2008 | 45 | AFFIDAVIT signed by : William Vuk. re 44 Plaintiff's MOTION for Protective Order *and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit 1# 2 Exhibit 2# 3 Exhibit 3)(Saikali, Alfred) (Entered: 02/14/2008) |
| 02/14/2008 | 46 | Plaintiff's MOTION for Hearing re 44 Plaintiff's MOTION for Protective |

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| | | Order *and Supporting Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/14/2008) |
| 02/15/2008 | 47 | REPLY to Response to Motion re 25 MOTION for Protective Order *and Incorporated Memorandum of Law Plaintiffs' Opposition to Motion for Protective Order* filed by Apotex, Inc., Apotex Corp.. (Coberly, Jennifer) (Entered: 02/15/2008) |
| 02/19/2008 | 48 | ORDER denying 32 Emergency Motion to Stay, denying 33 Motion for Hearing. Signed by Judge Federico A. Moreno on 02-18-2008. (lc1) (Entered: 02/19/2008) |
| 02/19/2008 | 49 | Corporate Disclosure Statement by Apotex, Inc., Apotex Corp.. (Coberly, Jennifer) (Entered: 02/19/2008) |
| 02/20/2008 | 50 | NOTICE of Attorney Appearance by Robert Burton Breisblatt on behalf of all defendants (Breisblatt, Robert) (Entered: 02/20/2008) |
| 02/20/2008 | 51 | ORDER granting Defendants' 25 Motion for Protective Order. Signed by Magistrate Judge Andrea M. Simonton on 2/20/08. (js) (Entered: 02/20/2008) |
| 02/20/2008 | 52 | Corporate Disclosure Statement by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 02/20/2008) |
| 02/21/2008 | 53 | AMENDED DOCUMENT by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Amendment to 52 Corporate Disclosure Statement/Certificate of Interested Parties. (Saikali, Alfred) (Entered: 02/21/2008) |
| 02/26/2008 | 54 | Plaintiff's MOTION to Compel *Defendants to Comply with Court's 2/20/08 Order , and Incorporated Memorandum of Law*, by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 3/11/2008 (Attachments: # 1 Text of Proposed Order Proposed Order) (Saikali, Alfred) (Entered: 02/26/2008) |
| 02/26/2008 | 55 | AFFIDAVIT signed by : William Vuk. re 54 Plaintiff's MOTION to Compel *Defendants to Comply with Court's 2/20/08 Order , and Incorporated Memorandum of Law*, by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit Exhibit 1# 2 Exhibit Exhibit 2# 3 Exhibit Exhibit 3# 4 Exhibit Exhibit 4# 5 Exhibit Exhibit 5# 6 Exhibit Exhibit 6)(Saikali, Alfred) (Entered: 02/26/2008) |
| 02/27/2008 | 56 | Plaintiff's MOTION for Hearing *(Status Conference) and Incorporated Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 02/27/2008) |
| 02/27/2008 | 57 | AFFIDAVIT signed by : Alexis Gorton. re 56 Plaintiff's MOTION for Hearing *(Status Conference) and Incorporated Memorandum of Law* by |

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| | | Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit Exhibit 1)(Saikali, Alfred) (Entered: 02/27/2008) |
| 02/28/2008 | 58 | Plaintiff's MOTION To Withdraw in Part Plaintiffs' Motion to Compel Defendants to Comply with the Court's 2/20/08 Order re 54 Plaintiff's MOTION to Compel *Defendants to Comply with Court's 2/20/08 Order , and Incorporated Memorandum of Law*, by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 02/28/2008) |
| 02/28/2008 | 59 | Notice of Supplemental Authority re 56 Plaintiff's MOTION for Hearing *(Status Conference) and Incorporated Memorandum of Law* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC (Attachments: # 1 Exhibit Exhibit 1)(Saikali, Alfred) (Entered: 02/28/2008) |
| 02/29/2008 | 60 | MEMORANDUM in Opposition re 44 Plaintiff's MOTION for Protective Order *and Supporting Memorandum of Law to Plaintiffs' Motion for Protective Order to Avoid Having to Respond to Outstanding Discovery* filed by Apotex, Inc.. (Attachments: # 1 Exhibit A # 2Exhibit B)(Davidson, Matthew) Modified text on 3/3/2008 (tp). (Entered: 02/29/2008) |
| 02/29/2008 | 61 | TEXT ORDER denying as moot 54 Motion to Compel, granting 58 Motion to withdraw motion to compel and for extension of time file joint proposed protective order. On or before March 10, 2008, the parties shall file a proposed Protective Order in accordance with this Court's February 20, 2008 Order. This is a paperless Order.Signed by Magistrate Judge Andrea M. Simonton on 2/29/08. (AMS) (Entered: 02/29/2008) |
| 03/06/2008 | 63 | Courtesy Copy of MDL #1941 Reply Brief in Further Support of Plaintiff's Motion to Transfer and Consolidate for Pretrial Proceedings. (SDFL Case #07cv61800-FAM) (Attachments: #(1) Exhibits #1-#9 and Certificate of Service) (de) (Entered: 03/10/2008) |
| 03/07/2008 | 62 | RESPONSE to Motion re 56 Plaintiff's MOTION for Hearing *(Status Conference) and Incorporated Memorandum of Law* filed by Apotex, Inc., Apotex Corp.. Replies due by 3/14/2008. (Attachments: # 1 Exhibit A)(Coberly, Jennifer) (Entered: 03/07/2008) |
| 03/10/2008 | 64 | REPLY to Response to Motion re 44 Plaintiff's MOTION for Protective Order *and Supporting Memorandum of Law* filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 03/10/2008) |
| 03/10/2008 | 65 | AFFIDAVIT signed by : William Vuk. re 64 Reply to Response to Motion, by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit 4# 2 Exhibit 5# 3 Exhibit 6)(Saikali, Alfred) |

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| | | (Entered: 03/10/2008) |
| 03/10/2008 | 66 | Joint MOTION for Extension of Time to File *Protective Order* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 03/10/2008) |
| 03/10/2008 | 67 | AMENDED DOCUMENT by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Amendment to 66 Joint MOTION for Extension of Time to File *Protective Order (Amended Proposed Order)*. (Saikali, Alfred) (Entered: 03/10/2008) |
| 03/11/2008 | 68 | NOTICE of Instruction to Filer: re 67 Amended Document, filed by Sanofi-Aventis, U.S. LLC, Sanofi-Aventis. Error: Proposed Order/Exhibit Docketed as Main Document; Instruction to Filer=Proposed Orders, unless otherwise directed by a Judge, shall be filed initially as an attachment to a motion, notice, or other filing. Please refer to the CM/ECF Administrative Procedures. This is for *FUTURE* reference only. It is not necessary to refile this document. (gp) (Entered: 03/11/2008) |
| 03/11/2008 | 69 | TEXT ORDER granting 66 Joint Motion for Enlargement of Time to File Proposed Protective Order. On or before March 12, 2008, the parties shall file a Proposed Protective Order in accordance with this Court's February 20, 2008 Order. This is a paperless Order. Signed by Magistrate Judge Andrea M. Simonton on 3/11/08. (js) (Entered: 03/11/2008) |
| 03/12/2008 | 70 | NOTICE of Compliance *with Order GRanting Defendants' Motion for Entry of a Protective Order* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC re 51 Order on Motion for Protective Order (Attachments: # 1 Exhibit 1 (Protective Order))(Saikali, Alfred) (Entered: 03/12/2008) |
| 03/12/2008 | 71 | Statement of: Apotex Defendants' Position on Disputed Paragraph 12 of the Protective Order Pertaining to Materials Believed to be Covered by the EU Privacy Directive by Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp.. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Breisblatt, Robert) (Entered: 03/13/2008) |
| 03/17/2008 | 72 | ORDER Regarding Protective Order. Signed by Magistrate Judge Andrea M. Simonton on 3/17/08.(js) (Entered: 03/17/2008) |
| 03/17/2008 | 73 | REPLY to Response to Motion re 56 Plaintiff's MOTION for Hearing *(Status Conference) and Incorporated Memorandum of Law* filed by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Saikali, Alfred) (Entered: 03/17/2008) |
| 03/17/2008 | 74 | AFFIDAVIT signed by : Alexis Gorton. re 73 Reply to Response to Motion, *for Status Conference*, by Sanofi-Aventis, Sanofi-Aventis, U.S. |

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| | | LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit Exhibit 1# 2 Exhibit Exhibit 2# 3 Exhibit Exhibit 3)(Saikali, Alfred) (Entered: 03/17/2008) |
| 03/20/2008 | 75 | NOTICE of Compliance *with Order Regarding Protective Order Dated March 17, 2008* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC re 72 Order (Attachments: # 1 Text of Proposed Order Exhibit 1) (Saikali, Alfred) (Entered: 03/20/2008) |
| 03/21/2008 | 76 | PROTECTIVE ORDER signed by Magistrate Judge Andrea M. Simonton on 3/21/08.(js) (Entered: 03/21/2008) |
| 03/24/2008 | 77 | Courtesy Copy of MDL #1941 Notice of Related Action. (SDFL Case #07cv61800-FAM) (Attachments: # 1 Complaint, Civil Cover Sheet and Docket Sheet for District of Delaware) (de) (Entered: 03/24/2008) |
| 03/25/2008 | 78 | Defendant's MOTION to Compel *Discovery Responses and Incorporated Memorandum of Law* by Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp.. Responses due by 4/8/2008 (Attachments: # 1 Exhibit A)(Breisblatt, Robert) (Entered: 03/25/2008) |
| 03/25/2008 | 79 | NOTICE of Compliance by Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp., Apotex, Inc., Apotex Corp. re 78 Defendant's MOTION to Compel *Discovery Responses and Incorporated Memorandum of Law* filed by Apotex, Inc.,, Apotex Corp., (Breisblatt, Robert) (Entered: 03/25/2008) |
| 03/27/2008 | 80 | MOTION to Withdraw as Attorney *Stephen Bronis, Jennifer Coberly, Walter Tache and the Law Firm of Zuckerman Spaeder LLP* by Apotex, Inc., Apotex Corp.. Responses due by 4/10/2008 (Attachments: # 1 Text of Proposed Order)(Coberly, Jennifer) (Entered: 03/27/2008) |
| 03/27/2008 | 81 | Notice of Pendency of Other Action by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC (Attachments: # 1 Exhibit 1)(Saikali, Alfred) (Entered: 03/27/2008) |
| 04/04/2008 | 82 | NOTICE of Attorney Appearance by Laurel White Marc-Charles on behalf of all defendants (Marc-Charles, Laurel) (Entered: 04/04/2008) |
| 04/07/2008 | 83 | ORDER granting 80 Motion to Withdraw as Attorney. Attorneys Walter J. Tache; Stephen Jay Bronis and Jennifer Rae Coberly terminated.Signed by Judge Federico A. Moreno on 04/07/2008. (lc1) (Entered: 04/07/2008) |
| 04/08/2008 | 84 | Case Reassignment of Paired Magistrate Judge pursuant to Administrative Order 2008-09 to Magistrate Judge Edwin G. Torres Judge Andrea M. Simonton no longer assigned to the case. (ra) (Entered: 04/08/2008) |
| 04/09/2008 | | Attorney Jennifer Rae Coberly and Walter J. Tache terminated. Sent terminated attorney(s) instructions for tracking future case activity. (lk) (Entered: 04/09/2008) |

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| 04/10/2008 | 85 | Unopposed MOTION for Extension of Time to File *Opposition to Defendants' Motion to Compel Discovery Responses* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Saikali, Alfred) (Entered: 04/10/2008) |
| 04/11/2008 | 86 | ORDER granting 85 Plaintiff's Unopposed Motion for Four-Day Enlargement of Time. Plaintiff shall file a response by no later than April 15, 2008. Signed by Judge Federico A. Moreno on 4/11/2008. (lc3) (Entered: 04/11/2008) |
| 04/14/2008 | 87 | ORDER STRIKING CASE FROM TRIAL CALENDAR. Signed by Judge Federico A. Moreno on 04/11/2008. (lc1) (Entered: 04/14/2008) |
| 04/15/2008 | 88 | Sealed Document. (vjk) (Entered: 04/16/2008) |
| 04/15/2008 | 89 | Sealed Document. (vjk) (Entered: 04/16/2008) |
| 04/15/2008 | 90 | Sealed Document. (vjk) (Entered: 04/16/2008) |
| 04/22/2008 | 91 | Unopposed MOTION to Continue *Mediation Deadline* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 5/6/2008 (Attachments: # 1 Text of Proposed Order Proposed Order) (Saikali, Alfred) (Entered: 04/22/2008) |
| 04/22/2008 | 92 | Unopposed MOTION to Continue *Mediation Deadline* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 5/6/2008 (Attachments: # 1 Text of Proposed Order)(Saikali, Alfred) (Entered: 04/22/2008) |
| 04/23/2008 | 93 | NOTICE of Striking *Document From Court Docket, Docket Entry 91 and [91-2] by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC (Saikali, Alfred) Modified on 4/28/2008 (lk). (Entered: 04/23/2008)* |
| 04/23/2008 | 94 | ORDER DENYING PLAINTIFFS' MOTION TO FILE UNDER SEAL. Signed by Judge Federico A. Moreno on 04/21/2008.(lc1) (Entered: 04/23/2008) |
| 04/23/2008 | 96 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings for James P. White, Filing Fee $75, Receipt #979080. (cw) (Entered: 04/24/2008) |
| 04/23/2008 | 97 | MOTION for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings for Phillip D. Segrest, Jr., Filing Fee $75, Receipt #979079. (cw) (Entered: 04/24/2008) |
| 04/24/2008 | 95 | Plaintiff's MOTION for clarification 94 Order *Denying Plaintiffs' Motion to File Under Seal* by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC, Sanofi-Aventis, Sanofi-Aventis, U.S. LLC. Responses due by 5/8/2008 (Saikali, Alfred) (Entered: 04/24/2008) |
| 04/28/2008 | 98 | NOTICE of Docket Correction and Instruction to Filer: re 93 Notice of |

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| | | Striking filed by Sanofi-Aventis, U.S. LLC,, Sanofi-Aventis, Error: NO Document Link; Correction=Document Relinked To DE 91 . Instruction to Filer=In the future please link the Document to the proper entry; (lk) (Entered: 04/28/2008) |
| 04/28/2008 | 99 | MOTION to Withdraw as Attorney *and to Substitute New Lead Counsel.* by Apotex, Inc., Apotex Corp.. Responses due by 5/12/2008 (Breisblatt, Robert) (Entered: 04/28/2008) |
| 04/29/2008 | 100 | ORDER RECONSIDERING ORDER DENYING EMERGENCY MOTION TO STAY, CLOSING CASE FOR STATISTICAL PURPOSES, AND PLACING MATTER IN CIVIL SUSPENSE FILE. Signed by Judge Federico A. Moreno on 04/28/2008.(lc1) (Entered: 04/29/2008) |
| 05/01/2008 | 101 | ORDER GRANTING MOTIONS FOR LIMITED APPEARANCE [96,97]. Signed by Judge Federico A. Moreno on 04/30/2008.(lc1) (Entered: 05/01/2008) |
| 05/01/2008 | 102 | ORDER GRANTING MOTION TO WITHDRAW AND TO SUBSTITUTE NEW LEAD COUNSEL. Signed by Judge Federico A. Moreno on 04/30/2008.(lc1) (Entered: 05/01/2008) |
| 05/02/2008 | | Attorney Robert Burton Breisblatt terminated per 102 ; Sent terminated attorney instructions for tracking future case activity. (nm) (Entered: 05/02/2008) |
| 06/10/2008 | 103 | NOTICE by Sanofi-Aventis, Sanofi-Aventis, U.S. LLC re 100 Order Staying Case *(Notice of JPML Decision)* (Attachments: # 1 Exhibit A) (Saikali, Alfred) (Entered: 06/10/2008) |
| 06/11/2008 | 104 | FINAL TRANSFER ORDER and ORDER CLOSING CASE. Signed by Chief Judge Federico A. Moreno on 06/10/2008. (lc1) (Entered: 06/11/2008) |
| 06/16/2008 | 105 | TRANSFER ORDER (Dated 06/09/2008) from Judicial Panel on Multidistrict Litigation transferring case to the District of Delaware re: MDL # 1941 for consolidated pretrial proceedings pursuant to 28 USC 1407 and assigned to Judge Gregory M. Sleet. (Signed by John G. Heyburn, II, Chairman) (de) (Entered: 06/16/2008) |
| 06/17/2008 | 106 | TRANSFER ORDER (Dated 06/09/2008) from Judicial Panel on Multidistrict Litigation transferring case to the District of Delaware re: MDL # 1941 for consolidated pretrial proceedings pursuant to 28 USC 1407 and assigned to Judge Gregory M. Sleet. (Signed by John G. Heyburn, II, Chairman) (de) (Entered: 06/17/2008) |
| 06/17/2008 | 107 | Transmittal Letter Sent With Certified Docket Sheet, To: District of Delaware re MDL 1941. The District of Delaware will obtain remaining documents via PACER. (de) (Entered: 06/17/2008) |

**PACER Service Center**

**Transaction Receipt**

06/18/2008 08:42:32

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| **PACER Login:** | ud0037 | **Client Code:** | |
| **Description:** | Docket Report | **Search Criteria:** | 0:07-cv-61800-FAM |
| **Billable Pages:** | 13 | **Cost:** | 1.04 |

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF PLAINTIFFS' MOTION FOR STATUS CONFERENCE**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit the attached February 28, 2008 docket entries from *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT), District of Delaware, as supplemental authority in support of Plaintiffs' Motion for Status Conference (D.I. 56). As explained in the Motion, on February 27, 2008, the Delaware court scheduled its Rule 16 status and scheduling conference with all parties in the three related Delaware actions for March 17. D.I. 56 at 2; D.I. 57 at Ex. 1. Today, the Delaware court ordered that the conference in all three actions would be changed to a status conference "[i]n light of the fact that before the Judicial Panel on Multidistrict Litigation there is an outstanding motion for transfer and consolidation of these matters" and ordered that "[d]uring the teleconference the parties will apprise the court of recent developments."

Dated: February 28, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

and

John M. Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)
William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on February 28, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

*Attorneys for Plaintiffs*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Robert B. Breisblatt, Esq.
Steven E. Feldman, Esq.
Sherry L. Rollo, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

PATENT

# U.S. District Court
## District of Delaware (Wilmington)
## CIVIL DOCKET FOR CASE #: 1:07-cv-00792-GMS-MPT

Sanofi-Aventis et al v. Apotex Inc. et al
Assigned to: Judge Gregory M. Sleet
Referred to: Judge Mary Pat Thynge
Related Cases: 1:07-cv-00572-GMS-MPT
1:07-cv-00574-GMS-MPT
Cause: 35:271 Patent Infringement

Date Filed: 12/06/2007
Jury Demand: Defendant
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Sanofi-Aventis**

represented by **Jack B. Blumenfeld**
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jbbefiling@mnat.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jparrett@mnat.com
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Sanofi-Aventis U.S. LLC**

represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Apotex Inc.**

represented by **Richard L. Horwitz**
Potter Anderson & Corroon, LLP
1313 N. Market St., Hercules Plaza, 6th Flr.
P.O. Box 951
Wilmington, DE 19899-0951

| | | |
|---|---|---|
| | | Sanofi-Aventis U.S. LLC. (Noreika, Maryellen) (Entered: 01/31/2008) |
| 02/01/2008 | | CORRECTING ENTRY: Exhibits R, S, and T have been added as attachments to D.I. 15, Declaration. (asw) (Entered: 02/01/2008) |
| 02/04/2008 | 17 | MOTION for Pro Hac Vice Appearance of Attorney Gerald J. Flattmann, Jr. and Alexis Gorton - filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. (Parrett, James) (Entered: 02/04/2008) |
| 02/05/2008 | | SO ORDERED, re 17 MOTION for Pro Hac Vice Appearance of Attorney Gerald J. Flattmann, Jr. and Alexis Gorton filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. Ordered by Chief Judge Gregory M. Sleet on 2/5/2008. (asw) (Entered: 02/05/2008) |
| 02/11/2008 | 18 | REPLY BRIEF re 10 MOTION to Transfer Case to Southern District of Florida *[REPLY BRIEF IN SUPPORT OF MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE ALTERNATIVE STAY THE DELAWARE LITIGATION]* filed by Apotex Inc., Apotex Corp.. (Attachments: # 1 Exhibit A) (Dorsney, Kenneth) (Entered: 02/11/2008) |
| 02/11/2008 | 19 | MOTION for Pro Hac Vice Appearance of Attorney William Thomas Vuk - filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. (Parrett, James) (Entered: 02/11/2008) |
| 02/21/2008 | 20 | Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. (Parrett, James) (Entered: 02/21/2008) |
| 02/26/2008 | | SO ORDERED, re 19 MOTION for Pro Hac Vice Appearance of Attorney William Thomas Vuk filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. Signed by Judge Gregory M. Sleet on 2/25/08. (mmm) (Entered: 02/26/2008) |
| 02/26/2008 | 21 | ORDER SCHEDULING RULE 16 SCHEDULING CONFERENCE: Pursuant to Rule 16.2b, a Scheduling Conference (see attached Order) has been set for Monday, March 17, 2008, at 9:30 AM in Chambers before the Honorable Gregory M. Sleet. Counsel with primary responsibility for this case shall appear and be prepared to address any pending motions. Unless otherwise excused, local counsel shall appear as well. A Joint Status Report shall be filed no later than the close of business on Monday, March 10, 2008. Ordered by Chief Judge Gregory M. Sleet on 2/26/2008.(ctd) (Entered: 02/26/2008) |
| 02/28/2008 | | ORAL ORDER SCHEDULING STATUS TELECONFERENCE: In light of the fact that before the Judicial Panel on Multidistrict Litigation there is an outstanding motion for transfer and consolidation of these matters, the Rule 16.2b Scheduling Conference scheduled for Monday, March 17, 2008, at 9:30 AM in Chambers before the Honorable Gregory M. Sleet HAS BEEN CHANGED TO A STATUS TELECONFERENCE. During the teleconference the parties will apprise the court of recent developments. Ordered by Chief Judge Gregory M. Sleet on 2/28/08. (ctd) (Entered: 02/28/2008) |

**PACER Service Center**

**Transaction Receipt**

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|---|---|---|---|
| **PACER Login:** | ke1342 | **Client Code:** | 14869-0003 |
| **Description:** | Docket Report | **Search Criteria:** | 1:07-cv-00792-GMS-MPT Start date: 1/1/1970 End date: 2/28/2008 |
| **Billable Pages:** | 3 | **Cost:** | 0.24 |

PATENT

# U.S. District Court
## District of Delaware (Wilmington)
## CIVIL DOCKET FOR CASE #: 1:07-cv-00572-GMS-MPT

Sanofi-Aventis et al v. Actavis South Atlantic LLC et al
Assigned to: Judge Gregory M. Sleet
Referred to: Judge Mary Pat Thynge
Related Cases: 1:07-cv-00574-GMS-MPT
1:07-cv-00792-GMS-MPT
Cause: 35:271 Patent Infringement

Date Filed: 09/21/2007
Jury Demand: None
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jbbefiling@mnat.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jparrett@mnat.com
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: menefiling@mnat.com
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Actavis South Atlantic LLC** represented by **David J. Margules**
Bouchard, Margules & Friedlander, P.A.
222 Delaware Avenue
Suite 1400
Wilmington, DE 19801
(302) 573-3500
Email: dmargules@BMF-law.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Dominick T. Gattuso**
Bouchard, Margules & Friedlander, P.A.
222 Delaware Avenue
Suite 1400
Wilmington, DE 19801
(302) 658-6541
Email: dgattuso@BMF-LAW.com
*TERMINATED: 12/27/2007*
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Chad A. Landmon**
Pro Hac Vice
Email: CAL@avhlaw.com
*ATTORNEY TO BE NOTICED*

**John Will Ongman**
Pro Hac Vice
Email: jwo@avhlaw.com
*ATTORNEY TO BE NOTICED*

**Sanjay B. Sitlani**
Pro Hac Vice
Email: JBS@avhlaw.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Aurobindo Pharma Ltd.** represented by **Mary Matterer**
Morris James LLP
500 Delaware Avenue, Suite 1500
P.O. Box 2306
Wilmington, DE 19899-2306
(302) 888-6800
Fax: (302) 571-1750
Email: mmatterer@morrisjames.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Aurobindo Pharma USA Inc.** represented by **Mary Matterer**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Defendant**

**Mylan Pharmaceuticals Inc.** represented by **Richard L. Horwitz**
Potter Anderson & Corroon, LLP
1313 N. Market St., Hercules Plaza, 6th Flr.
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
Email: rhorwitz@potteranderson.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**David Ellis Moore**
Potter Anderson & Corroon, LLP
1313 N. Market St., Hercules Plaza, 6th Flr.
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
Email: dmoore@potteranderson.com
*ATTORNEY TO BE NOTICED*

**Robert L. Florence**
Pro Hac Vice
Email: rflorence@mcguirewoods.com
*ATTORNEY TO BE NOTICED*

**Robert J. Waddell**
Pro Hac Vice
Email: rwaddell@mcguirewoods.com
*ATTORNEY TO BE NOTICED*

**Timothy H. Kratz**
Pro Hac Vice
Email: tkratz@mcguirewoods.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Par Pharmaceutical Inc.** represented by **David J. Margules**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Dominick T. Gattuso**
(See above for address)
*TERMINATED: 01/07/2008*
*ATTORNEY TO BE NOTICED*

**Defendant**

**Ranbaxy Inc.** represented by **Frederick L. Cottrell, III**
Richards, Layton & Finger

One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 658-6541
Email: cottrell@rlf.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Jameson A.L. Tweedie**
McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
302-984-6357
Fax: 302-220-4621
Email: jtweedie@mccarter.com
*TERMINATED: 12/21/2007*
*ATTORNEY TO BE NOTICED*

**William R. Zimmerman**
Pro Hac Vice
Email: bzimmerman@kmob.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Ranbaxy Laboratories Limited** represented by **Frederick L. Cottrell, III**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Darrell L. Olson**
Pro Hac Vice
Email: dolson@kmob.com
*ATTORNEY TO BE NOTICED*

**Jameson A.L. Tweedie**
(See above for address)
*TERMINATED: 12/21/2007*
*ATTORNEY TO BE NOTICED*

**Defendant**

**Sun Pharmaceutical Industries Inc.** represented by **Philip A. Rovner**
Potter Anderson & Corroon, LLP
1313 N. Market St., Hercules Plaza, 6th Flr.
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
Email: provner@potteranderson.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Eric Cohen**
Pro Hac Vice
Email: eric.cohen@kattenlaw.com
*ATTORNEY TO BE NOTICED*

**Manotti L. Jenkins**
Pro Hac Vice
Email: manotti.jenkins@kattenlaw.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Sun Pharmaceutical Industries Ltd.** represented by **Philip A. Rovner**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Eric Cohen**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Manotti L. Jenkins**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Defendant**

**Teva Pharmaceuticals USA Inc.** represented by **John W. Shaw**
Young, Conaway, Stargatt & Taylor
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
(302) 571-6600
Email: jshaw@ycst.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Christopher J. Sorenson**
Pro Hac Vice
Email: csorenson@merchantgould.com
*ATTORNEY TO BE NOTICED*

**Samuel T. Lockner**
Pro Hac Vice
Email: slockner@ccvl.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Torrent Pharma Inc.** represented by **Francis J. Murphy, Jr.**
Murphy, Spadaro & Landon
1011 Centre Road
Suite 210
Wilmington, DE 19805
(302) 472-8100
Email: fmurphy@msllaw.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**David B. Abramowitz**
Pro Hac Vice

Email: dabramowitz@lockelord.com
*ATTORNEY TO BE NOTICED*

**Keith D. Parr**
Pro Hac Vice
Email: kparr@lockelord.com
*ATTORNEY TO BE NOTICED*

**Kevin M. Nelson**
Pro Hac Vice
Email: knelson@lockelord.com
*ATTORNEY TO BE NOTICED*

**Scott B. Feder**
Pro Hac Vice
Email: sfeder@lockelord.com
*ATTORNEY TO BE NOTICED*

**Defendant**

**Torrent Pharmaceuticals Limited** represented by **Francis J. Murphy, Jr.**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**David B. Abramowitz**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Keith D. Parr**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Kevin M. Nelson**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Scott B. Feder**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Actavis South Atlantic LLC**

V.

**Counter Defendant**

**Sanofi-Aventis**

**Counter Defendant**

**Sanofi-Aventis US LLC**

**Counter Claimant**

**Mylan Pharmaceuticals Inc.** represented by **Richard L. Horwitz**
(See above for address)

*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**David Ellis Moore**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Torrent Pharma Inc.** represented by **Francis J. Murphy, Jr.**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Torrent Pharmaceuticals Limited** represented by **Francis J. Murphy, Jr.**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Teva Pharmaceuticals USA Inc.** represented by **John W. Shaw**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Mark D. Schuman**

Pro Hac Vice
Email: mschuman@ccvl.com
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Par Pharmaceutical Inc.** represented by **Dominick T. Gattuso**
(See above for address)
*TERMINATED: 01/07/2008*
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Aurobindo Pharma USA Inc.** represented by **Mary Matterer**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Aurobindo Pharma Ltd.** represented by **Mary Matterer**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)

*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Par Pharmaceutical Inc.**

V.

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Actavis South Atlantic LLC**

V.

**Counter Defendant**

**Sanofi-Aventis**

**Counter Defendant**

**Sanofi-Aventis US LLC**

**Counter Claimant**

**Ranbaxy Inc.** represented by **Frederick L. Cottrell, III**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Jameson A.L. Tweedie**
(See above for address)

*TERMINATED: 12/21/2007*
*ATTORNEY TO BE NOTICED*

**William R. Zimmerman**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Ranbaxy Laboratories Limited** represented by **Frederick L. Cottrell, III**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Darrell L. Olson**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Jameson A.L. Tweedie**
(See above for address)
*TERMINATED: 12/21/2007*
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Counter Defendant**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**James Walter Parrett, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Maryellen Noreika**
(See above for address)
*ATTORNEY TO BE NOTICED*

| Date Filed | # | Docket Text |
|---|---|---|
| | | |

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|---|---|---|
| 01/07/2008 | 80 | Disclosure Statement pursuant to Rule 7.1 filed by Ranbaxy Inc., Ranbaxy Laboratories Limited identifying (No Corporate Parent as to Ranbaxy Laboratories Limited) and (Ranbaxy Holdings (UK) Limited as to Ranbaxy Inc.) as Corporate Parent. (Cottrell, Frederick) (Entered: 01/07/2008) |
| 01/07/2008 | 81 | ANSWER to Complaint, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Ranbaxy Inc., Ranbaxy Laboratories Limited.(Cottrell, Frederick) (Entered: 01/07/2008) |
| 01/07/2008 | 82 | ANSWER to Counterclaim *of Ranbaxy Laboratories Limited and Ranbaxy Inc.* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Parrett, James) (Entered: 01/07/2008) |
| 01/08/2008 | 83 | MOTION for Pro Hac Vice Appearance of Attorney Scott B. Feder - filed by Torrent Pharma Inc., Torrent Pharmaceuticals Limited. (Murphy, Francis) (Entered: 01/08/2008) |
| 01/09/2008 | | SO ORDERED, re 83 MOTION for Pro Hac Vice Appearance of Attorney Scott B. Feder filed by Torrent Pharmaceuticals Limited, Torrent Pharma Inc. Ordered by Chief Judge Gregory M. Sleet on 1/9/2008. (asw) (Entered: 01/09/2008) |
| 01/10/2008 | 84 | NOTICE OF SUBSTITUTION OF COUNSEL re Par Pharmaceutical Inc.: Entry of appearance of attorney David J. Margules. Attorney Andre G. Bouchard terminated. (Margules, David) (Entered: 01/10/2008) |
| 01/10/2008 | 85 | NOTICE OF SUBSTITUTION OF COUNSEL re Actavis South Atlantic LLC: Entry of appearance of attorney David J. Margules. Attorney Andre G. Bouchard terminated. (Margules, David) (Entered: 01/10/2008) |
| 02/07/2008 | 86 | NOTICE of Withdrawal of Certain Pro Hac Vice Counsel by Teva Pharmaceuticals USA Inc. re SO ORDERED, (Pascale, Karen) (Entered: 02/07/2008) |
| 02/07/2008 | 87 | NOTICE of Change of Firm Affiliation of Pro Hac Vice Counsel by Teva Pharmaceuticals USA Inc. re SO ORDERED, SO ORDERED,,, (Pascale, Karen) (Entered: 02/07/2008) |
| 02/21/2008 | 88 | Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (Parrett, James) (Entered: 02/21/2008) |
| 02/26/2008 | 89 | ORDER SCHEDULING RULE 16 SCHEDULING CONFERENCE: Pursuant to Rule 16.2b, a Scheduling Conference in these matters (see attached Order) has been set for Monday, March 17, 2008, at 9:30 AM in Chambers before the Honorable Gregory M. Sleet. Counsel with primary responsibility for these cases shall appear and be prepared to address any pending motions. Unless otherwise excused, local counsel shall appear as well. A Joint Status Report shall be filed no later than the close of business on Monday, March 10, 2008. Ordered by Chief Judge Gregory M. Sleet on 2/26/2008. (ctd) (Entered: 02/26/2008) |
| 02/28/2008 | | ORAL ORDER SCHEDULING STATUS TELECONFERENCE: In light of the fact that before the Judicial Panel on Multidistrict Litigation there is an outstanding motion for transfer and consolidation of these matters, the Rule 16.2b Scheduling Conference scheduled for Monday, March 17, 2008, at 9:30 AM in Chambers before the Honorable Gregory M. Sleet HAS BEEN CHANGED TO A STATUS TELECONFERENCE. During the teleconference the parties will apprise the court of recent developments. Ordered by Chief Judge Gregory M. Sleet on 2/28/08. (ctd) (Entered: 02/28/2008) |

**PACER Service Center**

**Transaction Receipt**

PATENT

**U.S. District Court**
**District of Delaware (Wilmington)**
**CIVIL DOCKET FOR CASE #: 1:07-cv-00574-GMS-MPT**

Sanofi-Aventis et al v. Barr Laboratories Inc.
Assigned to: Judge Gregory M. Sleet
Referred to: Judge Mary Pat Thynge
Related Cases: 1:07-cv-00572-GMS-MPT
1:07-cv-00792-GMS-MPT
Cause: 35:271 Patent Infringement

Date Filed: 09/21/2007
Jury Demand: Defendant
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Sanofi-Aventis** represented by **Jack B. Blumenfeld**
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jbbefiling@mnat.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**John C. Phillips, Jr.**
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
Email: jcp@pgslaw.com
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Sanofi-Aventis US LLC** represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**John C. Phillips, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Barr Laboratories Inc.** represented by **Ivan M. Poullaos**
Pro Hac Vice
Email: ipoullao@winston.com
*ATTORNEY TO BE NOTICED*

**John C. Phillips, Jr.**

(See above for address)
*ATTORNEY TO BE NOTICED*

**Kurt A. Mathas**
Pro Hac Vice
Email: kmathas@winston.com
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**Barr Laboratories Inc.** represented by **Ivan M. Poullaos**
(See above for address)
*ATTORNEY TO BE NOTICED*

**John C. Phillips, Jr.**
(See above for address)
*ATTORNEY TO BE NOTICED*

**Kurt A. Mathas**
(See above for address)
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant**

**Sanofi-Aventis**

**Counter Defendant**

**Sanofi-Aventis US LLC**

| Date Filed | # | Docket Text |
|---|---|---|
| 09/21/2007 | 1 | COMPLAINT filed against Barr Laboratories Inc. - Magistrate Consent Notice to Pltf. ( Filing fee $ 350, receipt number 148988.) - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibits A and B# 2 Civil Cover Sheet # 3 Acknowledgement of Consent Form)(ead) (Entered: 09/24/2007) |
| 09/21/2007 | | Summons Issued as to Barr Laboratories Inc. on 9/21/2007. (ead) (Entered: 09/24/2007) |
| 09/21/2007 | 2 | Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (ead) (Entered: 09/24/2007) |
| 09/21/2007 | 3 | Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (ead) (Entered: 09/24/2007) |
| 09/24/2007 | 4 | Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number (s) 4,661,491; 6,149,940; (ead) (Entered: 09/24/2007) |
| 09/25/2007 | 5 | Return of Service Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Barr Laboratories Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007) |
| 10/03/2007 | | Case assigned to Judge Gregory M. Sleet and referred to Magistrate-Judge Mary Pat Thynge. Please include the initials of the Judge (GMS) after the case number on all documents filed. (rjb) (Entered: 10/03/2007) |
| 10/12/2007 | 6 | STIPULATION TO EXTEND TIME to answer complaint to October 29, 2007 - filed |

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| | | well. A Joint Status Report shall be filed no later than the close of business on Monday, March 10, 2008. Ordered by Chief Judge Gregory M. Sleet on 2/26/2008. (ctd) (Entered: 02/26/2008) |
| 02/28/2008 | | ORAL ORDER SCHEDULING STATUS TELECONFERENCE: In light of the fact that before the Judicial Panel on Multidistrict Litigation there is an outstanding motion for transfer and consolidation of these matters, the Rule 16.2b Scheduling Conference scheduled for Monday, March 17, 2008, at 9:30 AM in Chambers before the Honorable Gregory M. Sleet HAS BEEN CHANGED TO A STATUS TELECONFERENCE. During the teleconference the parties will apprise the court of recent developments. Ordered by Chief Judge Gregory M. Sleet on 2/28/08. (ctd) (Entered: 02/28/2008) |

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| **PACER Login:** | ke1342 | **Client Code:** | 14869-0003 |
| **Description:** | Docket Report | **Search Criteria:** | 1:07-cv-00574-GMS-MPT Start date: 1/1/1970 End date: 2/28/2008 |
| **Billable Pages:** | 3 | **Cost:** | 0.24 |

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**
CASE NO.: 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.

**DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PROTECTIVE ORDER TO AVOID HAVING TO RESPOND TO OUTSTANDING DISCOVERY**

Sanofi's motion for a protective order staying discovery should be denied. Sanofi initiated this litigation in Florida. It cannot now choose to opt of discovery. Sanofi's motion is the latest in a long line of similar motions that Sanofi has filed seeking to stay this case or otherwise slow it down. This is the fifth time Sanofi has requested the Court either extend the scheduling order or otherwise stay this litigation. (Dkt. 5, 12, 30, 32 and 44). Each time, this Court denied Sanofi's requests for lengthy delays of this litigation. (Dkt 23, 36). Most recently the Court denied Sanofi's "emergency" motion to stay the litigation altogether. (Dkt. 48).

The Court set a discovery cut-off date in August, 2008 with a trial date in October, 2008. (Dkt. 23). Sanofi's document production was due almost two weeks ago, as the Magistrate Judge recognized in granting Apotex's motion for entry of protective order to govern discovery. (Dkt. 51 at 4 (granting Apotex's motion for entry of protective order to govern discovery and

noting that "**Sanofi was scheduled to begin producing documents on February 18, 2008**, and the discovery deadlines and trial date are fast approaching." (emphasis added)).

The parties cannot put this case on hold while the Judicial Panel on Multidistrict Litigation ("the Panel") decides Sanofi's motion for transfer and consolidation, which Apotex has opposed. The discovery requested is necessary regardless of whether this litigation is transferred or consolidated. The Court should deny Sanofi's motion for protective order and, instead, order Sanofi to immediately produce the documents that are responsive to Apotex's document production requests and to respond in a timely manner to Apotex's outstanding discovery.

**SANOFI CANNOT OPT OUT OF DISCOVERY IN THIS CASE**

Sanofi cannot use a pending JPML motion to justify its refusal to participate in this litigation. JPML Rule 1.5 ("The pendency of a motion, order to show cause, conditional transfer order or conditional remand order before the Panel concerning transfer or remand of an action pursuant to 28 U.S.C. § 1407 **does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending** and does not in any way limit the pretrial jurisdiction of that court." (emphasis added)); *Kron Medical Corp. v. Groth*, 119 F.R.D. 636, 637 (M.D.N.C. 1988) ("Motions for a protective order which seek to prohibit or delay discovery are not favored."). Sanofi chose to file this suit in this district and is now obligated to respond to the outstanding discovery.

Disrupting the discovery schedule and prolonging litigation is generally in no one's best interest. *Kron Medical Corp. v. Groth*, 119 F.R.D. at 638. This case is no exception. This Court already entered a scheduling order and set a trial date for October, 2008. The Panel will not hear oral argument on Sanofi's pending motion until May, 2008 at the earliest. Granting Sanofi's request to delay discovery will potentially impact this trial date and thus the public's ability to

have the benefit of Apotex's generic alfuzosin product sooner. Discovery already is well underway – with initial disclosures already having been served, Sanofi's responses (mostly objections) to document requests having been received, Sanofi's actual document production still outstanding, interrogatory requests pending, and a motion for entry of a Protective Order having been granted by the Magistrate Judge. (Dkt. 51).

Sanofi will not be burdened in any significant way by proceeding with this litigation. Nor will judicial resources be wasted if discovery goes forward in this case. To the contrary, the same discovery in this case will be conducted regardless of the district in which this matter proceeds. Sanofi complains that without a stay of discovery it will be subjected to duplicative discovery if its 28 U.S.C. §1407 motion ultimately is granted by the JPML. (Dkt. 44 at 7). Regardless of whether a stay is issued, the parties will engage in the same discovery. Most of this production is electronic. It is just a matter of burning another CD or DVD. There is simply no additional burden to Sanofi to produce it now.

For example, Apotex's initial document production requests seek core documents underlying its claims in this case, such as Sanofi's New Drug Applications, lab notebooks, research notes, data and memoranda underlying the development of the drug product and method that are the subjects of Sanofi's patents in suit. Sanofi is going to have to produce this same basic information to each of the parties that it has sued. ***See Plaintiffs' Responses and Objections to Defendants' First Request For Production of Documents and Things to Plaintiff,*** **attached as Exhibit A.**

The interrogatories are similarly focused on core discovery such as Sanofi's infringement contentions and the bases for its infringement claims, an identification of the patent claims at issue, its knowledge of the prior art, and its bases for contending that there was anything

inventive about what is claimed in its patent. ***See Defendants' First Set of Interrogatories to Plaintiffs,* attached hereto as Exhibit B.** Again, Sanofi will be able to reuse its answers to these interrogatories with any of the other parties it sued. There is no additional burden to Sanofi to providing this information now. In short, there is no reason to delay the inevitable discovery that will take place.

## CONCLUSION

For the foregoing reasons, Sanofi's motion for a protective order staying discovery should be denied, and Sanofi should be ordered to immediately produce the documents that are responsive to Apotex's document production requests and to respond in a timely manner to Apotex's outstanding discovery, together with such other relief is just and proper under the circumstances. *See* In re Garrison Diversion Unit Litig., 458 F. Supp. 223 (J.P.M.L. 1978).

Dated: February 29, 2008

/s/ Stephen J. Bronis
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by the CM/ECF system and U.S. mail to the following:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

February 29, 2008

Matthew Davidson
*Attorney for Defendants*

# Exhibit A

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' RESPONSES AND OBJECTIONS TO DEFENDANTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFF**

Pursuant to Federal Rules of Civil Procedure 26 and 34 and Local Rules 26.1 and 34.1 for the Southern District of Florida, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") make the following objections and responses to Defendants Apotex Inc. and Apotex Corp.'s (collectively "Apotex") First Request For Production Of Documents And Things To Plaintiff.

Pursuant to Federal Rule of Civil Procedure 26(e), sanofi-aventis reserves the right to supplement its responses and objections as discovery and its investigation continues.

**PLAINTIFFS' GENERAL OBJECTIONS TO DEFENDANTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFFS**

Sanofi-aventis makes the following general objections to Defendants' First Request For Production Of Documents And Things To Plaintiff ("General Objections"), which General

Objections are hereby incorporated by reference and made part of its response to each such request:

1. Sanofi-aventis objects to each request to the extent that it seeks to impose requirements or obligations on sanofi-aventis in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

2. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

3. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to alter the plain meaning or scope of any request, on the ground that such alteration renders the request vague, ambiguous and uncertain.

4. Sanofi-aventis objects to Apotex's definition of "Parties" as overly broad to the extent that it purports to include individuals, corporations or entities over which sanofi-aventis has no control or are not otherwise parties to the present action.

5. Sanofi-aventis objects to Apotex's definition of "Communication" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

6. Sanofi-aventis objects to Apotex's definitions of "Concern(s)," "Concerning," "Concerned with," "Relate(s)," and "Relating to" as vague and ambiguous and, to the extent understood, to the extent that they purport to impose obligations or requirements in addition to or

different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

7. Sanofi-aventis objects to Apotex's definition of "Date" as overly broad and unduly burdensome and unlikely to lead to the discovery of admissible evidence, and to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

8. Sanofi-aventis objects to Apotex's definition of "Document" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

9. Sanofi-aventis objects to Apotex's definition of "Person" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

10. Sanofi-aventis objects to Apotex's "rules of construction" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

11. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as overly broad and unduly burdensome to the extent that they seek "All," "Each," or "Any" document or thing requested, and thus purport to impose obligations in addition to, or different from, those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

12. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are

protected by the attorney-client privilege, attorney work-product doctrine, or any other applicable privilege or immunity. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any such applicable privilege or immunity.

13. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not in sanofi-aventis's possession, custody or control.

14. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are in the possession, custody or control of Jagotec AG.

15. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents and things that contain confidential information of third parties.

16. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that the requests are duplicative in nature.

17. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as vague, ambiguous and uncertain to the extent that they seek information, documents or things that are not described with reasonable particularity.

18. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not relevant to the claims or defenses of any party, nor reasonably calculated to lead to the discovery of admissible evidence.

19. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are subject to either the European Union and/or member states privacy directives.

20. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they purport to seek documents, things or information generated after June 12, 2007, the date upon which sanofi-aventis first received written notification that an Abbreviated New Drug Application had been filed with the FDA seeking FDA approval for the commercial manufacture, use, offer for sale and sale of a generic version of sanofi-aventis's Uroxatral® brand product. Except for information related to secondary indicia of non-obviousness, sanofi-aventis will not provide any information generated after June 12, 2007 unless and until Apotex demonstrates the purported relevance of such information and/or how it is reasonably calculated to lead to the discovery of admissible evidence.

21. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to: this Court's decisions on sanofi-aventis's Motion to Transfer or Stay, Motion for Protective Order and Apotex's Motion for Entry of a Protective Order; the Judicial Panel on Multidistrict Litigation's decision on sanofi-aventis's Motion to Transfer and Consolidate for Pretrial Proceedings; and/or the Delaware Court's decision on Apotex's Motion to Transfer in Favor of Pending Florida Jurisdiction or in the Alternative Stay the Delaware Litigation (collectively "the currently pending motions").

22. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they seek information, documents or things that contain trade secret or other confidential, research, development or commercial information prior

to the entry of an agreed upon Protective Order in this action. Sanofi-aventis further objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to the Court's decision on Apotex's Motion for Entry of a Protective Order.

**REQUEST NO. 1:**

All documents concerning any proposal, consideration or decision by Plaintiff to draft and/or file the patents at issue.

**RESPONSE TO REQUEST NO. 1:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "proposal" and "consideration.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 2:**

All documents reviewed and/or relied on by Plaintiff in making the determination to seek patent protection for the subject matter of the patents at issue.

**RESPONSE TO REQUEST NO. 2:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 3:**

All documents which are relevant to establishing a date of invention by Plaintiff, or any person associated with Plaintiff, earlier than the filing date for each of the patents at issue.

**RESPONSE TO REQUEST NO. 3:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 4:**

All documents and communications that refer or relate to the preparation and/or prosecution of the patents at issue and/or any U.S. applications or foreign applications that constitute or are based in whole or in part on, or which claim priority from, or are the basis of priority for, any of the applications in the family of patent applications leading to the patents at issue and any related oppositions, re-examinations, and/or reissue proceedings including, without limitation:

a. all documents that provided the bases for any of said applications or proceedings;

b. all files in Plaintiff's possession, custody or control regarding the patents at issue, the patent applications for the patents at issue, or any related U.S. or foreign patents or applications;

c. all disclosures of the subject matter of any of said applications or proceedings;

d. all communications between the alleged inventor and his patent attorney(s) or agent(s) concerning the subject matter described or claimed in any of said applications or proceedings;

e. all documents referring or relating to any information used or supplied by the alleged inventor in connection with the preparation or prosecution of any of said applications or proceedings including invention disclosure prepared by or for the inventor;

f. all drafts of any said applications or proceedings;

g. all patents, publications, references or prior art, and all records or documents referring or relating to any prior art or possible prior art, and all records or documents referring or relating to any prior art or any possible ground of unpatentability and/or invalidity, submitted, cited, discussed or considered in connection with any of said applications or proceedings;

h. all documents referring or relating to the citation of, decision not to cite, or failure to cite, any references and/or prior art to the PTO or other patent office or patent authority in connection with said applications or proceedings; and

i. all copies (including drafts) of responses to Office Actions, amendments, affidavits, declarations and other communications or submissions of any kind with or to the PTO or other patent office, or patent authority with respect to any of said applications or proceedings.

**RESPONSE TO REQUEST NO. 4:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts, as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "possible prior art."

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 5:**

All documents and communications concerning any search, investigation, analysis, review, opinion or study relating to the scope, novelty, nonobviousness, patentability, validity, enforceability, value and/or infringement of any claim of the patents at issue, including without limitation:

a. all documents and communications, samples, prototypes and the like that refer or relate to the first public disclosure, first public use, first advertisement, first offer for sale, and/or the first sale of the alleged invention of the patents at issue in any country, including but not limited to, disclosures, advertisements, offers for sale, and sales of products prior to the priority date, filing date and/or bar date of the

patents at issue and concerning use of the subject matter claimed in the patents at issue on or before the respective filing dates(s) whether or not you contend such use was not public or was experimental;

b. all documents and communications concerning the scope and content of the prior art for the patents at issue and any foreign counterparts and all documents identified, found, described, or considered with regard to this prior art, regardless of whether such documents are considered prior art with regard to the patents at issue;

c. all documents and communications referring or relating to the scope of the 'art' and/or the level of skill in the 'art,' as the term 'art' is used in 35 U.S.C. § 103, of the subject matters described and claimed in the patents at issue, including all documents concerning the levels of education and experience of persons working in the field, the types of problems encountered in the art, the activities of others, prior art solutions to the problems encountered by the inventor, and the sophistication of the technology at issue;

d. all documents and communications that refer or relate to seminars, speeches, presentations, lectures, or talks (including without limitation, texts, drafts and notes thereof) given by any person employed or retained by, or otherwise affiliated with, or under authority or grant from Sanofi (or any predecessor in interest with regard to the patents at issue) concerning alfuzosin formulations or methods of treatment using alfuzosin formulations;

e. all documents and communications that refer or relate to any papers, articles, or other publications by any person employed or retained by, or otherwise affiliated with, or under the authority or grant by Sanofi, regarding alfuzosin or methods of treatment using alfuzosin formulations, including without limitation all drafts of any such materials and any memoranda or correspondence between co-authors or others concerning either the work reflected in the materials or the publications themselves;

f. all opinions of counsel concerning the validity, enforceability or infringement of the patents at issue or any foreign counterparts;

g. all documents and communications that (i) concern, (ii) support or tend to establish and/or otherwise support or (iii) refute or tend to refute any allegation that Apotex or any other person infringed the patents at issue or any foreign counterparts; and

h. all documents and communications that refer or relate to any oral or written statement made by Sanofi, or any other person or entity, that Sanofi, or any other person, was, is or might be infringing the patents at issue, or that any product made, used or sold by or for Sanofi, or any other person, was is, or might be infringing the patents at issue.

**RESPONSE TO REQUEST NO. 5:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request, and in particular to the over-breadth of subsection "d", as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "and the like." Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to its request for "prior art . . . regardless of whether such documents are considered prior art with regard to the patents at issue." Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts or documents related to

the first public disclosure, first public use, first advertisement, first offer for sale and/or the first sale "in any country", as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 6:**

All documents and communications concerning secondary factors or objective indicia of non-obviousness with regard to the patents at issue, including without limitation:

a. all documents and communications concerning any commercial success of products covered by the patents at issue and any asserted nexus with the claimed invention;

b. all documents and communications concerning any long-felt need in the art that was satisfied by the invention claimed in the patents at issue;

c. all documents and communications concerning whether or not others had tried, but failed to solve the problem solved by the invention claimed in the patents at issue;

d. all documents and communications concerning simultaneous or near simultaneous invention by others;

e. all documents and communications concerning whether others have copied the invention claimed in the patents at issue;

f. all documents and communications concerning any alleged superior, surprising or unexpected results achieved by the invention claimed in the patents at issue; and

g. all documents and communications concerning whether others have accepted licenses under patents in suit.

**RESPONSE TO REQUEST NO. 6:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 7:**

All documents and memos concerning or referring to any term extension of the patents at issue.

**RESPONSE TO REQUEST NO. 7:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 8:**

All documents and communications concerning the alleged conception, reduction to practice and development of the alleged invention or inventions claimed by the patents at issue, including without limitation:

a. all documents concerning any research, development, testing (both animal and human), and/or refinement of the subject matter of the patents at issue;

b. all documents referring or relating to any research, development, testing (both animal and human) and/or refinement of any commercial embodiments of the subject matter of the patents at issue;

c. all documents referring or relating to the conception and/or reduction to practice of the alleged invention of the patents at issue;

d. all documents referring or relating to any Sanofi product that is believed to be covered literally, or under the doctrine of equivalents, by any claim of the patents at issue; and

e. all documents concerning, created by, or created under the direction of the inventor named on the face of the patents at issue concerning alfuzosin or method of treatment using alfuzosin.

**RESPONSE TO REQUEST NO. 8:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested, including but not limited to all documents and things concerning the testing of Uroxatral®. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "refinement." Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 9:**

All documents and communications that refer or relate to any contemplated, proposed or actual license, or offers for or inquiries regarding license, of any patents, trade secrets or proprietary technology relating to Sanofi's UROXATRAL® products, including without limitation:

a. all documents and communications concerning any request, offer, acquisition or denial of any right (including any forbearance to assert a right), license, agreement, immunity, release, option, title or interest in, to or under the patents at issue, including all documents concerning why an agreement was not consummated (if not consummated), whether any agreement has been terminated, and any documents relating to the transfer and/or assignment of the patents at issue; and

b. all documents that refer or relate to any licensing policy(ies) of Sanofi and its predecessors-in-interest with regard to the patents at issue and products believed to be covered by the patents at issue.

**RESPONSE TO REQUEST NO. 9:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to the licensing of the patents at issue and sanofi-aventis's licensing policies regarding the patents at issue, within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 10:**

All document and communications or opinions concerning the value, strategic or pecuniary, of the patents at issue and commercial embodiments of the alleged invention of the patents at issue, including annual marketing reports, actual and estimated sales figures and the like.

**RESPONSE TO REQUEST NO. 10:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "strategic," "pecuniary" and "and the like.". Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the marketing and sales of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 11:**

All documents that compare any element, aspect or attribute of pharmaceutical tablets containing alfuzosin with any element, aspect or attribute of any other product sold anywhere in the world.

**RESPONSE TO REQUEST NO. 11:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis

objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "element," "aspect," and "attribute." Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 12:**

All documents concerning requests or desires to develop a pharmaceutical tablet containing alfuzosin.

**RESPONSE TO REQUEST NO. 12:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the

production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires.". Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 13:**

All documents concerning requests or desires to develop a method of treatment for dysuria using alfuzosin.

**RESPONSE TO REQUEST NO. 13:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation

and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 14:**

All documents and communications concerning Sanofi's corporate structure and organizational policies, including without limitation:

a. organizational charts that identify all persons involved in research, development, manufacturing, processing, marketing, sales or promotion of UROXATRAL® manufactured, marketed or sold by Sanofi;

b. all documents that constitute, refer or relate to any document retention policy program of Sanofi;

c. a copy of each of Sanofi's annual reports from its inception to the present; and

d. all documents and communications concerning development, manufacture, marketing, research and planning concerned with the subject matter of the patents at issue.

**RESPONSE TO REQUEST NO. 14:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it does not restrict the date range for the documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous

and uncertain, particularly with respect to the undefined term "processing." Sanofi-aventis also objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacture, production, or distribution of Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce: representative organizational charts; documents sufficient to demonstrate sanofi-aventis's document retention policies; and relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the research, development, marketing, sales and promotion of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 15:**

All documents relating or referring to Sanofi's contemplation or, decision to bring and maintain, a patent infringement lawsuit against Apotex, including without limitation:

a. all documents constituting or relating to communications with actual or potential purchasers of UROXATRAL® , or any third party other than an actual or potential purchaser of UROXATRAL® relating in anyway to (i) Apotex, (ii) the patents at issue, or (iii) this lawsuit;

b. all meeting minutes of Sanofi's Board of Directors or any committee of such Board of Directors, and all studies and reports submitted thereto that refer or relate to the Board's authorization to commence litigation charging infringement of the patents at issue, or its consideration of any claims or defenses relating to such litigation;

c. all documents reflecting Sanofi's knowledge of or belief in, the invalidity and/or enforceability of the patents at issue at the time this action was commenced or at any time thereafter; and

d. all documents reflecting knowledge by Sanofi and/or any attorney employed or retained by Sanofi who was involved in prosecuting the applications that ultimately led to the patents at issue or any document or pre-filing activity that constituted or could constitute prior art.

**RESPONSE TO REQUEST NO. 15:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 16:**

All documents, communications, and submissions made by Sanofi or its predecessors-in-interest with regard to the FDA as part of its INDA, NDA and those portions of the supporting Drug Master File for UROXATRAL® products, including but without limitation:

a. all documents and submissions which contain the product specifications and processing information for the manufacture of UROXATRAL®, including documents reflecting all starting materials and intermediates, test protocols and certificates of analysis;

b. all documents and submissions which describe the composition, function and use of UROXATRAL®;

c. all documents and submissions which relate to all treatment indications and/or use of UROXATRAL®, including proposed labeling, proposed package inserts and all other information relating or referring to any proposed or actual clinical use of UROXATRAL®;

d. all documents and submissions relating to the composition, formulation, chemistry, functionality or excipients, or other inactive or active ingredients testing and manufacture of UROXATRAL®; and

e. all documents, records, descriptions, agreements, results and product samples relating to the clinical testing of UROXATRAL® or earlier versions and formulations of alfuzosin products including all documents and product samples concerning or used in clinical trials resulting in side-effects descried in the package insert.

**RESPONSE TO REQUEST NO. 16:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client

privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and/or NDA 21-287 and documents relating to INDA 51,200 and/or NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 17:**

NDA 21-287 and all documents and communications concerning NDA 21-287 including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA, and all amendments to such NDA.

**RESPONSE TO REQUEST NO. 17:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of NDA 21-287 and documents relating to NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 18:**

All NDAs for any other dosage form or drug product containing alfuzosin submitted to the FDA and all documents and communications concerning such NDAs, including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA and all amendments to such NDA.

**RESPONSE TO REQUEST NO. 18:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by NDA 21-287 and/or ANDA 79-013. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

**REQUEST NO. 19:**

All documents comprising Plaintiff's Investigation New Drug application ("INDA") for UROXATRAL® or any other products containing alfuzosin and all documents and/or communications concerning or referring to that INDA, including but not limited to all clinical testing, protocols and results contained in or referred to in such INDA and all amendments to such INDA.

**RESPONSE TO REQUEST NO. 19:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by INDA 51,200. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and documents relating to INDA 51,200 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 20:**

All documents concerning a transfer of any rights or interest in commercial embodiments of the patents at issue from that patents' respective date of conception to the present.

**RESPONSE TO REQUEST NO. 20:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 21**

All documents and communications evidencing the educational background and qualifications for each or the named inventors of the patents at issue including but not limited to curriculum vitaes, resumes, publications, accreditations, honors, awards and/or certificates of recognition.

**RESPONSE TO REQUEST NO. 21:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-

aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 22:**

All documents that relate to the research, development and manufacture of pharmaceutical tablets containing alfuzosin, including without limitation;

a. all documents constituting or relating to any contemplated, proposed or implemented studies, measurements, evaluations, analyses, testing or other compilations of data;

b. all laboratory notebooks, memoranda, summaries, progress and research reports, meeting minutes, comparative tests or studies;

c. all documents relating or referring to each actual or proposed change in formulation, composition or process of manufacture of alfuzosin pharmaceutical tablets, from initial stages of development to the present;

d. all documents relating or referring to each process or method for making pharmaceutical tablets containing alfuzosin, that has been considered, tested,

used, or proposed for use by Plaintiff, including but not limited to the process or method by which Plaintiff, or any person or entity acting under Plaintiff's direction or with Plaintiff's authority manufacture pharmaceutical tablets.

**RESPONSE TO REQUEST NO. 22:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis also objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacturing process, or production of Uroxatral® or a treatment for dysuria.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate the research and development of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 23:**

All documents and communications concerning the research and/or development of any medicines containing alfuzosin in pharmaceutical tablets, including but not limited to laboratory notebooks, invention records, research results, studies, tests, memoranda, project status reports, forecasts and projections.

**RESPONSE TO REQUEST NO. 23:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "medicines." Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 24:**

All documents in Plaintiff's possession, custody or control which discuss pharmaceutical tablets containing alfuzosin.

**RESPONSE TO REQUEST NO. 24:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 25:**

All documents in Plaintiff's possession, custody or control which discuss a method for treatment of dysuria using alfuzosin.

**RESPONSE TO REQUEST NO. 25:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 26:**

All documents or communications concerning, discussing or expressing any complaints, concerns or dissatisfaction with any aspect, element or feature of any products or formulations containing alfuzosin.

**RESPONSE TO REQUEST NO. 26:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "complaints," "concerns," "dissatisfaction.". Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control sufficient to show consumer complaints to the extent that such documents or excerpts do not include individual patient data that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 27:**

All communications by and between Jagotec AG and Sanofi relating to pharmaceutical tablets containing alfuzosin including but not limited to documents relating to the '940 patent.

**RESPONSE TO REQUEST NO. 27:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or

things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 28:**

All documents and communications by and between Synthelabo, Sanofi-Synthelabo, Jagotec AG, Jagotec AB, and Sanofi-Aventis, including but not limited to all assignments and any other documents referring to the assignments or to which the assignments refer.

**RESPONSE TO REQUEST NO. 28:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of

admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 29:**

All documents that refer or relate to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled release of alfuzosin or a salt thereof.

**RESPONSE TO REQUEST NO. 29:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within

its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 30:**

All documents referring or relating to a method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human, including the development and efficacy of such method.

**RESPONSE TO REQUEST NO. 30:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 31:**

Please provide all documents concerning, analyzing, evaluating or referring to any and all of the following documents:

a. Cavero et al., *Br. J. Pharmacol.*, Vol. 81, *Alfuzosin (SL 77,499), A new Antihypertensive Agent with A Peripheral Site of Action : II. In Vitro Pharmacological Studies* ;

b. Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, *Alfuzosin, Antihypertensive Agent With a-Adrenoceptor Antagonist Properties*, abstract 2627 (1984);

c. Hedlund et al., *The Journal of Urology*, Vol. 133, *Effects of Prazosin in Patients With Benign Prostatic Obstruction*, Pgs 275-78 (1983);

d. Ronchi et al., *Urological Research*, Vol. 10, No. 3, *Symptomatic Treatment of Benign Prostatic Obstruction with Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation*, pgs. 131-34 (1982);

e. Whitefield et al., *Br. J. Pharmacol*, Vol. 47, *the Effect of Adrenergic Blocking Drugs on Outflow Resistance*, Pgs. 823-27 (1976);

**RESPONSE TO REQUEST NO. 31:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or

things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "evaluating".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 32:**

All documents produced or to be produced by Sanofi to opposing parties in any and all earlier filed or pending litigations relating to the patents at issue, including but not limited to documents produced by Sanofi in connection with the following cases: *Sanofi-Aventis et al v. Actavis South Atlantic LLC, et al* (Case No. 1:07-cv-00572); and *Sanofi-Aventis et al v. Barr Laboratories Inc.* (1:07-cv-00574).

**RESPONSE TO REQUEST NO. 32:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as

irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 33:**

All documents that have been disclosed or provided to any individual by, any scientist and/or consultant retained by Plaintiff in connection with the above-captioned action.

**RESPONSE TO REQUEST NO. 33:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that re protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "scientist.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 34:**

All documents relating to any investigation or test conducted by any scientist and/or consultant retained by Plaintiff in the above-captioned action.

**RESPONSE TO REQUEST NO. 34:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that re protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "scientist.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 35:**

All documents that Plaintiff may use as an exhibit in any trial, hearing, submission to the court or deposition in the above-captioned action.

**RESPONSE TO REQUEST NO. 35:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will identify documents it intends to use as exhibits: at hearing or trial in

accordance with the Scheduling Order set by the Court; in submissions to the Court when such submissions are made; and at depositions when such exhibits are formally marked as exhibits provided this request is not rendered moot by any of the currently pending motions.

Dated: February 19, 2008

Alfred J. Saikali (Fla. Bar No.: 178195)
asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

John M. Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)
William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was faxed and served by U.S. mail this 19th day of February, 2008 to **Stephen J. Bronis, Esq., Jennifer Coberly, Esq.**, Zuckerman Spaeder LLP, 201 South Biscayne Boulevard, Suite 900, Miami, FL 33131; and **Robert B. Breisblatt, Esq.**, Welsh & Katz, Ltd., 120 South Riverside Plaza, Chicago, IL 60606.

Respectfully submitted,

Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

# Exhibit B

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

**DEFENDANTS' FIRST SET OF INTERROGATORIES TO PLAINTFFS**

Pursuant to Federal Rules of Civil Procedure 33, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendant"), through counsel, hereby request that Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. L.L.C. (collectively "Sanofi" or "Plaintiff"), answer in writing within thirty (30) days of the date of service of these interrogatories.

A Protective Order has not yet been entered in this case. Apotex agrees to treat all answers as Attorneys Eyes Only until a Protective Order is entered by the Court.

**DEFINITIONS AND INSTRUCTIONS**

A. **Parties.** The terms "plaintiff" and "defendants" as well as a party's full or abbreviated name or a pronoun referring to a party mean the party and, where applicable, its officers, directors, employees, partners, corporate parent, subsidiaries, affiliates, or predecessors in interest. This definition is not intended to impose a discovery obligation on any person who is not a party to the litigation unless that person

is obligated to co-operate with Sanofi with regard to the instant action.

B. **Communication.** The term "communication" means the transmittal of information in the form of facts, ideas, inquiries, or otherwise.

C. **Concern(s), Concerning, Concerned with, Relate(s) or Relating to.** The terms "concern(s)," "concerning," "concerned with," "relates," or "relating to" are used interchangeably and mean concerning, evidencing, pertaining to, referring to, mentioning, memorializing, commenting on, containing, identifying, connected with, contemplating, discussing, stating, describing, reflecting, dealing with, consisting of, constituting, comprising, recording, or being relevant to all or any portion of the specified fact, conditions, events or incidents.

D. **Date.** The term "Date" means the exact day, month and year, if known or ascertainable, or, if not, the best approximation possible (including the temporal relationship to other events).

E. **Document.** The term "document" shall mean every means of recording any form of communication or representation upon any tangible thing, including letters, numbers, words, pictures, sounds, or symbols, or combinations thereof, whether recorded by handwriting, printing, photostatic, or photographic means, electronically stored information, including information stored on magnetic impulse, tape, computer disk, CD-ROM or any other form of data storage, data compilation, or mechanical or electronic recording, and all other tangible things which come within the meaning of writing contained in Rule 1001 of the Federal Rules of Evidence, or within the meaning of "document" or "tangible thing" contained in Rule 34 of the Federal Rules of Civil Procedure.

F. **Person.** The term "person" is defined as any natural person or any business, legal or governmental entity or association, and any functional division thereof.

G. **Describe.** The term "describe" means to provide a narrative statement or description, phrased in specifics, of facts or matters to which the interrogatory refers in full and complete detail, including, but not limited to, an identification of all persons, communication, acts, transactions, events, agreements, recommendations, and documents used, necessary or desirable to make such statement or description full and complete.

H. **Identify.** The term "identify" shall mean:

i. When used with respect to an individual or natural person, to state:

1. the person's full name;

2. any other name used by that person presently or in the past;

3. the person's present or last known address, residence address, and telephone numbers; and

4. the corporation, partnership, association, foundation, trust, organization or other entity, and the functional division thereof, with which the person is now associated, and the person's title, status, position, rank or classification with such entity at the present and throughout the time period specified.

ii. When used with respect to a person other than a natural person, including but not limited to, any corporation, partnership, association, foundation, trust, organization, or other entity or functional division thereof, to state:

1. its full name;

2. the address of its principal office or place of business;

3. all names under which it is doing business or ever has done business;

4. the nature of the venture (e.g. sole proprietorship, partnership, corporation, etc.); and

5. the identities of its officers, directors, partners or administrators.

iii. When used with respect to a communication to:

1. state the dates and places or origin and reception of such communication;

2. identify each person who was present at, or participated in, such communication;

3. identify the type of communication (e.g. letter, facsimile transmission, face-to-face conversation, telephone conversation, etc.);

4. describe in full and complete detail the substance of each such communication; and

5. identify each document which records, shows, or otherwise indicates the substance of such communication.

iv. When used with respect to a document or tangible thing, to state:

1. the type of document or tangible thing (e.g. letter, memoranda, computer disk, etc.);

2. the number of pages of which it consists where appropriate;

3. the date it was created (if no date appears, the response shall so state and shall supply the date or approximate date that such document or thing was created);

4. its author and signatories;

5. its addresses and all other persons receiving copies;

6. the nature and substance of the document with sufficient particularity to enable it to be identified; and

7. its location and its custody (or if it is no longer within your possession, custody or control, state what disposition was made of it; state the date such disposition; identify each

person who participated in or approved such disposition; and identify the person or persons having knowledge of its contents). In lieu of identifying documents and things in the foregoing manner, defendant may identify them by document number and produce such documents for inspection pursuant to Federal Rule of Civil Procedure 33(c).

v. When used with respect to a fact to:

1. describe the fact;

2. state when it became known;

3. identify the course from which the fact was learned;

4. identify documents that record, show or otherwise indicate the fact; and

5. state why the fact is believed true.

I. **Alfuzosin.** The term "Alfuzosin" or "Alfuzosine" is defined as the drug compound of this name identified in the '940 or '491 patents, including any compound of the formula N-[3-[(4-amino-6,7-dimethoxy-quinazolin-2-yl)-methyl-amino]propyl] tetrahydrofuran-2-carboxamide and any salts thereof.

J. **State the factual and legal basis.** When an interrogatory calls upon a party to "state the factual and legal basis" of or for a particular claim, assertion, allegation, or contention, the party shall:

i. specifically identify each and every document (and, where pertinent, the section, article, or subparagraph thereof), which forms any part of the source of the party's information regarding the alleged facts or legal conclusions referred to by the interrogatory;

ii. identify each and every communication which forms any part of the source of the party's information regarding the alleged facts or legal conclusions referred to by the interrogatory;

iii. state separately the acts or omissions to act on the part of any person (identifying the acts or omissions to act by stating their nature, time, and place and identifying the persons involved) which form any part of the party's information regarding the alleged facts or legal conclusions referred to in the interrogatory; and

iv. state separately any other fact that forms the basis of the party's information regarding the alleged facts or conclusions referred to in the interrogatory.

K. The following **rules of construction** apply to these interrogatories, definitions, and instructions:

i. **All/Each/Any.** The terms "all," "each," and "any" shall be construed as inclusive and synonymous and are as inclusive in scope as permitted by the Federal Rules of Civil Procedure.

ii. **And/Or.** The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside the scope.

iii. **Number.** The use of the singular form of any word includes the plural and vice versa.

iv. **Independence.** Except as otherwise expressly directed herein, each paragraph and subparagraph of an interrogatory and/or document request shall be construed independently and not by reference to any other paragraph or subparagraph herein for the purpose of limiting the scope of the interrogatory and/or document request being responded to.

L. If Plaintiff finds the meaning of any terms in these interrogatories unclear, Plaintiff shall assume a reasonable meaning, state what the assumed meaning is, and respond to the interrogatory according to the assumed meaning.

M. If Plaintiff objects to any interrogatory or part of any interrogatory, the reason(s) for the objection shall be stated in full. If an objection is made to any interrogatory, responses should be to any part of the interrogatory to which the objection

does not relate.

N. If any information, document or thing responsive to any of the following interrogatories are withheld on the basis of privilege and/or work-product doctrine, the following information is requested with respect to any such refusal:

i. the privilege and/or work-product rule of law being relied upon;

ii. the date the document was created;

iii. the identity of the person or persons who created the information, document, or thing;

iv. the identity of the present custodian of the information, document, or thing;

v. the addressee(s) and all other recipients of the information, document, or thing;

vi. the subject matter of the information, document or thing; and

vii. the location of the information, document or thing.

O. **The '940 Patent.** The term "the '940 Patent" means U.S. Patent No. 6,149,940.

P. **The '491 Patent.** The term "the '491 Patent" means U.S. Patent No. 4,661,491.

Q. **Patents at Issue.** The term "patents at issue" means U.S. Patent No. 6,149,940 and U.S. Patent No. 4,661,491.

These interrogatories are continuing in nature pursuant to Rule 26(e), Fed. R. Civ. P., and require timely supplementation of information as they come within Sanofi's possession custody and control.

## INSTRUCTIONS

1. In responding to these Interrogatories, the Plaintiff is requested to furnish all information known or available to plaintiff, regardless of whether such information is directly in its possession or that of its representative, attorneys, experts, as well as its respective agents, employees or representatives.

2. If plaintiff cannot answer an interrogatory completely, plaintiff shall answer to the extent possible, specifying the ways in which the response may be incomplete and stating the substance of its knowledge, information and belief concerning the subject matter of the unanswered portion.

3. If plaintiff finds the meaning of any terms in these interrogatories unclear, plaintiff shall assume a reasonable meaning, state what the assumed meaning is, and respond to the interrogatory according to the assumed meaning.

4. These interrogatories are continuing in nature so as to require prompt supplemental answers if plaintiff, directly or indirectly, obtains further or different information relative thereto, after the answers to interrogatories are served, or plaintiff learns that the answers to the interrogatories served are not full, complete, and/or correct, as required by Rule 26(e) of the Federal Rules of Civil Procedure.

## INTERROGATORIES

1. Identify by name, address and telephone number all persons or entities previously owning any right, title or interest in the '491 patent or '940 patent.

2. State the basis for Plaintiffs' contention that this is an exceptional case under § 285 and that Plaintiffs' are entitled to an award of attorney's fees as stated in Plaintiffs' Complaint (Civil No. 07-61800).

3. Describe in full and complete detail the level of ordinary skill of the art for the patents at issue, including the educational level of the inventor, the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field.

4. Identify any terms in the patents at issue that Plaintiffs will seek to have construed by the Court, including any terms that you contend were specifically defined in the specification or otherwise should be construed differently from their ordinary meaning, stating the definition you ascribe to those terms and the basis for your proposed definition.

5. Describe the problem(s), if any, Plaintiffs contend was solved by the subject matter claimed in the patents at issue.

6. Describe in full and complete detail any and all differences Plaintiffs contend exist between the subject matter claimed in the patents at issue and the prior art.

7. Identify which claims of the '491 patent Plaintiffs contend are infringed by the Apotex parties, and the factual and legal basis for those contentions.

8. Describe in full and complete detail any and all secondary considerations/objective indicia that you contend tend to show the subject matter claimed in the '491 patent would not have been obvious.

9. Identify all prior art for the '491 patent known to Francois Regnier, Helmuth Wegner, Michael Alexander, Paul Darkes, William E. Player, or any other person substantively involved in the prosecution of the '491 patent as of May 28, 1985

10. Identify all prior art for the '940 patent known to Lauretta Maggi, Ubaldo

Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau, Clemence Rauch-Desanti, D. Douglas Price, Elisabeth Thouret-Lemaitre, Harvey Jacobson, or any other person substantively involved in the prosecution of the '940 patent as of August 29, 1996.

Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by fax and mail on February 8, 2008, to:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

Jennifer Coberly

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

**DEFENDANTS' RESPONSE**
**TO PLAINTIFFS' MOTION FOR STATUS CONFERENCE**

Defendants' "Motion for Status Conference" is simply a rehashing of Sanofi's earlier arguments seeking to stay or otherwise alter this Court's January 3 and 23, 2008 Scheduling Orders and avoid trying this case in October, 2008. Undoubtedly the Court is well aware that Sanofi does not wish to proceed with this litigation in Florida and that it hopes to delay a Court determination that its patents are invalid or not infringed for as long as possible. A status conference is not necessary to discuss these matters further.

During the 3 month pendency of this lawsuit, Sanofi has filed essentially the same arguments in briefs with various captions seven times. (D.E. 5, 8, 12, 30, 32 and 44). These include two motions for a stay of proceedings, one motion for an "emergency" stay of proceedings, one motion for a continuance, a proposed revised scheduling order seeking to substantially delay deadlines in Court's scheduling order by almost a year, one motion for a protective order wherein Sanofi seeks to avoid producing any discovery in this case, and the instant motion for a status hearing. Sanofi also has filed four motions requesting hearings. In

spite of all these motions, the Court has consistently adhered to its Scheduling Order, and deemed it unnecessary to hold a hearing. The same result is appropriate here.

To the extent that a status conference is to be held in this case it should be used to make clear to Sanofi that this case is going forward and that it is required to participate. Since early January, Apotex has requested that Sanofi produce copies of core documents with obvious relevance to this litigation such as Sanofi's New Drug Applications, lab notebooks, research notes, data and memoranda underlying the development of the drug product and method that are the subjects of Sanofi's patents in suit. As recognized by the Magistrate's Order granting Apotex's Motion for a Protective Order, "Sanofi was scheduled to begin producing documents on February 18, 2008, and the discovery deadlines and trial dates are approaching rapidly." (D.E. 51 at 4). To date, Sanofi has not produced a single document[1], on the grounds that such discovery is "premature" or otherwise untimely with its spate of transfer motions still pending, even though the parties already had their Rule 26(f) conference, have exchanged initial disclosures, and under the Court's scheduling order are supposed to be conducting discovery.

On March 4, in yet another attempted end run around the Court's scheduling order, Sanofi filed a motion in the District of Delaware asking that court to effectively overrule this Court's scheduling order by **enjoining** Apotex from proceeding with this litigation. *See Plaintiffs' Opening Brief in Support of Its Motion to Enjoin the Parties from Prosecuting Second Filed, Duplicative Litigation,* attached hereto as Exhibit A. Sanofi's motion is unprecedented. Sanofi sued Apotex in Florida. Of course Apotex is entitled to defend itself. Apotex is not aware of any case (and Sanofi cites none) where a defendant has been enjoined from defending itself in an action instigated by the plaintiff in circumstances such as this. In its motion, Sanofi never mentions this Court's scheduling order and misleadingly describes this action as having "not

[1] Apotex has offered to receive any document produced by Sanofi on an attorney's eyes only basis until a protective order governing discovery is finalized and entered in the case.

progressed substantially." Of course the only reason that this case is not further along is that Sanofi has refused to participate, with its spate of dilatory stay motions and its refusal to provide discovery. As support for this argument, Sanofi also asserts that "[t]he parties have not yet had their case management conference with the Court." Exhibit A at 20. However, in its February 8, 2008 Order, the Court deemed a Rule 16 conference to be unnecessary in light of its earlier scheduling order. *See* February 8, 2008 Order (D.E. 36 (denying the parties' Rule 16.1 motions as "moot" in light of the Court's earlier scheduling order.)).

Enough is enough. The date for close of discovery is quickly approaching. Apotex has made every attempt to proceed expeditiously and meet all the Court's deadlines. Sanofi, on the other hand, has made every attempt to delay the progress of this litigation. To the extent the Court deems a status conference necessary, Apotex requests Sanofi's failure to participate in this litigation be the topic of discussion. A simpler solution would be for the Court to order Sanofi to immediately provide Apotex with documents responsive to Apotex's discovery requests and further order Sanofi to withdraw its motion to enjoin Apotex in Delaware.

**CONCLUSION**

For the foregoing reasons, Sanofi's motion for a status conference should be denied together with such other relief is appropriate under the circumstances.

Dated: March 7, 2008
Miami, FL

*s/. Jennifer Coberly*

Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131
Tel: 305-358-5000
Fax: 305-579-9749

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
Tel: 312-655-1500
Fax: 312-655-1501

*Attorneys for Apotex Corp and Apotex Inc.*

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by mail on March 7th, 2008 on all counsel of record on the attached service list.

*s/. Jennifer Coberly*
Jennifer Coberly

SERVICE LIST
Case No. 07-61800-CIV-MORENO/SIMONTON

Alfred John Saikali
e-mail: asaikali@shb.com
Shook Hardy & Bacon
201 South Biscayne Blvd., Suite 2400
Miami, FL 33131
Tel: 305-358-5171
Fax: 305-358-7470

Gerald J. Flattmann, Jr.
gflattmarm@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
Tel: 212-446-4800
Fax: 212-446-4900

*Attorneys for Plaintiffs,*
*Sanofi-Aventis and Sanofi-Aventis, U.S. LLC*

# EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, vs. APOTEX INC. and APOTEX CORP., Defendants. | C.A. No. 07-792 (GMS) (MPT) |

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS MOTION TO ENJOIN THE PARTIES FROM PROSECUTING SECOND FILED, DUPLICATIVE LITIGATION**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

March 4, 2008

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## INTRODUCTION

This is the first-filed forum for sanofi-aventis's and sanofi-aventis U.S. LLC's (collectively "sanofi-aventis"") claims against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex") and 13 other defendants. To protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction, sanofi-aventis filed a second, identical action in the Southern District of Florida ("the Florida action"). Once the duplicative Florida action was filed, Apotex immediately consented to personal jurisdiction in this first-filed action, but has refused to dismiss or stay the Florida action. Sanofi-aventis moves this Court to enjoin both parties from prosecuting the second-filed, duplicative Florida action. This is sanofi-aventis's opening brief in support of that motion.

## NATURE AND STAGE OF THE PROCEEDINGS

Sanofi-aventis filed this action against Apotex under the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Sanofi-aventis has filed two related actions in this District against 13 other defendants for patent infringement based on their ANDA filings for generic versions of Uroxatral®. The pleadings stage of all three litigations was completed in early January and a status teleconference has been scheduled for March 17, 2008.

Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act. It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window. Given the uncertain consequences under the Act if Apotex successfully

challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida where it was confident Apotex would not contest personal jurisdiction. Thus, sanofi-aventis filed a second, identical action against Apotex in the Southern District of Florida, Case No. 07-61800-CIV-MORENO/SIMONTON. That action involves exactly the same parties, claims, defenses, and counterclaims as this action. The pleading stage of that action was completed in mid-January.

Since the Florida action was filed, Apotex has consented to personal jurisdiction in Delaware. Consequently, sanofi-aventis has moved to transfer the second-filed Florida action to this District or to stay the action pending this Court's resolution of any venue issues. Briefing on sanofi-aventis's motion is complete and the parties await an order from the Florida court. Sanofi-aventis has also moved the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here; the briefing on this motion was completed on March 3. Apotex has moved to transfer this case to Florida.

## SUMMARY OF THE ARGUMENT

This is the first-filed forum for sanofi-aventis's claims against Apotex and the 13 other ANDA defendants. Sanofi-aventis only filed the second action in Florida to protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction. Both this action and the Florida action involve the same parties, the same accused product, the same patent and the same issues. Rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to squander judicial resources, game the system and engage in forum-shopping by insisting on prosecuting the Florida action in parallel. It is well-settled that this Court has a duty to enjoin the prosecution

of a second-filed action between the same parties which raises the same issues, absent rare or extraordinary circumstances. There are no such circumstances here. Consequently, this Court should enjoin both parties from prosecuting the second-filed Florida action.

## STATEMENT OF FACTS

### I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. *See* D.I. 1 ¶ 1. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in New Jersey. *See id.* ¶ 2.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. *See* D.I. 7 ¶ 3. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. *See id.* ¶ 4. Apotex Inc. and Apotex Corp. sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. A, The Apotex Group Corporate Info.[1]

### II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." D.I. 1 ¶ 11. It is also

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1 True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of Kathryn M. Liberatore in Support of Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin Second Filed, Duplicative Litigation.

a current assignee of United States Patent No. 6,149,940 ("the '940 patent," issued November 21, 2000), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] D.I. 8 ¶ 12. Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287. D.I. 1 ¶ 11; D.I. 8 ¶ 13.

## III. Infringement Of Sanofi-aventis's Patents By The ANDA Filers

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. B, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. C, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

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2 Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. D.I. 8 ¶ 12.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

## IV. Commencement Of The First-Filed District Of Delaware Actions

### A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In This District

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try sanofi-aventis's claims against every defendant, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in this District against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[3] *See* Ex. D, Delaware Complaint No. 07-572; Ex. E, Delaware Complaint No. 07-574.

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3 In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

**B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In This District Shortly Thereafter**

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. *See* Ex. B. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. F, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. Ex. C. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex for infringement of the '491 patent in this District on December 6, 2007. D.I. 1. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

**C. Apotex Agreed Not To Contest Jurisdiction In Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit**

Despite having previously admitted personal jurisdiction in several prior actions in this forum,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. H,

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[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. G, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. G, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4.

12/06/07 W. Vuk ltr to B. Sherman and T. McIntyre. It was only after the 45 days had run that Apotex stated that it would not contest jurisdiction in Delaware. Ex. I, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the Delaware complaint and conceded that jurisdiction and venue were proper in this forum:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." D.I. 7 ¶ 7;
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Nevertheless, Apotex indicated that it would move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* D.I. 7 ¶ 10; Ex. K, 01/07/08 S. Feldman ltr to W. Vuk; Ex. L, 01/07/08 W. Vuk ltr to S. Feldman.

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The Court in this action will hold a status teleconference on March 17, 2008 and all the parties are currently engaged in discussions to negotiate a global protective order. Ex. M, 02/28/08 J. Parrett email to P. Molino, et al.

## V. Plaintiffs Brought The Second-Filed Florida Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in this District within the 45-day window to bring suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action

after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in this Court and with respect to Apotex by its December 6, 2007 Complaint in this Court. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See, e.g., PDL BioPharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that this Court could properly exercise personal jurisdiction over Apotex, the Southern District of Florida was the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. *See* Exs. B, C. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring the second-filed Florida action within the 45-day window on

December 10, 2007.[5] Ex. O, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

> Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Ex. O ¶ 19 (emphasis added). Plaintiffs never served the Florida complaint on Apotex. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing before answering in Florida so that sanofi-aventis could voluntarily dismiss that complaint. Plaintiffs have since moved to transfer the Florida action to

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[5] The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. P, Plaintiff's Florida Motion To Transfer Or Stay.[6]

It is now clear that Apotex sought to make an end run around Plaintiffs' choice of this forum. Apotex filed its Answer and Counterclaims in the Florida action on December 28, 2007, one business day before answering the first-filed Delaware complaint.[7] *See* Ex. R, Florida Answer And Counterclaims; Ex. S, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that Florida is "more convenient" with the "fact" that the Florida action has progressed farther than the Delaware actions, arguing that the Florida action is well underway because the parties have exchanged initial disclosures and Apotex has served document requests and interrogatories. Ex. T, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. U, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. V, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1); Ex. W, Defendants Apotex Inc.'s and Apotex Corp.'s First Request For The Production Of Documents And Things To Plaintiffs; Ex. X, Defendants Apotex Inc.'s and Apotex Corp.'s First Interrogatories To Plaintiff. Sanofi-aventis has responded to Apotex's document requests, but has objected to

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6 Plaintiffs have also moved the Panel to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here. *See* Ex. Q, Plaintiffs' Motion To Transfer And Consolidate For Pretrial Proceedings. Apotex has moved to transfer this case to Florida. D.I. 10.

7 In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. Q ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest this Court's personal jurisdiction over Apotex Inc. D.I. 7 ¶ 8; *see also* Ex. I; Ex. J.

producing any documents pending the resolution of the outstanding motions. Ex. Y, Plaintiffs' Objections and Response to Defendants' Document Requests. Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. T. Moreover, the Florida court has not held its initial case management conference. As discussed below, this District, the Third Circuit and courts throughout the country have rejected attempts by defendants to game the system by enjoining the prosecuting of second-filed actions—like the Florida action—because such later-filed actions allow defendants to secure the forum of their choice at the expense of wasting court resources, duplicating pretrial activities, unduly burdening the parties and witnesses, and risking inconsistent rulings.

## ARGUMENT

The Court should apply the first-filed rule and enjoin both sanofi-aventis and Apotex from prosecuting the second-filed Florida action. Without enjoining further activities in Florida, the courts and the parties will engage in duplicative pretrial activities, thereby wasting resources, unduly burdening the parties and witnesses, and risking inconsistent rulings. Apotex will likely argue that the first-filed rule should not apply here because sanofi-aventis filed both the Delaware and Florida actions. This argument, however, is directly contradicted by the case law, which applies the first-filed rule even where both actions are initiated by plaintiffs and recognizes the need for protective suits in ANDA actions due to the jurisdictional ambiguities concerning the Hatch-Waxman Act. Finally, there are no extraordinary circumstances that would lead to a deviation from the first-filed rule in this case.

### I. This Court Has The Duty To Enjoin Both Parties From Prosecuting The Second-Filed Florida Action

There is no legitimate basis for requiring a party to prosecute the same lawsuit in two different courts. It is an utter waste of scarce judicial resources, requiring two judges to do

the same work in parallel and it wastes the parties' resources by necessitating duplicative discovery and other pretrial proceedings, as well as causing great inconvenience to the parties and witnesses. Allowing the same lawsuit to be prosecuted in two different courts also risks potentially inconsistent rulings on issues that impact the certainty of patent rights. For these reasons, courts follow the "first-filed" rule which provides that the first-filed action should proceed and the parties should be enjoined from prosecuting a second-filed action.

The first-filed rule originated with the United States Supreme Court in *Smith v. Mclver*, 22 U.S. (9 Wheat.) 532 (1824). In *Smith*, Chief Justice Marshall ruled that "in all cases of concurrent jurisdiction, the court which first has possession of the subject must decide it." *Id.* at 535. Over sixty years ago, the Court of Appeals for the Third Circuit applied this principle to federal concurrent jurisdiction in *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925 (3d Cir. 1941), *cert. denied*, 315 U.S. 813 (1942). The Third Circuit held that the district court had abused its discretion in failing to enjoin the parties from prosecuting a second-filed action, explaining that:

> [i]t is of obvious importance to all the litigants to have a single determination of their controversy, rather than several decisions which if they conflict may require separate appeals to different circuit courts of appeals. . . . The party who first brings a controversy into a court of competent jurisdiction for adjudication should, so far as our dual system permits, be free from the vexation of subsequent litigation over the same subject matter.

*Id.* at 930. The Third Circuit also noted that:

> [t]he economic waste involved in duplicating litigation is obvious. Equally important is its adverse affect upon the prompt and efficient administration of justice. . . . Courts already heavily burdened with litigation with which they must of necessity deal should therefore not be called upon to duplicate each other's work in cases involving the same issues and the same parties.

*Id.* at 930; *see also Crosley Corp. v. Westinghouse Elec. & Mfg. Co.*, 130 F.2d 474, 475 (3d Cir. 1942), *cert. denied*, 317 U.S. 681 (1942) ("[T]he district court first obtaining jurisdiction of the parties and issues in a patent cause on a complaint seeking declaratory relief should ordinarily proceed to adjudicate the controversy and should restrain the parties from seeking in the interim in a later suit in another district court to duplicate that adjudication").

Courts not only have the power to enjoin parties from prosecuting second-filed actions, but the case law makes clear that courts have the duty to enjoin the parties from prosecuting a second-filed action where the parties, patents, and issues are the same. In *Triangle Conduit & Cable Co., Inc. v. National Electric Products Corp.*, 125 F.2d 1008, 1009 (3d Cir. 1942), *cert. denied*, 316 U.S. 676 (1942), the Third Circuit explained this duty:

> "***it was the duty of the Court first obtaining jurisdiction to enjoin the prosecution of the subsequent proceedings in the other court.*** As we have seen, in the present case the district court in Delaware first obtained jurisdiction of Triangle and National and of the controversy between them. Having taken jurisdiction of the declaratory suit brought by Triangle, it became the duty of that court to adjudicate the controversy."

*Id.* at 1009 (emphasis added).

The Court of Appeals for the Federal Circuit likewise has adopted the "first-filed" doctrine. In *Laboratory Corp. of America Holdings v. Chiron Corp.*, the Federal Circuit affirmed a District of Delaware order enjoining the prosecution of a second-filed California action in favor of a first-filed Delaware action. 384 F.3d 1326, 1332-33 (Fed. Cir. 2004); *see also Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1140 (1994), *overruled in part on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995) ("The general rule favors the forum of the first-filed action, whether or not it is a

declaratory action."); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 935 F.2d 1263 (Fed. Cir. 1991) (affirming injunction by a Texas district court barring prosecution of second-filed action).

Following these authorities, this Court has repeatedly enjoined the prosecution of second-filed actions, and should not hesitate to do so in this action. *See, e.g., Cosden Oil & Chem. Co. v. Foster Grant Co., Inc.*, 432 F. Supp. 956, 960 (D. Del. 1977), *aff'd w/o op.*, 577 F.2d 725 (3d Cir. 1978) (citations omitted) (A plaintiff in this Court is "entitled to be free from the 'vexation of subsequent litigation over the same subject matter' . . . and the courts are entitled to be free from the waste and inefficiency involved in duplicative litigation."); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928 (D. Del. 1991); *Bamdad Mechanic Co., Ltd. v. United Tech. Corp.*, 109 F.R.D. 128 (D. Del. 1985). *Cf. Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (Judge Robinson dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'");[8] *Celgene Corp. v. Abrika Pharm., Inc.,* No. 06-5818, 2007 WL 1456156, at *4 (D.N.J. May 17, 2007) (recognizing plaintiffs' choice of forum and the first-filed rule, the court declined to transfer the first-filed New Jersey action to Delaware where "Plaintiffs had a legitimate reason to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); *Airport Investors Ltd. P'ship, Inc. v. Neatrour,* No. 03-831 GMS, 2004 WL 225060, at *2 (D. Del. Feb. 3, 2004) (recognizing that, although not addressed by the parties, "the 'first-filed' rule of this Circuit likely dictates" transfer of the second-filed

[8] Ex. Z is a compendium of unreported cases cited herein.

Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants).

## II. This Court Has Enjoined Parties From Prosecuting Second-Filed Actions When Both Actions Have Been Brought By The Same Party

Apotex will likely argue that the first-filed rule does not apply because sanofi-aventis filed both the initial action and the second action.[9] This argument is directly contradicted by the precedent of this Court and various district courts around the country; these courts have not only applied the first-filed rule where plaintiffs have brought both actions, but also have explicitly recognized the need for protective suits, such as the Florida action, in ANDA cases.

For example, in *Bamdad Mechanics Co. v. United Technologies Corp.*, this Court reasoned that even though "[t]he *Westinghouse* and *Hazeltine* decisions deal with the more common situation in which the defendant in the first action files suit in another forum against the original plaintiff[,] [t]he same rules applies, however, where two suits are initiated by the same plaintiff." 109 F.R.D. at 132 (enjoining plaintiffs, who "candidly admit to a degree of forum-shopping," from litigating a second-filed action in Connecticut in favor of the first-filed action in Delaware).

Likewise, in *Old Charter Distillery Co. v. Continental Distilling Corp.*, the plaintiff filed a first action in the District of Columbia ("the DC action") and the second action in the District of Delaware "***as a precautionary step*** in case the United States District Court or the

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9 In its motion to transfer this action to the Southern District of Florida, or in the alternative, to stay this case pending final resolution of that action, Apotex argued against the application of the first-filed rule where plaintiff has filed both actions. *See* D.I. 11 at 11, 13. Plaintiffs' answering brief in opposition to Apotex's motion includes a discussion of why the first-filed rule should apply. *See* D.I. 14 at 12-17.

Circuit Court of Appeals of the District of Columbia or the Supreme Court decided there was no jurisdiction over defendant" in the DC action. 59 F. Supp. 528, 530 (D. Del. 1945) (emphasis added). Plaintiffs requested an injunction preventing the parties from prosecuting the first-filed DC action, but this Court refused to grant such an injunction because "the District Court in the [DC] action has ruled that it has jurisdiction over defendant and the subject matter of the controversy between the parties. It is the court first acquiring jurisdiction and it is entitled to maintain that jurisdiction until it makes final adjudication of the matters for determination. In fact that court has power to enjoin defendant from prosecuting its present motion for preliminary injunction or proceeding with its counterclaim in this [Delaware] court." *Id.* at 530 (internal citations omitted). This Court went on to hold:

> Defendant's contention that this court is the court of greatest convenience for the parties has been examined and carefully considered. But there is nothing to be gained by elaborating this point. Plaintiff, by commencing the [DC] action, has selected what it considers to be the proper forum for the protection of its property right. The exercise of such selection should not, it seems to us, be subordinated by the application of the doctrine of forum non conveniens in favor of defendant under the circumstances presented here. It is appropriate that a stay of the case at bar should be granted, with the right reserved to each of the parties to make a renewal of their present motions or to file additional applications in the event the complexion of the litigation in the United States District Court for the District of Columbia changes in any material respect.

*Id.* at 531.

Moreover, courts, including this District and others in the Third Circuit, have applied the first-filed rule in ANDA cases where plaintiffs brought both actions and have expressly recognized the need for second-filed "protective suits" in ANDA litigations due to the ambiguities concerning jurisdictional challenges under the Hatch-Waxman Act and the serious risks patentees face if their first-filed actions are dismissed—namely the loss of the 30-month

stay of generic approval while a patent litigation is pending. *See e.g.*, *Celgene Corp. v. Abrika Pharms., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (dismissing second-filed protective suit because the court was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'"); *Celgene Corp. v. Abrika Pharms., Inc.,* No. 06-5818, 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007) (denying motion to transfer first-filed action where "Plaintiffs had a legitimate reason to file a similar, even identical action [as a protective suit] in [the second-filed forum], in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); Ex. AA, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (granting limited stay of second-filed ANDA action while first-filed court decided jurisdictional issues); *PDL Biopharma, Inc. v. Sun Pharm. Ind., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007) (staying second-filed ANDA action and recognizing the need for "protective" suits as a successful jurisdictional challenge in the first-filed court could preclude the patentee from bringing any suit under the Hatch-Waxman Act); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-14386, 2007 WL 1648908, at *4 (E.D. Mich. June 6, 2007) (staying second-filed ANDA action while first-filed court, where claims against 19 other ANDA defendants were pending, decided jurisdictional issues, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary"); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California 'in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application' sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *Abbott Labs. v.*

*Mylan Pharms., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006); *cf. Medpointe Healthcare Inc. v. Cobalt Pharms. Inc.*, No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008) (denying transfer from the first-filed forum even though plaintiff had filed both the initial ANDA patent infringement action and the second "protective" suit against the same defendant).

Here, the first-filed rule should apply because there is no question that sanofi-aventis had a legitimate need to bring the second-filed "protective suit" in Florida. Sanofi-aventis even expressly stated its motivation in the Florida complaint itself. *See* Ex. O ¶ 19. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act.[10] It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware. Given the uncertain consequences under the Act if Apotex successfully challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida

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10 Before the Panel, Apotex has suggested that NDA owners should file suit within the first 24 days of the 45-day period. This position defies logic and is contrary to the purpose of the Hatch-Waxman Act in providing a 45-day period of time for innovator companies to bring suit. *See* Ex. N, Apotex's Response And Opposition To Plaintiffs' Motion For Transfer of Action Pursuant to 28 U.S.C. § 1407, at 17 ¶ 14. The purpose of the 45-day period is to provide the patentee with sufficient time to determine whether the proposed generic product infringes the patent. Congress did not provide a 45-day period so that jurisdictional challenges could be resolved. If that were the case, every generic company would wait until the end of the 45-day period to contest jurisdiction, thereby ensuring that the jurisdictional question would not be resolved until after the 45-day period ended and the patentee lost the right to the 30-month stay.

where it was confident Apotex would not contest personal jurisdiction. Thus, the first-filed doctrine is clearly applicable here.

## III. There Are No Rare Or Extraordinary Circumstances Justifying Departure From The First-Filed Rule

While departure from the first-filed rule is only warranted in "rare or extraordinary circumstances," such as those involving "inequitable conduct, bad faith, or forum shopping," *EEOC v. University of Pennsylvania*, 850 F.2d 969, 972 (3d Cir. 1988), *aff'd on other grounds*, 510 U.S. 1140 (1994), there are no such circumstances here. Sanofi-aventis had a rational and legitimate reason to bring suit in Delaware because it is the district where it could bring each of the 15 ANDA filers and related defendants under the jurisdiction of one court so that all claims and counterclaims regarding Uroxatral® and the listed patents could be adjudicated in a single forum. In addition, this Court has significant expertise in handling patent matters, and has a record and policy of getting patent cases to trial promptly and efficiently.

Apotex can hardly argue that sanofi-aventis's filing of parallel actions is motivated by inequitable conduct, bad faith or forum shopping. Sanofi-aventis was forced by Apotex's initial refusal to consent to jurisdiction in Delaware and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights to file a "protective action" in Florida. Such protective suits have been found to be necessary, and do not constitute forum shopping. *See PDL Biopharma, Inc.*, No. 07-11709, 2007 WL 2261386, at *2 (noting that the reasons for filing protective suit "do not demonstrate bad faith or forum shopping on the part of Plaintiff."); *Aventis Pharma*, No. 06-3671 (MLC), 2007 WL 1101228, at *4 (explaining that the necessity of protect suits sufficiently refutes any allegation of judge or forum shopping). The first-filed rule should apply to enjoin the parties from prosecuting the later-filed, duplicative Florida action in

the absence of rare or extraordinary circumstances such as inequitable conduct, bad faith, or forum shopping.

As it argued in its motion to transfer to Florida, Apotex will likely argue here that the Florida court will expedite the resolution of the parties' claims. *See* D.I. 11 at 12. To date, the Florida action has not progressed substantially beyond the progression of this case. The parties have exchanged initial disclosures, and while Apotex has served document requests and interrogatories, sanofi-aventis has responded to Apotex's document requests, but has objected to producing any documents pending the resolution of the outstanding motions. The parties have not yet had their case management conference with the court.[11] The Court in this action, however, will hold a status teleconference on March 17, 2008 and the parties are currently engaged in discussions to negotiate a global protective order. Thus, any suggestion by Apotex that the Florida case is proceeding much more expeditiously is misleading. Here, the interests of justice are best served and the resolution of Plaintiffs' claims will best be expedited when all of sanofi-aventis's claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Enjoining the continued prosecution of the Florida action in favor of the Delaware action will avoid duplicating pretrial activities, thus preserving judicial resources, reducing costs for the parties, and expediting the resolution of the claims for all parties' involved.

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11 Indeed Apotex has refused sanofi-aventis's request to schedule a court conference in the Florida action and has forced sanofi-aventis to file a motion requesting a conference regarding essential issues in any patent litigation—discovery parameters and a Markman hearing. *See* Ex. BB, Plaintiff's Motion For Status Conference.

As it has argued in previous motions, Apotex will likely claim that the Florida action should proceed to further the Hatch-Waxman Act's goal of getting low-cost drugs into the hands of consumers. *See, e.g.*, Ex. CC, Defendants' Opposition to Plaintiffs' Motion To Stay Or Transfer in Florida, at 3. What Apotex fails to mention is that this is not the only goal of the Hatch-Waxman Act. Apotex further argues that the Hatch-Waxman Act requires that ANDA suits proceed to a "speedy resolution." *See, e.g.*, Ex. CC, at 9. But nothing in the Hatch-Waxman Act suggests that ANDA litigations should be tried as quickly as possible at any expense. Rather, in implementing the Act "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring lowcost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001).

Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act. In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing this case while seeking to delay the Delaware action is motivated by the potential for significant financial gain to Apotex if

it is able to enter the market with a generic copy of Uroxatral® without competition from the other defendants. In fact, the other ANDA defendants themselves agree that they would be unfairly prejudiced:

> [I]f Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, the FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. ***This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.***

Ex. DD, Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support of Motion to Transfer And Consolidate, at 9 (emphasis added). Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex proposes to espouse.

Moreover, the parties must be enjoined from prosecuting the later-filed, duplicative Florida action to avoid potentially enormous duplication of efforts concerning depositions and other discovery. Based on the invalidity arguments presented by defendants in their paragraph IV certification letters, it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each of the proposed generic products is a purported once-a-day formulation referencing Plaintiffs' Uroxatral® product, including its proposed indication. Enjoining the parties from prosecuting the Florida action will allow all of the defendants to equally participate in the depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the defendants may seek discovery. Multiple depositions of the same witnesses on the same issues will not be necessary. Discovery

disputes that arise will be handled by a single court, avoiding duplication of efforts and potentially inconsistent rulings. Sanofi-aventis, who has the burden of collecting, reviewing, and processing hundreds of thousands if not millions of pages of documents for production, will be able to proceed with discovery under a single court's rulings. Furthermore, with an injunction, only one court will be required to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, enjoining the parties from prosecuting the Florida action will prevent potentially inconsistent rulings on critical issues such as claim construction, the validity of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. Thus, enjoining the parties from prosecuting the later-filed, duplicative Florida action will serve the interests of justice for all parties.

## CONCLUSION

For the foregoing reasons, sanofi-aventis requests that the Court enjoin sanofi-aventis and Apotex from prosecuting the second-filed, duplicative Florida action.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr. (#4292)*
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

*Attorneys for Plaintiffs*
*sanofi-aventis and*
*sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

Dated: March 4, 2008
1751604

**CERTIFICATE OF SERVICE**

I hereby certify that on March 4, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on March 4, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*
*And HAND DELIVERY*

Robert B. Breisblatt, Esquire
Steven E. Feldman, Esquire
Sherry L. Rollo, Esquire
WELSH & KATZ LTD.
120 S. Riverside Plaza
22nd Floor
Chicago, IL 60606

*VIA ELECTRONIC MAIL*

*/s/ James W. Parrett, Jr. (#4292)*
James W. Parrett, Jr. (#4292)

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, | ) | C.A. No. 07-792 (GMS) (MPT) |
| vs. | ) | |
| APOTEX INC. and APOTEX CORP., Defendants. | ) | |

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS MOTION TO ENJOIN THE PARTIES FROM PROSECUTING SECOND FILED, DUPLICATIVE LITIGATION**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

March 4, 2008

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## INTRODUCTION

This is the first-filed forum for sanofi-aventis's and sanofi-aventis U.S. LLC's (collectively "sanofi-aventis'") claims against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex") and 13 other defendants. To protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction, sanofi-aventis filed a second, identical action in the Southern District of Florida ("the Florida action"). Once the duplicative Florida action was filed, Apotex immediately consented to personal jurisdiction in this first-filed action, but has refused to dismiss or stay the Florida action. Sanofi-aventis moves this Court to enjoin both parties from prosecuting the second-filed, duplicative Florida action. This is sanofi-aventis's opening brief in support of that motion.

## NATURE AND STAGE OF THE PROCEEDINGS

Sanofi-aventis filed this action against Apotex under the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Sanofi-aventis has filed two related actions in this District against 13 other defendants for patent infringement based on their ANDA filings for generic versions of Uroxatral®. The pleadings stage of all three litigations was completed in early January and a status teleconference has been scheduled for March 17, 2008.

Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act. It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window. Given the uncertain consequences under the Act if Apotex successfully

challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida where it was confident Apotex would not contest personal jurisdiction. Thus, sanofi-aventis filed a second, identical action against Apotex in the Southern District of Florida, Case No. 07-61800-CIV-MORENO/SIMONTON. That action involves exactly the same parties, claims, defenses, and counterclaims as this action. The pleading stage of that action was completed in mid-January.

Since the Florida action was filed, Apotex has consented to personal jurisdiction in Delaware. Consequently, sanofi-aventis has moved to transfer the second-filed Florida action to this District or to stay the action pending this Court's resolution of any venue issues. Briefing on sanofi-aventis's motion is complete and the parties await an order from the Florida court. Sanofi-aventis has also moved the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here; the briefing on this motion was completed on March 3. Apotex has moved to transfer this case to Florida.

## SUMMARY OF THE ARGUMENT

This is the first-filed forum for sanofi-aventis's claims against Apotex and the 13 other ANDA defendants. Sanofi-aventis only filed the second action in Florida to protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction. Both this action and the Florida action involve the same parties, the same accused product, the same patent and the same issues. Rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to squander judicial resources, game the system and engage in forum-shopping by insisting on prosecuting the Florida action in parallel. It is well-settled that this Court has a duty to enjoin the prosecution

of a second-filed action between the same parties which raises the same issues, absent rare or extraordinary circumstances. There are no such circumstances here. Consequently, this Court should enjoin both parties from prosecuting the second-filed Florida action.

## STATEMENT OF FACTS

### I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. *See* D.I. 1 ¶ 1. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in New Jersey. *See id.* ¶ 2.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. *See* D.I. 7 ¶ 3. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. *See id.* ¶ 4. Apotex Inc. and Apotex Corp. sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. A, The Apotex Group Corporate Info.[1]

### II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." D.I. 1 ¶ 11. It is also

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1 True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of Kathryn M. Liberatore in Support of Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin Second Filed, Duplicative Litigation.

a current assignee of United States Patent No. 6,149,940 ("the '940 patent," issued November 21, 2000), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] D.I. 8 ¶ 12. Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287. D.I. 1 ¶ 11; D.I. 8 ¶ 13.

**III. Infringement Of Sanofi-aventis's Patents By The ANDA Filers**

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. B, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. C, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

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2 Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. D.I. 8 ¶ 12.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

## IV. Commencement Of The First-Filed District Of Delaware Actions

### A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In This District

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try sanofi-aventis's claims against every defendant, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in this District against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[3] *See* Ex. D, Delaware Complaint No. 07-572; Ex. E, Delaware Complaint No. 07-574.

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3 In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

### B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In This District Shortly Thereafter

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. *See* Ex. B. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. F, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. Ex. C. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex for infringement of the '491 patent in this District on December 6, 2007. D.I. 1. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

### C. Apotex Agreed Not To Contest Jurisdiction In Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit

Despite having previously admitted personal jurisdiction in several prior actions in this forum,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. H,

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[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. G, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. G, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4.

12/06/07 W. Vuk ltr to B. Sherman and T. McIntyre. It was only after the 45 days had run that Apotex stated that it would not contest jurisdiction in Delaware. Ex. I, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the Delaware complaint and conceded that jurisdiction and venue were proper in this forum:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." D.I. 7 ¶ 7;
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Nevertheless, Apotex indicated that it would move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* D.I. 7 ¶ 10; Ex. K, 01/07/08 S. Feldman ltr to W. Vuk; Ex. L, 01/07/08 W. Vuk ltr to S. Feldman.

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The Court in this action will hold a status teleconference on March 17, 2008 and all the parties are currently engaged in discussions to negotiate a global protective order. Ex. M, 02/28/08 J. Parrett email to P. Molino, et al.

## V. Plaintiffs Brought The Second-Filed Florida Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in this District within the 45-day window to bring suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action

after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in this Court and with respect to Apotex by its December 6, 2007 Complaint in this Court. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See, e.g., PDL BioPharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that this Court could properly exercise personal jurisdiction over Apotex, the Southern District of Florida was the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. *See* Exs. B, C. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring the second-filed Florida action within the 45-day window on

December 10, 2007.[5] Ex. O, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

> Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Ex. O ¶ 19 (emphasis added). Plaintiffs never served the Florida complaint on Apotex. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing before answering in Florida so that sanofi-aventis could voluntarily dismiss that complaint. Plaintiffs have since moved to transfer the Florida action to

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5 The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. P, Plaintiff's Florida Motion To Transfer Or Stay.[6]

It is now clear that Apotex sought to make an end run around Plaintiffs' choice of this forum. Apotex filed its Answer and Counterclaims in the Florida action on December 28, 2007, one business day before answering the first-filed Delaware complaint.[7] *See* Ex. R, Florida Answer And Counterclaims; Ex. S, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that Florida is "more convenient" with the "fact" that the Florida action has progressed farther than the Delaware actions, arguing that the Florida action is well underway because the parties have exchanged initial disclosures and Apotex has served document requests and interrogatories. Ex. T, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. U, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. V, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1); Ex. W, Defendants Apotex Inc.'s and Apotex Corp.'s First Request For The Production Of Documents And Things To Plaintiffs; Ex. X, Defendants Apotex Inc.'s and Apotex Corp.'s First Interrogatories To Plaintiff. Sanofi-aventis has responded to Apotex's document requests, but has objected to

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6 Plaintiffs have also moved the Panel to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here. *See* Ex. Q, Plaintiffs' Motion To Transfer And Consolidate For Pretrial Proceedings. Apotex has moved to transfer this case to Florida. D.I. 10.

7 In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. Q ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest this Court's personal jurisdiction over Apotex Inc. D.I. 7 ¶ 8; *see also* Ex. I; Ex. J.

producing any documents pending the resolution of the outstanding motions. Ex. Y, Plaintiffs' Objections and Response to Defendants' Document Requests. Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. T. Moreover, the Florida court has not held its initial case management conference. As discussed below, this District, the Third Circuit and courts throughout the country have rejected attempts by defendants to game the system by enjoining the prosecuting of second-filed actions—like the Florida action—because such later-filed actions allow defendants to secure the forum of their choice at the expense of wasting court resources, duplicating pretrial activities, unduly burdening the parties and witnesses, and risking inconsistent rulings.

## ARGUMENT

The Court should apply the first-filed rule and enjoin both sanofi-aventis and Apotex from prosecuting the second-filed Florida action. Without enjoining further activities in Florida, the courts and the parties will engage in duplicative pretrial activities, thereby wasting resources, unduly burdening the parties and witnesses, and risking inconsistent rulings. Apotex will likely argue that the first-filed rule should not apply here because sanofi-aventis filed both the Delaware and Florida actions. This argument, however, is directly contradicted by the case law, which applies the first-filed rule even where both actions are initiated by plaintiffs and recognizes the need for protective suits in ANDA actions due to the jurisdictional ambiguities concerning the Hatch-Waxman Act. Finally, there are no extraordinary circumstances that would lead to a deviation from the first-filed rule in this case.

### I. This Court Has The Duty To Enjoin Both Parties From Prosecuting The Second-Filed Florida Action

There is no legitimate basis for requiring a party to prosecute the same lawsuit in two different courts. It is an utter waste of scarce judicial resources, requiring two judges to do

the same work in parallel and it wastes the parties' resources by necessitating duplicative discovery and other pretrial proceedings, as well as causing great inconvenience to the parties and witnesses. Allowing the same lawsuit to be prosecuted in two different courts also risks potentially inconsistent rulings on issues that impact the certainty of patent rights. For these reasons, courts follow the "first-filed" rule which provides that the first-filed action should proceed and the parties should be enjoined from prosecuting a second-filed action.

The first-filed rule originated with the United States Supreme Court in *Smith v. Mclver*, 22 U.S. (9 Wheat.) 532 (1824). In *Smith*, Chief Justice Marshall ruled that "in all cases of concurrent jurisdiction, the court which first has possession of the subject must decide it." *Id.* at 535. Over sixty years ago, the Court of Appeals for the Third Circuit applied this principle to federal concurrent jurisdiction in *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925 (3d Cir. 1941), *cert. denied*, 315 U.S. 813 (1942). The Third Circuit held that the district court had abused its discretion in failing to enjoin the parties from prosecuting a second-filed action, explaining that:

> [i]t is of obvious importance to all the litigants to have a single determination of their controversy, rather than several decisions which if they conflict may require separate appeals to different circuit courts of appeals. . . . The party who first brings a controversy into a court of competent jurisdiction for adjudication should, so far as our dual system permits, be free from the vexation of subsequent litigation over the same subject matter.

*Id.* at 930. The Third Circuit also noted that:

> [t]he economic waste involved in duplicating litigation is obvious. Equally important is its adverse affect upon the prompt and efficient administration of justice. . . . Courts already heavily burdened with litigation with which they must of necessity deal should therefore not be called upon to duplicate each other's work in cases involving the same issues and the same parties.

*Id.* at 930; *see also Crosley Corp. v. Westinghouse Elec. & Mfg. Co.*, 130 F.2d 474, 475 (3d Cir. 1942), *cert. denied*, 317 U.S. 681 (1942) ("[T]he district court first obtaining jurisdiction of the parties and issues in a patent cause on a complaint seeking declaratory relief should ordinarily proceed to adjudicate the controversy and should restrain the parties from seeking in the interim in a later suit in another district court to duplicate that adjudication").

Courts not only have the power to enjoin parties from prosecuting second-filed actions, but the case law makes clear that courts have the duty to enjoin the parties from prosecuting a second-filed action where the parties, patents, and issues are the same. In *Triangle Conduit & Cable Co., Inc. v. National Electric Products Corp.*, 125 F.2d 1008, 1009 (3d Cir. 1942), *cert. denied*, 316 U.S. 676 (1942), the Third Circuit explained this duty:

> "***it was the duty of the Court first obtaining jurisdiction to enjoin the prosecution of the subsequent proceedings in the other court.*** As we have seen, in the present case the district court in Delaware first obtained jurisdiction of Triangle and National and of the controversy between them. Having taken jurisdiction of the declaratory suit brought by Triangle, it became the duty of that court to adjudicate the controversy."

*Id.* at 1009 (emphasis added).

The Court of Appeals for the Federal Circuit likewise has adopted the "first-filed" doctrine. In *Laboratory Corp. of America Holdings v. Chiron Corp.*, the Federal Circuit affirmed a District of Delaware order enjoining the prosecution of a second-filed California action in favor of a first-filed Delaware action. 384 F.3d 1326, 1332-33 (Fed. Cir. 2004); *see also Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1140 (1994), *overruled in part on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995) ("The general rule favors the forum of the first-filed action, whether or not it is a

declaratory action."); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 935 F.2d 1263 (Fed. Cir. 1991) (affirming injunction by a Texas district court barring prosecution of second-filed action).

Following these authorities, this Court has repeatedly enjoined the prosecution of second-filed actions, and should not hesitate to do so in this action. *See, e.g., Cosden Oil & Chem. Co. v. Foster Grant Co., Inc.*, 432 F. Supp. 956, 960 (D. Del. 1977), *aff'd w/o op.*, 577 F.2d 725 (3d Cir. 1978) (citations omitted) (A plaintiff in this Court is "entitled to be free from the 'vexation of subsequent litigation over the same subject matter' . . . and the courts are entitled to be free from the waste and inefficiency involved in duplicative litigation."); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928 (D. Del. 1991); *Bamdad Mechanic Co., Ltd. v. United Tech. Corp.*, 109 F.R.D. 128 (D. Del. 1985). *Cf. Celgene Corp. v. Abrika Pharm., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (Judge Robinson dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'");[8] *Celgene Corp. v. Abrika Pharm., Inc.*, No. 06-5818, 2007 WL 1456156, at *4 (D.N.J. May 17, 2007) (recognizing plaintiffs' choice of forum and the first-filed rule, the court declined to transfer the first-filed New Jersey action to Delaware where "Plaintiffs had a legitimate reason to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); *Airport Investors Ltd. P'ship, Inc. v. Neatrour*, No. 03-831 GMS, 2004 WL 225060, at *2 (D. Del. Feb. 3, 2004) (recognizing that, although not addressed by the parties, "the 'first-filed' rule of this Circuit likely dictates" transfer of the second-filed

[8] Ex. Z is a compendium of unreported cases cited herein.

Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants).

## II. This Court Has Enjoined Parties From Prosecuting Second-Filed Actions When Both Actions Have Been Brought By The Same Party

Apotex will likely argue that the first-filed rule does not apply because sanofi-aventis filed both the initial action and the second action.[9] This argument is directly contradicted by the precedent of this Court and various district courts around the country; these courts have not only applied the first-filed rule where plaintiffs have brought both actions, but also have explicitly recognized the need for protective suits, such as the Florida action, in ANDA cases.

For example, in *Bamdad Mechanics Co. v. United Technologies Corp.*, this Court reasoned that even though "[t]he *Westinghouse* and *Hazeltine* decisions deal with the more common situation in which the defendant in the first action files suit in another forum against the original plaintiff[,] [t]he same rules applies, however, where two suits are initiated by the same plaintiff." 109 F.R.D. at 132 (enjoining plaintiffs, who "candidly admit to a degree of forum-shopping," from litigating a second-filed action in Connecticut in favor of the first-filed action in Delaware).

Likewise, in *Old Charter Distillery Co. v. Continental Distilling Corp.*, the plaintiff filed a first action in the District of Columbia ("the DC action") and the second action in the District of Delaware "***as a precautionary step*** in case the United States District Court or the

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9 In its motion to transfer this action to the Southern District of Florida, or in the alternative, to stay this case pending final resolution of that action, Apotex argued against the application of the first-filed rule where plaintiff has filed both actions. *See* D.I. 11 at 11, 13. Plaintiffs' answering brief in opposition to Apotex's motion includes a discussion of why the first-filed rule should apply. *See* D.I. 14 at 12-17.

Circuit Court of Appeals of the District of Columbia or the Supreme Court decided there was no jurisdiction over defendant" in the DC action. 59 F. Supp. 528, 530 (D. Del. 1945) (emphasis added). Plaintiffs requested an injunction preventing the parties from prosecuting the first-filed DC action, but this Court refused to grant such an injunction because "the District Court in the [DC] action has ruled that it has jurisdiction over defendant and the subject matter of the controversy between the parties. It is the court first acquiring jurisdiction and it is entitled to maintain that jurisdiction until it makes final adjudication of the matters for determination. In fact that court has power to enjoin defendant from prosecuting its present motion for preliminary injunction or proceeding with its counterclaim in this [Delaware] court." *Id.* at 530 (internal citations omitted). This Court went on to hold:

> Defendant's contention that this court is the court of greatest convenience for the parties has been examined and carefully considered. But there is nothing to be gained by elaborating this point. Plaintiff, by commencing the [DC] action, has selected what it considers to be the proper forum for the protection of its property right. The exercise of such selection should not, it seems to us, be subordinated by the application of the doctrine of forum non conveniens in favor of defendant under the circumstances presented here. It is appropriate that a stay of the case at bar should be granted, with the right reserved to each of the parties to make a renewal of their present motions or to file additional applications in the event the complexion of the litigation in the United States District Court for the District of Columbia changes in any material respect.

*Id.* at 531.

Moreover, courts, including this District and others in the Third Circuit, have applied the first-filed rule in ANDA cases where plaintiffs brought both actions and have expressly recognized the need for second-filed "protective suits" in ANDA litigations due to the ambiguities concerning jurisdictional challenges under the Hatch-Waxman Act and the serious risks patentees face if their first-filed actions are dismissed—namely the loss of the 30-month

stay of generic approval while a patent litigation is pending. *See e.g.*, *Celgene Corp. v. Abrika Pharms., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (dismissing second-filed protective suit because the court was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'"); *Celgene Corp. v. Abrika Pharms., Inc.*, No. 06-5818, 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007) (denying motion to transfer first-filed action where "Plaintiffs had a legitimate reason to file a similar, even identical action [as a protective suit] in [the second-filed forum], in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); Ex. AA, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (granting limited stay of second-filed ANDA action while first-filed court decided jurisdictional issues); *PDL Biopharma, Inc. v. Sun Pharm. Ind., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007) (staying second-filed ANDA action and recognizing the need for "protective" suits as a successful jurisdictional challenge in the first-filed court could preclude the patentee from bringing any suit under the Hatch-Waxman Act); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-14386, 2007 WL 1648908, at *4 (E.D. Mich. June 6, 2007) (staying second-filed ANDA action while first-filed court, where claims against 19 other ANDA defendants were pending, decided jurisdictional issues, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary"); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California 'in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application' sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *Abbott Labs. v.*

*Mylan Pharms., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006); *cf. Medpointe Healthcare Inc. v. Cobalt Pharms. Inc.*, No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008) (denying transfer from the first-filed forum even though plaintiff had filed both the initial ANDA patent infringement action and the second "protective" suit against the same defendant).

Here, the first-filed rule should apply because there is no question that sanofi-aventis had a legitimate need to bring the second-filed "protective suit" in Florida. Sanofi-aventis even expressly stated its motivation in the Florida complaint itself. *See* Ex. O ¶ 19. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act.[10] It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware. Given the uncertain consequences under the Act if Apotex successfully challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida

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10 Before the Panel, Apotex has suggested that NDA owners should file suit within the first 24 days of the 45-day period. This position defies logic and is contrary to the purpose of the Hatch-Waxman Act in providing a 45-day period of time for innovator companies to bring suit. *See* Ex. N, Apotex's Response And Opposition To Plaintiffs' Motion For Transfer of Action Pursuant to 28 U.S.C. § 1407, at 17 ¶ 14. The purpose of the 45-day period is to provide the patentee with sufficient time to determine whether the proposed generic product infringes the patent. Congress did not provide a 45-day period so that jurisdictional challenges could be resolved. If that were the case, every generic company would wait until the end of the 45-day period to contest jurisdiction, thereby ensuring that the jurisdictional question would not be resolved until after the 45-day period ended and the patentee lost the right to the 30-month stay.

where it was confident Apotex would not contest personal jurisdiction. Thus, the first-filed doctrine is clearly applicable here.

## III. There Are No Rare Or Extraordinary Circumstances Justifying Departure From The First-Filed Rule

While departure from the first-filed rule is only warranted in "rare or extraordinary circumstances," such as those involving "inequitable conduct, bad faith, or forum shopping," *EEOC v. University of Pennsylvania*, 850 F.2d 969, 972 (3d Cir. 1988), *aff'd on other grounds*, 510 U.S. 1140 (1994), there are no such circumstances here. Sanofi-aventis had a rational and legitimate reason to bring suit in Delaware because it is the district where it could bring each of the 15 ANDA filers and related defendants under the jurisdiction of one court so that all claims and counterclaims regarding Uroxatral® and the listed patents could be adjudicated in a single forum. In addition, this Court has significant expertise in handling patent matters, and has a record and policy of getting patent cases to trial promptly and efficiently.

Apotex can hardly argue that sanofi-aventis's filing of parallel actions is motivated by inequitable conduct, bad faith or forum shopping. Sanofi-aventis was forced by Apotex's initial refusal to consent to jurisdiction in Delaware and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights to file a "protective action" in Florida. Such protective suits have been found to be necessary, and do not constitute forum shopping. *See PDL Biopharma, Inc.*, No. 07-11709, 2007 WL 2261386, at *2 (noting that the reasons for filing protective suit "do not demonstrate bad faith or forum shopping on the part of Plaintiff."); *Aventis Pharma*, No. 06-3671 (MLC), 2007 WL 1101228, at *4 (explaining that the necessity of protect suits sufficiently refutes any allegation of judge or forum shopping). The first-filed rule should apply to enjoin the parties from prosecuting the later-filed, duplicative Florida action in

the absence of rare or extraordinary circumstances such as inequitable conduct, bad faith, or forum shopping.

As it argued in its motion to transfer to Florida, Apotex will likely argue here that the Florida court will expedite the resolution of the parties' claims. *See* D.I. 11 at 12. To date, the Florida action has not progressed substantially beyond the progression of this case. The parties have exchanged initial disclosures, and while Apotex has served document requests and interrogatories, sanofi-aventis has responded to Apotex's document requests, but has objected to producing any documents pending the resolution of the outstanding motions. The parties have not yet had their case management conference with the court.[11] The Court in this action, however, will hold a status teleconference on March 17, 2008 and the parties are currently engaged in discussions to negotiate a global protective order. Thus, any suggestion by Apotex that the Florida case is proceeding much more expeditiously is misleading. Here, the interests of justice are best served and the resolution of Plaintiffs' claims will best be expedited when all of sanofi-aventis's claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Enjoining the continued prosecution of the Florida action in favor of the Delaware action will avoid duplicating pretrial activities, thus preserving judicial resources, reducing costs for the parties, and expediting the resolution of the claims for all parties' involved.

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11 Indeed Apotex has refused sanofi-aventis's request to schedule a court conference in the Florida action and has forced sanofi-aventis to file a motion requesting a conference regarding essential issues in any patent litigation—discovery parameters and a Markman hearing. *See* Ex. BB, Plaintiff's Motion For Status Conference.

As it has argued in previous motions, Apotex will likely claim that the Florida action should proceed to further the Hatch-Waxman Act's goal of getting low-cost drugs into the hands of consumers. *See, e.g.*, Ex. CC, Defendants' Opposition to Plaintiffs' Motion To Stay Or Transfer in Florida, at 3. What Apotex fails to mention is that this is not the only goal of the Hatch-Waxman Act. Apotex further argues that the Hatch-Waxman Act requires that ANDA suits proceed to a "speedy resolution." *See, e.g.*, Ex. CC, at 9. But nothing in the Hatch-Waxman Act suggests that ANDA litigations should be tried as quickly as possible at any expense. Rather, in implementing the Act "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring lowcost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001).

Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act. In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing this case while seeking to delay the Delaware action is motivated by the potential for significant financial gain to Apotex if

it is able to enter the market with a generic copy of Uroxatral® without competition from the other defendants. In fact, the other ANDA defendants themselves agree that they would be unfairly prejudiced:

> [I]f Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, the FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. ***This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.***

Ex. DD, Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support of Motion to Transfer And Consolidate, at 9 (emphasis added). Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex proposes to espouse.

Moreover, the parties must be enjoined from prosecuting the later-filed, duplicative Florida action to avoid potentially enormous duplication of efforts concerning depositions and other discovery. Based on the invalidity arguments presented by defendants in their paragraph IV certification letters, it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each of the proposed generic products is a purported once-a-day formulation referencing Plaintiffs' Uroxatral® product, including its proposed indication. Enjoining the parties from prosecuting the Florida action will allow all of the defendants to equally participate in the depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the defendants may seek discovery. Multiple depositions of the same witnesses on the same issues will not be necessary. Discovery

disputes that arise will be handled by a single court, avoiding duplication of efforts and potentially inconsistent rulings. Sanofi-aventis, who has the burden of collecting, reviewing, and processing hundreds of thousands if not millions of pages of documents for production, will be able to proceed with discovery under a single court's rulings. Furthermore, with an injunction, only one court will be required to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, enjoining the parties from prosecuting the Florida action will prevent potentially inconsistent rulings on critical issues such as claim construction, the validity of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. Thus, enjoining the parties from prosecuting the later-filed, duplicative Florida action will serve the interests of justice for all parties.

## CONCLUSION

For the foregoing reasons, sanofi-aventis requests that the Court enjoin sanofi-aventis and Apotex from prosecuting the second-filed, duplicative Florida action.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr. (#4292)*

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

*Attorneys for Plaintiffs*
*sanofi-aventis and*
*sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

Dated: March 4, 2008
1751604

**CERTIFICATE OF SERVICE**

I hereby certify that on March 4, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on March 4, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*
*And HAND DELIVERY*

Robert B. Breisblatt, Esquire
Steven E. Feldman, Esquire
Sherry L. Rollo, Esquire
WELSH & KATZ LTD.
120 S. Riverside Plaza
22nd Floor
Chicago, IL 60606

*VIA ELECTRONIC MAIL*

*/s/ James W. Parrett, Jr. (#4292)*
James W. Parrett, Jr. (#4292)

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STEVEN M. LARIMORE
CLERK U.S. DIST. CT
S.D. OF FLA. MIAMI

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

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|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**REPLY BRIEF IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS**

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## I. INTRODUCTION

Plaintiffs sanofi-aventis and sanofi-aventis U.S. L.L.C. (collectively "sanofi-aventis") respectfully submit this reply in further support of their Motion To Transfer And Consolidate For Pretrial Proceedings.

Transfer and consolidation of the four Uroxatral® actions will benefit the courts, parties, and witnesses by avoiding duplicative litigation and the potential for inconsistent rulings. Thirteen out of 15 defendants support transfer and consolation in Delaware—a strong indicator that transfer appropriately balances the interests of the parties.[1] Only Apotex Inc. and Apotex Corp. (collectively "Apotex") oppose, and that is not surprising as they are the only ones to gain from the individual prosecution of these cases. All of Apotex's arguments are based on its assumptions that the Florida action is more advanced than the Delaware cases and that nothing—not the efficient administration of justice, the potential for inconsistent rulings, the waste of judicial resources, the inconvenience to the parties and the witnesses—nothing at all can outweigh Apotex's desire for the Florida action to be tried as fast as possible.

Clearly, Apotex's position ignores the precedent of the Panel which supports transfer and consolidation when common questions, such as patent claim construction, infringement, and invalidity, pervade a number of actions and their consolidated proceedings will best promote the fair and just resolution of each action. It also ignores the fact that both the Florida and Delaware actions are all in their infancy—no substantial pretrial activities have taken place that would result in a burden to any party if the actions are consolidated for pretrial proceedings. Moreover, any alleged burden claimed by Apotex is vastly outweighed by the benefits of having one court

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[1] *See* Brief In Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407 by Defendants Actavis South Atlantic L.L.C. ("Actavis") and Par Pharmaceutical, Inc. ("Par") ("Actavis and Par's Resp.."); Brief in Support of Barr Laboratories, Inc.'s Response to Plaintiffs' Motion to Transfer and Consolidate for Pretrial Proceedings. The remaining ten defendants are deemed to have acquiesced to the motion, as they did not file any opposition. *See* J.P.M.L. Rule 7.2(c).

conduct pretrial proceedings for all actions as they each involve numerous common questions of law and fact concerning the validity and infringement of the same patents-in-suit.

In any event, Apotex's arguments here, and its conduct in the district court actions to date, highlight its true motives: to delay the first-filed Delaware actions against all defendants while trying to expedite the later-filed Florida action in which it is the only defendant in order to gain an advantage over its rival defendants. These tactics are contrary to the purposes of 28 U.S.C. § 1407 and the Hatch-Waxman Act that Apotex claims to espouse. Even the other generic defendants have called Apotex out for gaming the system and have stated that they support the transfer and consolidation in Delaware as the only way to truly enforce the intent of the Hatch-Waxman Act. Consequently, the Panel should transfer the Florida action to the District of Delaware and consolidate all four actions for pretrial proceedings in that district.

## II. ARGUMENT

### A. The Requirements For Transfer Under 28 U.S.C. § 1407 Are Met.

The Florida action should be transferred because: (1) the four subject actions in Delaware and Florida involve "one or more common questions of fact;" (2) transfer will promote "the just and efficient conduct" of the actions; and (3) transfer will promote "the convenience of the parties and witnesses." 28 U.S.C. § 1407(a). *See also In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007). Nothing in Apotex Opposition supports a different conclusion.

#### 1. The Florida And Delaware Actions Involve Multiple Common Questions Of Fact And Law

Apotex's argument that the cases should not be consolidated because they supposedly involve only some common questions of fact, Apotex Opp. at 11, ignores the Panel's precedent that provides that "transfer under Section 1407 does not require a complete identity or even a

majority of common factual or legal issues as a prerequisite to transfer." *See In re Acacia Media Techs. Corp. Patent Litig.*, 360 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005). Even if section 1407 required a majority of common questions, here, the common issues of law and fact will predominate because all the actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations where "[i]n each action [the patentee] has asserted that a proposed generic product infringes its patent ..."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361 (J.P.M.L. 2005) (ordering consolidation of three patent infringement actions where "[a]ll three actions involve one or more patents related to ... [the branded pharmaceutical] product sold by [the plaintiff]"); *In re Gabapentin*, 2001 U.S. District LEXIS 1726, at *2. At the very minimum, both the Florida and Delaware courts will have to construe the asserted claims of these patents. In an effort to minimize the significant duplication of claim construction efforts, Apotex argues that the Delaware court will benefit from any claim construction performed by the Florida court. *See* Apotex Opp. at 3. That is simply not true. The Delaware court would still have to conduct its own claim construction analysis because the Florida claim construction would not include input from the remaining 13 defendants in the Delaware actions. *See Kim v. The Earthgrains Co.*, No. 01 C 3895, 2005 WL 66071, at *6-11 (N.D.Ill. Jan. 11, 2005) (refusing to adopt prior claim construction by different court in support of conducting its own claim construction).

Moreover, the defendants have raised the same defenses and counterclaims with respect to the infringement and invalidity of these patents.[2] Each of these issues will further comprise

[2] Apotex distorts the record with respect to the '940 patent in an attempt to establish that there are no overlapping issues with respect to that patent by stating that "Sanofi admits that Apotex's proposed ANDA product does not infringe the '940 patent." *See* Apotex Opp. at 3. Sanofi-aventis has never made such an admission. *See* Ex. 1, 10/01/07 W. Vuk ltr to B. Tao. Furthermore, Apotex ignores the fact that Apotex, like the other ANDA defendants

numerous common sub-issues including, for example, identification of the person skilled in the art, construction of disputed claim terms, and identification and interpretation of any relevant prior art. The fact that some defendants might be proposing slightly different generic formulations does not mean that there are no common questions of fact regarding infringement, as Apotex claims. *See* Apotex Opp. at 11. Indeed, the Panel has already rejected this argument in similar circumstances. *See In re Omeprazole Patent*, 1999 U.S. Dist. LEXIS 12589, at *2 ("Several opposing defendants argue that centralization is not warranted in light of the fact that issues of patent infringement are unique in each action, because each defendant's allegedly infringing formulation is different. We disagree."). Similarly, because the validity of both patents are challenged in each case, and defendants have already alleged the same or similar prior art as invalidating the patents, both the Florida and Delaware courts may be required to address the state of the science and the knowledge of one of ordinary skill in the art at the relevant time, and the scope and content of each prior art reference asserted with respect to each asserted claim from the patents. This commonality warrants transfer and consolidation. *See, e.g.*, *In re Smith Patent Litig.*, 407 F. Supp.1403, 1404 (J.P.M.L. 1976) (holding that common issues of validity "justify transfer"); *In re Nabumetone,* 1998 U.S. Dist. LEXIS 13735, at *2 (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin,* 2001 U.S. Dist. LEXIS 1726, at *2 (ordering transfer where four actions involved "validity of the same complex pharmaceutical patent"). The complexity of the common issues of fact and law also warrants consolidation. *See In re Nabumetone*, 1998 U.S. Dist. LEXIS 13735, at *2 (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin*, 2001 U.S. Dist. LEXIS 1726, at *2 (ordering transfer where four actions involved "the same

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in the related Delaware actions, has moved to invalidate the '940 patent. Thus, there is clear overlap with respect to the '940 patent.

complex pharmaceutical patent"). Consideration of the complicated issues described herein and in sanofi-aventis's opening brief will require complex scientific analysis and consideration of expert evidence. *See In re Molinaro/Catanzaro Patent Litig.*, 380 F. Supp. 794, 795 (J.P.M.L. 1974) ("[I]t is not an insubstantial burden which patent litigation imposes upon a district judge."); *In re Rivastigmine*, 360 F. Supp. 2d at 1362.

The other decisions cited by Apotex are inapposite. For example, Apotex cites to *In re Cessna Aircraft Distributorship Antitrust Litig.*, 460 F. Supp. 159 (J.P.M.L. 1978),[3] where the Panel denied consolidation in part because some of the actions had been pending for six years, the movants waited more than two years before asking for consolidation, and the presumptive transferee court had disallowed a claim that the movant was asserting in one of the actions sought to be transferred. *Id.* at 162. These circumstances are not present here where two of the Delaware actions have been pending for approximately five months and the other Delaware action and the Florida action have been pending for only two and a half months. Further, sanofi-aventis promptly moved to consolidate, within two months of filing the Florida action. Finally, neither the Florida nor the Delaware court has made any determination as to any of the claims or defenses in any of the actions.

Additionally, Apotex attempts to make much of the fact that in *In re Rivastigmine* none of the defendants opposed the motion to consolidate before the Panel. *See* Apotex Opp. at 12. That fact however is irrelevant to the present inquiry because the Panel was still obligated to analyze whether consolidation was appropriate. Indeed, the Panel still issued substantive

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[3] Apotex also cites to: *In re Royal Am. Indus., Inc., Sec. Litig.*, 407 F. Supp. 242 (1976); *In re Scotch Whiskey*, 299 F. Supp. 543 (1969); and *In re Garrison Diversion Unit Litig.*, 458 F. Supp 223 (1978). These cases are irrelevant because they involved factors not present here: two cases pending in two districts and no showing that issues were complex and discovery was time consuming. *In re Royal*, 407 F. Supp. at 244; *In re Scotch*, 299 F. Supp. at 544; *In re Garrison*, 458 F. Supp. at 225. In contrast, the present motion involves: four cases in two districts, complex, technical issues, and voluminous and time consuming discovery.

findings and found that the actions sought to be consolidated would share numerous factual and legal questions because, in each of the actions, the plaintiff asserted that a proposed generic product defined by an ANDA with the same active ingredient infringed the same patents. *In re Rivastigmine*, 360 F. Supp. 2d at 1361-62. Furthermore, the Panel has made similar findings in ordering consolidation in other Hatch-Waxman patent infringement actions in which the motion *was* opposed by the defendants. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355; *In re Nabumetone Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998); *In re Gabapentin Patent Litig.*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (J.P.M.L. Feb. 5, 2001); *In re Omeprazole Patent Litig.*, No. 1291, 1999 U.S. Dist. LEXIS 12589, at *2 (J.P.M.L. Aug. 12, 1999).

**2. Transfer And Consolidation Will Promote The Just And Efficient Conduct Of The Action For All Parties And The Courts**

Apotex's assertion that "a transfer will disrupt the progress already made in the Florida action," Apotex Opp. at 10, completely ignores the fact that the Florida action is only one of four related suits involving 17 total parties in two separate courts.[4] A determination of whether to consolidate should balance the interests of *all* the parties. When those interests are balanced, it is beyond dispute that transfer and consolidation will promote the just and efficient conduct of the actions for all parties and the courts. Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of the both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency in at least three ways. *See Eason v. Linden*

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[4] *In re Gasoline Lessee Dealers Antitrust Litig.* is inapposite because the actions sought to be consolidated: (1) shared few common questions (they relied on different conspiracy theories); (2) were in an advanced discovery stage (numerous depositions had been taken, and plaintiffs had received a "substantial number of documents"); and (3) had been pending for three to eight years. 479 F. Supp. 578, 579580 (J.P.M.L. 1979). In contrast, the present actions share substantial factual and legal questions, are at early stages of pretrial discovery, and have been pending for only two and a half to five months.

*Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

First, consolidation will promote judicial economy because only one judge will be required to understand the complexities of the technology involved in the patents-in-suit and the prior art for the purposes of all pretrial proceedings. For example, transfer will avoid two separate courts hearing identical discovery disputes, interpreting the same disputed claim terms. *See, e.g., In re Rivastigmine*, 360 F. Supp. 2d at 1362.

Second, consolidation will prevent inconsistent pretrial rulings on many different issues in dispute, including the meaning of disputed claim terms. These issues will also include, for example, the state of knowledge in the pertinent art, interpretation of the prior art, and consideration of whether that prior art anticipates the patents-in-suit or renders them obvious. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (stating that centralization will "prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim construction;"); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same). Certainty in patent law is a significant public interest that would be thwarted by inconsistent rulings on these issues. *See In re Graff*, 111 F.3d 874, 877 (Fed. Cir. 1997) (acknowledging the public interest in "finality and certainty of patent rights").

In an attempt to minimize the impact of inconsistent pretrial rulings, Apotex states that there is little danger of inconsistent rulings because "Florida is scheduled to be completed so far ahead of Delaware." *See* Apotex Opp. at 3. Apotex is simply incorrect. The Florida and Delaware actions are all in their early stages. In Florida, the parties have not exchanged any discovery, although Apotex has served a set of document requests and interrogatories.

Moreover, no court has construed the claims or received claim construction briefs from the parties. Also, the Delaware Court has ordered a status conference for the Delaware actions on March 17, 2008. Actavis Dkt., Barr Dkt., Apotex DE Dkt., unnumbered (February 28, 2008 Oral Order scheduling status conference). This is in sharp contrast to the situation in Florida where the parties have yet to have their initial scheduling conference with the court and where Apotex has even refused sanofi-aventis's request for a status conference with the court; thereby forcing sanofi-aventis to have to burden the court by moving for an initial status conference to discuss such fundamental issues as the timing of a Markman hearing and the discovery limitations. Apotex Fl. Dkt. 56.

Finally, consolidation will avoid duplicative discovery burdens on sanofi-aventis. Given that the same patents are at issue in the actions, that the defendants' products are all generic versions of the same Uroxatral® brand product, and the substantial overlap of the defenses in each action, the scope of discovery will substantially overlap in each action. Here, discovery is likely to be voluminous given the complexity of the issues. For example, in Florida, Apotex has served on sanofi-aventis thirty-five (35) broad Rule 34 requests for production. Documents responsive to these requests are likely to comprise well over several hundred thousand pages of material, and their review and production is likely to encompass many months. Under these circumstances, if the actions are consolidated, the defendants may submit a consolidated list of Rule 34 requests, thus requiring sanofi-aventis to conduct a single review of all documents. If pretrial proceedings are not consolidated, sanofi-aventis will essentially be required to review the same documents multiple times, leading to significant additional burden and expense. *See In re Burke, Inc., Pers. Mobility Vehicle Patent Litig.*, MDL No. 809, 1989 U.S. Dist. LEXIS 13662, at *2 (J.P.M.L. Aug. 22, 1989) (consolidating infringement actions involving a single patent "to

eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary"). The same is true for the interrogatories served by Apotex and which sanofi-aventis expects the other 13 defendants will serve as well.

**3. Transfer And Consolidation Will Serve The Convenience Of The Parties And Witnesses**

Given the numerous common issues of fact and law involved in the Florida and Delaware actions, transfer and consolidation for pretrial proceedings will be most convenient for the parties and witnesses. *See, e.g., In re Rivastigmine*, 360 F. Supp. 2d at 1362. Consolidation will preserve the resources of the parties and the court and avoid subjecting witnesses to multiple depositions on identical subject matter; thus serving as a cost-saving measure to the parties and the courts by avoiding duplicative discovery. Rather than addressing these significant benefits, Apotex brushes them aside, stating that "Sanofi's argument that consolidation will promote the just and efficient conduct of these actions is nonsense." *See* Apotex Opp. at 7. Apotex's position disregards the Panel's many decisions holding that centralization conserves the resources of the parties and the courts. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 ("[c]entralization under Section 1407 will eliminate duplicative discovery… and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F Supp. 2d at 1362 (same); *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001) (explaining that centralization would effectuate "an overall savings of cost and a minimum of inconvenience to all concerned" with the pretrial activities).

Apotex does not dispute the facts that: (a) if discovery were to proceed in two courts in parallel, sanofi-aventis would be required to seek and provide the same discovery twice; (b) sanofi-aventis would be forced to litigate claim construction issues twice; and (c) countless witnesses will be inconvenienced by being subjected to multiple depositions. None of these

factors will promote convenience, especially if the Florida action proceeds on a different schedule than the Delaware actions where all defendants, other than Apotex, would have to continue to participate.

Transfer and consolidation, however, will negate the need for duplicative discovery, claim construction, and motion practice. It also will avoid subjecting witnesses to multiple depositions on identical subject matter.[5] *See In re M3Power Razor Sys. Mktg. & Sales Prac. Litig.*, 398 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004) ("Section 1407 will offer the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to accommodate all parties' legitimate discovery needs while ensuring that common party and witnesses are not subjected to discovery demands that duplicate activity that will or has occurred in other actions."). This burden is significant here because many of the witnesses are abroad, will require interpreters, and may have travel restrictions due to health and age-related complications. These factors will lengthen both the individual depositions themselves as well as the time necessary to coordinate and complete all fact deposition discovery. The burden on the witnesses of being subjected to two depositions, that may require multiple days of testimony, compels the consolidation of these four actions. Lessening such burdens and promoting the efficient use of the courts and parties' resources is clearly not nonsense as Apotex contends. *See* Apotex Opp. at 12-13.

Apotex also argues that its witnesses in Florida would be inconvenienced if the Florida action is transferred to Delaware. *See* Apotex Opp. at 13. In making that argument Apotex fails to alert the Panel to the fact that to date—including in its Initial Disclosures—Apotex has failed to identify a single witness located in Florida. *See* Ex. 2, Apotex's Initial Disclosures.

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[5] Apotex asserts that sanofi-aventis stated in its motion that "Apotex will require at least 100 fact depositions." *See* Apotex Opp. at 8. Apotex again distorts the record–in its opening brief sanofi-aventis actually stated that the parties as a whole in all four actions would require this number of depositions. *See* sanofi-aventis's Br. at 16.

Moreover, because consolidation by the Panel would be for pretrial purposes only, the consolidation will not necessarily require Apotex's witnesses–to the extent any actually reside in Florida–to travel to Delaware for depositions or otherwise. *See, e.g., In re MLR, LLC, Patent Litig.*, 269 F. Supp. 2d 1380, 1381 (J.P.M.L. 2003).

### B. Sanofi-aventis And Several Defendants Agree That Transfer And Consolidation Will Promote The Purposes Of The Hatch-Waxman Act

Apotex would have the Panel believe that ANDA litigation may not be consolidated under § 1407 because the Hatch-Waxman Act requires expeditious resolution of these suits. In fact, the Panel has rejected such arguments and has routinely granted transfer and consolidation in ANDA litigations to promote judicial economy, avoid inconsistent rulings, and prevent undue hardships to the parties and witnesses. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355; *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361. In fact, there is no justification for Apotex's position that the Hatch-Waxman Act requires that ANDA cases be tried as quickly as possible with no regard to any other interests of the courts or the parties. *See* Apotex Opp. at 1, 9-10.[6] Indeed, the Act expressly provides a 30-month period in which the litigation should proceed in order to afford the parties adequate time to litigate any infringement action in an orderly fashion without any damages issues or questions of emergency injunctions while there is a stay of FDA approval. 21 U.S.C. § 355(j)(5)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 578 (D.N.J. 2001).

What each of Apotex's arguments ignores is the fact that in implementing the Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering

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6 To support this argument, Apotex cites to *In re Barr Labs, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). This reliance is misplaced because *In re Barr* did not deal with an ANDA litigation. In that case, the court was confronted with a petition for a writ of mandamus by a drug manufacturer to compel the FDA to expedite the processing of an application for approval of generic drugs. *Id.* at 73.

research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). Thus, the Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement. Further, as noted above, the Act expressly provides for a 30-month stay of FDA approval to allow the parties adequate time to litigate ANDA infringement actions in an orderly fashion. 21 U.S.C. § 355(j)(5)(iii); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 344; *Ben Venue Labs.*, 146 F. Supp.2d at 578. Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act.

Moreover, Apotex's conduct in the litigation to date in both Florida and Delaware demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing this case while seeking to delay the Delaware action is motivated by the potential for significant financial gain to Apotex if it is able to enter the market with a generic copy of sanofi-aventis's Uroxatral® product without competition from the other 13 ANDA defendants.[7]

Indeed, two other generic defendants call Apotex out for trying to place itself on unequal footing with respect to the 13 other defendants. In their response in support of sanofi-aventis's motion, Actavis and Par note that Apotex clearly is seeking to "obtain an unfair advantage, to the

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[7] Apotex's delay in Delaware is evidenced by its refusal to timely consent to jurisdiction in that venue and by the timing of its motion to transfer in Delaware. Apotex first alerted the Delaware court that it preferred the Southern District of Florida in its Answer and Counterclaims on January 2, 2008. *See* Ex. 3 ¶10, Apotex's Delaware Answer and Counterclaims. Apotex then confirmed during a meet and confer with Plaintiffs on January 7 that it would move to transfer the Delaware action to Florida. *See* Ex. 4, 01/07/08 S. Feldman ltr to W Vuk. But Apotex waited another three weeks before filing its motion to transfer, after the parties exchanged their local rules disclosures in Florida and after Apotex was entitled to serve document requests in Florida. *See* Ex. 5, Apotex's Delaware Motion to Transfer. Apotex's failure to timely consent to Delaware jurisdiction and the timing of its motion to transfer in that forum certainly would not be considered "cooperating to expedite" under the Hatch-Waxman Act.

detriment of the other [13] first filers" in order "to go to market before the other [13] first filers". Actavis and Par's Resp. at 8-9. Actavis and Par agree that Apotex's actions are "contrary to the Hatch-Waxman Act . . . ." Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to continue to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex purports to espouse. Transferring the Florida action to Delaware and consolidating it with the actions pending there will place all ANDA defendants on equal footing. As other defendants here have noted, this is a primary purpose of the Act. Indeed, resolution of Plaintiffs' claims will best be expedited under the Hatch-Waxman Act through cooperation between sanofi-aventis and all 15 defendants in a single forum. This will also preserve judicial resources and avoid subjecting witnesses to multiple depositions on identical subject matter.

Apotex's suggestion that sanofi-aventis is not cooperating to expedite because it supposedly filed this motion to slow down the Florida action, Apotex Opp. at 2, 7, 9, 10, is completely without merit. In moving to transfer and consolidate, sanofi-aventis has been motivated by a desire to avoid duplicative litigation and inconsistent rulings. In fact, sanofi-aventis's conduct throughout this litigation has been entirely proper and consistent with its effort to promote efficiency and judicial economy. First, sanofi-aventis commenced suit against all defendants in the single forum—the District of Delaware—in which it believed all defendants were subject to personal jurisdiction. Although Apotex had previously appeared in Delaware ANDA litigations, including as a Plaintiff, without complaint, it refused to consent to personal jurisdiction within the window to file suit.[8] Because Apotex would not consent to personal

[8] Apotex argues that if sanofi-aventis was really concerned about jurisdiction in Delaware, it could have sued Apotex there any time during the first 24 days of the 45-day period, and still had sufficient time to file suit in Florida after Apotex answered, if Apotex had challenged personal jurisdiction. *See* Apotex Opp. at 17. This argument ignores the purpose of the 45-day period, which is to provide the patentee with sufficient time to determine whether

jurisdiction in Delaware, sanofi-aventis faced a serious dilemma, either risk losing its right to a 30-month stay or file a second protective suit in a district where it knew Apotex would not contest jurisdiction.[9] Sanofi-aventis made clear from the filing of its complaint against Apotex in Florida that its sole purpose was to protect its rights under the Act and that it would dismiss the suit if Apotex did not contest personal jurisdiction in Delaware. Thus, sanofi-aventis's motion practice before the Panel and the Florida court has been directed at resolving the venue issues created by Apotex's attempt at forum shopping.[10]

Apotex argues that unlike the ANDA actions that were transferred and consolidated in *In re Desloratadine*, 502 F. Supp. 2d at 1355, and *In re Rivastigmine*, 360 F. Supp.2d at 1361, discovery in the Florida action has "progressed substantially." *See* Apotex Opp. at 12. As discussed above, this is simply not true. In the Florida action, the parties have not had their initial case management conference with the court and discovery has been limited to the exchange of initial disclosures and Apotex's service of document requests and interrogatories.[11] Thus, while discovery in Florida has begun, it is in its infancy. Moreover, the Delaware Court has ordered a status conference for the Delaware actions on March 17, 2008. This is in sharp

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the proposed generic formulation infringes the patent. Congress did not provide a 45-day period so that jurisdictional challenges could be resolved. If that were the case, every generic company would wait until the end of the 45-day period to contest jurisdiction. Such late filing would ensure that the jurisdictional question would not be resolved until after the 45-day period ended and the patentee lost the right to the 30-month stay.

9 Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). It is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

10 Apotex also distorts the Florida record, claiming that the Florida court has rejected all attempts by sanofi-aventis to stay the Florida action. *See* Apotex Opp. at 2, 6. In reality, sanofi-aventis's motion to transfer or stay is still pending and the Florida court has yet to rule on it. *See* Ex. 6, sanofi-aventis's Florida Motion to Transfer or Stay.

11 To further the illusion that discovery in the Florida action is at advanced stage, Apotex incorrectly states that sanofi-aventis has served discovery. *See* Apotex Opp. at 1, 7. Sanofi-aventis has not served any discovery in the Florida action.

contrast to the situation in Florida where Apotex has refused sanofi-aventis's request for a status conference.

The cases relied on by Apotex in support of its position, including *In re Celotex Corp. 'Technifoam' Prods. Liab. Litig.* and *In re Women's Clothing Antitrust Litig.*, are inapposite. For example, in *In re Celotex*, the Panel considered whether to consolidate ten actions pending in four districts against the manufacturer of an insulation building product. 68 F.R.D. 502, 503-04 (J.P.M.L. 1975). The Panel consolidated nine of the ten cases. *Id.* at 505. One case was not consolidated for discovery purposes because discovery had already been completed. *Id.* Here, there has been no meaningful discovery in Florida, let alone to a level that could be considered completed. Furthermore, every party but Apotex supported or acquiesced to the pretrial coordination of these actions.

Similarly, *In re Women's Clothing* involved circumstances that are substantially different from the ones present here. In that case, the Panel considered whether to consolidate seven antitrust actions pending in three districts. 455 F. Supp. 1388, 1389 (J.P.M.L. 1978). The Panel declined to consolidate the actions for a variety of factors, *inter alia*: (1) substantial discovery had taken place in most actions (plaintiffs had reviewed thousands of documents), (2) most parties opposed transfer, (3) defendants offered to stipulate that depositions of top management witnesses could be used in each action, and (4) most parties demonstrated their willingness to cooperate in elimination of duplicative discovery. *Id.* at 1390-91. None of those factors are present here: (1) no substantial discovery has taken place; (2) every party but Apotex has supported or acquiesced to pretrial coordination of these four actions; (3) there has not been, nor is there likely to be, a stipulation to limit the number of depositions or to coordinate their use;

and (4) Apotex has not demonstrated any willingness to cooperate in eliminating duplicative discovery.[12]

**C. Coordinated Pretrial Proceedings Should Proceed In Delaware**

The Florida action should be consolidated for pretrial proceedings in Delaware. First, all parties to the four actions, except for Apotex, have supported or acquiesced to consolidation in Delaware. *See In re Static Random Access Memory (SRAM) Antitrust Litig.*, 473 F. Supp. 2d 1353, 1385 (J.P.M.L. 2007) (transferring to a district in part because that district was "favored (or not opposed)" by most parties). Further, the Panel has routinely recognized the advantage of consolidating cases in a district where most of the actions are pending. *See, e.g., In re TFT-LCD (Flat Panel) Antitrust Litig.*, 483 F. Supp. 2d 1353, 1354 (J.P.M.L. 2007) (transferring to a district where several actions were pending); *In re Static*, 473 F. Supp.2d at 1385 (same); *In re Mirtazapine Patent Litig.*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (same). Finally, the Panel has stated that it is appropriate that the action be consolidated in the district where the most broadly-based and earliest-filed action is pending. *See In re Regents of Univ. of Cal.*, 964 F.2d 1128, 1136 (Fed. Cir. 1992).

In view of these policies, the District of Delaware is the only forum situated to promote the interests of justice, efficiency, and convenience to all of the parties. The Delaware actions were earliest filed with two of the suits being filed against 13 defendants nearly three months before the Florida action was filed against just two related defendants. The first-filed Delaware actions also encompass all 15 defendants, making them the most broadly-based of the actions.

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[12] Indeed, Apotex has attempted to stymie sanofi-aventis's efforts to avoid duplicative discovery. Based on the Florida court's recommendation, sanofi-aventis sought to negotiate with all 15 defendants the terms of a "global" protective order to govern the Florida and Delaware actions. *See* Ex.7, 2/25/08 and 2/28/08 J. Parrett e-mails to all counsel. Apotex deemed this "unacceptable." *See* Ex. 8, 02/22/08 S. Rollo ltr to W. Vuk. Sanofti-aventis thus was forced to burden the Florida court with needless motion practice in order to compel Apotex to meet and confer on a protective order so that sanofi-aventis was not required to negotiate multiple separate orders. *See* Ex. 9, sanofi-aventis's Motion to Compel Apotex to Comply with Court's Order.

*Id.* Because sanofi-aventis's first-filed Delaware actions are already pending against all defendants in that district, it is most efficient to keep the cases there. Again, Apotex has conceded that jurisdiction and venue are proper in Delaware and has failed to identify any witnesses or documents relating to sanofi-aventis's action against Apotex that are located in Florida. These factors weigh considerably in favor of transfer of the Florida action to the District of Delaware for consolidation with the first-filed Delaware actions.

## III. CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Panel transfer *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON, pending in the Southern District of Florida to the District of Delaware, and consolidate that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Labs, Inc.*, No. 07-574 (GMS) (MPT), pending in that District.

Dated: March 3, 2008.

Respectfully submitted,

_____

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

*Id.* Because sanofi-aventis's first-filed Delaware actions are already pending against all defendants in that district, it is most efficient to keep the cases there. Again, Apotex has conceded that jurisdiction and venue are proper in Delaware and has failed to identify any witnesses or documents relating to sanofi-aventis's action against Apotex that are located in Florida. These factors weigh considerably in favor of transfer of the Florida action to the District of Delaware for consolidation with the first-filed Delaware actions.

## III. CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Panel transfer *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON, pending in the Southern District of Florida to the District of Delaware, and consolidate that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Labs, Inc.*, No. 07-574 (GMS) (MPT), pending in that District.

Dated: March 3, 2008.

Respectfully submitted,

Gerald J. Flattmann Jr. /AB

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

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FILED by D.C.
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STEVEN M. LARIMORE
CLERK U.S. DIST CT
S.D. OF FLA. MIAMI

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**EXHIBITS TO REPLY BRIEF IN SUPPORT OF PLAINTIFF'S MOTION FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407**

ATTACHMENT / EXHIBIT 1

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

William T. Vuk
To Call Writer Directly:
212 446-4757
wvuk@kirkland.com

212 446-4800

www.kirkland.com

Facsimile:
212 446-4900

October 1, 2007

**By Email**
Bernice Tao
Director, Regulatory Affairs US
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Re: Notification of Paragraph IV Certification
for Apotex Inc.'s Alfuzosin Hydrochloride Tablets, 10 mg

Dear Ms. Tao:

By letter dated August 14, 2007, Apotex Inc. ("Apotex") indicated that it submitted Abbreviated New Drug Application ("ANDA") 79-013 for alfuzosin hydrochloride extended release tablets, 10 mg, including a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") against U.S. Patent No. 6,149,940 ("the '940 patent"). Apotex further indicated that it intends to engage in the commercial manufacture, use, import, sale and/or offer for sale of the generic 10 mg alfuzosin hydrochloride extended release product defined by ANDA 79-013 before the expiration of the '940 patent.

In compliance with the procedures provided by the Hatch-Waxman Act, we have reviewed Apotex's letter and the portions of ANDA 79-013 provided by Apotex, as well as discussed Apotex's documents and method of manufacturing with you. In connection with this review, we carefully considered, *inter alia*:

(1) Apotex's representation at page 2 of the August 14th letter that Apotex's proposed alfuzosin hydrochloride tablets "do not comprise two or more layers;" and

(2) Apotex's representations in the portions of ANDA 79-013 provided regarding the composition of its proposed generic alfuzosin hydrochloride extended release product and the method of manufacturing for that product.

In reliance on Apotex's representations in its letter, the portions of ANDA 79-013 provided and the conversation with you, including the specific representations recited above,

KIRKLAND & ELLIS LLP



sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") will not file an action for infringement of the '940 patent against Apotex at this time. Sanofi-aventis, however, reserve the right to file such an action if they learn that Apotex's representations were incorrect or if Apotex or any other party amends ANDA 79-013.

In this regard, we remind Apotex that it is required to submit to the U.S. Food and Drug Administration an additional certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '940 patent if it amends ANDA 79-013 to change the composition or the method of manufacturing f the generic alfuzosin hydrochloride product defined therein. To the extent that Apotex makes any such certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it must also provide sanofi-aventis with the notice required by 21 U.S.C. § 355(j)(2)(B).

Sincerely,



William T. Vuk

cc: Dr. Bernard C. Sherman (via Federal Express)

ATTACHMENT / EXHIBIT 2

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) | |
| | ) | Case No. 07 C 61800 |
| Plaintiffs, | ) | Judge Moreno |
| vs. | ) | Magistrate Judge Simonton |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S RULE 26(a) (1) INITIAL DISCLOSURES**

Pursuant to Fed. R. Civ. P. 26(a) (1), Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") make the following initial disclosures based on the information available to Defendants at this time. Defendants reserve the right to supplement these disclosures.

**A. The Name and, If Known, the Address and Telephone Number of Each Individual Likely to Have Discoverable Information that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment, Identifying the Subjects of the Information**

1. Francois Regnier
6, rue de la Source
54000 Nancy, France

Subjects: The subject matter claimed in U.S. Patent No. 4,661,491; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

2. Helmuth A. Wegner
Wegner & Bretschneider
PO Box 18218
Washington, DC 20036-8218
(202) 887-0400

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 4,661,491; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

3. Lauretta Maggi
Via Folperti N.3
I-27100 Pavia
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

4. Ubaldo Conte
Via Treviglio n.6
I-20052 Busto Arisizio
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

5. Pascal Grenier
23a rue du Marechal de Saxe
68300 Saint Louis
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

6. Guy Vergnault
9 rue du Bois Vert
68300 Saint Louis
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

7. Alain Dufour
42 Avenue de Saxe
75007 Paris
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

8. Francois Xavier Jarreau
5 rue L. Herve
78000 Versailles
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

9. Clemence Rauch-Desanti
19 rue Prix d'Amerique
77330 Ozoire la Ferriere
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

10. D. Douglas Price
Jacobson, Price, Holman 7 Stern, PLLC
400 7th Street, N.W., Suite 600
Washington, DC 20004
(202) 638-6666

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 6,149,940; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

11. Bernice Tao
Apotex Inc.
c/o Welsh & Katz, Ltd.
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606

Subjects: Information on the non-infringement of the patents at issue.

12. Any other person substantively involved in the preparation and/or prosecution of U.S. Patent Nos. 4,661,491 and 6,149,940.

**B. A Copy of, or a Description by Category and Location of, All Documents, Data Compilations, and Tangible Things that Are in Possession, Custody, or Control of the Party and that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment**

Defendants identify the following documents, compilations and things that Defendants may use to support their claims or defenses:

1. Prior art and other documents and things identified in Apotex Inc's August 14, 2007 and October 15, 2007 Paragraph IV letters.

2. Documents related to U.S. Patents No. 4,661,491 and 6,149,940, including the patents themselves, the prosecution histories, and the prior art cited during the prosecution of the patents.

3. Abbreviated New Drug Application No. 79-013.

**C. A Computation of Any Category of Damages Claimed by the Disclosing Party, Making Available for Inspection and Copying as Under Rule 34 and Documents or Other Evidentiary Material, Not Privileged or Protected from Disclosure, in Which Such Computation Is Based, Including Materials Bearing on the Nature and Extent of Injuries Suffered.**

Defendants are not seeking damages at this time.

**D. For Inspection and Copying as Under Rule 34 Any Insurance Agreement Under Which Any Person Carrying on an Insurance Business May Be Liable to Satisfy Part or All of a Judgment Which May Be Entered in the Action or to Indemnify or Reimburse for Payments Made to Satisfy Judgment**

Defendants have not identified any documents of this type at this time.

Dated: January 17, 2008

Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

January 17, 2008

Sherry L. Rollo

ATTACHMENT / EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs | ) | |
| | ) | C.A. No. 07-792 (GMS) |
| v. | ) | |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**ANSWER OF APOTEX INC. AND APOTEX CORP.**
**TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufacturers numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufacturers numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used "throughout the United States", and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

**Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Plaintiffs' Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 ("the '491 patent") and that a copy of the '491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 et seq.

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufacturers numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

**ANSWER:** Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court's personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent

infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia,* its systematic and continuous contacts with Delaware, including through its sister corporation and agent Apotex Corp.

**ANSWER:** For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Delaware corporation.

**ANSWER:** Apotex Corp. does not dispute the Court's jurisdiction over it.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Apotex, Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action, but believe that the Southern District of Florida is a more convenient venue and that this case should be transferred there and joined with the copending civil action no. 07 C 61800 (S.D. Fla.), in which Apotex, Inc. and Apotex Corp. already have filed answers and counterclaims.

**The '491 Patent**

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended

release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

**Acts Giving Rise to this Action**
**Infringement of the '491 Patent by Defendants**

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

## GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

## DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses to the Complaint:

## FIRST DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

## SECOND DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

## THIRD DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted.

Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

## COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

### The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.

3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

### Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food,

Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).

7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District and because Apotex Corp. is incorporated in this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

**Patents-in-Suit**

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491 ("the '491 patent"), entitled "ALFUZOSINE COMPOSITIONS AND USE" to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 ("the '940 patent") entitled "TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE" to Lauretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in'940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the '940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The '491 patent and the '940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the '940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.'s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use of sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the'940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

**COUNT I**
**(Declaration of Non-Infringement of the '491 Patent)**

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s

ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

**COUNT II**
**(Declaration of Invalidity of the '491 Patent)**

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

**COUNT III**
**(Declaration of Non-infringement of the '940 Patent)**

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets,

10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

**COUNT IV**
**(Declaration of Invalidity of the '940 Patent)**

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

**REQUEST FOR RELIEF**

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;

(b) Declaring that the claims of the '491 patent are invalid;

(c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;

(d) Declaring that the claims of the '940 patent are invalid;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and

(f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (No. 2246)
Kenneth L. Dorsney (No. 3726)
Hercules Plaza, 6th Floor
1313 N. Market Street
P.O. Box 951
Wilmington, DE 19801
(302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

*Counsel for Defendants*
*Apotex Inc. and Apotex Corp.*

OF COUNSEL:

Robert B. Breisblatt
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
Tel: (312) 655-1500

Dated: January 2, 2008
840396 / 32533

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Richard L. Horwitz, hereby certify that on January 2, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 2, 2008, I have Electronically Mailed the document to the following person(s)

Jack B. Blumenfeld
Maryellen Noreika
James W. Parrett
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022
jdesmarais@kirkland.com
gflattmann@kirkland.com
wvuk@kirkland.com

*/s/ Richard L. Horwitz*
Richard L. Horwitz
Kenneth L. Dorsney
Potter Anderson & Corroon LLP
Hercules Plaza – Sixth Floor
1313 North Market Street
Wilmington, DE 19801
(302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

840408 / 32533

ATTACHMENT / EXHIBIT 4

**WELSH & KATZ, LTD.**

*Attorneys at Law*

120 SOUTH RIVERSIDE PLAZA · 22ND FLOOR
CHICAGO, ILLINOIS 60606-3912

TELEPHONE (312) 655-1500
FACSIMILE (312) 655-1501

www.welshkatz.com

**Steven E. Feldman**
sefeldman@welshkatz.com
Direct Dial (312) 526-1551

January 7, 2008

**Via Electronic Mail (wvuk@kirland.com) &**
**Confirmation by U.S. Mail**

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

***Re:*** ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
**Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear William:

We acknowledge receipt of your January 4, 2008 correspondence. We do not agree to transfer the above-captioned case to Delaware. Nor do we agree to a stay of the Florida action pending resolution of any motions to transfer. Sanofi is obligated under the Hatch-Waxman Act to "reasonably cooperate in expediting the action." *E.g.,* 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, we believe that Sanofi should dismiss its Delaware lawsuit against our clients in favor of the Florida action, which necessarily will proceed more quickly to resolution. Please let us know whether your client will agree to dismissal of the Delaware complaint.

I am available this afternoon (after 2pm (CST)) to discuss this and other issues related to the Court's scheduling order.

Very truly yours,

WELSH & KATZ, Ltd.

By: Steven E. Feldman

SEF/mh
cc: Alfred J. Saikali, Esq. (asikali@shb.com)
Stephen J. Bronis, Esq. (sbronis@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Sherry L. Rollo, Esq. (srollo@welshkatz.com)

ATTACHMENT / EXHIBIT 5

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) | |
| Plaintiffs, | ) | C.A. No. 07-792 (GMS) |
| v. | ) | **JURY TRIAL DEMANDED** |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**MOTION TO TRANSFER, OR IN THE ALTERNATIVE, TO STAY**

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") respectfully move this Court, pursuant to 28 U.S.C. § 1404, for an Order transferring this litigation to the Southern District of Florida where an identical lawsuit is pending. Alternatively, Apotex moves for an Order staying this litigation until a resolution is reached in Florida. The grounds for this Motion are fully set forth in Apotex's Opening Brief in Support filed contemporaneously herewith.

Apotex conferred with Plaintiffs regarding this Motion; Plaintiffs will oppose the Motion.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
Kenneth L. Dorsney (#3726)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

*Counsel for Defendants*
*Apotex Inc. and Apotex Corp.*

OF COUNSEL:

Robert B. Breisblatt
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
Tel: (312) 655-1500

Dated: January 24, 2008
843768 / 32533

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

Jack B. Blumenfeld
Maryellen Noreika
James W. Parrett
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022
jdesmarais@kirkland.com
gflattmann@kirkland.com
wvuk@kirkland.com

*/s/ Richard L. Horwitz*
Richard L. Horwitz
Kenneth L. Dorsney
Potter Anderson & Corroon LLP
Hercules Plaza – Sixth Floor
1313 North Market Street
Wilmington, DE 19801
(302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

840408 / 32533

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) | |
| Plaintiffs, | ) | C.A. No. 07-792 (GMS) |
| v. | ) | **JURY TRIAL DEMANDED** |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**ORDER**

Having considered Defendants Apotex Inc. and Apotex Corp.'s Motion to Transfer, Or In The Alternative, To Stay, it is hereby ORDERED this _____ day of _____, 2008 that the Motion is GRANTED. This Civil Action is hereby TRANSFERRED to the Southern District of Florida.

_____
UNITED STATES DISTRICT JUDGE

843781

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ATTACHMENT / EXHIBIT 6

Case 1:08-cv-00347-GMS Document 1-10 Filed 06/23/2008 Page 35 of 80


**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' MOTION TO TRANSFER OR STAY**
**AND SUPPORTING MEMORANDUM OF LAW**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action is currently pending. Defendants Apotex Corp. and Apotex Inc. do not contest personal jurisdiction in Delaware and admit that venue in that forum is proper. Plaintiffs' choice of forum, the first-filed rule, and the interests of justice and convenience to the parties and witnesses favor transfer of this action to Delaware where it will proceed before the same Judge and Magistrate Judge as two related actions involving 13 other defendants and the parallel action against Apotex Corp. and Apotex Inc. Alternatively, Plaintiffs respectfully move this Court to stay the present action pending the disposition of any transfer issues raised by Defendants in the first-filed forum.

Counsel for Plaintiffs certify that pursuant to Local Rule 7.1.A.3(a) it has met and conferred with counsel for Defendants in an effort to resolve the issues raised by Plaintiffs' Motion to Transfer or Stay. The parties were unable to resolve those issues.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully requests that the Court enter an Order granting Plaintiffs' Motion to Transfer or Stay.

**MEMORANDUM OF LAW**

This is an action brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this memorandum in support of their motion to transfer this action to the District of Delaware where an identical, parallel, first-filed action and two related cases against 13 other defendants are currently pending. Alternatively, Plaintiffs request that the Court stay this action pending the resolution of any venue issues raised in the Delaware action by Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex").

The District of Delaware is Plaintiffs' forum of choice and the first-filed forum. This is true not only for the parallel proceeding against Apotex, but also for sanofi-aventis's claims against 13 other defendants. Plaintiffs would not have even filed this action if Apotex had timely confirmed what it has now admitted in its pleadings and in its representations to Plaintiffs — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in that forum.

But rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions as the majority of Apotex's documents and witnesses are likely located in Canada where it develops its generic products, and the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum

in which they proceed. If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of time and resources on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts. Apotex's tactics will not only impact the parties in this case, but also the 13 additional defendants in Delaware where sanofi-aventis's other patent infringement actions will proceed regardless of what happens in this jurisdiction. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and transfer this case to Delaware so that all claims for patent infringement may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

Alternatively, if the Court does not transfer at this time, Plaintiffs respectfully request that it stay the present action and defer to the first-filed District of Delaware on the issue of venue while the parties continue to litigate their claims and defenses in that forum.

## BACKGROUND

### I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in the state of New Jersey.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. Apotex Inc. and Apotex Corp.

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sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. 1, The Apotex Group Corporate Info.[1]

**II. Sanofi-aventis's Patents And Innovator Drug**

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 (issued April 28, 1987) ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000) ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287.

**III. Infringement Of Sanofi-Aventis's Patents By The ANDA Filers**

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation and/or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale

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[1] True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Motion to Transfer or Stay.

[2] Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. 2, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. 3, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

## IV. Commencement Of The First-Filed District Of Delaware Actions

### A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In the District of Delaware

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try each of sanofi-aventis's claims against all defendants, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications. [3]

[3] In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940

*See* Ex. 4, Delaware Complaint No. 07-572; Ex. 5, Delaware Complaint No. 07-574.

**B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In The District Of Delaware Shortly Thereafter**

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. 6, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent. Ex. 7, Apotex Delaware Complaint. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

**C. Apotex Agreed Not To Contest Jurisdiction In The District Of Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit**

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. 9, 12/06/07 W. Vuk ltr to B. Sherman. It was only after that period ran that Apotex represented

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patent alone against four additional defendants.

[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. 8, Answer in *Allergan, Inc. v. Apotex Inc.et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. 8, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4.

that it would not contest jurisdiction in Delaware. Ex. 10, 12/11/07 M. Noreika email to S. Rollo; Ex. 11, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the complaint in Delaware and conceded that jurisdiction and venue were proper in Delaware:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." *See* Ex. 12, Apotex Delaware Answer And Counterclaims ¶ 7.
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Despite these clear admissions to the Delaware court as to the appropriateness of jurisdiction and venue, Apotex has indicated that it will move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* Ex. 12 ¶ 10; Ex. 13, 01/07/08 S. Feldman ltr to W. Vuk; Ex. 14, 01/07/08 W. Vuk ltr to S. Feldman.

All three first-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and the same Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. *See* Ex. 15, Delaware Docket Sheets. [5]

## V. Plaintiffs Brought The Present Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in Delaware within the 45-day window to bring

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[5] One additional protective suit is currently pending against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. Plaintiffs have not served the complaint in that action and expect that their claims against the Aurobindo defendants will proceed in the District of Delaware where jurisdiction and venue are proper with respect to both parties.

suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over Apotex, this is the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring this second-filed action within the 45-day window on December 10, 2007.[6] Ex. 16, Florida

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6 The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

Complaint. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing so that sanofi-aventis could voluntarily dismiss the Florida complaint.

It is now clear that this tactic was an attempt to make an end rule around Plaintiffs' choice of forum. Apotex filed its Answer and Counterclaims in this action on December 28, 2007, one business day before answering the first-filed Delaware action, in a thinly-veiled attempt to manufacture an argument that this action is at a more advanced state than the first-filed Delaware actions.[7] *See* Ex. 17, Florida Answer And Counterclaims; Ex. 18, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that this forum is "more convenient" with the "fact" that this action has progressed farther than the Delaware actions because it filed its answer in Florida one business day before answering in Delaware. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have failed.

## ARGUMENT

### I. All Relevant Factors Favor Transfer To Delaware Where Identical Claims And Counterclaims Are Pending With Related Claims Against 13 Other Defendants

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been

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[7] In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. 17 ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest the Delaware court's personal jurisdiction over Apotex Inc. Ex. 12 ¶ 8; *see also* Ex. 10; Ex. 11.

brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Manuel v. Convergys Corp.*, 430 F.3d 1132, 1135 n.1 (11th Cir. 2005).

There is no dispute that this Court has the power to transfer this action to the District of Delaware as, unlike the circumstances of many motions to transfer, sanofi-aventis and Apotex agree that jurisdiction and venue are proper in Delaware. The Court should exercise its power and transfer this action to the first-filed forum for adjudication with the parties' identical claims pending in that court along with two related patent infringement litigations involving the same patents-in-suit and reference drug—actions that will proceed regardless of what happens in this forum. First, Delaware is both Plaintiffs' forum of choice and the first-filed forum, two factors that weigh heavily in favor of transfer. Second, transfer would avoid the duplicative efforts and costs of two separate courts conducting extensive pretrial activities and prevent potentially inconsistent rulings on critical issues such as claim construction and summary judgment. Finally, although Apotex claims that it would be more convenient for it to proceed in this forum, that convenience is minimal as most of its relevant witnesses and documents are likely located in Canada where it develops generic products. Additionally, it is likely that this action will take a significant amount of time to adjudicate regardless of where it proceeds in light of the complex nature of the case and the expected scope of discovery. Any minimal added burden of litigating in Delaware, where Apotex has recently litigated several other ANDA actions without moving to transfer, is heavily outweighed by the interests of judicial economy and certainty of patent rights as well as the inconvenience the parties would experience by litigating the same issues in two separate judicial districts. *See Abbott,* 2006 WL 850916, at *8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint).

**A. Both the Plaintiffs' Choice of Forum and the First-Filed Rule Favor Transfer**

Plaintiff's choice of forum weighs in favor of a request to transfer and should not be disturbed unless clearly outweighed by other considerations. *Cf. Robinson v. Giarmarco & Bill, P.C.*, 74 F.3d 253, 260 (11th Cir. 1996) (refusing to transfer outside of plaintiffs' forum where such a transfer would merely shift the burdens on the parties). Here, sanofi-aventis chose the District of Delaware because it was the district where Plaintiffs could bring each of the ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. Plaintiffs were only forced to bring this second-filed action because Apotex refused to confirm that it would not contest jurisdiction in Delaware within the 45-day window Plaintiffs had to bring suit under the Hatch-Waxman Act. *See, e.g.,* Ex. 9. As discussed above, the law remains unclear as to whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act, namely the 30-month stay of approval of the proposed generic product, if its action, properly brought within the 45-day window, is later dismissed for lack of personal jurisdiction. *See Abbott*, 2006 WL 850916, at *8; *PDL,* 2007 WL 2261386, at *2. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should transfer this action to Plaintiffs' forum of choice. *See* Ex. 10; Ex. 11; Ex. 12 ¶¶ 7-10.

Transfer under this set of facts would also comport with the 11th Circuit's "first-filed" rule. Under that standard, if two actions involving the same parties and identical issues are pending in different districts, the first-filed action should typically be given priority and be allowed to proceed in favor of the later action. *See Manuel*, 430 F.3d at 1135-38 ("[W]here two actions involving overlapping issues and parties are pending in two federal courts, there is a strong presumption across the federal circuits that favors the forum of the first-filed suit under the first-filed rule."); *Philibert v. Ethicon, Inc.*, No. 04-81101-CIV, 2005 WL 525330, at *1 (S.D.

Fla. Jan. 14, 2005). Contrary to Apotex's unsupported assertions, this rule applies even where plaintiff files both actions, a measure that courts have recognized as necessary under the Hatch-Waxman Act. Ex. 14; *PDL*, 2007 WL 2261386, at *2; *see also Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202-03 (S.D. Fla. 1987) (rejecting defendants' assertion that a plaintiff must show a change of circumstances when moving under § 1404 and ordering transfer to the first filed forum where four related litigations involving these and other defendants were already pending).[8]

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Consequently, the Court should transfer this action under the first-filed rule. *Philibert*, 2005 WL 525330 at *2 (transferring to the first-filed forum where identical claims were pending to serve the interests of justice); *Tiber Labs., LLC v. Cypress Pharm., Inc.*, No. 2:07-CV-0014-RWS, 2007 WL 3216625, at *2-3 (N.D. Ga. May 11, 2007).

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[8] The first-filed rule is measured by which action was filed first, not by when counterclaims are first filed. Consequently, Delaware is the first-filed forum in this case, even though Apotex's counterclaims with respect to the '940 patent were filed in this District one business day before filing them in Delaware. *See Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d 738, 740-41 (E.D. Wis. 2003) (rejecting a similar argument concerning declaratory judgment counterclaims asserted in the second-filed action concerning patents not initially at issue in the first-filed action because "[t]he issue, however, is not which of the claims was filed first, but rather which action was filed first."); *Versus Tech., Inc. v. Hillenbrand Indus., Inc.*, No. 1:04-CV-168, 2004 WL 3457629, at *6-7 (W.D. Mich. Nov. 23, 2004); *cf. Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 831-32 (2002) (holding that counterclaims cannot serve as the basis for "arising under" jurisdiction under the well-pleaded complaint rule).

**B. The Interests of Justice Can Only Be Served By Transfer To The Forum Where All Others Claims Concerning The Patents Are Pending**

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997).

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.,* a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at *1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a separate declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at *2; *Cordis Corp.*, 682 F. Supp. at 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel

between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the Court held that all the parties would benefit because:

> The two actions should be consolidated before one judge thereby promoting judicial efficiency, pretrial discovery could be conducted in a more orderly manner, witnesses could be saved the time and expense of appearing at trial in more than one court, duplicative litigation involving the filing of records in both courts could be avoided eliminating unnecessary expense and the possibility of inconsistent results could be avoided."

*Id.* at 888 (internal quotations omitted).

The facts supporting transfer are even more compelling here where sanofi-aventis has multiple suits pending in the District of Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to the parallel action against Apotex, there are two other cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of what happens in this forum. Each of these actions has been assigned to the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order from the court. Plaintiffs expect that the Delaware court will coordinate pretrial activities in all three pending cases, and may consolidate all three actions for pretrial proceedings, in order to avoid duplicative discovery efforts and improve the efficiency of its docket.

By transferring this action for coordination with the Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. For example, as the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer will avoid multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the ANDA filers may seek discovery.

Likewise, transfer will avoid duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Delaware will obviate the need for multiple courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, transfer will prevent potentially inconsistent rulings on critical issues such as the validity and enforceability of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to the specialized *Markman* hearing courts must hold to construe the meaning of asserted claim terms as a matter of law, where inconsistent rulings could result in identical claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MRL, LLC v. U.S. Robotics Corp.,* No. 02 C 2898, 2003 WL 685504, at *1-2 (N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

### C. Apotex's Unsupported Convenience And Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors

Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in this District. Ex. 12 ¶ 10; Ex. 18 ¶ 19. As discussed above, Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations without moving to transfer. In this case, as in the *Alere* and *Tingley* cases discussed above, any marginal convenience to Apotex of proceeding in Florida is vastly outweighed by the courts' and the

parties' interests in avoiding duplicative pretrial activities, in preventing potentially inconsistent rulings, and the inconvenience to the parties of having to proceed in two separate jurisdictions.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to this forum even though there were no related actions pending in Indiana, let alone claims against 13 other defendants as in the case at bar. *See Alcon Mfg., Ltd. v. Apotex Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007). In *Alcon*, Apotex argued that (1) this forum was more convenient to Apotex and its witnesses and no less convenient for the plaintiff and (2) the interests of justice favored this forum because it had an interest in deciding local controversies and could conduct a more speedy trial.

The *Alcon* court rejected both of Apotex's arguments. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally; thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon,* 2007 WL 854026, at *2-3. Second, Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.; see also Abbott*, 2006 WL 850916, at *7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). Finally, the court rejected Apotex's interest of justice arguments as the suit was likely to affect consumers nationwide, not just in Florida, and because the case involved complex issues concerning patent infringement, it would likely take several years to

adjudicate, regardless of the venue. *Alcon,* 2007 WL 854026, at *4.

This case falls squarely within the *Alcon* court's rationale. Sanofi-aventis's witnesses and documents are likely to be found in Europe, New Jersey, and Pennsylvania, not Florida. As in *Alcon*, Apotex Inc., the Canadian corporation, is the holder of the ANDA, and it is likely that Canada is the situs of events such as preparation of that ANDA and its underlying research and development as well as the documents concerning and the witnesses with knowledge of those issues. Likewise, Apotex can make no showing this is a local dispute over which Florida has any specialized interest because Uroxatral® is sold throughout the country and Plaintiffs expect that Apotex will seek to market its products well beyond the borders of this forum as it has with its other generic products developed and manufactured abroad.

Apotex has indicated that the interest of a speedy trial necessitates proceeding in this Court. Ex. 13, Ex. 14. That argument failed in *Alcon* and should fail here as well. This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art, and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, sanofi-aventis will ask Apotex to consent, or otherwise move the Court, to place this action on a Complex Track under Local Rule 16.1.A to ensure that the parties conduct

discovery in a fair and efficacious manner and fully develop their claims and defenses prior to trial.

And here of course, there is the additional factor that was not present in *Alcon*: that there are actions pending against 13 other defendants in the first-filed forum that must proceed regardless of where the present case is adjudicated.[9]

## II. Alternatively, This Court Should Exercise Its Discretion To Stay This Action Pending The District Of Delaware's Adjudication Of Any Transfer Issues

If the Court does not transfer, sanofi-aventis respectfully requests that it stay the present action pending resolution of any transfer issues raised by Apotex in the first-filed Delaware action. It is well-settled that district courts have discretion to stay an action to give priority to first-filed parallel proceedings in another district. *See, e.g., Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183-4 (1952); *Landis v. N. Am. Co.*, 299 U.S. 248 (1936); *Perkins v. Am. Nat. Ins. Co.*, 446 F. Supp. 2d 1350, 1353-54 (M.D. Ga. 2006). This power to stay actions is in the interest of "[w]ise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation . . . ." *Kerotest*, 342 U.S. at 183; *Landis*, 299 U.S. at 254; *Lisa v. Mayorga*, 232 F. Supp. 2d 1325, 1326 (S.D. Fla. 2002). In deciding whether to order a stay, a district court should weigh the factors of judicial economy and balance the interests of the parties and the Court. *Id.*

The court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay a second-filed so-called "protective action" based on the "first-filed" rule. ANDA filer and defendant Sun opposed

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9 For the forgoing reasons, Plaintiffs expect that Apotex will likely fail in any motion to transfer the Delaware action to this forum. *See, e.g., Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at *2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where, *inter alia*, plaintiff had a rational and legitimate reason to sue defendants in the forum and noting that "a flight to Delaware is not an onerous task warranting transfer.").

the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *PDL*, 2007 WL 2261386, at *2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

> Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the 'extraordinary circumstances' of the case weighs in favor of the stay.

*Id.* "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay." *Id.; see* Ex. 19, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (staying second-filed action while jurisdictional issues were pending before the first-filed court).

The facts in the present case are identical in all relevant respects to those in *PDL*. Sanofi-aventis was forced by Apotex's temporary refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in this District. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge

jurisdiction. *See* Ex. 12. Apotex can hardly argue that sanofi-aventis's filing of parallel actions, or this motion, are motivated by bad faith or forum shopping. *See PDL*, 2007 WL 2261386, at *2; *see also Abbott*, 2006 WL 850916, at *8.

As in *PDL*, balancing the interests of the parties favors a stay of this action. Requiring the parties to litigate the same issues in this action in parallel to the first-filed Delaware actions is likely to lead to significant duplication of effort and expense, as discussed above with respect to transfer. There is no prejudice to weigh against these interests as the parties will continue to litigate their claims and defenses in the District of Delaware. Moreover, in the unlikely event that Apotex successfully moves the Delaware court to transfer the first-filed action here, the Court can immediately lift the stay and proceed in this case.

**CONCLUSION**

For all the foregoing reasons sanofi-aventis requests that the Court transfer this action to the District of Delaware. In the alternative, sanofi-aventis requests that the Courts stay this action until the District of Delaware adjudicates any motion to transfer brought by Apotex.

Dated: January 8, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

s/ Alfred J. Saikali_____
Alfred J. Saikali
Fla. Bar No.: 178195
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470
asaikali@shb.com
*Attorneys for Plaintiffs*

Case 1:08-cv-20847-CMS Document 1-10 Filed 06/23/2008 Page 55 of 80


**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470

*Attorneys for Plaintiffs*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and*
*Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, vs. APOTEX INC. and APOTEX CORP., Defendants. | ) |

**[PROPOSED] ORDER GRANTING**
**PLAINTIFFS' MOTION TO TRANSFER OR STAY**

THIS CAUSE is before the Court on Plaintiffs' Motion to Transfer or Stay, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that:

1. [ ] The above-captioned proceeding is hereby transferred to the United States District Court for the District of Delaware.

   [ ] The above-caption proceeding is hereby stayed until the District of Delaware adjudicates any motion to transfer brought by Defendants.

2. The Parties are hereby authorized to take action consistent with this Court's ruling.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of January, 2008.

_____
Honorable Federico A. Moreno
United States District Court Judge

ATTACHMENT / EXHIBIT 7



**"Parrett, James"**
**<JParrett@mnat.com>**

02/25/2008 09:05 PM

To "'Andre G. Bouchard'" <abouchard@bmf-law.com>, "'Chad A. Landmon'" <cal@avhlaw.com>, "'Christine J. Siwik'" <csiwik@rmmslegal.com>, "'Darrell L. Olson'" <dolson@kmob.com>, "'David B. Abramowitz'" <dabramowitz@lockelord.com>, "'David E. Moore'" <dmoore@potteranderson.com>, 'David Margules' <dmargules@bmf-law.com>, "'Deanne M. Mazzochi'" <dmazzochi@rmmslegal.com>, 'Eric Cohen' <eric.cohen@kattenlaw.com>, "'Francis J. Murphy'" <fmurphy@msllaw.com>, "'Frederick L. Cottrell'" <cottrell@rlf.com>, 'John Shaw' <jshaw@ycst.com>, 'John Will Ongman' <jwo@avhlaw.com>, 'Josy Ingersoll' <jingersoll@ycst.com>, "'Keith D. Parr'" <kparr@lockelord.com>, "'Kevin M. Nelson'" <knelson@lockelord.com>, "'Lynn E. Eccleston'" <leccleston@mcguirewoods.com>, 'Manotti Jenkins' <manotti.jenkins@kattenlaw.com>, 'Mark Schuman' <mschuman@ccvl.com>, 'Mary Matterer' <mmatterer@morrisjames.com>, "'Paul J. Molino'" <pmolino@rmmslegal.com>, "'Philip A. Rovner'" <provner@potteranderson.com>, "'Richard L. Horwitz'" <rhorwitz@potteranderson.com>, "'Robert B. Breisblatt'" <rbbreisblatt@welshkatz.com>, "'Robert J. Waddell Jr.'" <rwaddell@mcguirewoods.com>, "'Robert L. Florence'" <rflorence@mcguirewoods.com>, 'Samuel Lockner' <slockner@ccvl.com>, "'Sanjay B. Sitlani'" <jbs@avhlaw.com>, "'Sherry L. Rollo'" <srollo@welshkatz.com>, "'Steven E. Feldman'" <sefeldman@welshkatz.com>, "'T. Chiacchio'" <tchiacchio@rmmslegal.com>, "'T. Raghavan'" <traghavan@rmmslegal.com>, 'Theresa Pullan' <tpullan@morrisjames.com>, "'Timothy H. Kratz'" <tkratz@mcguirewoods.com>, 'William Zimmerman' <bzimmerman@kmob.com>, "'Kenneth L. Dorsney'" <kdorsney@potteranderson.com>, "'Richard L. Horwitz'" <rhorwitz@potteranderson.com>, "'Robert B. Breisblatt'" <rbbreisblatt@welshkatz.com>, "'Sherry L. Rollo'" <srollo@welshkatz.com>, "'Steven E. Feldman'" <sefeldman@welshkatz.com>, "'Brian E. Farnan'" <bef@pgslaw.com>, "'George C. Lombardi'"




<glombardi@winston.com>, "'Ivan M. Poullaos'" <ipoullaos@winston.com>, "'John C. Phillips, Jr.'" <jcp@pgslaw.com>, "'Kurt A. Mathas'" <kmathas@winston.com>, "'Taras A. Gracey'" <tgracey@winston.com>, "'jcoberly@zuckerman.com'" <jcoberly@zuckerman.com>

cc 'William T Vuk' <wvuk@kirkland.com>, Alexis Gorton <agorton@kirkland.com>, "Blumenfeld, Jack" <JBlumenfeld@MNAT.com>


Subject Sanofi aventis v. Actavis, Barr & Apotex- protective order

Dear Counsel,
Attached please find a draft Protective Order proposed by plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC to govern the disclosure, use and maintenance of confidential information in *Sanofi-aventis et al. v. Actavis South Atl. LLC et al.*, C.A. No. 07-572 (D. Del.); *Sanofi-aventis et al. v. Apotex Inc. et al.*, C.A. No. 07-792 (D. Del.); *Sanofi-aventis et al. v. Apotex Inc. et al.*, 0:07-CV-6 1800-FAM-AMS (S.D. Fla..) and *Sanofi-aventis et al. v. Barr Labs, Inc.*, C.A. No. 07-574 (D. Del.). We propose that the parties meet and confer on the terms of this proposed order on Wednesday, February 27, 2008 at noon Eastern. Please let me know if you can participate at that time or provide your alternative availability to meet and confer this week.

Sincerely,
James Parrett


**James W. Parrett, Jr.** ☎ (302) 351-9678 ✉ jparrett@mnat.com
Morris, Nichols, Arsht & Tunnell LLP | 1201 North Market Street | Wilmington, DE 19801



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Sanofi-Aventis - Proposed Global Stipulated Protective Order.DOC



**"Parrett, James"**
**<JParrett@mnat.com>**
02/28/2008 07:20 PM

To "'Paul J. Molino'" <paul@rmmslegal.com>, "Andre G. Bouchard" <abouchard@bmf-law.com>, "Chad A. Landmon" <cal@avhlaw.com>, Christine Siwik <csiwik@rmmslegal.com>, "Darrell L. Olson" <dolson@kmob.com>, "David B. Abramowitz" <dabramowitz@lockelord.com>, "David E. Moore" <dmoore@potteranderson.com>, David Margules <dmargules@bmf-law.com>, "Deanne M. Mazzochi" <DMazzochi@rmmslegal.com>, Eric Cohen <eric.cohen@kattenlaw.com>, "Francis J. Murphy" <fmurphy@msllaw.com>, "Frederick L. Cottrell" <cottrell@rlf.com>, John Shaw <jshaw@ycst.com>, John Will Ongman <jwo@avhlaw.com>, Josy Ingersoll <jingersoll@ycst.com>, "Keith D. Parr" <kparr@lockelord.com>, "Kevin M. Nelson" <knelson@lockelord.com>, "Lynn E. Eccleston" <leccleston@mcguirewoods.com>, Manotti Jenkins <manotti.jenkins@kattenlaw.com>, Mark Schuman <mschuman@ccvl.com>, Mary Matterer <mmatterer@morrisjames.com>, "Philip A. Rovner" <provner@potteranderson.com>, "Richard L. Horwitz" <rhorwitz@potteranderson.com>, "Robert B. Breisblatt" <rbbreisblatt@welshkatz.com>, "Robert J. Waddell Jr." <rwaddell@mcguirewoods.com>, "Robert L. Florence" <rflorence@mcguirewoods.com>, Samuel Lockner <slockner@ccvl.com>, "Sanjay B. Sitlani" <jbs@avhlaw.com>, "Sherry L. Rollo" <srollo@welshkatz.com>, "Steven E. Feldman" <sefeldman@welshkatz.com>, "Theodore J. Chiacchio" <tchiacchio@rmmslegal.com>, Tara Raghavan <traghavan@rmmslegal.com>, Theresa Pullan <tpullan@morrisjames.com>, "Timothy H. Kratz" <tkratz@mcguirewoods.com>, William Zimmerman <bzimmerman@kmob.com>, "Kenneth L. Dorsney" <kdorsney@potteranderson.com>, "Richard L. Horwitz" <rhorwitz@potteranderson.com>, "Robert B. Breisblatt" <rbbreisblatt@welshkatz.com>, "Sherry L. Rollo" <srollo@welshkatz.com>, "Steven E. Feldman" <sefeldman@welshkatz.com>, "Brian E. Farnan" <bef@pgslaw.com>, "George C. Lombardi" <glombardi@winston.com>, "Ivan M. Poullaos" <ipoullaos@winston.com>, "John C. Phillips, Jr." <jcp@pgslaw.com>, "Kurt A. Mathas" <kmathas@winston.com>, "Taras A. Gracey" <tgracey@winston.com>, "jcoberly@zuckerman.com" <jcoberly@zuckerman.com>, "pjl@kmob.com" <pjl@kmob.com>, "kpascale@ycst.com" <kpascale@ycst.com>

cc William T Vuk <wvuk@kirkland.com>, Alexis Gorton <agorton@kirkland.com>, "Blumenfeld, Jack"



<JBlumenfeld@MNAT.com>, "'ASAIKALI@shb.com'" <ASAIKALI@shb.com>

Subject RE: Alfuzosin Litigation, Delaware, Meet and Confer Proposed Dates

Dear Counsel,

Sanofi-aventis is available for a meet and confer at the time proposed (March 6, 2008 at 2:00 pm EST). So that we have time to review your proposed revisions and so that the parties can have a productive call, could you please circulate your proposed revisions by noon on March 5th?

I will circulate call-in information for the teleconference early next week.

Sincerely,

James

**James W. Parrett, Jr.** ☎ (302) 351-9678 ✉ jparrett@mnat.com
Morris, Nichols, Arsht & Tunnell LLP | 1201 North Market Street | Wilmington, DE 19801

ATTACHMENT / EXHIBIT 8

**Sherry L. Rollo**
srollo@welshkatz.com
Direct Dial (312) 526-1547

February 22, 2008

**Via Electronic Mail (wvuk@kirkland.com) &**
**Confirmation by U.S. Mail**

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

***Re:*** ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
**Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear Bill:

Your proposal to negotiate a protective order in the Florida litigation with 13 other defendants not involved in that litigation is unacceptable. The other parties are not involved in this litigation and would not be bound by any order entered by Magistrate Judge Simonton. The parties to this lawsuit, Sanofi and Apotex should negotiate the protective order as ordered by Magistrate Judge Simonton.

Again, if it is your position that Apotex's proposed protective order does not protect the interests of your client, provide your comments by Monday, February 25, 2008 so that we may have a meaningful discussion and meet the magistrate's March 3, 2008 deadline.

Very truly yours,

WELSH & KATZ, Ltd.

By: Sherry L. Rollo

SLR/lo
cc: Alfred J. Saikali, Esq. (asaikali@shb.com)
Alexis Gorton, Esq. (agorton@kirkland.com)
Jennifer R. Coberly, Esq. (jcoberly@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Steven E. Feldman, Esq. (sefeldman@welshkatz.com)

ATTACHMENT / EXHIBIT 9

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' MOTION TO COMPEL DEFENDANTS TO COMPLY WITH THE COURT'S FEBRUARY 20, 2008 ORDER AND INCORPORATED MEMORANDUM OF LAW**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-aventis"), pursuant to S.D. Fla. L. R. 16.1.B.6, respectfully move the Court to compel Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") to comply with this Court's February 20, 2008 Order directing the parties to confer and submit a joint proposed Protective Order on or before March 3, 2008.

Apotex has refused to comply with the February 20th Order. While continuing to profess that a Protective Order must be entered immediately, Apotex has refused three separate requests by sanofi-aventis to provide a date and time for the parties to meet and confer. Based on these refusals, sanofi-aventis believes that Apotex will continue to avoid compliance with the February 20th Order, or to engage in any meaningful discussion with sanofi-aventis and/or the

13 other defendants in the related Delaware actions on the terms of a Protective Order, unless further ordered to do so by the Court.

So that the parties may fully negotiate the terms of a Protective Order and avoid additional motion practice before the Court, sanofi-aventis also requests a seven (7) day extension until March 10, 2008 for the parties to submit a joint proposed Protective Order to the Court.

Pursuant to S.D. Fla. L.R. 7.1.A.3(a), Plaintiffs' counsel conferred with Defendants' counsel in a good faith effort to resolve the issues raised by this Motion. No resolution was obtained.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully request that the Court enter an Order granting Plaintiff's Motion to Compel Defendants to Comply with the Court's February 20, 2008 Order and extend the deadline for the parties to submit a joint proposed Protective Order to the Court until March 10, 2008.

## MEMORANDUM OF LAW

### I. THE COURT'S FEBRUARY 20TH ORDER REQUIRES THE PARTIES TO MEET AND CONFER ON THE TERMS OF THE PROTECTIVE ORDER

On February 20, 2008, the Court issued an Order Granting Defendants' Motion for Entry of a Protective Order (D.E. 51) ("February 20th Order"), noting the various concerns raised in sanofi-aventis's opposition to the motion with respect to the deficiencies of Apotex's proposal as well as its concerns over inconsistent or conflicting obligations with respect to the disclosure of confidential information in this Action and the three related Delaware actions. Thus, the Court required the parties to meet and confer and submit a joint proposed Protective Order, or a redlined version reflecting competing proposals for issues on which the parties are unable to agree, on or before March 3, 2008. D.E. 51 at 5. The Court also noted that the parties had not

"addressed whether any effort has been made to draft a global Protective Order that encompasses the parties' discovery obligations in this Court and in the Delaware Court, nor identified any rule, statute or reason that would prevent them from drafting and submitting such a proposed Order." *Id.* at 5 n.2.

## II. APOTEX HAS REFUSED TO MEET AND CONFER IN RESPONSE TO SANOFI-AVENTIS'S REPEATED REQUESTS

To comply with the February 20th Order, sanofi-aventis tried on three separate occasions to schedule a meet and confer with Apotex to resolve the parties' disputes concerning the terms of the Protective Order. Taking the Court's suggestion concerning a global Protective Order, sanofi-aventis has attempted to resolve these issues as they apply to both the Florida and Delaware actions. *See* D.E. 39, Plaintiffs' Opposition to Defendants' Motion for Entry of A Protective Order (outlining sanofi-aventis's concerns with Apotex's proposed order and the potential for inconsistencies between Protective Orders enter by this Court and the Delaware court). Apotex has refused to participate in any of these efforts, and consequently, is in violation of the Court's February 20th Order. Without an order compelling Apotex to comply with the February 20th Order, sanofi-aventis believes that Apotex will continue to refuse to meet and confer and that the parties will be forced to burden the Court with additional, unnecessary motion practice on these issues.

For example, on February 21st, one day after receiving the February 20th Order, sanofi-aventis requested that Apotex provide a date and time to meet and confer to negotiate an appropriate Protective Order to govern all pending ANDA litigations involving Uroxatral®. Ex. 1, 2/21/08 ltr from William T. Vuk to Sherry R. Rollo.[1] In its response, Apotex ignored sanofi-

[1] True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk In Support of Plaintiff's Motion to Compel Defendants to Comply with the Court's February 20, 2008 Order.

aventis's request to provide its availability and—despite sanofi-aventis's repeated assertions to the contrary—stated that its proposed Protective Order (D.I. 25-2, Apotex's Proposed Protective Order) "adequately protects both parties' interests." Ex. 2, 2/21/08 ltr from Sherry R. Rollo to Alexis Gorton. Also, in spite of the Court's February 20th Order setting March 3, 2008 as the date by which the parties had to complete negotiations, Apotex demanded that sanofi-aventis provide comments to its protective order no later than noon on February 25, 2008. *Id.*

Sanofi-aventis made a second attempt the next day to obtain a date and time from Apotex for the parties to meet and confer. Ex. 3, 2/22/08 ltr from William T. Vuk to Sherry R. Rollo. Apotex asserted that sanofi-aventis's proposal for a global protective order, as recommended by the Court, was "unacceptable" and again refused to provide a time to meet and confer. Ex. 4, 2/22/08 ltr from Sherry R. Rollo to William T. Vuk.

Finally, sanofi-aventis made a third attempt to arrange a meet and confer with Apotex and informed Apotex that, if necessary, it would seek relief from the Court to compel compliance with the Court's Order. Ex. 5, 2/25/08 ltr from Alexis Gorton to Sherry R. Rollo. Sanofi-aventis also forwarded Apotex, as well as the 13 other defendants in Delaware, a proposed global protective order to govern the disclosure of confidential information in this Action and the three related Delaware actions and again requested a time to meet and confer. Ex. 6, 2/25/08 email from James W. Parrett, Jr. to Delaware Defendants.

## III. THE COURT SHOULD COMPEL APOTEX TO MEET AND CONFER

Apotex is in violation of the Court's February 20th Order by its refusal to meet and confer with sanofi-aventis on the terms of a Protective Order. In fact, Apotex has either rejected or ignored sanofi-aventis's requests to meet and confer on three separate occasions and has completely rejected sanofi-aventis's proposal to meet and confer on a global Protective Order that would apply to this case and the related Delaware actions. A meet and confer is necessary

so that the parties can resolve their differences with respect to the terms governing the disclosure and use of confidential information. As sanofi-aventis outlined in its opposition to Apotex's motion, these differences are substantial and will greatly impact the parties' rights and obligations going forward. Further, the global Protective Order suggested by the Court will address sanofi-aventis's concerns over the potential for inconsistent and conflicting confidentiality obligations in this Court and the Delaware court, where sanofi-aventis's claims against Apotex and 13 other defendants are currently pending. Moreover, the likelihood that the transferee court, in the event this action is transferred to Delaware by the Court or the Judicial Panel on Multidistrict Litigation, will need to reconsider, modify, or vacate the Protective Order issued by this Court will decrease significantly if sanofi-aventis, Apotex, and the 13 other defendants confer and agree on the terms of an appropriate Protective Order now.

Consequently, the Court should compel Apotex to meet and confer and provide the parties with a seven (7) day extension until March 10, 2008 to comply with the February 20th Order so that the parties can avoid burdening the Court with additional motion practice on issues they should be able to resolve on their own.

Dated: February 26, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

and

John M. Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)

William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

Case 1:08-cv-20847-CMS Document 1-10 Filed 06/23/2008 Page 73 of 80


**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on February 26, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

*Attorneys for Plaintiffs*

Case 1:08-cv-00347-GMS Document 1-10 Filed 06/23/2008 Page 74 of 80


**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Robert B. Breisblatt, Esq.
Steven E. Feldman, Esq.
Sherry L. Rollo, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO COMPEL DEFENDANTS TO COMPLY WITH THE COURT'S FEBRUARY 20, 2008 ORDER**

THIS CAUSE is before the Court on Plaintiffs' Motion to Compel Defendants To Comply With The Court's February 20, 2008 Order filed on February 26, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is:

ORDERED AND ADJUDGED that Plaintiffs' Motion to Compel Defendants To Comply With The Court's February 20, 2008 Order is GRANTED.

The Defendants shall meet and confer with the Plaintiffs on or before _____, 2008.

The parties shall propose a joint stipulated Protective Order that is in line with the Court's February 20, 2008 Order, on or before March 10, 2008.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of February, 2008.

Case 0:07-cv-00847-CMS Document 110-10 Filed 06/23/2008 Page 76 of 80


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Honorable Federico A. Moreno

United States District Court Judge

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**CERTIFICATE OF SERVICE**

In accordance with Rule 5.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, I hereby certify that true and correct copies of PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS and accompanying papers were served this 3rd day of March, 2008, by depositing such copies with Federal Express, on each of the following parties:

**Judicial Panel on Multidistrict Litigation - Panel Attorney Service List** Page 1

Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation
Status: Pending on / /
Transferee District: Judge: Printed on 02/15/2008

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Cohen, Eric C.<br>KATTEN MUCHIN ROSENMAN<br>525 West Monroe Street<br>Suite 1600<br>Chicago, IL 60661-3693 | =>Phone: (312) 902-5200 Fax: (312) 902-1061 Email: eric.cohen@kattenlaw.com<br>Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries, Ltd. |
| Feldman, Steven E.<br>WELSH & KATZ LTD<br>120 South Riverside Plaza<br>22nd Floor<br>Chicago, IL 60606 | =>Phone: (312) 526-1551 Fax: (312) 655-1501 Email: sefeldman@welshkatz.com<br>Apotex Corp.*; Apotex, Inc.* |
| Flattmann, Jr, Gerald J.<br>KIRKLAND & ELLIS LLP<br>Citicorp Center<br>153 East 53rd Street<br>New York, NY 10022 | =>Phone: (212) 445-4800 Fax: (212) 446-4900 Email: gflattmann@kirkland.com<br>Sanofi Aventis*; Sanofi-Aventis, US, LLC* |
| Kratz, Timothy H.<br>MCGUIREWOODS LLP<br>1170 Peachtree Street, N.E.<br>Suite 2100<br>Atlanta, GA 30309 | =>Phone: (404) 443-5500 Fax: (404) 443-5784 Email: tkratz@mcguirewoods.com<br>Mylan Pharmaceuticals, Inc.* |
| Olson, Darrell L.<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 Main Street<br>14th Floor<br>Irvine, CA 92614 | =>Phone: (949) 760-0404 Fax: (949) 760-9502 Email: dolson@kmob.com<br>Ranbaxy Laboratories, Ltd.; Ranbaxy, Inc. |
| Ongman, John Will<br>AXINN VELTROP & HARKRIDER LLP<br>1330 Connecticut Avenue, NW<br>Washington, DC 20036 | =>Phone: (202) 912-4700 Fax: (202) 912-4701 Email: jwo@avhlaw.com<br>Actavis South Atlantic, LLC*; PAR Pharmaceutical, Inc.* |
| Parr, Keith D.<br>LOCKE LORD BISSELL & LIDDELL LLP<br>111 South Wacker Drive<br>Chicago, IL 60606-4410 | =>Phone: (312) 443-0497 Fax: (312) 896-6497 Email: kparr@lockelord.com<br>Torrent Pharma, Inc.*; Torrent Pharmaceuticals, Ltd.* |
| Poullaos, Ivan M.<br>WINSTON & STRAWN LLP<br>35 West Wacker Drive<br>Chicago, IL 60601 | =>Phone: (312) 558-5600 Fax: (312) 558-5700 Email: ipoullaos@winston.com<br>Barr Laboratories, Inc.* |
| Schuman, Mark D.<br>CARLSON CASPERS VANDENBURGH & LINDQUIST<br>225 South Sixth Street<br>Suite 3200<br>Minneapolis, MN 55402 | =>Phone: (612) 436-9600 Fax: (612) 436-9605 Email: mschuman@ccvl.com<br>Teva Pharmaceuticals USA, Inc.* |

Note: Please refer to the report title page for complete report scope and key.

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Siwik, Christine J.<br>RAKOCZY MOLINO MAZZOCHI SIWIK LLP<br>6 West Hubbard Street<br>Suite 500<br>Chicago, IL 60610 | =>**Phone: (312) 222-6304 Fax: (312) 222-6324**<br>Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc. |

I further certify that I caused true and correct copies of the foregoing documents to be filed with the Clerk of the United States District Court for the District of Delaware, on this 3rd day of March, 2008, by depositing such copies with Federal Express.

I further certify that I caused true and correct copies of the foregoing documents to be filed with the Clerk of the United States District Court for the Southern District of Florida on this 3rd day of March, 2008, by depositing such copies with Federal Express.

Dated: March 3, 2008

Respectfully submitted,

Gerald J. Flattmann, Jr. -KT

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PROTECTIVE ORDER**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this reply brief in further support of their motion for a Protective Order temporarily staying discovery on the merits of this action, including the discovery requested to date by Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex"), pending the Court's decision on sanofi-aventis's motion to transfer or stay and the Judicial Panel on Multidistrict Litigation's ("the Panel") ruling on sanofi-aventis's motion for transfer and consolidation under 28 U.S.C. § 1407.

Sanofi-aventis is not trying to "opt out" of the discovery process or "avoid having to respond to outstanding discovery." No matter what misnomers Apotex chooses for its brief title and headings, the fact is that sanofi-aventis will fully participate in discovery, but believes those activities should be conducted in the forum where this action will ultimately proceed to avoid burdening the courts, parties, and witnesses—a group completely ignored by Apotex—with time

consuming and costly, duplicative litigation efforts. Any claimed burden to Apotex is minimized by the fact that the requested Protective Order may immediately be lifted, if necessary, once the Court and the Panel rule, and that discovery will continue in Delaware where all 15 ANDA defendants, including Apotex, are participating. In any event, any burden claimed by Apotex is greatly outweighed by the benefits to this Court, the Delaware court, sanofi-aventis, the 13 other ANDA defendants, the witnesses, and the public of conducting discovery in single forum on a coordinated schedule where all defendants are on equal footing. Consequently, the Court should grant the very limited Protective Order sought by sanofi-aventis's motion and stay discovery on the merits of this action until the Court and the Panel rule on the pending motions to transfer or stay.

## I. The Requested Protective Order Will Ensure That Discovery Proceeds In An Efficient Manner To Minimize The Burden On The Judicial System, Witnesses, Third Parties And The Parties Themselves

Apotex does not contest that the discovery it seeks goes to the merits of this action and not to the venue issues pending before the Court, the Delaware court, and the Panel. *See* D.I. 44 at 4. Additionally, Apotex does not even attempt to address the case law that supports the Court exercising its inherent power to stay discovery on the merits for a limited time while the question of venue is resolved so that all involved, including third parties and witnesses, can avoid duplicative discovery. *See* D.I. 44 at 6-7 (citing *Enplanar, Inc. v. Marsh*, 11 F.3d 1284, 1291 (5th Cir. 1994); *McDonnell Douglas Corp. v. Polin,* 429 F.2d 30, 31 (3d Cir. 1970); *Sawgrass Sys. Inc. v. BASF Corp.,* 50 U.S.P.Q.2d 1692, 1693 (D.S.C. 1999); *Narco Avionics, Inc. v. Sportsman's Mkt., Inc.,* No. 90-8056, 1991 WL 255669, *2 (E.D. Pa. Nov. 27, 1991)). All Apotex can say is that the Panel's rules do not automatically stay pretrial proceedings while a motion is pending before it. *See* D.I. 60 at 2. While Apotex's quotation of the rule is correct, it completely ignores the fact that district courts routinely issue stays while motions are pending

before the Panel to avoid wasteful duplication and the potential for inconsistent rulings. *See* D.I. 44 at 6 n. 4 (citing *Bonenfant v. R. J. Reynolds Tobacco Co.*, No. 07-60301-CIIV, 2007 WL 2409980, at *1 (S.D. Fla. July 31, 2007); *Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007); *Anderson v. Merck & Co. Inc.*, 417 F.Supp.2d 842, 849 (E.D. Ky. Feb. 28, 2006); *U.S. Bank v. Royal Indem. Co.*, No. CIV.A.3:02-CV-0853-P, 2002 WL 31114069, at *2 (N.D. Tex. Sept. 23, 2002).[1]

The Court will realize those same benefits here with a limited stay of discovery on the merits. Far from trying to "opt out" of discovery in this case, (D.I. 60 at 1-2),[2] sanofi-aventis has repeatedly stated that it will fully participate in discovery, but requests that those activities go forward in the forum where the case will proceed to prevent sanofi-aventis from having to provide discovery on multiple occasions and witnesses from having to appear for multiple depositions on identical subject matter in both Florida and Delaware. Even other ANDA defendants agree that the overlap of issues will lead to duplication:

---

[1] Apotex cites *Kron Medical Corp. v. Groth*, but in that case Defendant sought "to stay discovery because most of his witness will be from Ohio [the transferee district]." 119 F.R.D. 636, 638 (M.D.N.C. 1988). In balancing the burdens to each party, the court noted that "a major part of the discovery will involve the parties themselves who are located in each state." *Id.* at 638. While the court in *Kron* ultimately denied the motion to stay discovery, the factors it considered in evaluating *Kron*'s relatively simple dispute between two parties are minimal in comparison to the burdens on the courts, parties, and witnesses cited by sanofi-aventis. Moreover, *Kron* is easily distinguishable because Apotex has not identified a single relevant witness or document in Florida.

[2] Sanofi-aventis disagrees that it has requested any "lengthy delays" as Apotex claims. *See* D.I. 60 at 1. For example, the motion to transfer or stay (D.I. 5), which is still pending, requests a limited stay while the Delaware court resolves the venue issues raised in that forum by Apotex. Likewise, sanofi-aventis's request to stay pending the JPML proceeding (D.I. 32) was limited to the time during which the Panel considers sanofi-aventis's motion to transfer and consolidate. These limited stay requests, such as the request of the present Motion, are in stark contrast to Apotex's request in Delaware, where it has sought to delay sanofi-aventis's first-filed action indefinitely until there is a final resolution of this case. *See, e.g., Landis v. N. Am. Co.*, 299 U.S. 248, 257 (1936) (noting disfavor of unlimited stays).

> Given that many common issues of fact exist in all four Related Actions, discovery will substantially overlap. If the cases are consolidated, the transferee court can order common discovery on the overlapping issues, avoid the need for multiple and duplicative discovery and limit the number of discovery motions that would need to be filed. . . . [B]ecause the testimony of many witnesses is likely to be needed in more than one of the Related Actions, consolidation would prevent the need for multiple depositions of each witness.

Ex. 4 at 7, Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support of Motion to Transfer And Consolidate.[3]

The other ANDA defendants clearly recognize what Apotex completely fails to address in its opposition—that avoiding duplicative discovery not only impacts the parties and the judicial system, but also the witnesses that will be forced to appear for deposition in multiple actions. *See* D.I. 44 at 7-8. As all four related actions involve the same patents and reference product, all 15 ANDA defendants are likely to seek deposition testimony from sanofi-aventis, its employees, and third-parties concerning the infringement and validity of the patents-in-suit as well as the development of Uroxatral®. Many of the witnesses reside outside of the United States, and may not even be within the power of the federal courts, will require interpreters for deposition, and may have health-related travel restrictions. Without the limited Protective Order requested by sanofi-aventis, the witnesses may be forced to travel and appear for deposition twice on identical subject matter, the parties will have to coordinate various schedules across the globe to make the depositions happen and two courts will have to rule on discovery motions concerning the methods by which the deposition testimony may be sought. *See* D.I. 44 at 8-9.

Instead of addressing these significant considerations, Apotex attempts to discount the burden to all involved by claiming that duplicating discovery "is just a matter of burning another

[3] True and correct copies of Exhibits 1-3 cited herein are attached to the Declaration of William T. Vuk In Support of Plaintiffs' Motion for Protective Order (D.I. 45). True and correct copies of Exhibits 4-6 cited herein are attached to the accompanying Declaration of William T. Vuk In Support of Plaintiffs' Reply In Support of Plaintiffs' Motion for Protective Order.

CD or DVD." (D.I. 60 at 3). This argument completely ignores the burden on witnesses and third parties. Additionally, Apotex's flippant dismissal of the burden to sanofi-aventis fails to address the fact that all 15 ANDA defendants will seek to serve requests for production, interrogatories, and other written discovery. There is nothing to support Apotex's contention that sanofi-aventis's responses would constitute nothing more than a cut-and-paste job. *See* D.I. 60 at 4.

As an initial matter, the discovery requests served by Apotex may change or be eliminated altogether if this action proceeds in Delaware where Apotex will likely have to work with the other ANDA defendants on the service of discovery requests. *See* D.I. 44 at 7. The reality is that sanofi-aventis will have to review and analyze all requests, negotiate with all defendants on terms for electronic searching, conduct a thorough search for documents based on the requests, review the returns for responsiveness to the specific requests and under the confidentiality rules agreed to by the parties and ordered by the court, and then produce the documents in a specific electronic format. Changes to any of these conditions in the forum where this action ultimately proceeds would lead to sanofi-aventis re-collecting, re-reviewing and re-processing documents for production at the cost of countless client and attorney hours and processing costs that can reach into the tens of thousands of dollars, if not higher, even if those costs amount to only a few cents per page produced. The potential for these harms is especially acute if this action proceeds in a district, such as Delaware, that provides guidelines for the parties to follow in setting the parameters for electronic discovery. *See* D.I. 44 at 7 (*citing* Ad Hoc Comm. for Elec. Discovery of the U.S. District Court for the District of Delaware, Default Standard for Discovery of Electronic Documents (E-Discovery"), available at http://www.ded.uscourts.gov/OrdersMain.htm (last visited Mar. 7, 2008).

There is little if any harm to Apotex to weigh against these significant considerations. First, the Protective Order may immediately be lifted, if necessary, as soon as the Court and the Panel rule on sanofi-aventis's motions.[4] Moreover, while the stay is in effect, discovery will continue in Delaware where sanofi-aventis is currently working with all 15 ANDA defendants. For example, sanofi-aventis's negotiations with all 15 ANDA defendants, including Apotex, are well underway to ensure that a single set of confidentiality rules govern the disclosure, use and maintenance of confidential information with respect to sanofi-aventis's claims against all defendants. The most recent meet and confer regarding the global protective order took place on March 10th; the parties have a few minor issues to resolve, but the parameters of the protective order are largely in place. *See* Ex. 5, 03/10/08 J. Parrett email to S. Feldman, et al.[5]

## II. Without A Protective Order In This Case, Apotex Will Prejudice Sanofi-Aventis And Other ANDA Filers, Frustrating Key Purposes Of The Hatch-Waxman Act

When Apotex states that the requested stay is in "no one's best interests," no one means Apotex as it continues to ignore that the judicial system, 15 other parties, as well as multiple witnesses and third parties have an interest in how this litigation proceeds. *See* D.I. 60 at 2. Apotex uses its opposition as another attempt to promote its own interests under the cloak of the Hatch-Waxman Act by arguing that a stay of discovery will be to the public's detriment. Again,

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[4] The briefing on sanofi-aventis's motion to transfer or stay in this Court was completed on February 11th. The briefing on sanofi-aventis's motion before the Panel was completed on March 3, 2008.

[5] While sanofi-aventis has replied to all discovery requests by Apotex in a timely fashion, Apotex has sought to delay discovery in the Delaware actions by initially refusing to engage in substantive and meaningful negotiations regarding the protective order governing document production. For example, Apotex repeatedly rejected sanofi-aventis's requests to negotiate the terms of a global protective order to govern discovery in all four actions, even though this approach was suggested by Magistrate Judge Simonton, until sanofi-aventis filed a motion requesting the Court to compel Apotex to do so. D.I. 51, at 5; *see* Ex. 6, Compilation of correspondence concerning meet and confer process. In fact, Apotex would not even provide a date and time to discuss the terms of a protective order in any way until sanofi-aventis moved to compel.

Apotex ignores that in enacting the Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). Thus, the Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement, and by expressly providing for a 30-month stay of FDA approval to allow the parties adequate time to litigate ANDA infringement actions in an orderly fashion. 21 U.S.C. § 355(j)(5)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs.,* 146 F.Supp.2d 572, 578 (D.N.J. 2001). Requiring innovators such as sanofi-aventis to conduct duplicative discovery in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act.

Likewise, the Act provides a market exclusivity incentive for generics to file their ANDAs with the FDA as soon as possible:

> To encourage prospective ANDA applicants to risk the costly patent infringement suits triggered by their filing ANDAs, the statute also provides [that] . . . an applicant who files an ANDA . . . is eligible for a 180-day marketing exclusivity period during which no other generic drug maker who subsequently files an ANDA containing a paragraph IV certification on that patent can be approved for marketing its version of the drug product. ***This marketing exclusivity period starts on the earlier of the date the first-to-file ANDA applicant begins commercially marketing its generic drug or the date of "a decision of a court" finding the patent invalid, unenforceable, or not infringed.***

*Dr. Reddy's Labs.,* 302 F. Supp. 2d at 344 (internal citations omitted) (emphasis added); 21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. 314.107(c)(1) & (2).

Apotex argues that a protective order "potentially impact[s] . . . the public's ability to have the benefit of ***Apotex's*** generic alfuzosin product sooner." (D.I. 60 at 2-3) (emphasis added). Apotex's carefully-worded argument, however, sidesteps a key issue recognized by

other first filers—that Apotex is merely attempting to game the system to secure sole generic market exclusivity:

> [I]f Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, [the] FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.

Ex. 4 at 9. Apotex's motivations are apparent by its willingness to prejudice other generics and frustrate the purpose and incentives of the Hatch-Waxman Act. If Apotex is successful in preventing this Court's entry of a Protective Order, and manipulating the Hatch-Waxman Act for its own gain, the public will ultimately suffer—in the short term there would be a lack of alfuzosin generic competition, and in the long term there would be a diminished incentive for multiple generics to try to become potential first filers once they realize that a single generic may use procedural maneuvers to improperly jump ahead of them.

**CONCLUSION**

For the foregoing reasons, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully request that the Court enter a Protective Order staying discovery on the merits of this action until the Court and the Panel decide sanofi-aventis's motions to transfer or stay.

Dated: March 10, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

and

John Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)
William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 10, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

*Attorneys for Plaintiffs*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Robert B. Breisblatt, Esq.
Steven E. Feldman, Esq.
Sherry L. Rollo, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

**DECLARATION OF WILLIAM T. VUK IN SUPPORT OF PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PROTECTIVE ORDER**

I, William T. Vuk, declare:

I am an attorney with the law firm Kirkland & Ellis LLP, counsel for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC in this action. I submit this declaration in support of Plaintiffs' Reply In Support of Plaintiffs' Motion For Protective Order, and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 4 is a true and accurate copy of Defendants Actavis South Atlantic LLC's and Par Pharmaceutical, Inc.'s Response In Support of Motion To Transfer and Consolidate filed on February 25, 2008 in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

2. Attached hereto as Exhibit 5 is a true and accurate copy of an electronic mail from James Parrett to Steve Feldman, et al. dated March 10, 2008, without attachment.

3. Attached hereto as Exhibit 6 are true and accurate copies of:

- a letter dated February 21, 2008 from W. Vuk to Sherry R. Rollo, sent by electronic mail on February 21, 2008.
- a letter dated February 21, 2008 from Sherry R. Rollo to Alexis Gorton, received by electronic mail on February 21, 2008, without enclosure.
- a letter dated February 22, 2008 from W. Vuk to Sherry R. Rollo, sent by electronic mail on February 22, 2008.
- a letter dated February 22, 2008 from Sherry R. Rollo to William T. Vuk, received by electronic mail on February 22, 2008.
- a letter dated February 25, 2008 from Alexis Gorton to Sherry R. Rollo, sent by electronic mail on February 25, 2008.
- a letter dated February 26, 2008 from Sherry R. Rollo to Alexis Gorton, received by electronic mail on February 26, 2008.
- a letter dated February 26, 2008 from Alexis Gorton to Sherry R. Rollo, sent by electronic mail on February 26, 2008.

I declare under penalty of perjury that the foregoing is true and accurate.

/s/ William T. Vuk

William T. Vuk

March 10, 2008
New York, New York

# EXHIBIT 4

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**DEFENDANTS ACTAVIS SOUTH ATLANTIC LLC'S AND PAR PHARMACEUTICAL, INC.'S RESPONSE IN SUPPORT OF MOTION TO TRANSFER AND CONSOLIDATE**

Defendants Actavis South Atlantic LLC ("Actavis") and Par Pharmaceutical, Inc. ("Par") respectfully submit this response in support of Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC's (collectively, "sanofi") February 1, 2008 Motion to Transfer and Consolidate for Pretrial Proceedings ("sanofi's Motion"). Transfer and consolidation of the related actions for pretrial proceedings would promote the just and efficient conduct of the actions, conserve judicial resources and satisfy the purpose of the Hatch-Waxman Act by treating all first filers the same.

The four cases sanofi seeks to consolidate include three actions pending in the District of Delaware, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., No. 07-572 (GMS) (MPT), Sanofi-Aventis et al. v. Barr Laboratories, Inc., No. 07-754 (GMS) (MPT), and Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-792 (GMS) (MPT) (collectively, the "Delaware Actions"), as well as an action pending in the Southern District of Florida, Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-61800-CIV (S.D. Fla.) (the "Florida Action") (collectively, the "Related Actions").

All four cases involve the alleged infringement, validity and enforceability of two sanofi patents, U.S. Patent No. 4,661,491 ("the '491 patent") and U.S. Patent No. 6,149,940 ("the '940 patent"). The Related Actions are all at the early stages of pretrial discovery, and no undue prejudice will be imposed upon Apotex or any of the other defendants by consolidation. Given the overlapping issues, consolidation is appropriate. Moreover, if these actions are not consolidated, Actavis, Par and other first filers may be unfairly prejudiced.

**RESPONSES TO SANOFI'S AVERMENTS**

In response to the averments in sanofi's Motion, Actavis and Par, pursuant to Rule 7.1(b), respond as follows:

1. Admit.

2. Admit except that Actavis and Par do not have sufficient information to either admit or deny whether the '491 and '940 patents "cover" Uroxatral®.

3. Actavis and Par admit that Actavis filed an ANDA for a generic version of in the Summer of 2007 seeking to market its ANDA product before the expiration of the

'491 and '940 patents. Acatvis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

4. Actavis and Par admit that Actavis filed an ANDA with a Paragraph IV certification, asserting that the claims of the '491 and '940 patents are invalid and/or not infringed by the manufacture, use or sale of the proposed ANDA product. Actavis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

5. Actavis and Par do not have sufficient information to either admit or deny the truth of this averment because it involves communications between Apotex and sanofi.

6. Deny as to Actavis and Par. Actavis and Par do not have sufficient information to admit or deny the truth of this averment with respect to the filing of ANDAs by other defendants.

7. Admit that sanofi commenced the named actions. Actavis and Par do not have sufficient information to admit or deny sanofi's motivation for commencing these actions.

8. Admit.

9. Admit only that sanofi commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex, Inc, and Apotex Corp. (collectively, "Apotex") in Delaware on December 6, 2007 for infringement of the '491 patent, and that this action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge. Actavis and Par do not have sufficient information to either admit or deny that Apotex's second paragraph IV certification was dated October 25, 2007, or that

Apotex alleged therein that its proposed generic product did not infringe any valid claim of the '491 patent.

10. Admit.

11. Actavis and Par do not have sufficient information to admit or deny whether sanofi met its asserted deadline with respect to 13 defendants. The remaining content of Paragraph 11 of the sanofi motion reflects sanofi's view of the law rather than an averment, and thus no further response need be given.

12. Actavis and Par do not have sufficient information to admit or deny this averment because it is based on sanofi's beliefs or concerns regarding personal jurisdiction.

13. Admit that the District of Delaware can properly exercise personal jurisdiction over Actavis and Par. Actavis and Par do not have sufficient information to admit or deny that the District of Delaware can properly exercise jurisdiction over the remaining defendants. Actavis and Par admit that sanofi brought second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007 and against Apotex on December 10, 2007. Actavis and Par do not have sufficient information to admit or deny the remaining allegations in this averment because they are based on sanofi's beliefs or concerns regarding personal jurisdiction.

14. Actavis and Par do not have sufficient information to admit or deny this averment, because it is based on communications between Apotex and sanofi.

15. Admit.

16. Admit.

17. Admit.

18. Admit.

19. Admit.

20. Admit.

21. Agree with the relief requested by sanofi that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

## ARGUMENT

I. The Related Actions Should Be Consolidated Pursuant to Section 1407

A. The Related Actions Involve Common Questions of Fact and Law

The Related Actions should be consolidated because they involve many common issues, including claim construction, validity and enforceability issues relating to the '491 and '940 patents. Cases involving common questions of fact should be consolidated for pretrial proceedings when the transfer would "be for the convenience of parties and witnesses and [would] promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a) (2008); In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007). Transfer and consolidation do not require "complete identity or even a majority of common factual or legal issues." In re Kugel Mesh Hernia Patch Prods. Liab. Litig., 493 F. Supp. 2d 1371, 1374 (J.P.M.L. 2008). To the extent that non-common issues are involved, the transferee court can address those through pretrial procedures such as separate but concurrent discovery tracks. Id.

The Panel has repeatedly transferred and consolidated actions involving the alleged infringement of a patent by defendants seeking to make a generic version of a

pharmaceutical product. See, e.g., In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354 (J.P.M.L. 2007); In re Rivastigmine Patent Litig., 360 F. Supp. 2d 1361 (J.P.M.L. 2005); In re Omeprazole Patent Litig., MDL No. 1291, 1999 U.S. Dist. LEXIS 12589 (J.P.M.L. 1999).

Here, the Related Actions involve many common issues, including claim construction, validity and enforceability of the '491 and '940 patents. Both the Delaware and Florida courts will have to engage in a claim construction analysis of both patents, which involves analyzing the language of the relevant claims of each patent, the patents' specifications and the file histories of each patent. Claim construction could potentially include the consideration of extrinsic evidence as well, including scientific treatises and dictionaries and expert and inventor testimony. Common resolution of these issues would prevent inconsistent rulings that could prejudice Actavis, Par and the other defendants.

B. Consolidation Would Promote the Just and Efficient Resolution of the Related Actions

Consolidation of the Related Actions would promote the just and efficient resolution of the actions because it would "eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claims construction; and conserve the resources of the parties, their counsel and the judiciary." In re Desloratadine Patent Litig., 502 F. Supp. 2d at 1355. Consolidation of the Related Actions would conserve judicial resources, as it would require only one court to engage in the time- and labor-intensive tasks of analyzing the patents at issue, construing their claims and resolving the parties' disputes. Consolidation would also obviate the possibility of inconsistent pretrial rulings, which would not only

be fundamentally unfair to the parties, but which could also engender further appellate practice, thus consuming further judicial resources.

Transfer and consolidation are especially desirable here, where all four Related Actions are at a similar stage, and where no significant discovery has taken place. According to sanofi's Motion, Apotex has served one set of document requests, but no other discovery has been exchanged between any of the parties. Given that many common issues of fact exist in all four Related Actions, discovery will substantially overlap. If the cases are consolidated, the transferee court can order common discovery on the overlapping issues, avoid the need for multiple and duplicative discovery and limit the number of discovery motions that would need to be filed.

C. Consolidation Would Best Serve the Convenience of the Parties and Witnesses

Finally, transfer and consolidation is warranted under Section 1407 because it would be more convenient for the parties and witnesses, and would likely produce substantial cost savings for each party. Specifically, because the testimony of many witnesses is likely to be needed in more than one of the Related Actions, consolidation would prevent the need for multiple depositions of each witness. See In re Inter-Op Hip Prosthesis Prods. Liab. Litig., 149 F.Supp.2d 931, 933 (J.P.M.L. 2001) (stating that consolidation would result in "an overall savings of cost and a minimum of inconvenience to all concerned").

II. Consolidation Would Satisfy the Purposes of the Hatch-Waxman Act

Consolidation of the Related Actions would also be consistent with the incentive structure established by the Hatch-Waxman Act by treating all first generic filers the same. Through the Hatch-Waxman Act, Congress established an incentive structure to

encourage generic applicants to challenge brand patents with the express purpose of enhancing generic market competition. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2008); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n. 11 (D.C. Cir. 1998) (exclusivity grant an important incentive); see also Understahl, B., Authorized Generics: Careful Balance Undone, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 365 (2005). The 180-day exclusivity period was the cornerstone of this incentive structure. Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 44 (D.D.C. 2000) ("The 180-day exclusivity provision was specifically adopted to reward generic drug makers who . . . undertake the potentially time-consuming and costly efforts to establish that a pioneer drug maker's patent is wrongfully keeping generic drugs off the market."); see also Understahl, B., 16 Fordham Intell. Prop. Media & Ent. L.J. at 365.

According to sanofi's Motion, "each of the nine separate ANDAs seeking approval to market a copy of sanofi-aventis's Uroxatral® brand drug product was filed on the same day, and thus each of the ANDA filers is a 'first-filer' eligible for the 180 day exclusivity."[1] (Sanofi Motion at 19.) Assuming this is true, each first-filer defendant should be treated the same.

If the Apotex Florida Action is not consolidated with the other Related Actions, Apotex could obtain an unfair advantage, to the detriment of the other first filers. For example, FDA approval of all of the ANDAs was automatically stayed by 30 months when sanofi filed suit within 45 days of receiving notice from the first filers that the ANDAs had been filed. 21 U.S.C. §355(j)(5)(B)(iii). This 30-month stay will be terminated, however, upon a district court decision finding the relevant patent invalid or

[1] Actavis and Par do not have any information to corroborate whether each ANDA was, in fact, filed on the same day and whether each ANDA filer is entitled to the 180-day exclusivity period.

not infringed. 21 U.S.C. §355(j)(5)(B)(iii)(I). Under this structure, if Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.

## CONCLUSION

For the foregoing reasons, Actavis and Par respectfully request that this Panel transfer the Florida action Sanofi-Aventis et al. v. Apotex Inc. et al. to the District of Delaware and consolidate that action with the three Delaware actions, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., Sanofi-Aventis et al. v. Barr Laboratories, Inc., and Sanofi-Aventis et al. v. Apotex Inc. et al., for coordinated pretrial proceedings.

Dated: February 25, 2008

Respectfully submitted,

John Will Ongman
AXINN, VELTROP & HARKRIDER LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
(202) 912-4700
*Attorneys for Actavis South Atlantic LLC and Par Pharmaceutical, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that copies of the foregoing Response in Support of the Motion to Transfer and Consolidate were mailed via first-class mail on February 25, 2008 to the counsel of record in the associated cases listed in the attached Panel Attorney Service List.

John Will Ongman

**Judicial Panel on Multidistrict Litigation - Panel Attorney Service List**



Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation
Status: Pending on / /
Transferee District: Judge:

Printed on 02/15/2008

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Cohen, Eric C.<br>KATTEN MUCHIN ROSENMAN<br>525 West Monroe Street<br>Suite 1600<br>Chicago, IL 60661-3693 | =>**Phone: (312) 902-5200 Fax: (312) 902-1061 Email: eric.cohen@kattenlaw.com**<br>Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries, Ltd. |
| Feldman, Steven E.<br>WELSH & KATZ LTD<br>120 South Riverside Plaza<br>22nd Floor<br>Chicago, IL 60606 | =>**Phone: (312) 526-1551 Fax: (312) 655-1501 Email: sefeldman@welshkatz.com**<br>Apotex Corp.*; Apotex, Inc.* |
| Flattmann, Jr, Gerald J.<br>KIRKLAND & ELLIS LLP<br>Citicorp Center<br>153 East 53rd Street<br>New York, NY 10022 | =>**Phone: (212) 445-4800 Fax: (212) 446-4900 Email: gflattmann@kirkland.com**<br>Sanofi Aventis*; Sanofi-Aventis, US, LLC* |
| Kratz, Timothy H.<br>MCGUIREWOODS LLP<br>1170 Peachtree Street, N.E.<br>Suite 2100<br>Atlanta, GA 30309 | =>**Phone: (404) 443-5500 Fax: (404) 443-5784 Email: tkratz@mcguirewoods.com**<br>Mylan Pharmaceuticals, Inc.* |
| Olson, Darrell L.<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 Main Street<br>14th Floor<br>Irvine, CA 92614 | =>**Phone: (949) 760-0404 Fax: (949) 760-9502 Email: dolson@kmob.com**<br>Ranbaxy Laboratories, Ltd.; Ranbaxy, Inc. |
| Ongman, John Will<br>AXINN VELTROP & HARKRIDER LLP<br>1330 Connecticut Avenue, NW<br>Washington, DC 20036 | =>**Phone: (202) 912-4700 Fax: (202) 912-4701 Email: jwo@avhlaw.com**<br>Actavis South Atlantic, LLC*; PAR Pharmaceutical, Inc.* |
| Parr, Keith D.<br>LOCKE LORD BISSELL & LIDDELL LLP<br>111 South Wacker Drive<br>Chicago, IL 60606-4410 | =>**Phone: (312) 443-0497 Fax: (312) 896-6497 Email: kparr@lockelord.com**<br>Torrent Pharma, Inc.*; Torrent Pharmaceuticals, Ltd.* |
| Poullaos, Ivan M.<br>WINSTON & STRAWN LLP<br>35 West Wacker Drive<br>Chicago, IL 60601 | =>**Phone: (312) 558-5600 Fax: (312) 558-5700 Email: ipoullaos@winston.com**<br>Barr Laboratories, Inc.* |
| Schuman, Mark D.<br>CARLSON CASPERS VANDENBURGH & LINDQUIST<br>225 South Sixth Street<br>Suite 3200<br>Minneapolis, MN 55402 | =>**Phone: (612) 436-9600 Fax: (612) 436-9605 Email: mschuman@ccvl.com**<br>Teva Pharmaceuticals USA, Inc.* |

*(Panel Attorney Service List for MDL 1,941 Continued)*



| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Siwik, Christine J.<br>RAKOCZY MOLINO MAZZOCHI SIWIK LLP<br>6 West Hubbard Street<br>Suite 500<br>Chicago, IL 60610 | =>**Phone: (312) 222-6304 Fax: (312) 222-6324**<br>Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc. |

# EXHIBIT 5



"Parrett, James"
<JParrett@mnat.com>
03/10/2008 05:22 PM

To "'Feldman, Steve'" <sefeldman@welshkatz.com>, "Paul J. Molino" <paul@rmmslegal.com>, "Andre G. Bouchard" <abouchard@bmf-law.com>, "Chad A. Landmon"
cc William T Vuk <wvuk@kirkland.com>, Alexis Gorton <agorton@kirkland.com>, "Blumenfeld, Jack" <JBlumenfeld@MNAT.com>, "ASAIKALI@shb.com"
bcc

Subject RE: Alfuzosin Litigation, Delaware, Meet and Confer, All Counsel, Revised PO

Dear Counsel,

Following today's meet and confer teleconference, attached is a revised proposed protective order. Please let me know if this is acceptable or if you have any further objections. Regards,

James

**James W. Parrett, Jr.** ☎ (302) 351-9678 ✉ jparrett@mnat.com
Morris, Nichols, Arsht & Tunnell LLP | 1201 North Market Street | Wilmington, DE 19801

# EXHIBIT 6

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

William T. Vuk
To Call Writer Directly:
212 446-4757
wvuk@kirkland.com

212 446-4800

www.kirkland.com

Facsimile:
212 446-4900

February 21, 2008

**By Electronic Mail**
Sherry L. Rollo, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
srollo@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.,*
C.A. No. 07-792 (GMS)
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Sherry:

I write in response to your February 20, 2008 letter to Alexis Gorton and to arrange a time to meet and confer regarding negotiating an appropriate protective order to govern all currently pending ANDA litigations involving Uroxatral®.

Contrary to Apotex's repeated assertions, sanofi-aventis has not refused to participate in discovery and to date has timely met all of its pretrial discovery obligations. Sanofi-aventis disagrees that its responses and objections to Apotex's first request for production of documents and things are inadequate. In accordance with the Federal Rules of Civil Procedure and the Local Rules of the Southern District of Florida, sanofi-aventis fully responded and/or objected to each of Apotex's requests. Sanofi-aventis also disagrees with Apotex's claim that sanofi-aventis's pending motion for a protective order was rendered moot, or in any other way addressed, by the Court's February 19, 2008 Order. Furthermore, Magistrate Judge Simonton has instructed the parties to meet and confer in order to negotiate an appropriate protective order to govern this litigation, including the production of documents; thereby acknowledging that entry of an appropriate protective order should precede the production of documents in this action. Sanofi-aventis therefore maintains its objections.

Based on Magistrate Judge Simonton's recommendation that the parties attempt to draft a protective order that would globally govern all currently pending ANDA litigations involving Uroxatral®, sanofi-aventis proposes that all parties to the Florida and Delaware litigations meet and confer in order to negotiate the parameters of an appropriate "global" protective order. Please let me know what times, if any, on February 26, 27 or 28 are convenient for Apotex to

KIRKLAND & ELLIS LLP



participate in such a conference. Sanofi-aventis will then contact the additional parties to determine their availability.

Sincerely,

William T. Vuk

cc (via email):
Jack Blumenfeld, Esq.
Robert B. Breisblatt, Esq.
Jennifer Coberly, Esq.
Steven Feldman, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

**WELSH & KATZ, LTD.**
*Attorneys at Law*
120 SOUTH RIVERSIDE PLAZA - 22ND FLOOR
CHICAGO, ILLINOIS 60606-3912

TELEPHONE (312) 655-1500
FACSIMILE (312) 655-1501

**www.welshkatz.com**

**Sherry L. Rollo**
srollo@welshkatz.com
Direct Dial (312) 526-1547

February 21, 2008

**Via Electronic Mail (agorton@kirkland.com)**
**& Confirmation by U.S. Mail**

Alexis Gorton, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

***Re:*** ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
**Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear Alexis:

In accordance with the Court's February 20, 2008 Order we are providing you with a copy of Apotex's proposed Protective Order. This protective order, which previously was agreed to by your firm (and many of the same lawyers as have entered appearances in this case) in the *Medpointe v. Apotex* case, adequately protects both parties' interests. However, to the extent you have genuine concerns regarding your clients' interests please propose specific language dealing with those concerns.

To expedite this process please provide any comments you have by noon Monday, February 25, 2008.

Very truly yours,

WELSH & KATZ, LTD.

By
Sherry L. Rollo

SLR/lao
Enclosure

cc: Alfred J. Saikali, Esq. (asaikali@shb.com)
William Vik, Esq. (wvuk@kirkland.com)
Jennifer R. Coberly, Esq. (jcoberly@zuckerman.com)
Robert B. Breisblatt (rbbreisblatt@welshkatz.com)
Steven E. Feldman (sefeldman@welshkatz.com)

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

William T. Vuk
To Call Writer Directly:
212 446-4757
wvuk@kirkland.com

212 446-4800

www.kirkland.com

Facsimile:
212 446-4900

February 22, 2008

**By Electronic Mail**
Sherry L. Rollo, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
srollo@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.,*
C.A. No. 07-792 (GMS); Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Sherry:

I write in response to your February 21, 2008 letter to Alexis Gorton which ignores my letter from earlier in the evening that requested a date and time to meet and confer in order to negotiate a "global" protective order, as advocated by Magistrate Judge Simonton.

Once again, you propose the protective order from the *Medpointe v. Apotex* action, despite the fact that sanofi-aventis has repeatedly stated that it considers that protective order inadequate to properly protect the parties interests in the Uroxatral® ANDA litigations. Again, that sanofi-aventis's counsel entered into that protective order for an unrelated client is irrelevant to the present litigations. Furthermore, your arbitrary deadline of noon on February 25, 2008 for sanofi-aventis to "provide any comments" disregards Magistrate Judge Simonton's order that permits the parties to negotiate a proper protective order until March 3, 2008.

Sanofi-aventis renews its request that Apotex provide the times, if any, on February 26, 27 and 28 that are convenient for it to meet and confer with respect to negotiating a "global" protective order, as recommended by Magistrate Judge Simonton, to govern the Delaware and Florida Uroxatral® ANDA litigations. Sanofi-aventis will then contact the additional parties to the Delaware actions in order to determine their availability.

Sincerely,

/s/

William T. Vuk

cc (via email):
Jack Blumenfeld, Esq.
Robert B. Breisblatt, Esq.
Jennifer Coberly, Esq.
Steven Feldman, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

**Sherry L. Rollo**
srollo@welshkatz.com
Direct Dial (312) 526-1547

February 22, 2008

**Via Electronic Mail (wvuk@kirkland.com) &**
**Confirmation by U.S. Mail**

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

***Re:*** ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
**Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear Bill:

Your proposal to negotiate a protective order in the Florida litigation with 13 other defendants not involved in that litigation is unacceptable. The other parties are not involved in this litigation and would not be bound by any order entered by Magistrate Judge Simonton. The parties to this lawsuit, Sanofi and Apotex should negotiate the protective order as ordered by Magistrate Judge Simonton.

Again, if it is your position that Apotex's proposed protective order does not protect the interests of your client, provide your comments by Monday, February 25, 2008 so that we may have a meaningful discussion and meet the magistrate's March 3, 2008 deadline.

Very truly yours,

WELSH & KATZ, Ltd.

By: Sherry L. Rollo

SLR/lo
cc: Alfred J. Saikali, Esq. (asaikali@shb.com)
Alexis Gorton, Esq. (agorton@kirkland.com)
Jennifer R. Coberly, Esq. (jcoberly@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Steven E. Feldman, Esq. (sefeldman@welshkatz.com)

# KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Alexis Gorton
To Call Writer Directly:
212 446-4887
agorton@kirkland.com

(212) 446-4800
www.kirkland.com

Facsimile:
(212) 446-4900
Dir. Fax: 212 446-4900

February 25, 2008

**BY ELECTRONIC MAIL**
Sherry L. Rollo, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
srollo@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,
C.A. No. 07-792 (GMS); Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Sherry:

I write in response to your February 22, 2008 letter to Bill Vuk.

By your letter, Apotex takes the position that sanofi-aventis's proposal for a global protective order is unacceptable, even though that is what Magistrate Judge Simonton suggested be done. Further, your refusal to provide a date and time to meet and confer is also contrary to Magistrate Judge Simonton's Order, and is needlessly delaying resolution of this issue.

Sanofi-aventis's proposed global protective order for use in all pending Uroxatral® ANDA litigations will follow under separate cover. Please let me know what times are convenient on February 26, 27 or 28 for Apotex to meet and confer regarding a global protective order. If Apotex continues to refuse to meet and confer, sanofi-aventis will seek appropriate relief from the Court.

Sincerely,

Alexis Gorton

cc (via email):
Jack Blumenfeld, Esq.
Robert B. Breisblatt, Esq.
Jennifer Coberly, Esq.
Steven Feldman, Esq.

KIRKLAND & ELLIS LLP



Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

**WELSH & KATZ, LTD.**

*Attorneys at Law*

120 SOUTH RIVERSIDE PLAZA · 22ND FLOOR
CHICAGO, ILLINOIS 60606-3912

TELEPHONE (312) 655-1500
FACSIMILE (312) 655-1501

www.welshkatz.com

**Sherry L. Rollo**
srollo@welshkatz.com
Direct Dial (312) 526-1547

February 26, 2008

**Via Electronic Mail (agorton@kirkland.com) &**
**Confirmation by U.S. Mail**
Alexis Gorton, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

***Re:*** ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
**Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear Alexis:

I write in response to your February 25, 2008 letter. We have fully complied with Magistrate Judge Simonton's Order. We have conferred and submitted a proposed protective order for your comments. You refused to respond with any comments on our proposed protective order despite being ordered to do so by the Magistrate Judge. Instead, yesterday evening at 9:06 p.m. (est), your local counsel in the Delaware case, James Parrett sent an email proposing a "global protective order' for litigation pending in Delaware and suggested that all the parties to the pending Delaware cases confer tomorrow at noon (est). We are still reviewing Mr. Parrett's proposed protective order. Then this evening you filed a pretextual "motion to compel" us to confer. There is no Rule 11 basis for this motion, and if it is not withdrawn we will seek sanctions. We have conferred with you.

If you wish to discuss the protective order further, we are available to do so tomorrow afternoon. Please let us know what time is convenient. However, the most productive avenue would still be for you to provide us with your comments or proposed edits to the Protective Order that is presently under submission to the Court.

Very truly yours,

WELSH & KATZ, Ltd.

By: Sherry L. Rollo

SLR/lo
cc: Alfred J. Saikali, Esq. (asaikali@shb.com)
William Vik, Esq. (wvuk@kirkland.com)
Jennifer R. Coberly, Esq. (jcoberly@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Steven E. Feldman, Esq. (sefeldman@welshkatz.com)

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Alexis Gorton
To Call Writer Directly:
212 446-4887
agorton@kirkland.com

(212) 446-4800
www.kirkland.com

Facsimile:
(212) 446-4900
Dir. Fax: 212 446-4900

February 26, 2008

**BY ELECTRONIC MAIL**
Sherry L. Rollo, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
srollo@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,
C.A. No. 07-792 (GMS); Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Sherry:

I write in response to your February 26, 2008 letter.

Thank you for providing Apotex's availability for a meet and confer to discuss the terms of the Protective Order. Had Apotex previously provided its availability and agreed to discuss these issues we would not have been forced to file a motion to compel with the Florida court. There was nothing "pretextual" about the motion, and your Rule 11 allegations and sanctions threats are completely without merit. The Court, by its February 20, 2008 Order, required the parties to confer on the terms of the Protective Order and provide a joint proposed order on March 3. Prior to sanofi-aventis filing its motion, Apotex had either rejected or ignored sanofi-aventis's repeated requests to discuss these issues; clearly, Apotex's actions do not meet the parties' obligation to confer as you suggest. Consequently, the motion was necessary to ensure that the parties would in fact engage in a substantive discussion concerning the disclosure, maintenance, and use of confidential information to comply with the Court's February 20th Order. If Apotex will now actually participate in a meaningful meet and confer, we will naturally withdraw our motion to compel as moot on a voluntary basis.

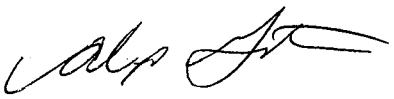
As stated in our previous correspondence, sanofi-aventis believes that the parties should negotiate the terms of the Protective Order along with the 13 other defendants in Delaware. Contrary to your assertion, our proposed order is the draft circulated by James Parrett yesterday for all four matters, including the Florida action, as indicated by the cover email and footnote 1 of the draft. This approach will avoid the potential for inconsistencies between Protective Orders issued by the Florida and Delaware courts and will decrease the likelihood that such orders will be reconsidered, modified, or vacated in the event that this action is transferred. The Court's February 20th Order suggests a Protective Order that would govern both the Florida and

KIRKLAND & ELLIS LLP



Delaware actions and Apotex has not "identified any rule, statute or reason that would prevent [the parties] from drafting and submitting such a proposed Order." *See* D.I. 51 at 5n.2. In fact, the need for an order governing the actions in Delaware, where Apotex is a party, is all the more necessary in light of the Rule 16 Orders issued by the Delaware court today. Sanofi-aventis will continue to work on scheduling a global meet and confer on its proposed order for this week.

Sincerely,



Alexis Gorton

cc (via email):
Jack Blumenfeld, Esq.
Robert B. Breisblatt, Esq.
Jennifer Coberly, Esq.
Steven Feldman, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**JOINT MOTION FOR TWO-DAY ENLARGEMENT OF TIME TO FILE PROPOSED PROTECTIVE ORDER**

Pursuant to Federal Rule of Civil Procedure 6(b) and Southern District Local Rule 7.1, Plaintiffs, sanofi-aventis and sanofi-aventis U.S. LLC, and Defendants, Apotex Inc. and Apotex Corp., (collectively referred to as "the parties") hereby file this Joint Motion for Two-Day Enlargement of Time to File Proposed Protective Order in order to give them sufficient time to finalize a protective order as provided in the Magistrate Judge's Orders of February 20, 2008 (Dkt. 51) and March 10, 2008 (Dkt. 61). The parties have substantially narrowed the issues in dispute. The parties are continuing to meet and confer to resolve or narrow any remaining issues, and anticipate being able to submit a joint proposed protective order to the Court on March 12, 2008. Pursuant to Local Rule 7.1, counsel for all parties join in this motion.

Date: March 10, 2008

Respectfully submitted,

_/s/_ Alfred J. Saikali _____
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.

Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

-and-

s/ *Jennifer Coberly*
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 S. Biscayne Blvd., Suite 900
Miami, FL 33131
Tel: (305) 358 -5000
Fax: (305) 579-9749

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fla. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & Katz, LTD.
120 S. Riverside Plaza
Chicago, Illinois 60606
Tel: (312) 655-1500
Fax: (312) 655-1501

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 10, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Sherry L. Rollo, Esq.
Steven E. Feldman, Esq.
Robert B. Breisblatt, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**[PROPOSED] ORDER GRANTING**
**JOINT MOTION FOR TWO-DAY ENLARGEMENT OF TIME**
**TO FILE PROPOSED PROTECTIVE ORDER**

THIS CAUSE is before the Court on the parties' Joint Motion for Two-Day Enlargement of Time to File Proposed Protective Order, filed on March 10, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that the parties' Joint Motion for Two-Day Enlargement of Time to File Proposed Protective Order is GRANTED.

A status conference will be held on _____, 2008, at _____.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of March, 2008.

Honorable Federico A. Moreno
United States District Court Judge

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**[PROPOSED] ORDER GRANTING**
**JOINT MOTION FOR TWO-DAY ENLARGEMENT OF TIME TO FILE PROPOSED PROTECTIVE ORDER**

THIS CAUSE is before the Court on the parties' Joint Motion for Two-Day Enlargement of Time to File Proposed Protective Order, filed on March 10, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that the parties' Joint Motion for Two-Day Enlargement of Time to File Proposed Protective Order is GRANTED.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of March, 2008.

Honorable Andrea M. Simonton
United States Magistrate Judge

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' NOTICE OF COMPLIANCE WITH ORDER GRANTING DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER**

Plaintiffs, sanofi-avenis and sanofi-aventis U.S. LLC ("Plaintiffs"), hereby file this Joint Notice of Compliance with Order Granting Defendants' Motion for Entry of a Protective Order.[1]

1. On February 20, 2008, Magistrate Judge Simonton, entered an order requiring the Parties to confer and to submit either a joint proposed protective order or a redlined version of the proposed protective order delineating the positions of both parties. (DE 51) The Parties' proposed protective order is due today, March 12, 2008. (DE 69).

2. The Parties have met and conferred on several occasions amongst themselves and with the other defendants in the Delaware actions and have reached agreement on all but one provision for the proposed protective order. The only term that the parties were unable to agree upon is a section that would govern the discovery of information that may be protected by the

[1] Defendants' counsel has indicated to undersigned that Defendants intend to file a separate document setting forth their position on this issue.

European Union Privacy Directive, this same provision is the only significant term in dispute with respect to the protective order for the Delaware actions. Attached as Exhibit "1" is a redlined version of the proposed protective order. Below, Plaintiffs set forth their arguments as to why their version of Section 12 should be adopted in the protective order. Plaintiffs request that the Court enter the proposed protective order upon determining which version of Section 12 should be included.

**Plaintiffs' Argument Regarding Section 12**

Sanofi-aventis's proposes paragraph 12 to ensure compliance with the EU Data Protection Directive ("Privacy Directive"), as implemented in EU member-states. The Privacy Directive protects an individual's private personal data, defined as "any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity." Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Oct. 24, 1995) at Article 2(a). The Privacy Directive delineates how material containing that information can be processed including, *inter alia*, the collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, and erasure or destruction of that information. *Id.* at Article 2(b), Article 3. Typically, such materials may not be freely transported to the United States without the individual's consent because the United States is considered to be a third party country which does not ensure an

adequate level of protection for personal data.[2] Given that the inventions of both the patent asserted by sanofi-aventis and the patent in Apotex's counterclaims were developed in the European Union, a vast amount of material related to those inventions is located in Europe. Thus, sanofi-aventis must seek consent of the individuals whose privacy rights are implicated in order to transport such materials to the United States for review and possible production.

Of course, sanofi-aventis will review and produce all relevant information in Europe that does not reflect private personal data, and will rigorously seek consent from those persons whose private personal data is subject to any discovery requests. If, however, for example an individual revokes his/her consent after documents have been produced, sanofi-aventis believes a mechanism should be in place under which those documents will be returned in order to comply with the Privacy Directive while the parties discuss how to proceed. Sanofi-aventis's proposed paragraph 12 provides such a mechanism. Any inadvertently-produced document subject to the Privacy Directive will first be returned, much like an inadvertently-produced privileged document. If the parties cannot come to an agreement that the document cannot be produced because of the Privacy Directive, sanofi-aventis will have the responsibility of going to the Court for a determination. This procedure strikes a balance between sanof-aventis's obligations to produce all relevant documents and its obligations to comply with the Privacy Directive to protect individual's privacy data.

Apotex's argument that the protective order should not have a provision related to the Privacy Directive because sanofi-aventis chose to litigate in the United States is baseless. First, Apotex is seeking discovery with respect to a patent that sanofi-aventis did not assert.

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2 The Privacy Directive does have a litigation exception— Article 26(d) provides that if "the data transfer is necessary or legally required on public interest grounds or to establish, exercise or defend a legal claim" it may be transported to the United States—however that exception is narrowly construed.

Documents related to that patent also will be subject to the Privacy Directive. Second, commencing a law suit does not permit sanofi-aventis to disregard the Privacy Directive or any other laws.

Sanofi-aventis therefore respectfully requests that the Court enter the Protective Order with Paragraph 12 as proposed by sanofi-aventis.

Date: March 12, 2008

Respectfully submitted,

/s/ Alfred J. Saikali
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
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agorton@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 12, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
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Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Sherry L. Rollo, Esq.
Steven E. Feldman, Esq.
Robert B. Breisblatt, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PROTECTIVE ORDER**

WHEREAS discovery in the above captioned action may involve the disclosure of certain documents, things and information in the possession, custody or control of the plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), the defendants, Apotex Inc. and Apotex Corp. (collectively "Defendants"), or other persons, that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order to advance this Action and prevent unnecessary dissemination or disclosure of such secret or other confidential research, development, or commercial information; and

WHEREAS the parties have established good cause for entry of this Protective Order ("Protective Order");

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in the Action:

## 1. DEFINITIONS

**1.1** "Action" refers to the above-captioned matter.

**1.2** The term "Protected Information" shall mean any document or other tangible thing or oral testimony that contains or reveals what a party considers to be its trade secret, business confidential, or proprietary information. In designating information as "Protected Information," a party shall designate only its trade secrets, information that it has maintained in confidence, or information in which it has a proprietary interest. Each party shall act in good faith in designating information as "Protected Information."

**1.3** "Party" shall mean any party to the Action, including all its officers, directors, and employees, and its outside counsel retained by that party for the Action, including such counsel's support staff.

**1.4** "Document" shall mean all information, documents or things within the scope of Rule 34 of the Fed. R. Civ. P.

**1.5** "Outside Counsel" shall mean attorneys who are not employees of a Party and whose firm has entered an appearance in any or all of the Action.

**1.6** "In-House Counsel" shall mean attorneys who are employees of a Party, or its parents, subsidiaries, or affiliates, to the Action.

**1.7** "Producing Party" shall mean a Party that produces and/or designates documents or testimony pursuant to the categories allowed under this Protective Order.

**1.8** "Receiving Party" shall mean a Party that receives documents or other things in the Action.

**1.9** "Third Party" shall mean any person or entity not a Party as defined in this Protective Order.

**1.10** "Independent Expert" or "Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the subject matter of this Action solely for the purpose of assisting in the Action to furnish expert or consulting services or to give expert testimony with regard to the Action.

**1.11** "Non-Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the Action solely for the purpose of assisting in the Action to furnish expert services that is not based on the subject matter of the Action, such as a jury consultant, interpreter, or translator.

**1.12** "Termination of the Action" shall mean the earlier of either (a) final settlement in the Action with respect to all causes of action, or (b) a final judgment ending the Action which judgment is not subject to appeal.

## 2. DESIGNATION OF PROTECTED INFORMATION

**2.1** This Protective Order establishes two categories of Protected Information. Information in the higher category is referred to as "Outside-Counsel-Only Confidential Information." Protected Information in the lower category is referred to as "Confidential Information."

**2.2** **"Outside-Counsel-Only Confidential Information"**: A Producing Party may in good faith invoke the designation "Outside-Counsel-Only Confidential Information" only for highly sensitive information:

a. Information appropriate for designation as Outside-Counsel-Only Confidential Information shall presumptively include, but is not limited to:

i. Information relating to customer, supplier, distributor, licensee, licensor or partner identities; agreements with customers, suppliers, distributors, licensees, licensors or partners;

ii. Financial projections, sales volumes, pricing, costs, profit margins, marketing materials and plans, strategy documents relating to business plans, and financial trade secrets, and the calculation of same;

iii. Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration;

iv. Information relating to research, development, product development reports, formulation, testing or studies on proposed potential, un-marketed, or future products or new indications including testing on inactive ingredients;

v. Trade secrets;

vi. Information relating to pending and unpublished patent applications;

vii. Technical notebooks, or similar documents, and records for any current or proposed future products, including schematic diagrams, technical reference manuals, operation manuals, or other like, non-public, sensitive information including process formulation data and chemical synthesis routes.

viii. Correspondence and communications with active pharmaceutical ingredient suppliers and excipient suppliers.

ix. Any and all Drug Master Files and Amendments.

b. Disputes regarding the propriety in designating particular Protected Information as "Outside-Counsel-Only Confidential Information" shall be resolved in accordance with Section 8 of this Protective Order.

**2.3** "**Confidential Information**": A Producing Party may in good faith only invoke the designation "Confidential Information" with respect to other information that is not publicly known and which the Producing Party would not normally reveal to Third Parties or if disclosed, would require such Third Parties to maintain in confidence.

**2.4** **Copies and Derivative Works from Protected Information**: All copies, derivative abstracts, summaries, or notes that refer to Protected Information shall be entitled to the same designation as the original source of the information contained therein.

**2.5** **Restraint In Designation**: Each Producing Party agrees to designate Protected Information on a good faith basis and not to harass the Receiving Party or unnecessarily restrict access to information concerning the lawsuit. Each Producing Party must take care to designate for protection only those documents or testimony that qualify. A Producing Party shall further have the duty to notify the Receiving Party whenever it comes to light that the Producing Party has mistakenly or improperly invoked a designation.

## 3. PERSONS WITH ACCESS TO PROTECTED INFORMATION

**3.1** **Access to material designated "Confidential Information":** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Confidential Information" to:

a. A Receiving Party's Outside Counsel of record in the Action, as well as employees of said Outside Counsel working solely in legal, secretarial, clerical, and paralegal capacities and who are assisting attorneys in the Action, as well as other persons working for outsourced litigation support services, including, without limitation, translation, interpreter, reprographic, and electronic discovery services, for the purpose of the Action, however, each such person is prohibited from involvement in either U.S. or foreign patent prosecution relating to alpha-andrenergic antagonists for the treatment of

dysuria, including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review);

b. Any Independent Expert, Technical Consultant or Non-Technical Consultant. All such Independent Experts, Technical Consultants and Non-Technical Consultants shall be instructed not to disclose the Protected Information to any person, except as may be necessary within such person's organization to research, test, investigate or perform tasks associated solely with the Action. Disclosure of Protected Information to any Independent Expert, Technical Consultant or Non-Technical Consultant shall be made pursuant to Subsections 3.3 or 3.4, as may be applicable.

c. Authors, creators, addressees and other recipients of Protected Information, who, prior to the commencement of the Action, lawfully received or had access to the Protected Information;

d. Licensed stenographers, videographers, and their support staff, retained for the Action;

e. the Court and its personnel; and

f. Three (3) In-House Counsels or other personnel responsible for overseeing Outside Counsel in connection with the Action for each Party, or its parents, subsidiaries, or affiliates, as well as one (1) additional employee technical representative for each Party, or its parents, subsidiaries, or affiliates, who need to be consulted by, and at the direction of such Outside Counsel. Persons designated under this subsection shall not be involved in U.S. or foreign patent prosecution relating to alpha-andrenergic anatagonists for the treatment of dysuria, including any alfuzosin products (and their

generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review), or business decision-making relating to any alfuzosin product, or the scientific development of any alfuzosin product.

**3.2 Access to material designated "Outside-Counsel-Only Confidential Information"**: Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Outside-Counsel-Only Confidential Information" to persons identified under (a) through (e) of Subsection 3.1.

**3.3 Persons for Whom a Signed Declaration and Agreement to be Bound by Protective Order Is Required**: Prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the party desiring to disclose Protected Information to such a person shall have complied with the notification procedure set forth in this Section:

a. Outside Counsel for the Receiving Party seeking to disclose such information to a person under this Subsection shall obtain from such person a written Declaration and Agreement to be Bound by Protective Order attached hereto as Exhibit A.

b. Outside Counsel obtaining said executed Declaration and Agreement to be Bound by Protective Order shall maintain all original copies of same until, at a minimum, the Termination of the Action, and copies of the same shall be sent to counsel for the Producing Party.

**3.4 Notification Required Prior to Disclosure to Independent Experts, Technical Consultants, Non-Technical Consultants and In-House Counsel**: In addition to complying

with Section 3.3, prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the following conditions must first be met:

a. Outside Counsel for the Receiving Party wishing to disclose Protected Information to such person shall, at least five (5) business days in advance of the proposed disclosure, notify the Producing Party's counsel, in writing, of the intent to disclose such information. The notice must include;

i. a copy of an executed Declaration and Agreement to be Bound by Protective Order as provided in Exhibit A. and in compliance with Subsection 3.3;

ii. if such person is identified under Subsection 3.1(b):

(1) a true and accurate copy of such person's current curriculum vitae or resume;

(2) a statement indicating whether or not such person was an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party;

(3) in the event that such person is not a natural person, but an entity such as a firm retained to provide consulting services in the Action, such entity shall provide a statement indicating whether or not the entity (or a predecessor or related entity of same) has ever been engaged by the Producing Party, including a statement indicating whether or not any employee of the entity who is expected to provide such consulting services on behalf of the entity has ever been an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party in the

Action, as well as a Declaration and Agreement to be Bound by Protective Order executed as required under Subsection 3.3 by an authorized representative of such entity.

b. No disclosure of Protected Information shall be made to such person identified under Subsection 3.1(b) until at least five (5) business days after all of the requirements set forth under (a) of this Subsection have been met. If the Producing Party objects in writing within said five (5) business day period, no disclosure of Protected Information shall be made to that person pending the resolution of the objection. Such written objection shall set forth in sufficient detail the grounds on which the objection is based.

c. If the Producing Party objects to the disclosure under Subsection 3.4(b), the Producing Party and the Receiving Party wishing to make the disclosure must meet and confer to try to resolve the matter. If the parties in good faith are unable to reach an agreement, the Producing Party may seek an Order from the Court requesting that the proposed disclosure not be permitted, the Producing Party carrying the burden to show that the disclosure should not be made. Such motion must be filed and served within seven (7) business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen (14) days after the written objection to disclosure is received by the Receiving Party, whichever is longer, but in no event longer than twenty-one (21) days after the written objection is received. Failure to so move within this stated period will be deemed a waiver of the Producing Party's objection, upon which the Receiving Party may then proceed with the disclosure of the Protected Information to such extent permitted by this Protective Order.

## 4. MARKING PROTECTED MATERIAL

All documents produced by any Producing Party shall, to the extent possible, be numbered using a prefix bearing the Party's name or an abbreviation thereof. The prefix should be used on a consistent basis and in a manner which makes clear the identity of the Producing Party.

a. **Documents:** Any document produced during discovery or otherwise disclosed in the Action, and any information contained therein, may be properly designated as "Confidential Information" or "Outside-Counsel-Only Confidential Information" by affixing the respective legends "CONFIDENTIAL" and "OUTSIDE-COUNSEL-ONLY CONFIDENTIAL" upon every page of the document that contains Protected Information, including the first page, in a conspicuous manner.

b. **Documents on Electronic Media**: Where a document containing Protected Information is produced in an electronic medium such as on a hard drive, compact disc, or a digital versatile disk (DVD), or other media of electronic storage, it shall be marked with the appropriate legend. To the extent possible, the information or documents contained therein shall also be appropriately marked. The parties shall further negotiate the format for such designations as part of their meet and confers on electronic discovery.

c. **Tangible Items**: Where a physical exhibit or other tangible item is produced, designation shall be made by marking the item in a prominently visible location with the appropriate designation if practicable, or, if not practicable, by affixing the marking on a package or container associated with the item.

d. **Discovery Responses and Testimonial Documents**: Where Protected Information is incorporated into correspondence, written answers to interrogatories,

document requests, responses to requests for admission, or other discovery requests and responses, a designation shall be made by placing the appropriate legend on the first page of the document.

e. **Originals**: Where original files are produced for inspection, no markings need be made by the Producing Party in advance of the inspection. For the purpose of inspection, all documents produced shall be considered designated as "Outside-Counsel-Only Confidential Information." Thereafter, upon selection of specific documents for copying, the Producing Party shall mark the copies of such documents with the appropriate designation in accordance with the provisions of this Protective Order.

f. **Court Filings**: Any document, pleading, or tangible item containing Protected Information, if filed or submitted to the Court, shall be properly designated as provided in this Protective Order and filed under seal pursuant to the provisions of the Local Rules of the Court. The Clerk of the Court is directed to maintain under seal in accordance with the Local Rules of the Court any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, under the categories provided in this Protective Order.

In the event that a Party wishes to use any Protected Information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper to be filed with the Court, such paper shall be filed under seal in accordance with the Local Rules of the Court and the Court's electronic filing procedures if applicable.

g. **Deposition Testimony:** Designation of portions or the entirety of deposition transcripts (including attached exhibits) as Confidential Information or

Outside-Counsel-Only Confidential Information shall be made by a statement to such effect on the record in the course of the deposition, or upon review of the deposition transcript by Counsel for the Producing Party within five (5) business days after Counsel's receipt of the transcript. All information disclosed during a deposition shall be treated as Outside-Counsel-Only Confidential Information until at least five (5) business days after a transcript of the deposition is received by counsel for each Party. Upon designation of the transcript or a portion thereof on the record during the deposition, the Producing Party shall be allowed to exclude, for the portion of the deposition likely to elicit Protected Information, all persons to whom access to Protected Information has not been granted under the terms of this Protective Order. The Court Reporter or other person recording the proceeding may only furnish copies of any portion of the deposition transcript that has been stated to contain Protected Information designated "Outside-Counsel-Only Confidential Information" in a sealed envelope to: the deponent as required by law, the Court, and the Outside Counsel for the Party to the deposition. Designations made within the five (5) business day period after receipt of a deposition transcript shall be made by sending written notices to the Court Reporter, to counsel for the Parties to the Action, and to any other person known to have a copy of said transcript. The notice shall reference this Protective Order and identify the pages, lines and/or exhibits of the transcript so designated. All copies of transcripts thus designated shall be marked with a notice indicating the confidentiality of the material therein, and the distribution of said transcript shall be governed by the terms of this Protective Order.

h. Any Protected Information not reduced to documentary or physical form, which cannot be conveniently labeled shall be designated by a Party serving a written notification of the designation on the Receiving Party.

## 5. SCOPE OF PROTECTIVE ORDER AND USE OF PROTECTED INFORMATION

**5.1** Protected Information shall not be made available to anyone other than as provided in this Protective Order.

**5.2** The restrictions set forth in this Protective Order will not apply to information that is in the lawful possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party by the Producing Party and not otherwise subject to a confidentiality agreement. Similarly, the restrictions set forth in this Protective Order will not apply to information that becomes known to the public after the date of its transmission to the Receiving Party, and not otherwise subject to a confidentiality agreement, provided that such information does not become publicly known by any act or omission of or attributable to the Receiving Party, its employees, or agents, which act or omission is in violation of this Protective Order or any other confidentiality agreement.

**5.3** A Receiving Party shall use Protected Information solely for the purpose of the Action, and not for any other purpose or for any other legal, regulatory, commercial or business purpose, including the pursuit of intellectual property rights, and cannot be used in any or cited within any citizens petitions or any other submission to FDA or other regulatory bodies, including but not limited to the United States Pharmacopeia.

**5.4** Nothing in this Protective Order shall restrict a Producing Party from using its own Protected Information for any purpose.

**5.5** This Protective Order also applies to all copies, summaries, translations, abstracts or similar compilations containing information, documents or things derived from a designating Party's trade secret or other confidential research, development, or commercial information.

**5.6** A Party's designation under the provisions of this Protective Order shall constitute a representation that counsel for the Producing Party believes in good faith that the designation is appropriate under the standards set forth herein.

**5.7** This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Protected Information. This Protective Order shall not limit a Party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive Protected Information under the terms of this Protective Order, so long as such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as demonstrated by the Protected Information itself or by foundation testimony during a deposition, hearing or trial.

**5.8** Protected Information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the Party who produced such Protected Information and (b) the Protected Information was in existence during the period of his or her service or employment.

**5.9** Only persons qualified to receive Protected Information under Section 3 of this Protective Order, including counsel, the deponent, translators, the court reporter, and the videographer, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

**5.10** Should any Protected Information be disclosed by a Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) within three (3) business days of the discovery of the disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party in a written notice; (b) use its best efforts to obtain the prompt return of any such Protected

Information and to bind such person to the terms of this Protective Order; and (c) request such person to sign Declaration and Agreement to be Bound by Protective Order, Exhibit A attached hereto. The executed Declaration and Agreement to be Bound by Protective Order shall be served upon counsel of record for the Producing Party within three (3) business days of its execution.

**5.11** In the event that a Receiving Party desires to provide access to Protected Information to any person not entitled to such access under this Protective Order, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing Party refuses to enter into such an agreement within ten (10) business days, the Receiving Party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to Protected Information after first signing an undertaking in the form of Exhibit A attached hereto, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the parties to the Action may agree or the Court may order.

**5.12** No Party shall be responsible to another Party for any use made of information that was produced and not designated as Protected Information.

**5.13** In the event that a new party is added, substituted, or brought into the Action or a coordinated action, this Protective Order shall be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of the Protective Order.

**5.14** Nothing in this Protective Order shall prejudice the right of any Party to bring before the Court at any time the question of whether any greater or lesser restriction should be placed upon the disclosure of any Protected Information.

**5.15** This Protective Order may be amended as need may arise by written agreement of the Parties without leave of the Court.

**5.16 Drafts of Expert Reports:** The Parties agree that no Party or testifying Independent Expert or Technical Consultant witness is required to maintain or produce drafts of Independent Expert reports or communications with Counsel relating to the captioned matter, or notes taken during the preparation of Independent Expert reports. In all other respects, however, the Parties and their Independent Expert, Technical Consultants, and Non-Technical Consultants shall fully comply with the disclosure requirements of Rule 26(a)(2) of the Fed. R. Civ. P.

## 6. PROCEDURES GOVERNING HANDLING OF PROTECTED INFORMATION

Protected Information must be stored and maintained by a Receiving Party or Third Party at a secure location and in a secure manner at all times to ensure that access is limited to persons authorized under this Protective Order. Upon the Termination of the Action, a Receiving Party or Third Party must comply with the provisions of Section 13 of this Protective Order.

## 7. CORRECTION OF INADVERTENT FAILURE TO DESIGNATE

The disclosure and/or production of any information, document or tangible item without one of the designations provided by this Protective Order shall constitute a waiver of any claim of confidentiality, except where such undesignated disclosure or production resulted from inadvertence or mistake on the part of the Producing Party and such inadvertence or mistake is brought to the attention of the Receiving Party promptly after its discovery. Along with the notice of such inadvertence or mistaken undesignated disclosure or production, the Producing Party shall provide properly designated documents and/or tangible items if applicable. Upon receipt of such notice and properly designated documents and/or tangible items if applicable, the Receiving Party shall substitute properly designated copies for those previously received and

treat the information contained in or derived from said replaced documents and/or tangible items as Protected Information.

## 8. CHALLENGES TO PROTECTED INFORMATION DESIGNATION

A Receiving Party's acceptance of Protected Information from a Producing Party shall not constitute an admission, or create an inference that the material is in fact confidential as designated. This Protective Order shall not foreclose any Party from moving for an order that materials designated Protected Information are not confidential within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P. Prior to bringing such a motion, however, the Receiving Party shall first request in writing that the Producing Party change or remove its designation. If the Producing Party refuses to change its confidentiality designation within ten (10) business days, the Receiving Party may move for an order changing or removing the designation. On such motion, the Producing Party shall have the burden of proving that the material it designated Protected Information embodies its trade secrets or other confidential information within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P.

## 9. PROTECTED INFORMATION RECEIVED FROM THIRD PARTIES

If, in responding to a discovery request, subpoena or other legal process or otherwise, a Third Party discloses Protected Information belonging to or owned by a Party, the information disclosed by the Third Party shall be accorded the same protection as if it were received from a Producing Party under this Protective Order. In such an event, a Party, in good faith believing the information disclosed to be its Protected Information, may designate such information pursuant to this Protective Order. Likewise, a Third Party disclosing its own or a Party's Protected Information may do so under the terms of this Protective Order.

## 10. DISCOVERY REQUESTS RECEIVED FROM THIRD PARTIES

In the event that any Protected Information in the possession, custody or control

of any Receiving Party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the Receiving Party to whom the process or discovery request is directed shall: (1) give written notice of such process or discovery request, together with a copy thereof, to counsel for the Producing Party, and request an agreement to make the requested disclosure; (2) refuse to produce any Protected Information as long as permitted under law until such a time that the Producing Party has had a reasonable opportunity to object, which reasonable time to object shall not be less than ten (10) business days from the date of receipt of the notice under (1); and (3) in the event that the Producing Party objects as provided under (2) and the parties fail to reach an agreement to make the requested disclosure, the Producing Party may move the Court for an order that the disclosure not be made. An agreement in the form of Exhibit A must be obtained from all persons to whom disclosure is made under this section, or under such other conditions to which the Producing Party may agree or that the Court may order.

## 11. DISCOVERY OF INFORMATION RESTRICTED BY CONFIDENTIALITY AGREEMENTS WITH THIRD PARTIES

If discovery in the Action calls for the production of information, documents or tangible items that a Party cannot produce because its disclosure would breach an existing confidentiality obligation to a Third Party to maintain such information in confidence, the Producing Party shall, no less than ten (10) business days before the date scheduled for production, give written notice to the Third Party that its information is subject to discovery in the Action and provide the Third Party with a copy of this Protective Order. In addition to written notice, the Producing Party shall advise the Party requesting discovery of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the Third Party. The Producing Party shall use all reasonable efforts to secure permission from the Third Party to produce said Third Party's information, documents, or tangible items in the possession of the Producing Party, and shall not impede discovery by the Receiving Party of said Third Party's information, documents or tangible items in the possession

of the Producing Party.

## 12. DISCOVERY OF INFORMATION PROTECTED BY EUROPEAN UNION PRIVACY DIRECTIVE OR MEMBER STATE

[**SANOFI-AVENTIS'S PROPOSAL:** In the event that a Party believes in good faith that it is legally precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in sufficient detail, but without disclosing the information subject to the EU Privacy Directive, to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. To the extent that a Producing Party discovers that information already produced to a Receiving Party must be returned in order to comply with the EU Privacy Directive, the Producing Party shall promptly notify the Receiving Party in writing of the specific documents to be returned and the basis for the return. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items identified. The Receiving Party shall also destroy all copies or summaries of, or notes relating to any such documents. The Producing Party shall also identify the documents with sufficient detail as described above. If the Parties are unable to resolve the issue informally, the Producing Party seeking to withhold the document shall within five (5) days of the return of the requested documents or the conclusion of the parties' meet and confer on this issue, whichever is later, seek protection from the Court and shall have the burden of establishing that the document cannot be produced. The same procedure shall apply to the extent that documents are not initially produced under this section.]

[**APOTEX'S PROPOSAL:** In the event that a Party believes in good faith that it is legally

precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in sufficient detail to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. If the Parties are unable to resolve the issue informally, the Party seeking to withhold the document shall within (5) days following the meet and confer on this issue seek protection from the Court and shall have the burden of establishing that the document cannot be produced.

In the event that a Producing Party inadvertently produces a document that it believes in goods faith it was legally precluded from producing under the EU Privacy Directive as implemented in the applicable member state, the Producing Party shall promptly notify the Receiving Party in writing of such document and the basis for its belief that it was legally precluded from producing it in this litigation . If the Parties are unable to resolve the issue informally, the Producing Party shall within five (5) days following the meet and confer on this issue, file a motion with the Court seeking to have the document returned and shall have the burden of establishing that the document should be returned or destroyed. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicable jurisdiction.]

[**REDLINE REFLECTING APOTEX'S CHANGES TO SANOFI-AVENTIS'S PROPOSAL:** In the event that a Party believes in good faith that it is legally precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in

sufficient detail~~, but without disclosing the information subject to the EU Privacy Directive,~~ to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. If the Parties are unable to resolve the issue informally, the Party seeking to withhold the document shall within (5) days following the meet and confer on this issue seek protection from the Court and shall have the burden of establishing that the document cannot be produced. In the event that a Producing Party inadvertently produces a document that it believes in good faith it was legally precluded from producing under the EU Privacy Directive as implemented in the applicable member state, that Producing Party shall promptly notify the Receiving Party in writing of such document and the basis for its belief that it was legally precluded from producing it in this litigation. If the Parties are unable to resolve the issue informally, the Producing Party shall within five (5) days following the meet and confer on this issue, file a motion with the Court seeking to have the document returned and shall have the burden of establishing that the document should be returned or destroyed. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicable jurisdiction.]~~To the extent that a Producing Party discovers that information already produced to a Receiving Party must be returned in order to comply with the EU Privacy Directive, the Producing Party shall promptly notify the Receiving Party in writing of the specific documents to be returned and the basis for the return. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items identified. The Receiving Party shall also destroy all copies or summaries of, or notes relating to any such documents. The Producing Party shall also identify the documents with sufficient detail as described above. If the Parties are unable to resolve the issue informally, the Producing Party seeking to withhold the document shall within five (5) days of the return of the requested documents or the conclusion of the parties' meet and confer on this issue, whichever is later, seek protection from the Court and shall have the burden of establishing that~~

~~the document cannot be produced. The same procedure shall apply to the extent that documents are not initially produced under this section.]~~

## 13. HANDLING PROTECTED INFORMATION AFTER TERMINATION OF THE ACTION

**13.1** The provisions of this Protective Order shall survive and remain in full force and effect after the Termination of the Action (including any appeals).

**13.2** Within ninety (90) days after the Termination of the Action (including any appeals), each document and other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the Producing Party or (b) destroyed with a representation of such destruction being made to the attorney of record for the Receiving Party. The provisions of this Protective Order insofar as it restricts disclosure, communication, and use of Protected Information produced hereunder to a Receiving Party, shall continue to be binding on such Receiving Party after the Termination of the Action. Notwithstanding the foregoing, outside counsel for a Receiving Party may retain one (1) file copy of all court filings, discovery, correspondence, expert reports and exhibits, and deposition transcripts and exhibits, as well as Protected Information to the extent such Protected Information is contained in counsel's work product or in any materials filed with the Court.

**13.3** The Court retains jurisdiction even after the Termination of the Action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate.

## 14. ATTORNEY ADVICE TO CLIENT

Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to the Action and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such

advice and in otherwise communicating with his or her client, the attorney shall not disclose any Protected Information if such disclosure would be contrary to the provisions of this Protective Order.

## 15. INADVERTENT PRODUCTION OF PRIVILEGED DOCUMENTS OR WORK-PRODUCTS

If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in the Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice or otherwise constitute a waiver of any claim of privilege or immunity for such information, provided that the Producing Party, within five (5) business days of the date on which it becomes aware, makes a good faith representation that such production was inadvertent or mistaken and takes remedial action to withdraw the disclosure. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information. The Producing Party shall retain copies of all returned documents and tangible items for further disposition. Within five (5) days of the return of any documents or tangible items, the Producing Party shall provide a privilege log with entries for all returned documents and tangible items.

## 16. SEEKING RELIEF FROM, MODIFICATION OR ENFORCEMENT OF THIS PROTECTIVE ORDER

This Protective Order shall not prevent any Party from applying to the Court for relief therefrom, or from applying to the Court for further additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court.

## 17. NO LIMITATION ON OTHER RIGHTS

Nothing in this Protective Order shall prejudice the right of any Party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality. Further, nothing in this Protective Order prevents a Party from disclosing its own documents and information as it sees fit.

SO ORDERED this _____ day of March, 2008

The Honorable Andrea M. Simonton
United States Magistrate Judge

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case Number: 07-61800-CIV-MORENO/SIMONTON**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) |
| Plaintiffs, | ) |
| vs. | ) |
| APOTEX INC. and APOTEX CORP., | ) |
| Defendants. | ) |

**APOTEX DEFENDANTS' POSITION ON DISPUTED PARAGRAPH 12 OF THE PROTECTIVE ORDER PERTAINING TO MATERIALS BELIEVED TO BE COVERED BY THE EU PRIVACY DIRECTIVE**

The parties are now in substantial agreement on nearly every provision of the protective order except for Paragraph 12, relating to the treatment of documents purportedly covered by the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995). Apotex's position is that the EU Privacy Directive provision is a red herring, designed to facilitate Sanofi's withholding of otherwise discoverable documents and should not be included in the draft protective order at all.

Although Sanofi is a French company, it chose to sue Apotex in the United States, and as such is bound by the rules of this jurisdiction, including the discovery rules and obligations. *Societe Nationale Industrielle Aerospatiale v. United States District Court*, 482 U.S. 522, 544 n.29 (1987) ("The French "blocking statute," [], does not alter our conclusion. It is well settled that such statutes do not deprive an American court of the power to order a party subject to its

jurisdiction to produce evidence even though the act of production may violate that statute.")). Indeed, it is well settled that in instances where United States discovery laws conflict with laws of a foreign country, that the court has the power to enforce the laws of the United States against a foreign entity such as Sanofi choosing to avail itself of a U.S. forum. *Id.*; *see also Reino De Espana v. Am. Bureau of Shipping, Inc.,*No. 03-cv-3573, 2006 U.S. Dist. LEXIS 54112, *7 (S.D.N.Y. Aug. 4, 2006) (affirming magistrate judge's determination that Spanish company must comply with U.S. discovery "in spite of Spanish laws or rulings").

Sanofi's insistence on a Protective Order provision dealing with the EU Privacy Directive is further undermined by the fact that Sanofi has previously entered into protective orders that do not include any provision dealing with the European Privacy Directive, including the protective order currently in place between Apotex and Sanofi in a litigation on the drug Plavix that is pending in the Southern District of New York, *Sanofi-Sythelabo, et al v. Apotex Inc, et al.*, 02-cv-03672 (RWS) (Exhibit A).

Additionally, although the Directive is over 10 years old, a search on Lexis of Federal Cases did not produce a single hit for a case where the EU Privacy Directive was an issue. Apotex's counsel similarly has never included a provision on the EU Privacy Directive in any protective order it has entered into in the past, including many protective orders involving European based companies. There is no compelling reason to include it in this protective order.

In any event, the EU directive, is limited to certain categories of information stored electronically, and expressly includes as a carve out that the transfer of personal data to a third country may take place on the condition that "(d) the transfer is necessary or legally required on important public interest grounds, or for the establishment, exercise **or defense of legal claims**." (EU Privacy Directive Art. 26(1)(d).) Such is the case here. Accordingly, there is no need for

protective order language to deal with the Directive. If a legitimate issue concerning the application of the EU Privacy Directive were to come up in this litigation, Sanofi always could make a motion before the Court for a relief and explain and support the bases for that relief.

In an effort to compromise on this issue, Apotex has offered to include a provision that permits a party to seek such relief, but making clear that the burden would be on the party seeking to withhold the document to establish that it cannot be produced and explain why. (*See* Exhibit B, Apotex's Proposed Protective Order.) Initially, Sanofi had proposed a blanket exclusion for materials that a party believed to be covered by the EU Privacy Directive. However, it now appears that Sanofi is willing to accept a requirement that a party make a motion seeking a protective order before unilaterally withholding a document that it believes to be covered by the EU Directive.

The main sticking point resides in what to do with a document that is inadvertently produced. Sanofi has requested a provision that requires a party to immediately return or destroy such a document upon notice by the producing party. Apotex's position is that the producing party may move for that relief, but that it is inappropriate to require Apotex to destroy a relevant, discoverable document before the Court has decided the issue. Apotex's reasoning is that the presumption here is that the document is discoverable and was properly produced. Fed. R. Civ. P. 26. It is not like a privileged document where the privilege and basis for relief is readily apparent from the face of the document (*see* Exhibit B, Paragraph 15). Instead, the burden at all times should be on Sanofi to establish a compelling basis for requiring the document to be destroyed preventing the use of the document. As noted above, given that the EU Privacy Directive in all likelihood does not apply to this proceeding anyway, this burden will likely be insurmountable for Sanofi. Such a rule also will prevent mischief. For example, if after Apotex

has relied on a document in depositions or in preparing its case for trial, Sanofi should not be permitted to pull the rug out from under Apotex by claiming that the document is in fact covered by the EU Privacy Directive and force Apotex to destroy it and all notes etc. that relate to the document.

## CONCLUSION

Wherefore, for the foregoing reasons, Apotex respectfully requests that the Protective Order governing discovery in this case not include a provision allowing for the withholding of documents believed to be covered by the EU Privacy Directive.

In the alternative, to the extent that the Court deems it appropriate to include such a provision, Apotex requests that its proposed compromise provision for Paragraph 12, , included in the proposed Protective Order filed herewith as Exhibit B, be implemented and Sanofi's proposed EU Privacy Directive provision be rejected.

Dated: March 12, 2008

/s/ Robert B. Breisblatt
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.

120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

March 12, 2008

/s/ Robert B. Breisblatt
*Attorney for Defendants*

# EXHIBIT A

APR.
JUDGE SWEET CHAMBERS

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

| | |
|---|---|
| SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC., and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP,<br><br>Plaintiffs<br><br>v.<br><br>APOTEX INC. and APOTEX CORP.,<br><br>Defendants. | CIVIL ACTION NO. 02-CV-2255 (RWS) |

Filed 4/13/03

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CAESAR, RIVISE, BERNSTEIN COHEN & POKOTILOW, LTD.

| | |
|---|---|
| SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC., and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP,<br><br>Plaintiffs<br><br>v.<br><br>DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,<br><br>Defendants. | CIVIL ACTION NO. 02-CV-3672 (RWS)<br>Consolidated with NO. 02-CV-2255 (RWS) |

**STIPULATED PROTECTIVE ORDER**

The parties having stipulated to the entry of a Protective Order pursuant to Fed. R. Civ. P. 26(c), and it appearing to the Court that such an order is necessary, appropriate, and will facilitate discovery;

IT IS HEREBY ORDERED that:

1. The term **"Confidential Information"** includes (a) proprietary technical information and specifications, (b) trade secrets, (c) confidential know-how, and (d) proprietary business and financial information, and (e) any other information the disclosure of which is likely to have the effect of causing harm to the competitive position of the person, partnership, corporation, or other organization from which the information is obtained.

2. All Confidential Information produced or exchanged in the course of this civil action shall be used solely for the purpose of preparing for and conducting this civil action, including trial and appeals, if any, and shall not be used in any other civil action or for any other purpose.

3. Access to Confidential Information shall be given to:

(a) The attorneys of record in this action, including:

For Plaintiffs:

Fitzpatrick, Cella, Harper & Scinto
30 Rockefeller Plaza
New York, NY 10112

Cravath, Swaine & Moore
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019



A2

For Defendants Apotex Inc. and Apotex Corp. (the "Apotex Defendants"):

Amster, Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

Caesar, Rivise, Bernstein,
Cohen & Pokotilow, Ltd.
1635 Market Street
Philadelphia, PA 19103-2212

For Defendants Dr. Reddy's Laboratories, Ltd.
and Dr. Reddy's Laboratories, Inc. (the "Dr. Reddy's Defendants"):

Budd Larner Rosenbaum Greenberg & Sade, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078

and necessary clerical staff, support staff, and other attorneys employed by the foregoing attorneys or their law firms, except Andrew Miller, Esq., provided that other parties be given 10 days notice prior to any changes or substitutions of the above;

(b) Persons independent from any of the parties to this action who are consulted as experts under Fed. R. Civ. P. 26 in connection with this action (and secretarial and clerical staff of such experts), provided that:

(i) not less than five (5) business days prior to the first disclosure of Confidential Information to the expert, counsel for the party who designated the information as confidential has received a written notice, which can be sent by facsimile, identifying the expert and enclosing a copy of the expert's curriculum vitae and publication list;

(ii) prior to the first disclosure of Confidential Information to the expert, the expert shall execute an Acknowledgment in the form annexed hereto as Exhibit A. Promptly after execution, a copy of such Acknowledgment shall be served upon counsel for the party who designated the information as confidential (counsel serving such Acknowledgment

shall retain the original Acknowledgment); and

(iii) the party who designated the information as confidential does not object in writing to the designation of the expert within five (5) business days of receipt of the written notice of sub-part (i). Failure to object during said five (5) business day period shall be deemed approval of disclosure to the expert. If a party provides written objection pursuant to this subpart, that party's Confidential Information shall not be disclosed to the expert unless and until the matter is resolved by agreement of the parties or by an order of the Court. If the parties are unable to reach agreement within five (5) business days after receipt of an objection to disclosure to a proposed expert, the party seeking to disclose Confidential Information to the expert may file a motion for an Order that access to Confidential Information be granted to the proposed expert.

(c) Independent litigation support service personnel, including copying services, translation services, imaging services, and coding services.

(d) Court personnel (including stenographic reporters) including any law clerk, paralegal, secretarial, clerical, or other court personnel.

(e) An officer before whom a deposition is taken, including stenographic reporters and any secretarial, clerical, or other lay personnel assisting such officer.

4. The persons entitled to have access to Confidential Information pursuant to the terms of paragraph 3 shall not make available such Confidential Information to any person other than (i) those persons entitled to such access pursuant to the terms of paragraph 3 or (ii) the parties who produced the Confidential Information

5. Documents and other discovery materials containing Confidential

Information shall be designated as such by marking each page of each document or other discovery material with the following legend (or some other comparable notice, including "Highly Confidential," which will mean the same thing as "Confidential" for purposes of this protective order):

CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER

A physical specimen or thing containing Confidential Information shall be designated as such by marking such physical specimen or thing with a legend including the phrase "CONFIDENTIAL" as appropriate.

6. (a) Information disclosed at the deposition of any party or one of its present or former officers, directors, employees, or agents, or of experts retained by counsel for any party for purposes of this litigation, including both testimony and exhibits, may be designated as Confidential Information by indicating on the record at the deposition that the testimony and/or exhibit is subject to the provisions of this Stipulated Protective Order.

(b) A party may also designate Confidential Information disclosed at such a deposition by notifying the other parties, during the course of the deposition or by notifying the other parties in writing, within thirty (30) days after receipt of the transcript, of the specific pages and lines of the transcript which should be treated as Confidential Information. Each transcript of a deposition taken of any party, its present or former officers, directors, employees, or agents, or of experts retained by counsel for any party for purposes of this litigation shall be treated as Confidential Information for a period of thirty (30) days after receipt of the transcript.

(c) Notwithstanding anything to the contrary in this Stipulated Protective Order, any deponent may review the transcript of his own deposition at any time.

7. Any person receiving Confidential Information from any party shall not make it available to persons other than those individuals identified in paragraph 3, except that with respect to each document designated as containing Confidential Information, any person indicated on the face of the document to be its originator, author, or recipient of a copy thereof or who would otherwise reasonably be expected to have had prior access to the document, may be shown the document.

8. If a party believes that inspection, measuring, testing, sampling, or photographing of that party's processes, products, equipment, premises, or other property pursuant to Fed. R. Civ. P. 34 will reveal or disclose information that is in good faith deemed Confidential Information, that party shall advise in advance the party or parties seeking such discovery that the inspection, measuring, testing, sampling, or photographing will be permitted only on a Confidential basis and that the material discovered and any information derived from that material, shall be treated as Confidential Information. Nothing contained in this Order shall be deemed a waiver of any requirements for showing of good cause under the Court rules or of any right of the producing party to seek an order from the Court regarding further conditions for any inspection of its premises.

9. If a party, through inadvertence, produces any document or information that it believes is immune from discovery pursuant to the attorney-client privilege or work product immunity, such production shall not be deemed a waiver of any privilege or immunity, and the producing party may give written notice to the receiving party that the document or

information produced is deemed privileged or immune and that return of the document or information is requested. Upon receipt of such written notice, the receiving party shall immediately gather the original and all copies of the document or information of which the receiving party is aware and shall immediately return the original and all such copies to the producing party. The return of the document(s) and/or information to the producing party shall not preclude the receiving party from later moving the Court to compel production of the returned documents and/or information.

10. If a party, through inadvertence, produces any Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Stipulated Protective Order, the producing party may promptly give written notice to the receiving party that the document or thing produced is deemed Confidential Information and should be treated as such in accordance with the provisions of this Stipulated Protective Order. The receiving party must treat such documents and things as Confidential Information.

11. All correspondence, legal memoranda, motion papers, pleadings, and other written materials that quote or refer to the substance of any Confidential Information shall also be treated as confidential in accordance with the provisions of this Stipulated Protective Order, and the cover or first page of such documents shall be marked in accordance with paragraph 5 of this Stipulated Protective Order.

12. The parties will use reasonable care to avoid designating as Confidential any documents or information which has been published or can otherwise be shown to be publicly available. A party shall not be obligated to challenge the confidentiality of a designation as Confidential Information at the time the designation is made, and a failure to do so shall not

preclude a subsequent challenge to the designation. In the event of a dispute with respect to the designation of any discovery material as Confidential Information, counsel shall attempt to resolve their dispute on an informal basis before presenting the matter to the Court for resolution. If a resolution cannot be reached, the party challenging the Confidential Information designation shall send a written notice to the designating party (i) identifying with particularity the challenged Confidential Information, (ii) stating the reasons why the Confidential Information designation is being challenged, and (iii) stating that the party will, within fifteen (15) days, move the Court to remove the designated status of Confidential Information. Until such time as the challenge is resolved, such Confidential Information shall be maintained in accordance with this Stipulated Protective Order. Notwithstanding any other provision of this Stipulated Protective Order, in any motion to the Court pursuant to this paragraph the designating party has the burden of demonstrating that the challenged information is Confidential Information.

13. All deposition transcripts and exhibits, written discovery requests and responses thereto, legal memoranda, motion papers, or other written materials or things submitted to the Court which contain or quote or refer to Confidential Information shall be filed with the Court in a sealed envelope or other appropriate sealed container which shall be endorsed with (i) the title of this action, (ii) an indication of the nature of the contents of such sealed envelope or other container, and (iii) a statement substantially in the following applicable form:

CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER
FILED UNDER SEAL

This envelope (or container) which is filed in this action by (name of party and, if applicable, the name of deponent) is not to be opened nor its contents displayed, copied, or revealed except by Court Order.

14. Nothing in this Stipulated Protective Order shall prevent a party or its attorneys from using any Confidential Information (i) at a deposition (provided the witness may see the Confidential Information as permitted by this Stipulated Protective Order) or hearing, (ii) to prepare for and conduct discovery in this action, (iii) to support or oppose any motion made in this action, (iv) to prepare for trial, (v) during trial, or (vi) during any appeal. Under these circumstances, steps shall be taken to preserve the confidentiality of the proceedings in which the Confidential Information is being used and the portion of any document or transcript designated as containing Confidential Information shall be subject to all of the provisions of this Stipulated Protective Order.

15. Documents and things designated as containing Confidential Information and any copies or extracts thereof, shall be retained in the custody of the attorneys of record during the pendency of this action, except as reasonably necessary to provide access to persons authorized under the provisions of this Stipulated Protective Order.

16. Within sixty (60) days after final termination of this action, each party shall assemble all documents and things furnished and designated by any other party as containing Confidential Information and shall either destroy all such documents and things or return them to the producing party, such election to be made by the producing party. The attorneys of record for each party shall be entitled to retain a copy of all pleadings, motion papers, discovery responses, deposition and trial transcripts, exhibits, legal memoranda, correspondence, attorney work product, and any other documents related to this litigation,

provided said attorney and the employees of said attorney shall not disclose such information except pursuant to a written agreement with the disclosing party or as compelled by law.

17. This Stipulated Protective Order is without prejudice to the right of any party to seek modification by the Court of any of the terms of this Stipulated Protective Order, or to present to the Court any matter which is the subject of this Stipulated Protective Order.

18. The terms of the Stipulated Protective Order shall survive the final termination of this civil action to the extent that any Confidential Information is not or does not become known to the public.

19. A determination that information designated by another party as Confidential Information is public knowledge shall not be made unilaterally by any receiving party, but rather, a challenge to the propriety of a designation of Confidential Information shall be made in accordance with paragraph 12. Until a challenge is resolved in accordance with paragraph 12, the challenged information shall be treated as Confidential Information under the terms of this Order.

20. Notwithstanding the foregoing provisions, this Order shall be without prejudice to the right of any party to challenge the propriety of discovery on grounds of privilege, relevance, materiality, etc., and nothing contained herein shall be construed as a waiver of any objection which might be raised as to the admissibility at trial of any evidentiary material.

21. This Order may be amended by the agreement of counsel for the parties, subject to approval of the Court, provided it is in the form of a stipulation that shall be filed with the Clerk and made part of the record in this civil litigation.

22. This Order shall be without prejudice to the right of any party to apply to

the Court for such further protective order under the provisions of the Court rules, the Federal Rules of Civil Procedure, the Local Civil Rules, or as justice may require.

SIGNED this 1st day of April, 2003.

Robert W. Sweet
United States District Judge

FITZPATRICK, CELLA, HARPER & SCINTO

Date: 3/26, 2003

By _____
Robert L. Baechtold (RB6866)
Thomas H. Beck (TB 4400)
William E. Solander (WS 2073)
30 Rockefeller Plaza
New York, NY 10112
Attorneys for Plaintiffs

CRAVATH, SWAINE & MOORE

Date: 3/26, 2003

By _____
Evan R. Chesler (EC 1692)
Richard J. Stark (RS 3416)
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
Attorneys for Plaintiffs

AMSTER, ROTHSTEIN & EBENSTEIN

Date: March 26, 2003

By _____
Anthony F. Lo Cicero (AL 7532)
90 Park Avenue
New York, NY 10016
Attorneys for Defendants

CAESAR, RIVISE, BERNSTEIN
COHEN & POKOTILOW, LTD.

Date: March 26, 2003

By _____
Alan H. Bernstein
Robert S. Silver
William J. Castillo
Seven Penn Center - 12th Floor
1635 Market Street
Philadelphia, PA 19103-2212
Attorneys for Defendants

BUDD LARNER GROSS
ROSENBAUM GREENBERG & SADE, P.C.

Date: March 26, 2003

By _____
Stuart D. Sender (SS 4986)
David J. Novak (DN 9527)
Louis H. Weinstein (LW 7868)
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
Attorneys for Defendants

**Exhibit A**

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

| | |
|---|---|
| SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC., and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP,<br>Plaintiffs<br>v.<br>APOTEX INC. and APOTEX CORP.,<br>Defendants. | CIVIL ACTION NO. 02-CV-2255 (RWS) |
| SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC., and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP,<br>Plaintiffs<br>v.<br>DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,<br>Defendants. | CIVIL ACTION NO. 02-CV-3672 (RWS) |

**ACKNOWLEDGMENT OF OBLIGATION**

J. B. Hendrickson states:

That I reside at 9 Acacia St. in the city/~~county~~ of Cambridge, MA;

That I have been retained as an expert witness on behalf of Caesar Rivise;

That I have read the STIPULATED PROTECTIVE ORDER (hereinafter "PROTECTIVE ORDER") entered in the above action;

That I am fully familiar with and agree to comply with and be bound by the provisions of that PROTECTIVE ORDER; and

That I will not divulge Confidential Information to persons other than those specifically authorized by that PROTECTIVE ORDER, and will not copy, use, or disclose any such information except as provided for by the PROTECTIVE ORDER.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 18 April 03 (date)

J. B. Hendrickson (signature)

NY_MAIN 325370v1

# EXHIBIT B

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case Number: 07-61800-CIV-MORENO/SIMONTON**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) |
| Plaintiffs, | ) |
| vs. | ) |
| APOTEX INC. and APOTEX CORP., | ) |
| Defendants. | ) |

**STIPULATED PROTECTIVE ORDER**

WHEREAS discovery in the above captioned actions (individually and collectively, the "Actions") may involve the disclosure of certain documents, things and information in the possession, custody or control of the plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), the defendants, Actavis South Atlantic LLC, Apotex Inc., Apotex Corp., Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc., Barr Laboratories, Inc., Mylan Pharmaceuticals Inc., Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Defendants"), or other persons, that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties have, through counsel, stipulated to the entry of this Stipulated Protective Order to advance these Actions and prevent unnecessary dissemination or disclosure of such secret or other confidential research, development, or commercial information; and

WHEREAS the parties have established good cause for entry of this Stipulated Protective Order ("Protective Order");

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in the Actions:

## 1. DEFINITIONS

**1.1** "Actions" refers to the above-captioned matters.

**1.2** The term "Protected Information" shall mean any document or other tangible thing or oral testimony that contains or reveals what a party considers to be its trade secret, business confidential, or proprietary information. In designating information as "Protected Information," a party shall designate only its trade secrets, information that it has maintained in confidence, or information in which it has a proprietary interest. Each party shall act in good faith in designating information as "Protected Information."

**1.3** "Party" shall mean any party to any or all of the Actions, including all its officers, directors, and employees, and its outside counsel retained by that party for the Actions, including such counsel's support staff.

**1.4** "Document" shall mean all information, documents or things within the scope of Rule 34 of the Fed. R. Civ. P.

**1.5** "Outside Counsel" shall mean attorneys who are not employees of a Party and whose firm has entered an appearance in any or all of the Actions.

**1.6** "In-House Counsel" shall mean attorneys who are employees of a Party, or its parents, subsidiaries, or affiliates, to any or all of the Actions.

**1.7** "Producing Party" shall mean a Party that produces and/or designates documents or testimony pursuant to the categories allowed under this Protective Order.

**1.8** "Receiving Party" shall mean a Party that receives documents or other things in the Actions.

**1.9** "Third Party" shall mean any person or entity not a Party as defined in this Protective Order.

**1.10** "Independent Expert" or "Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the subject matter of any or all of these Actions solely for the purpose of assisting in the Actions to furnish expert or consulting services or to give expert testimony with regard to the Actions.

**1.11** "Non-Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the Actions solely for the purpose of assisting in the Actions to furnish expert services that is not based on the subject matter of the Actions, such as a jury consultant, interpreter, or translator.

**1.12** "Termination of the Actions" shall mean the earlier of either (a) final settlement in the Actions with respect to all causes of action, or (b) a final judgment ending the Actions which judgment is not subject to appeal.

## 2. DESIGNATION OF PROTECTED INFORMATION

**2.1** This Protective Order establishes two categories of Protected Information. Information in the higher category is referred to as "Outside-Counsel-Only Confidential Information." Protected Information in the lower category is referred to as "Confidential Information."

**2.2 "Outside-Counsel-Only Confidential Information"**: A Producing Party may in good faith invoke the designation "Outside-Counsel-Only Confidential Information" only for highly sensitive information:

a. Information appropriate for designation as Outside-Counsel-Only Confidential Information shall presumptively include, but is not limited to:

i. Information relating to customer, supplier, distributor, licensee, licensor or partner identities; agreements with customers, suppliers, distributors, licensees, licensors or partners;

ii. Financial projections, sales volumes, pricing, costs, profit margins, marketing materials and plans, strategy documents relating to business plans, and financial trade secrets, and the calculation of same;

iii. Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration;

iv. Information relating to research, development, product development reports, formulation, testing or studies on proposed potential, un-marketed, or future products or new indications including testing on inactive ingredients;

v. Trade secrets;

vi. Information relating to pending and unpublished patent applications;

vii. Technical notebooks, or similar documents, and records for any current or proposed future products, including schematic diagrams, technical

reference manuals, operation manuals, or other like, non-public, sensitive information including process formulation data and chemical synthesis routes.

viii. Correspondence and communications with active pharmaceutical ingredient suppliers and excipient suppliers.

ix. Any and all Drug Master Files and Amendments.

b. Disputes regarding the propriety in designating particular Protected Information as "Outside-Counsel-Only Confidential Information" shall be resolved in accordance with Section 8 of this Protective Order.

**2.3** "**Confidential Information**": A Producing Party may in good faith only invoke the designation "Confidential Information" with respect to other information that is not publicly known and which the Producing Party would not normally reveal to Third Parties or if disclosed, would require such Third Parties to maintain in confidence.

**2.4** **Copies and Derivative Works from Protected Information**: All copies, derivative abstracts, summaries, or notes that refer to Protected Information shall be entitled to the same designation as the original source of the information contained therein.

**2.5** **Restraint In Designation**: Each Producing Party agrees to designate Protected Information on a good faith basis and not to harass the Receiving Party or unnecessarily restrict access to information concerning the lawsuit. Each Producing Party must take care to designate for protection only those documents or testimony that qualify. A Producing Party shall further have the duty to notify the Receiving Party whenever it comes to light that the Producing Party has mistakenly or improperly invoked a designation.

## 3. PERSONS WITH ACCESS TO PROTECTED INFORMATION

**3.1 Access to material designated "Confidential Information":** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Confidential Information" to:

a. A Receiving Party's Outside Counsel of record in the Actions, as well as employees of said Outside Counsel working solely in legal, secretarial, clerical, and paralegal capacities and who are assisting attorneys in the Actions, as well as other persons working for outsourced litigation support services, including, without limitation, translation, interpreter, reprographic, and electronic discovery services, for the purpose of the Actions, however, each such person is prohibited from involvement in either U.S. or foreign patent prosecution relating to alpha-andrenergic antagonists for the treatment of dysuria, including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review);

b. Any Independent Expert, Technical Consultant or Non-Technical Consultant. All such Independent Experts, Technical Consultants and Non-Technical Consultants shall be instructed not to disclose the Protected Information to any person, except as may be necessary within such person's organization to research, test, investigate or perform tasks associated solely with the Actions. Disclosure of Protected Information to any Independent Expert, Technical Consultant or Non-Technical Consultant shall be made pursuant to Subsections 3.3 or 3.4, as may be applicable.

c. Authors, creators, addressees and other recipients of Protected Information, who, prior to the commencement of the Actions, lawfully received or had access to the Protected Information;

d. Licensed stenographers, videographers, and their support staff, retained for the Actions;

e. the Court and its personnel; and

f. Three (3) In-House Counsels or other personnel responsible for overseeing Outside Counsel in connection with the Actions for each Party, or its parents, subsidiaries, or affiliates, as well as one (1) additional employee technical representative for each Party, or its parents, subsidiaries, or affiliates, who need to be consulted by, and at the direction of such Outside Counsel. Persons designated under this subsection shall not be involved in U.S. or foreign patent prosecution relating to alpha-andrenergic anatagonists for the treatment of dysuria , including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review), or business decision-making relating to any alfuzosin product, or the scientific development of any alfuzosin product.

**3.2 Access to material designated "Outside-Counsel-Only Confidential Information"**: Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Outside-Counsel-Only Confidential Information" to persons identified under (a) through (e) of Subsection 3.1.

**3.3 Persons for Whom a Signed Declaration and Agreement to be Bound by Protective Order Is Required**: Prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the party desiring to disclose Protected Information to such a person shall have complied with the notification procedure set forth in this Section:

a. Outside Counsel for the Receiving Party seeking to disclose such information to a person under this Subsection shall obtain from such person a written Declaration and Agreement to be Bound by Protective Order attached hereto as Exhibit A.

b. Outside Counsel obtaining said executed Declaration and Agreement to be Bound by Protective Order shall maintain all original copies of same until, at a minimum, the Termination of the Actions, and copies of the same shall be sent to counsel for the Producing Party.

**3.4 Notification Required Prior to Disclosure to Independent Experts, Technical Consultants, Non-Technical Consultants and In-House Counsel**: In addition to complying with Section 3.3, prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the following conditions must first be met:

a. Outside Counsel for the Receiving Party wishing to disclose Protected Information to such person shall, at least five (5) business days in advance of the proposed disclosure, notify the Producing Party's counsel, in writing, of the intent to disclose such information. The notice must include;

i. a copy of an executed Declaration and Agreement to be Bound by Protective Order as provided in Exhibit A. and in compliance with Subsection 3.3;

ii. if such person is identified under Subsection 3.1(b):

(1) a true and accurate copy of such person's current

curriculum vitae or resume;

(2) a statement indicating whether or not such person was an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party;

(3) in the event that such person is not a natural person, but an entity such as a firm retained to provide consulting services in the Actions, such entity shall provide a statement indicating whether or not the entity (or a predecessor or related entity of same) has ever been engaged by the Producing Party, including a statement indicating whether or not any employee of the entity who is expected to provide such consulting services on behalf of the entity has ever been an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party in the Actions, as well as a Declaration and Agreement to be Bound by Protective Order executed as required under Subsection 3.3 by an authorized representative of such entity.

b. No disclosure of Protected Information shall be made to such person identified under Subsection 3.1(b) until at least five (5) business days after all of the requirements set forth under (a) of this Subsection have been met. If the Producing Party objects in writing within said five (5) business day period, no disclosure of Protected Information shall be made to that person pending the resolution of the objection. Such

written objection shall set forth in sufficient detail the grounds on which the objection is based.

c. If the Producing Party objects to the disclosure under Subsection 3.4(b), the Producing Party and the Receiving Party wishing to make the disclosure must meet and confer to try to resolve the matter. If the parties in good faith are unable to reach an agreement, the Producing Party may seek an Order from the Court requesting that the proposed disclosure not be permitted, the Producing Party carrying the burden to show that the disclosure should not be made. Such motion must be filed and served within seven (7) business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen (14) days after the written objection to disclosure is received by the Receiving Party, whichever is longer, but in no event longer than twenty-one (21) days after the written objection is received. Failure to so move within this stated period will be deemed a waiver of the Producing Party's objection, upon which the Receiving Party may then proceed with the disclosure of the Protected Information to such extent permitted by this Protective Order.

## 4. MARKING PROTECTED MATERIAL

All documents produced by any Producing Party shall, to the extent possible, be numbered using a prefix bearing the Party's name or an abbreviation thereof. The prefix should be used on a consistent basis and in a manner which makes clear the identity of the Producing Party.

a. **Documents:** Any document produced during discovery or otherwise disclosed in the Actions, and any information contained therein, may be properly designated as "Confidential Information" or "Outside-Counsel-Only Confidential Information" by affixing the respective legends "CONFIDENTIAL" and "OUTSIDE-

COUNSEL-ONLY CONFIDENTIAL" upon every page of the document that contains Protected Information, including the first page, in a conspicuous manner.

b. **Documents on Electronic Media**: Where a document containing Protected Information is produced in an electronic medium such as on a hard drive, compact disc, or a digital versatile disk (DVD), or other media of electronic storage, it shall be marked with the appropriate legend. To the extent possible, the information or documents contained therein shall also be appropriately marked. The parties shall further negotiate the format for such designations as part of their meet and confers on electronic discovery.

c. **Tangible Items**: Where a physical exhibit or other tangible item is produced, designation shall be made by marking the item in a prominently visible location with the appropriate designation if practicable, or, if not practicable, by affixing the marking on a package or container associated with the item.

d. **Discovery Responses and Testimonial Documents**: Where Protected Information is incorporated into correspondence, written answers to interrogatories, document requests, responses to requests for admission, or other discovery requests and responses, a designation shall be made by placing the appropriate legend on the first page of the document.

e. **Originals**: Where original files are produced for inspection, no markings need be made by the Producing Party in advance of the inspection. For the purpose of inspection, all documents produced shall be considered designated as "Outside-Counsel-Only Confidential Information." Thereafter, upon selection of specific documents for copying, the Producing Party shall mark the copies of such documents with the appropriate designation in accordance with the provisions of this Protective Order.

f. **Court Filings**: Any document, pleading, or tangible item containing Protected Information, if filed or submitted to the Court, shall be properly designated as provided in this Protective Order and filed under seal pursuant to the provisions of the Local Rules of the Court. The Clerk of the Court is directed to maintain under seal in accordance with the Local Rules of the Court any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, under the categories provided in this Protective Order.

In the event that a Party wishes to use any Protected Information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper to be filed with the Court, such paper shall be filed under seal in accordance with the Local Rules of the Court and the Court's electronic filing procedures if applicable.

g. **Deposition Testimony:** Designation of portions or the entirety of deposition transcripts (including attached exhibits) as Confidential Information or Outside-Counsel-Only Confidential Information shall be made by a statement to such effect on the record in the course of the deposition, or upon review of the deposition transcript by Counsel for the Producing Party within five (5) business days after Counsel's receipt of the transcript. All information disclosed during a deposition shall be treated as Outside-Counsel-Only Confidential Information until at least five (5) business days after a transcript of the deposition is received by counsel for each Party. Upon designation of the transcript or a portion thereof on the record during the deposition, the Producing Party shall be allowed to exclude, for the portion of the deposition likely to elicit Protected Information, all persons to whom access to Protected Information has not

been granted under the terms of this Protective Order. The Court Reporter or other person recording the proceeding may only furnish copies of any portion of the deposition transcript that has been stated to contain Protected Information designated "Outside-Counsel-Only Confidential Information" in a sealed envelope to: the deponent as required by law, the Court, and the Outside Counsel for the Party to the deposition. Designations made within the five (5) business day period after receipt of a deposition transcript shall be made by sending written notices to the Court Reporter, to counsel for the Parties to the Actions, and to any other person known to have a copy of said transcript. The notice shall reference this Protective Order and identify the pages, lines and/or exhibits of the transcript so designated. All copies of transcripts thus designated shall be marked with a notice indicating the confidentiality of the material therein, and the distribution of said transcript shall be governed by the terms of this Protective Order.

h. Any Protected Information not reduced to documentary or physical form, which cannot be conveniently labeled shall be designated by a Party serving a written notification of the designation on the Receiving Party.

## 5. SCOPE OF PROTECTIVE ORDER AND USE OF PROTECTED INFORMATION

**5.1** Protected Information shall not be made available to anyone other than as provided in this Protective Order.

**5.2** The restrictions set forth in this Protective Order will not apply to information that is in the lawful possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party by the Producing Party and not otherwise subject to a confidentiality agreement. Similarly, the restrictions set forth in this Protective Order will not apply to information that becomes known to the public after the date of its transmission to

the Receiving Party, and not otherwise subject to a confidentiality agreement, provided that such information does not become publicly known by any act or omission of or attributable to the Receiving Party, its employees, or agents, which act or omission is in violation of this Protective Order or any other confidentiality agreement.

**5.3** A Receiving Party shall use Protected Information solely for the purpose of the Actions, and not for any other purpose or for any other legal, regulatory, commercial or business purpose, including the pursuit of intellectual property rights, and cannot be used in any or cited within any citizens petitions or any other submission to FDA or other regulatory bodies, including but not limited to the United States Pharmacopeia.

**5.4** Nothing in this Protective Order shall restrict a Producing Party from using its own Protected Information for any purpose.

**5.5** This Protective Order also applies to all copies, summaries, translations, abstracts or similar compilations containing information, documents or things derived from a designating Party's trade secret or other confidential research, development, or commercial information.

**5.6** A Party's designation under the provisions of this Protective Order shall constitute a representation that counsel for the Producing Party believes in good faith that the designation is appropriate under the standards set forth herein.

**5.7** This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Protected Information. This Protective Order shall not limit a Party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive Protected Information under the terms of this Protective Order, so long as such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as

demonstrated by the Protected Information itself or by foundation testimony during a deposition, hearing or trial.

**5.8** Protected Information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the Party who produced such Protected Information and (b) the Protected Information was in existence during the period of his or her service or employment.

**5.9** Only persons qualified to receive Protected Information under Section 3 of this Protective Order, including counsel, the deponent, translators, the court reporter, and the videographer, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

**5.10** Should any Protected Information be disclosed by a Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) within three (3) business days of the discovery of the disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party in a written notice; (b) use its best efforts to obtain the prompt return of any such Protected Information and to bind such person to the terms of this Protective Order; and (c) request such person to sign Declaration and Agreement to be Bound by Protective Order, Exhibit A attached hereto. The executed Declaration and Agreement to be Bound by Protective Order shall be served upon counsel of record for the Producing Party within three (3) business days of its execution.

**5.11** In the event that a Receiving Party desires to provide access to Protected Information to any person not entitled to such access under this Protective Order, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing Party refuses to enter into such an agreement within ten (10) business days, the

Receiving Party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to Protected Information after first signing an undertaking in the form of Exhibit A attached hereto, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the parties to the Actions may agree or the Court may order.

**5.12** No Party shall be responsible to another Party for any use made of information that was produced and not designated as Protected Information.

**5.13** In the event that a new party is added, substituted, or brought into the Actions or a coordinated action, this Protective Order shall be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of the Protective Order.

**5.14** Nothing in this Protective Order shall prejudice the right of any Party to bring before the Court at any time the question of whether any greater or lesser restriction should be placed upon the disclosure of any Protected Information.

**5.15** This Protective Order may be amended as need may arise by written agreement of the Parties without leave of the Court.

**5.16 Drafts of Expert Reports:** The Parties agree that no Party or testifying Independent Expert or Technical Consultant witness is required to maintain or produce drafts of Independent Expert reports or communications with Counsel relating to the captioned matter, or notes taken during the preparation of Independent Expert reports. In all other respects, however, the Parties and their Independent Expert, Technical Consultants, and Non-Technical Consultants shall fully comply with the disclosure requirements of Rule 26(a)(2) of the Fed. R. Civ. P.

**6. PROCEDURES GOVERNING HANDLING OF PROTECTED INFORMATION**

Protected Information must be stored and maintained by a Receiving Party or Third Party at a secure location and in a secure manner at all times to ensure that access is limited to persons authorized under this Protective Order. Upon the Termination of the Actions, a Receiving Party or Third Party must comply with the provisions of Section 13 of this Protective Order.

**7. CORRECTION OF INADVERTENT FAILURE TO DESIGNATE**

The disclosure and/or production of any information, document or tangible item without one of the designations provided by this Protective Order shall constitute a waiver of any claim of confidentiality, except where such undesignated disclosure or production resulted from inadvertence or mistake on the part of the Producing Party and such inadvertence or mistake is brought to the attention of the Receiving Party promptly after its discovery. Along with the notice of such inadvertence or mistaken undesignated disclosure or production, the Producing Party shall provide properly designated documents and/or tangible items if applicable. Upon receipt of such notice and properly designated documents and/or tangible items if applicable, the Receiving Party shall substitute properly designated copies for those previously received and treat the information contained in or derived from said replaced documents and/or tangible items as Protected Information.

**8. CHALLENGES TO PROTECTED INFORMATION DESIGNATION**

A Receiving Party's acceptance of Protected Information from a Producing Party shall not constitute an admission, or create an inference that the material is in fact confidential as designated. This Protective Order shall not foreclose any Party from moving for an order that materials designated Protected Information are not confidential within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P. Prior to bringing such a motion, however, the Receiving Party shall first request in writing that the Producing Party change or remove its designation. If the

Producing Party refuses to change its confidentiality designation within ten (10) business days, the Receiving Party may move for an order changing or removing the designation. On such motion, the Producing Party shall have the burden of proving that the material it designated Protected Information embodies its trade secrets or other confidential information within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P.

**9. PROTECTED INFORMATION RECEIVED FROM THIRD PARTIES**

If, in responding to a discovery request, subpoena or other legal process or otherwise, a Third Party discloses Protected Information belonging to or owned by a Party, the information disclosed by the Third Party shall be accorded the same protection as if it were received from a Producing Party under this Protective Order. In such an event, a Party, in good faith believing the information disclosed to be its Protected Information, may designate such information pursuant to this Protective Order. Likewise, a Third Party disclosing its own or a Party's Protected Information may do so under the terms of this Protective Order.

**10. DISCOVERY REQUESTS RECEIVED FROM THIRD PARTIES**

In the event that any Protected Information in the possession, custody or control of any Receiving Party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the Receiving Party to whom the process or discovery request is directed shall: (1) give written notice of such process or discovery request, together with a copy thereof, to counsel for the Producing Party, and request an agreement to make the requested disclosure; (2) refuse to produce any Protected Information as long as permitted under law until such a time that the Producing Party has had a reasonable opportunity to object, which reasonable time to object shall not be less than ten (10) business days from the date of receipt of the notice under (1); and (3) in the event that the Producing Party objects as provided under (2) and the parties fail to reach an agreement to make the requested disclosure, the Producing Party may move the Court for an order that the disclosure not be made.

An agreement in the form of Exhibit A must be obtained from all persons to whom disclosure is made under this section, or under such other conditions to which the Producing Party may agree or that the Court may order.

**11. DISCOVERY OF INFORMATION RESTRICTED BY CONFIDENTIALITY AGREEMENTS WITH THIRD PARTIES**

If discovery in the Actions calls for the production of information, documents or tangible items that a Party cannot produce because its disclosure would breach an existing confidentiality obligation to a Third Party to maintain such information in confidence, the Producing Party shall, no less than ten (10) business days before the date scheduled for production, give written notice to the Third Party that its information is subject to discovery in the Actions and provide the Third Party with a copy of this Protective Order. In addition to written notice, the Producing Party shall advise the Party requesting discovery of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the Third Party. The Producing Party shall use all reasonable efforts to secure permission from the Third Party to produce said Third Party's information, documents, or tangible items in the possession of the Producing Party, and shall not impede discovery by the Receiving Party of said Third Party's information, documents or tangible items in the possession of the Producing Party.

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**12. DISCOVERY OF INFORMATION PROTECTED BY EUROPEAN UNION PRIVACY DIRECTIVE OR MEMBER STATE**

In the event that a Party believes in good faith that it is legally precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in sufficient detail to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the

withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. If the Parties are unable to resolve the issue informally, the Party seeking to withhold the document shall within (5) days following the meet and confer on this issue seek protection from the Court and shall have the burden of establishing that the document cannot be produced.

In the event that a Producing Party inadvertently produces a document that it believes in goods faith it was legally precluded from producing under the EU Privacy Directive as implemented in the applicable member state, the Producing Party shall promptly notify the Receiving Party in writing of such document and the basis for its belief that it was legally precluded from producing it in this litigation . If the Parties are unable to resolve the issue informally, the Producing Party shall within five (5) days following the meet and confer on this issue, file a motion with the Court seeking to have the document returned and shall have the burden of establishing that the document should be returned or destroyed. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicable jurisdiction. }

**13. HANDLING PROTECTED INFORMATION AFTER TERMINATION OF THE ACTIONS**

**13.1** The provisions of this Protective Order shall survive and remain in full force and effect after the Termination of the Actions (including any appeals).

**13.2** Within ninety (90) days after the Termination of the Actions (including any appeals), each document and other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the Producing Party or (b) destroyed with a representation of such destruction being made to the attorney of record for the Receiving Party. The provisions of this Protective Order insofar as it restricts disclosure, communication, and use of Protected Information produced hereunder to a Receiving

Party, shall continue to be binding on such Receiving Party after the Termination of the Actions. Notwithstanding the foregoing, outside counsel for a Receiving Party may retain one (1) file copy of all court filings, discovery, correspondence, expert reports and exhibits, and deposition transcripts and exhibits, as well as Protected Information to the extent such Protected Information is contained in counsel's work product or in any materials filed with the Court.

**13.3** The Court retains jurisdiction even after the Termination of the Actions to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate.

## 14. ATTORNEY ADVICE TO CLIENT

Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to the Actions and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any Protected Information if such disclosure would be contrary to the provisions of this Protective Order.

## 15. INADVERTENT PRODUCTION OF PRIVILEGED DOCUMENTS OR WORK-PRODUCTS

If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in the Actions that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice or otherwise constitute a waiver of any claim of privilege or immunity for such information, provided that the Producing Party, within five (5) business days of the date on which it becomes aware, makes a good faith representation that such production was inadvertent or mistaken and takes remedial action to withdraw the disclosure. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of

attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information. The Producing Party shall retain copies of all returned documents and tangible items for further disposition. Within five (5) days of the return of any documents or tangible items, the Producing Party shall provide a privilege log with entries for all returned documents and tangible items.

**16. SEEKING RELIEF FROM, MODIFICATION OR ENFORCEMENT OF THIS PROTECTIVE ORDER**

This Protective Order shall not prevent any Party from applying to the Court for relief therefrom, or from applying to the Court for further additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court.

**17. NO LIMITATION ON OTHER RIGHTS**

Nothing in this Protective Order shall prejudice the right of any Party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality. Further, nothing in this Protective Order prevents a Party from disclosing its own documents and information as it sees fit.

**STIPULATION**

It is hereby stipulated that the foregoing Protective Order may be made and entered by the Court. It is further stipulated that the Parties will abide by this Protective Order from the date of the execution of this Stipulation by counsel for the Parties. The Parties, through their undersigned counsel, respectfully request the Court to enter this Stipulation as an Order.

**SO STIPULATED:**

Alfred J. Saikali
Fla. Bar No. 178195
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard
Suite 2400
Miami, Florida 33131-4332
Telephone: 305-358-5171
Facsimile: 305-358-7470

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS
153 East 53rd Street
New York, NY 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

Stephen J. Bronis
Jennifer Coberly
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard
Suite 900
Miami, Florida 33131-4332

*Attorneys for Apotex Inc. and Apotex Corp.*

Robert B. Breisblatt
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ LTD.
120 S. Riverside Plaza
22nd Floor
Chicago, IL 60606

*Attorneys for Apotex Inc. and Apotex Corp.*

Dated: March __, 2008

SO ORDERED this _____ day of March, 2008

The Honorable Gregory M. Sleet
United States District Court Judge

**EXHIBIT A**

**DECLARATION AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

I, _____ , declare under penalty of perjury that:

I have read and understand the annexed Protective Order that has been signed and entered in the Actions.

I have been retained by [Party] _____ as a [role] _____ for the Actions,

I hereby agree to be bound by and comply with the terms of the Protective Order, and not to disseminate or disclose any information subject to the Protective Order that I either review or about which I am told, to any person, entity, party, or agency for any reason, except in accordance with the terms of this Protective Order.

I am aware that if I violate the provisions of this Protective Order, the Court may order the entry of contempt sanctions against me.

I further agree to submit to the jurisdiction of this Court for the purpose of enforcing the terms of this Protective Order.

Dated this _____ day of _____, 200__.

_____
**(Signature)**

_____
**(Typed Name)**

_____
**(Title)**

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**

**CASE NO. 07-61800-CIV-MORENO/SIMONTON**

**SANOFI-AVENTIS and**
**SANOFI-AVENTIS U.S. LLC,**

**Plaintiffs,**

**v.**

**APOTEX, INC. and**
**APOTEX CORP.,**

**Defendants.**
**_____/**

**ORDER REGARDING PROTECTIVE ORDER**

**This matter arose upon the Motion for Protective Order filed by Defendants, Apotex, Inc. and Apotex Corp. (collectively, "Apotex") (DE # 25). This motion was referred to the undersigned Magistrate Judge (DE # 28). As stated below, all matters except for the provision regarding discovery of information protected by the European Union Privacy Directive have been previously resolved either by the Court or the parties. This Order resolves this remaining item of dispute, and requires the parties to submit a proposed Protective Order which contains the provision set forth below in the body of this Order.**

**Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively, "Sanofi"), did not oppose Defendants' Motion for Protective Order, yet the parties disagreed over the substance and timing of the entry of such an order. In an order entered February 20, 2008, the undersigned concluded that a protective order should issue immediately, and required the parties to confer in an attempt to resolve any substantive disagreements they had and to file a proposed protective order with the Court or submit a redlined version if they could not agree (DE # 51). In compliance with that Order, the parties were**

able to resolve all of their substantive disputes except for one, relating to the handling of discovery materials in light of the European Union ("EU") Privacy Directive.

Plaintiffs assert that the EU Privacy Directive typically prevents the production of materials concerning individuals' identifying information to a third party country, like the United States, without the subject individuals' consent (DE # 70). Defendants, however, argue that there is no basis for including provisions relating to the EU Privacy Directive in this protective order because (1) in the event that a domestic law governing discovery conflicts with a foreign law, the former prevails over the latter; (2) Plaintiffs have submitted stipulated protective orders in other, similar cases that do not address the EU Privacy Directive; (3) the EU Privacy Directive expressly permits the exchange of information during litigation discovery, as is the case here; and (4) if the protective order addresses the EU Privacy Directive at all, the party seeking to use it to preclude discovery should bear the burden of explaining why the EU Privacy Directive bars the production of the requested information (DE # 71).

Though Plaintiffs promise to rigorously seek to obtain the consent necessary to produce all responsive discovery materials that are subject to the EU Privacy Directive, the parties were unable to agree on a procedure to govern the inadvertent production of such materials. Plaintiffs would require the recipient of those materials to return them to the producing party and to destroy "all copies or summaries of, or notes relating to any such documents" (DE # 70, Ex. A at ¶ 12). Defendants, on the other hand, contend that the recipient should not automatically be required to return or destroy inadvertently disclosed information that is protected by the EU Privacy Directive. Rather, Defendants' proposed protective order requires the parties to confer; then, if no informal resolution is reached, requires the producing party to file a motion with the Court and bear the

**burden of establishing that the document should be returned or destroyed.**

**The undersigned finds that the dispute at hand is analogous to situations addressed in Federal Rule of Civil Procedure 26(b)(5), involving the inadvertent disclosure of privileged or protected information. In light of that Rule and the principles expressed in the accompanying 2006 Advisory Committee Notes, it is inappropriate to require the recipient of such information to destroy its notes and summaries related to inadvertently disclosed information during the pendency of litigation over whether the information should be disclosed. This is especially true in the present situation since one of the bases for seeking the return of that information is the withdrawal of consent previously given. Thus, the undersigned has determined that it is appropriate to take a middle ground between the two divergent positions of the parties, *i.e.* immediate return and destruction vs. continued use until there is a contrary order. Therefore, if a party is notified that it possesses inadvertently produced material subject to the EU Privacy Directive, until the resolution of any dispute concerning the material, that party shall return, sequester or destroy and make no further use of such material; and, that party shall sequester or destroy all copies or summaries of, or notes relating to any such material. If the parties are unable to informally resolve any dispute, the party seeking to withhold the material shall file a motion with the Court within five days of meeting and conferring with the opposing party. That party shall bear the burden of proving that the document cannot be produced. The following language should be included at the end of paragraph 12 of the Protective Order:**

> **Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return, sequester or destroy any documents or tangible items**

identified. The Receiving Party shall also sequester or destroy all copies or summaries of, or notes relating to any such documents. The Producing Party shall also identify the documents with sufficient detail as described above. If the Parties are unable to resolve the issue informally, the Producing Party seeking to withhold the document shall within five (5) days of the conclusion of the parties' meet and confer on this issue, seek protection from the Court and shall have the burden of establishing that the document cannot be produced. The same procedure shall apply to the extent that documents are not initially produced under this section. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicable jurisdiction.

It is accordingly

**ORDERED AND ADJUDGED** that, on or before March 20, 2008, the parties shall confer and submit a joint Proposed Protective Order consistent with the rulings set forth above. The parties are required to comply with CM/ECF Administrative Procedure Rule 3I(6) by forwarding a copy of the Proposed Protective Order in WordPerfect format by e-mail to simonton@flsd.uscourts.gov.

**DONE AND ORDERED** in Chambers in Miami, Florida, on March 17, 2008.

Andrea M. Simonton

**ANDREA M. SIMONTON**
**UNITED STATES MAGISTRATE JUDGE**

**Copies to:**
**The Honorable Federico A. Moreno, Chief United States District Judge**
**All counsel of record**

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**REPLY IN SUPPORT OF**
**PLAINTIFFS' MOTION FOR STATUS CONFERENCE**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this reply brief in further support of their motion for a status conference.

In that motion, sanofi-aventis asked the Court to schedule a brief status conference to provide the parties an opportunity to: (1) update the Court on the now four related actions currently pending in Delaware,[1] including the identical, first-filed action against Apotex; (2) discuss with the Court the various venue issues raised in the motions to transfer, stay, and/or consolidate pending before the Court, the Delaware court, and the Judicial Panel on Multidistrict Litigation Panel ("The Panel") and the impact of these motions on the present litigation; (3) the

[1] On March 14, 2008, sanofi-aventis filed suit against Wockhardt Limited and Wockhardt USA, Inc. in the District of Delaware. That action has been assigned Civil Action No. 08-150. Ex. 1, Delaware Complaint No. 08-150 and Civil Cover Sheet. True and accurate copies of Exhibits 1-3 are attached to the accompanying Declaration of Alexis Gorton In Support of Plaintiffs Reply In Support of Plaintiffs Motion for Status Conference.

necessity and timing of a claim construction briefing and a Markman hearing, which are necessary for the Court to issue claim constructions that will govern the parties' infringement and invalidity positions in this case; and (4) discovery limitations and scheduling of dispositive motions. (D.I. 56-1 at 1.) Rather than addressing these pressing issues, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") utilized their responsive brief to rehash its venue arguments and allegations that sanofi-aventis is seeking to delay discovery. A status conference will not cause delay and is absolutely necessary to address issues that will have an immediate effect on the parties' conduct in, and this Court's management of, this litigation.

Apotex does not challenge–because it cannot–sanofi-aventis's stated purposes for the requested status conference. Instead, Apotex uses its brief as an opportunity to restate its previous incorrect allegation that sanofi-aventis is seeking to delay the progression of this litigation. Contrary to Apotex's accusations, throughout this litigation sanofi-aventis has been motivated by a desire to avoid wasting the resources of two courts, the parties themselves, and witnesses as well as risking inconsistent rulings. For these reasons, sanofi-aventis has sought to transfer this case to the District of Delaware where four other related Urotraxal® actions are pending against 17 ANDA filers, or in the alternative to stay this action. Sanofi-aventis has repeatedly stated that it will fully participate in discovery, but believes those activities should be conducted in the forum where this action will ultimately proceed to avoid burdening the courts, parties, and witnesses—a group completely ignored by Apotex—with time consuming and costly, duplicative litigation efforts. That is the reason that sanofi-aventis requested a Protective Order (D.I. 44), and seeks to enjoin *both* parties from prosecuting this action in favor of the first-filed, Delaware action, Ex. 2, Plaintiffs' Motion To Enjoin The Parties From Prosecuting Second-Filed Duplicative Litigation, where the rights of sanofi-aventis and all 17 defendants can

be adjudicated together in a single forum.[2] Rather than addressing the merits of sanofi-aventis's arguments and motions, Apotex falls back on its mantra that this case has progressed substantially. However, discovery is in its infancy.[3] Moreover, the parties have yet to have their initial case management conference with the Court.

Apotex's sole purpose in aggressively pursuing this case, where it is the only defendant, is its potential for significant financial gain. Apotex has opposed sanofi-aventis's efforts to conserve the resources of the courts and the parties through consolidation because Apotex does not want to be on equal footing with those other 15 ANDA defendants. Instead of having to share exclusivity with other ANDA first-filers, Apotex would be able to enter the market by itself if it is able to obtain a non-infringement finding as to sanofi-aventis's patent in Florida before resolution of the Delaware action. Even other ANDA defendants have pointed out Apotex's attempt to game the system in this manner. *See* Ex. 3, Actavis South Atlantic L.L.C. and Par Pharmaceutical, Inc.'s Brief In Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407, at 8-9. These other ANDA defendants support the transfer and consolidation in Delaware as the only solution consistent with the policy and purpose behind the Hatch-Waxman Act provisions.

Apotex concludes its responsive brief by stating that it "has made every attempt to proceed expeditiously" in this case. (D.I. 62-1 at 3). Sanofi-aventis respectfully disagrees.

---

[2] Apotex mischaracterizes sanofi-aventis's recent motion before the Delaware court as a request to enjoin Apotex from defending itself. (D.I. 62-1 at 2.) In fact, sanofi-aventis moved the Delaware court to enjoin *both* parties from prosecuting this action and Apotex may continue to defend itself in Delaware, where all 17 ANDA defendants including Defendants Apotex Inc. and Apotex Corp. will participate.

[3] To date, discovery has been limited: the parties have exchanged initial disclosures; Apotex has served document requests and interrogatories, to which sanofi-aventis has responded; and Apotex on its own volition has produced its ANDA.

Apotex's conduct has squarely delayed this case, as demonstrated by its refusal to meet and confer with respect to negotiating a protective order. Following the Court's February 20, 2008 Order directing the parties to confer and submit a joint proposed Protective Order, D.I. 51, sanofi-aventis tried on three separate occasions to schedule a conference with Apotex to negotiate the terms of a global Protective Order. Because Apotex refused or ignored each of these requests, sanofi-aventis was forced to move the Court on February 26, 2008 to compel Apotex to comply with the Court's Order. (D.I. 54.) It was only *after* this motion to compel was filed that Apotex provided sanofi-aventis with Apotex's availability for a meet and confer. Clearly, Apotex's refusal to meet and confer on three separate occasions does not show it has "made every attempt to proceed expeditiously" in this case. (D.I. 62-1 at 3.)

Now, Apotex fails to provide a colorable argument as to why this Court should not hold a status conference. It is undisputed that a status conference at this stage of litigation would benefit both the parties and the Court. Addressing the issues outlined above will directly and immediately impact the parties' conduct in, and the Court's management of, the litigation.

For the foregoing reasons, Plaintiffs sanofi-aventis and sanofi-aventis LLC respectfully request that the Court enter an Order granting Plaintiffs' Motion for Status Conference.

Dated: March 17, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

and

John M. Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)
William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 17, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali (Fla. Bar No.: 178195)
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470
asaikali@shb.com

*Attorneys for Plaintiffs*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Robert B. Breisblatt, Esq.
Steven E. Feldman, Esq.
Sherry L. Rollo, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**DECLARATION OF ALEXIS GORTON IN SUPPORT OF PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR STATUS CONFERENCE**

I, Alexis Gorton, declare:

I am an attorney with the law firm Kirkland & Ellis LLP, counsel for sanofi-aventis and sanofi-aventis U.S. LLC in this action. I submit this declaration in support of Plaintiffs' Reply In Support Of Its Motion For Status Conference and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 is a true and accurate copy of the Complaint and Civil Cover Sheet dated March 14, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Wockhardt Limited and Wockhardt USA, Inc.*, Civil Action No. 08-150, in the District Court for the District of Delaware.

2. Attached hereto as Exhibit 2 is a true and accurate copy of Plaintiffs' Motion To Enjoin The Parties From Prosecuting Second-Filed, Duplicative Litigation dated March 4, 2008

filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT), in the District Court for the District of Delaware.

3. Attached hereto as Exhibit 3 is a true and accurate copy of Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support Of Motion To Transfer And Consolidate filed on February 25, 2008 in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

I declare under penalty of perjury that the foregoing is true and accurate.

s/ Alexis Gorton

Alexis Gorton

March 17, 2008
New York, New York

# EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

v.

C.A. No. _____



WOCKHARDT LIMITED and
WOCKHARDT USA, INC.,

Defendants.

**COMPLAINT**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Wockhardt Limited and Wockhardt USA, Inc., hereby allege as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Wockhardt USA, Inc. is a Delaware Corporation, and a wholly-owned subsidiary and agent of Wockhardt Limited, having a principal place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

4. Upon information and belief, Defendant Wockhardt Limited is an Indian Corporation having a place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra

(East), Mumbai - 400 051. Upon information and belief, Defendant Wockhardt Limited manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Wockhardt USA, Inc.

**Nature of the Action**



5. This is a civil action for the infringement of United States Patent No. 6,149,940 ("the '940 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Wockhardt USA, Inc. by virtue of the fact that, *inter alia,* Wockhardt USA, Inc. is a Delaware Corporation.

9. This Court has personal jurisdiction over Defendant Wockhardt Limited by virtue of, *inter alia*, (1) its presence in Delaware through its subsidiary and agent Wockhardt USA, Inc.; and (2) its systematic and continuous contact with Delaware, including through its subsidiary and agent Wockhardt USA, Inc.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**The '940 Patent**

11. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.



**Acts Giving Rise to this Action**
**Infringement of the '940 Patent by Defendants**

12. Upon information and belief, Wockhardt Limited, through its subsidiary and agent Wockhardt USA, Inc., submitted Abbreviated New Drug Application ("ANDA") 90-221 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 90-221 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

13. Wockhardt Limited alleged in ANDA 90-221 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of

sanofi-aventis's Uroxatral® brand product. Plaintiffs received written notification of ANDA 90-221 on or about February 20, 2008.

14. Wockhardt Limited's submission of ANDA 90-221 to the FDA, through Wockhardt USA, Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt Limited's commercial use, offer



for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

15. Wockhardt USA, Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Wockhardt USA, Inc. participated in, contributed to, aided, abetted and/or induced Wockhardt Limited's submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Wockhardt USA, Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Wockhardt USA, Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis's Uroxatral® brand product would infringe the '940 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Wockhardt Limited and Wockhardt USA, Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 90-221 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

18. Plaintiffs will be irreparably harmed by Wockhardt Limited's and Wockhardt USA, Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Prayer for Relief**

**WHEREFORE**, Plaintiffs pray for judgment as follows:



A. That Defendants have infringed the '940 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Wockhardt Limited's ANDA identified in this Complaint shall not be earlier than the expiration date of the '940 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis's Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com
*Attorneys for Plaintiffs*
*sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022
(212) 446-4800

March 14, 2008

JS 44 (Rev. 11/04)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**
sanofi-aventis and
sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

**DEFENDANTS**
Wockhardt Limited and
Wockhardt USA, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.



(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**CIVIL RIGHTS**
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

**FORFEITURE/PENALTY**
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

**V. ORIGIN** (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
35 U.S.C. § 271
Brief description of cause: patent infringement

**VII. REQUESTED IN COMPLAINT:** ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☐ Yes ☒ No

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE Sleet DOCKET NUMBER 07-572, 07-574 and 07-792

DATE March 14, 2008 SIGNATURE OF ATTORNEY OF RECORD Jack Blumenfeld

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 11/04)

# INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the defendant is the location of the tract of land involved.)



(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

**III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V. Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

**VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

# EXHIBIT 2

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. 07-792 (GMS) (MPT) |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**PLAINTIFFS' MOTION TO ENJOIN THE PARTIES FROM PROSECUTING SECOND FILED, DUPLICATIVE LITIGATION**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC. hereby move to enjoin the parties from prosecuting the second filed, duplicative action in the Southern District of Florida. The grounds for this motion are set forth in Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin The Parties From Prosecuting Second Filed, Duplicative Litigation. A proposed form of Order is attached hereto as Exhibit 1.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr. (#4292)*

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com

*Attorneys for Plaintiffs*
*sanofi-aventis*
*sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

March 4, 2008
1751384

**RULE 7.1.1 CERTIFICATION**

I hereby certify that counsel for sanofi-aventis has raised the subject of the foregoing motion with counsel for Apotex, and that the parties have not been able to reach agreement on the issues raised in the motion.

*James W. Parrett, Jr. (#4292)*
James W. Parrett, Jr. (#4292)

**CERTIFICATE OF SERVICE**

I hereby certify that on March 4, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on March 4, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*
*And HAND DELIVERY*

Robert B. Breisblatt, Esquire
Steven E. Feldman, Esquire
Sherry L. Rollo, Esquire
WELSH & KATZ LTD.
120 S. Riverside Plaza
22nd Floor
Chicago, IL 60606

*VIA ELECTRONIC MAIL*

*/s/ James W. Parrett, Jr. (#4292)*

James W. Parrett, Jr. (#4292)

# EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,<br><br>Plaintiffs,<br><br>vs.<br><br>APOTEX INC. and APOTEX CORP.,<br><br>Defendants. | ) | C.A. No. 07-792 (GMS) (MPT) |

**[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO ENJOIN SECOND FILED, DUPLICATIVE LITIGATION**

IT IS HEREBY ORDERED this _____ day of _____, 2008, that Plaintiffs' Motion to Enjoin Second Filed, Duplicative Litigation is GRANTED.

_____
United States District Judge

# EXHIBIT 3

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**DEFENDANTS ACTAVIS SOUTH ATLANTIC LLC'S AND PAR PHARMACEUTICAL, INC.'S RESPONSE IN SUPPORT OF MOTION TO TRANSFER AND CONSOLIDATE**

Defendants Actavis South Atlantic LLC ("Actavis") and Par Pharmaceutical, Inc. ("Par") respectfully submit this response in support of Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC's (collectively, "sanofi") February 1, 2008 Motion to Transfer and Consolidate for Pretrial Proceedings ("sanofi's Motion"). Transfer and consolidation of the related actions for pretrial proceedings would promote the just and efficient conduct of the actions, conserve judicial resources and satisfy the purpose of the Hatch-Waxman Act by treating all first filers the same.

The four cases sanofi seeks to consolidate include three actions pending in the District of Delaware, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., No. 07-572 (GMS) (MPT), Sanofi-Aventis et al. v. Barr Laboratories, Inc., No. 07-754 (GMS) (MPT), and Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-792 (GMS) (MPT) (collectively, the "Delaware Actions"), as well as an action pending in the Southern District of Florida, Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-61800-CIV (S.D. Fla.) (the "Florida Action") (collectively, the "Related Actions").

All four cases involve the alleged infringement, validity and enforceability of two sanofi patents, U.S. Patent No. 4,661,491 ("the '491 patent") and U.S. Patent No. 6,149,940 ("the '940 patent"). The Related Actions are all at the early stages of pretrial discovery, and no undue prejudice will be imposed upon Apotex or any of the other defendants by consolidation. Given the overlapping issues, consolidation is appropriate. Moreover, if these actions are not consolidated, Actavis, Par and other first filers may be unfairly prejudiced.

**RESPONSES TO SANOFI'S AVERMENTS**

In response to the averments in sanofi's Motion, Actavis and Par, pursuant to Rule 7.1(b), respond as follows:

1. Admit.

2. Admit except that Actavis and Par do not have sufficient information to either admit or deny whether the '491 and '940 patents "cover" Uroxatral®.

3. Actavis and Par admit that Actavis filed an ANDA for a generic version of in the Summer of 2007 seeking to market its ANDA product before the expiration of the

'491 and '940 patents. Acatvis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

4. Actavis and Par admit that Actavis filed an ANDA with a Paragraph IV certification, asserting that the claims of the '491 and '940 patents are invalid and/or not infringed by the manufacture, use or sale of the proposed ANDA product. Actavis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

5. Actavis and Par do not have sufficient information to either admit or deny the truth of this averment because it involves communications between Apotex and sanofi.

6. Deny as to Actavis and Par. Actavis and Par do not have sufficient information to admit or deny the truth of this averment with respect to the filing of ANDAs by other defendants.

7. Admit that sanofi commenced the named actions. Actavis and Par do not have sufficient information to admit or deny sanofi's motivation for commencing these actions.

8. Admit.

9. Admit only that sanofi commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex, Inc, and Apotex Corp. (collectively, "Apotex") in Delaware on December 6, 2007 for infringement of the '491 patent, and that this action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge. Actavis and Par do not have sufficient information to either admit or deny that Apotex's second paragraph IV certification was dated October 25, 2007, or that

Apotex alleged therein that its proposed generic product did not infringe any valid claim of the '491 patent.

10. Admit.

11. Actavis and Par do not have sufficient information to admit or deny whether sanofi met its asserted deadline with respect to 13 defendants. The remaining content of Paragraph 11 of the sanofi motion reflects sanofi's view of the law rather than an averment, and thus no further response need be given.

12. Actavis and Par do not have sufficient information to admit or deny this averment because it is based on sanofi's beliefs or concerns regarding personal jurisdiction.

13. Admit that the District of Delaware can properly exercise personal jurisdiction over Actavis and Par. Actavis and Par do not have sufficient information to admit or deny that the District of Delaware can properly exercise jurisdiction over the remaining defendants. Actavis and Par admit that sanofi brought second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007 and against Apotex on December 10, 2007. Actavis and Par do not have sufficient information to admit or deny the remaining allegations in this averment because they are based on sanofi's beliefs or concerns regarding personal jurisdiction.

14. Actavis and Par do not have sufficient information to admit or deny this averment, because it is based on communications between Apotex and sanofi.

15. Admit.

16. Admit.

17. Admit.

18. Admit.

19. Admit.

20. Admit.

21. Agree with the relief requested by sanofi that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

## ARGUMENT

I. The Related Actions Should Be Consolidated Pursuant to Section 1407

A. The Related Actions Involve Common Questions of Fact and Law

The Related Actions should be consolidated because they involve many common issues, including claim construction, validity and enforceability issues relating to the '491 and '940 patents. Cases involving common questions of fact should be consolidated for pretrial proceedings when the transfer would "be for the convenience of parties and witnesses and [would] promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a) (2008); In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007). Transfer and consolidation do not require "complete identity or even a majority of common factual or legal issues." In re Kugel Mesh Hernia Patch Prods. Liab. Litig., 493 F. Supp. 2d 1371, 1374 (J.P.M.L. 2008). To the extent that non-common issues are involved, the transferee court can address those through pretrial procedures such as separate but concurrent discovery tracks. Id.

The Panel has repeatedly transferred and consolidated actions involving the alleged infringement of a patent by defendants seeking to make a generic version of a

pharmaceutical product. See, e.g., In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354 (J.P.M.L. 2007); In re Rivastigmine Patent Litig., 360 F. Supp. 2d 1361 (J.P.M.L. 2005); In re Omeprazole Patent Litig., MDL No. 1291, 1999 U.S. Dist. LEXIS 12589 (J.P.M.L. 1999).

Here, the Related Actions involve many common issues, including claim construction, validity and enforceability of the '491 and '940 patents. Both the Delaware and Florida courts will have to engage in a claim construction analysis of both patents, which involves analyzing the language of the relevant claims of each patent, the patents' specifications and the file histories of each patent. Claim construction could potentially include the consideration of extrinsic evidence as well, including scientific treatises and dictionaries and expert and inventor testimony. Common resolution of these issues would prevent inconsistent rulings that could prejudice Actavis, Par and the other defendants.

B. Consolidation Would Promote the Just and Efficient Resolution of the Related Actions

Consolidation of the Related Actions would promote the just and efficient resolution of the actions because it would "eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claims construction; and conserve the resources of the parties, their counsel and the judiciary." In re Desloratadine Patent Litig., 502 F. Supp. 2d at 1355. Consolidation of the Related Actions would conserve judicial resources, as it would require only one court to engage in the time- and labor-intensive tasks of analyzing the patents at issue, construing their claims and resolving the parties' disputes. Consolidation would also obviate the possibility of inconsistent pretrial rulings, which would not only

be fundamentally unfair to the parties, but which could also engender further appellate practice, thus consuming further judicial resources.

Transfer and consolidation are especially desirable here, where all four Related Actions are at a similar stage, and where no significant discovery has taken place. According to sanofi's Motion, Apotex has served one set of document requests, but no other discovery has been exchanged between any of the parties. Given that many common issues of fact exist in all four Related Actions, discovery will substantially overlap. If the cases are consolidated, the transferee court can order common discovery on the overlapping issues, avoid the need for multiple and duplicative discovery and limit the number of discovery motions that would need to be filed.

C. Consolidation Would Best Serve the Convenience of the Parties and Witnesses

Finally, transfer and consolidation is warranted under Section 1407 because it would be more convenient for the parties and witnesses, and would likely produce substantial cost savings for each party. Specifically, because the testimony of many witnesses is likely to be needed in more than one of the Related Actions, consolidation would prevent the need for multiple depositions of each witness. See In re Inter-Op Hip Prosthesis Prods. Liab. Litig., 149 F.Supp.2d 931, 933 (J.P.M.L. 2001) (stating that consolidation would result in "an overall savings of cost and a minimum of inconvenience to all concerned").

II. Consolidation Would Satisfy the Purposes of the Hatch-Waxman Act

Consolidation of the Related Actions would also be consistent with the incentive structure established by the Hatch-Waxman Act by treating all first generic filers the same. Through the Hatch-Waxman Act, Congress established an incentive structure to

encourage generic applicants to challenge brand patents with the express purpose of enhancing generic market competition. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2008); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n. 11 (D.C. Cir. 1998) (exclusivity grant an important incentive); see also Understahl, B., Authorized Generics: Careful Balance Undone, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 365 (2005). The 180-day exclusivity period was the cornerstone of this incentive structure. Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 44 (D.D.C. 2000) ("The 180-day exclusivity provision was specifically adopted to reward generic drug makers who . . . undertake the potentially time-consuming and costly efforts to establish that a pioneer drug maker's patent is wrongfully keeping generic drugs off the market."); see also Understahl, B., 16 Fordham Intell. Prop. Media & Ent. L.J. at 365.

According to sanofi's Motion, "each of the nine separate ANDAs seeking approval to market a copy of sanofi-aventis's Uroxatral® brand drug product was filed on the same day, and thus each of the ANDA filers is a 'first-filer' eligible for the 180 day exclusivity."[1] (Sanofi Motion at 19.) Assuming this is true, each first-filer defendant should be treated the same.

If the Apotex Florida Action is not consolidated with the other Related Actions, Apotex could obtain an unfair advantage, to the detriment of the other first filers. For example, FDA approval of all of the ANDAs was automatically stayed by 30 months when sanofi filed suit within 45 days of receiving notice from the first filers that the ANDAs had been filed. 21 U.S.C. §355(j)(5)(B)(iii). This 30-month stay will be terminated, however, upon a district court decision finding the relevant patent invalid or

[1] Actavis and Par do not have any information to corroborate whether each ANDA was, in fact, filed on the same day and whether each ANDA filer is entitled to the 180-day exclusivity period.

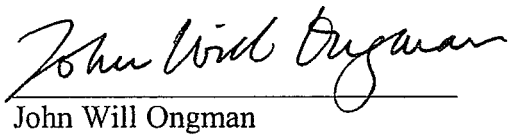
not infringed. 21 U.S.C. §355(j)(5)(B)(iii)(I). Under this structure, if Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.

## CONCLUSION

For the foregoing reasons, Actavis and Par respectfully request that this Panel transfer the Florida action Sanofi-Aventis et al. v. Apotex Inc. et al. to the District of Delaware and consolidate that action with the three Delaware actions, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., Sanofi-Aventis et al. v. Barr Laboratories, Inc., and Sanofi-Aventis et al. v. Apotex Inc. et al., for coordinated pretrial proceedings.

Dated: February 25, 2008

Respectfully submitted,



John Will Ongman
AXINN, VELTROP & HARKRIDER LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
(202) 912-4700
*Attorneys for Actavis South Atlantic LLC and Par Pharmaceutical, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that copies of the foregoing Response in Support of the Motion to Transfer and Consolidate were mailed via first-class mail on February 25, 2008 to the counsel of record in the associated cases listed in the attached Panel Attorney Service List.

John Will Ongman

**Judicial Panel on Multidistrict Litigation - Panel Attorney Service List**



Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation
Status: Pending on / /
Transferee District: Judge:

Printed on 02/15/2008

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Cohen, Eric C.<br>KATTEN MUCHIN ROSENMAN<br>525 West Monroe Street<br>Suite 1600<br>Chicago, IL 60661-3693 | =>**Phone: (312) 902-5200 Fax: (312) 902-1061 Email: eric.cohen@kattenlaw.com**<br>Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries, Ltd. |
| Feldman, Steven E.<br>WELSH & KATZ LTD<br>120 South Riverside Plaza<br>22nd Floor<br>Chicago, IL 60606 | =>**Phone: (312) 526-1551 Fax: (312) 655-1501 Email: sefeldman@welshkatz.com**<br>Apotex Corp.*; Apotex, Inc.* |
| Flattmann, Jr, Gerald J.<br>KIRKLAND & ELLIS LLP<br>Citicorp Center<br>153 East 53rd Street<br>New York, NY 10022 | =>**Phone: (212) 445-4800 Fax: (212) 446-4900 Email: gflattmann@kirkland.com**<br>Sanofi Aventis*; Sanofi-Aventis, US, LLC* |
| Kratz, Timothy H.<br>MCGUIREWOODS LLP<br>1170 Peachtree Street, N.E.<br>Suite 2100<br>Atlanta, GA 30309 | =>**Phone: (404) 443-5500 Fax: (404) 443-5784 Email: tkratz@mcguirewoods.com**<br>Mylan Pharmaceuticals, Inc.* |
| Olson, Darrell L.<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 Main Street<br>14th Floor<br>Irvine, CA 92614 | =>**Phone: (949) 760-0404 Fax: (949) 760-9502 Email: dolson@kmob.com**<br>Ranbaxy Laboratories, Ltd.; Ranbaxy, Inc. |
| Ongman, John Will<br>AXINN VELTROP & HARKRIDER LLP<br>1330 Connecticut Avenue, NW<br>Washington, DC 20036 | =>**Phone: (202) 912-4700 Fax: (202) 912-4701 Email: jwo@avhlaw.com**<br>Actavis South Atlantic, LLC*; PAR Pharmaceutical, Inc.* |
| Parr, Keith D.<br>LOCKE LORD BISSELL & LIDDELL LLP<br>111 South Wacker Drive<br>Chicago, IL 60606-4410 | =>**Phone: (312) 443-0497 Fax: (312) 896-6497 Email: kparr@lockelord.com**<br>Torrent Pharma, Inc.*; Torrent Pharmaceuticals, Ltd.* |
| Poullaos, Ivan M.<br>WINSTON & STRAWN LLP<br>35 West Wacker Drive<br>Chicago, IL 60601 | =>**Phone: (312) 558-5600 Fax: (312) 558-5700 Email: ipoullaos@winston.com**<br>Barr Laboratories, Inc.* |
| Schuman, Mark D.<br>CARLSON CASPERS VANDENBURGH & LINDQUIST<br>225 South Sixth Street<br>Suite 3200<br>Minneapolis, MN 55402 | =>**Phone: (612) 436-9600 Fax: (612) 436-9605 Email: mschuman@ccvl.com**<br>Teva Pharmaceuticals USA, Inc.* |

*(Panel Attorney Service List for MDL 1,941 Continued)*



| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Siwik, Christine J.<br>RAKOCZY MOLINO MAZZOCHI SIWIK LLP<br>6 West Hubbard Street<br>Suite 500<br>Chicago, IL 60610 | =>**Phone: (312) 222-6304 Fax: (312) 222-6324**<br>Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc. |

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' NOTICE OF COMPLIANCE WITH**
**ORDER REGARDING PROTECTIVE ORDER, DATED MARCH 17, 2008**

Plaintiffs, sanofi-avenis and sanofi-aventis U.S. LLC ("Plaintiffs"), hereby file this Notice of Compliance with the Court's Order Regarding Protective Order, Dated March 17, 2008.

1. On March 17, 2008, Magistrate Judge Simonton entered an Order that required the parties to confer and submit a joint Proposed Protective Order consistent with the rulings set forth in that Order. (D.E. 72). Those rulings related to the entry of a Protective Order and to language governing documents that a producing party determined were protected by the EU Privacy Directive. (D.E. 72).

2. Undersigned counsel incorporated the changes required by the Court's March 17th Order into the protective order draft that Plaintiffs submitted with their March 12, 2008 Notice of Compliance. (D.E. 70). That new draft is attached hereto as Exhibit "1."

3. Undersigned counsel has conferred with Defendants' counsel concerning the attached revisions and Defendants' counsel does not object.

WHEREFORE, Plaintiffs respectfully request that the Court enter the attached proposed Protective Order pursuant to its March 17, 2008 Order.

Date: March 20, 2008

Respectfully submitted,

/s/ Alfred J. Saikali
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 20, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Sherry L. Rollo, Esq.
Steven E. Feldman, Esq.
Robert B. Breisblatt, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

# PROTECTIVE ORDER

WHEREAS discovery in the above captioned action may involve the disclosure of certain documents, things and information in the possession, custody or control of the plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), the defendants, Apotex Inc. and Apotex Corp. (collectively "Defendants"), or other persons, that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order to advance this Action and prevent unnecessary dissemination or disclosure of such secret or other confidential research, development, or commercial information; and

WHEREAS the parties have established good cause for entry of this Protective Order ("Protective Order");

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in the Action:

## 1. DEFINITIONS

**1.1** "Action" refers to the above-captioned matter.

**1.2** The term "Protected Information" shall mean any document or other tangible thing or oral testimony that contains or reveals what a party considers to be its trade secret, business confidential, or proprietary information. In designating information as "Protected Information," a party shall designate only its trade secrets, information that it has maintained in confidence, or information in which it has a proprietary interest. Each party shall act in good faith in designating information as "Protected Information."

**1.3** "Party" shall mean any party to the Action, including all its officers, directors, and employees, and its outside counsel retained by that party for the Action, including such counsel's support staff.

**1.4** "Document" shall mean all information, documents or things within the scope of Rule 34 of the Fed. R. Civ. P.

**1.5** "Outside Counsel" shall mean attorneys who are not employees of a Party and whose firm has entered an appearance in any or all of the Action.

**1.6** "In-House Counsel" shall mean attorneys who are employees of a Party, or its parents, subsidiaries, or affiliates, to the Action.

**1.7** "Producing Party" shall mean a Party that produces and/or designates documents or testimony pursuant to the categories allowed under this Protective Order.

**1.8** "Receiving Party" shall mean a Party that receives documents or other things in the Action.

**1.9** "Third Party" shall mean any person or entity not a Party as defined in this Protective Order.

**1.10** "Independent Expert" or "Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the subject matter of this Action solely for the purpose of assisting in the Action to furnish expert or consulting services or to give expert testimony with regard to the Action.

**1.11** "Non-Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the Action solely for the purpose of assisting in the Action to furnish expert services that is not based on the subject matter of the Action, such as a jury consultant, interpreter, or translator.

**1.12** "Termination of the Action" shall mean the earlier of either (a) final settlement in the Action with respect to all causes of action, or (b) a final judgment ending the Action which judgment is not subject to appeal.

## 2. DESIGNATION OF PROTECTED INFORMATION

**2.1** This Protective Order establishes two categories of Protected Information. Information in the higher category is referred to as "Outside-Counsel-Only Confidential Information." Protected Information in the lower category is referred to as "Confidential Information."

**2.2** **"Outside-Counsel-Only Confidential Information"**: A Producing Party may in good faith invoke the designation "Outside-Counsel-Only Confidential Information" only for highly sensitive information:

a. Information appropriate for designation as Outside-Counsel-Only Confidential Information shall presumptively include, but is not limited to:

i. Information relating to customer, supplier, distributor, licensee, licensor or partner identities; agreements with customers, suppliers, distributors, licensees, licensors or partners;

ii. Financial projections, sales volumes, pricing, costs, profit margins, marketing materials and plans, strategy documents relating to business plans, and financial trade secrets, and the calculation of same;

iii. Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration;

iv. Information relating to research, development, product development reports, formulation, testing or studies on proposed potential, un-marketed, or future products or new indications including testing on inactive ingredients;

v. Trade secrets;

vi. Information relating to pending and unpublished patent applications;

vii. Technical notebooks, or similar documents, and records for any current or proposed future products, including schematic diagrams, technical reference manuals, operation manuals, or other like, non-public, sensitive information including process formulation data and chemical synthesis routes.

viii. Correspondence and communications with active pharmaceutical ingredient suppliers and excipient suppliers.

ix. Any and all Drug Master Files and Amendments.

b. Disputes regarding the propriety in designating particular Protected Information as "Outside-Counsel-Only Confidential Information" shall be resolved in accordance with Section 8 of this Protective Order.

**2.3** "**Confidential Information**": A Producing Party may in good faith only invoke the designation "Confidential Information" with respect to other information that is not publicly known and which the Producing Party would not normally reveal to Third Parties or if disclosed, would require such Third Parties to maintain in confidence.

**2.4** **Copies and Derivative Works from Protected Information**: All copies, derivative abstracts, summaries, or notes that refer to Protected Information shall be entitled to the same designation as the original source of the information contained therein.

**2.5** **Restraint In Designation**: Each Producing Party agrees to designate Protected Information on a good faith basis and not to harass the Receiving Party or unnecessarily restrict access to information concerning the lawsuit. Each Producing Party must take care to designate for protection only those documents or testimony that qualify. A Producing Party shall further have the duty to notify the Receiving Party whenever it comes to light that the Producing Party has mistakenly or improperly invoked a designation.

## 3. PERSONS WITH ACCESS TO PROTECTED INFORMATION

**3.1** **Access to material designated "Confidential Information":** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Confidential Information" to:

a. A Receiving Party's Outside Counsel of record in the Action, as well as employees of said Outside Counsel working solely in legal, secretarial, clerical, and paralegal capacities and who are assisting attorneys in the Action, as well as other persons working for outsourced litigation support services, including, without limitation, translation, interpreter, reprographic, and electronic discovery services, for the purpose of the Action, however, each such person is prohibited from involvement in either U.S. or foreign patent prosecution relating to alpha-andrenergic antagonists for the treatment of

dysuria, including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review);

b. Any Independent Expert, Technical Consultant or Non-Technical Consultant. All such Independent Experts, Technical Consultants and Non-Technical Consultants shall be instructed not to disclose the Protected Information to any person, except as may be necessary within such person's organization to research, test, investigate or perform tasks associated solely with the Action. Disclosure of Protected Information to any Independent Expert, Technical Consultant or Non-Technical Consultant shall be made pursuant to Subsections 3.3 or 3.4, as may be applicable.

c. Authors, creators, addressees and other recipients of Protected Information, who, prior to the commencement of the Action, lawfully received or had access to the Protected Information;

d. Licensed stenographers, videographers, and their support staff, retained for the Action;

e. the Court and its personnel; and

f. Three (3) In-House Counsels or other personnel responsible for overseeing Outside Counsel in connection with the Action for each Party, or its parents, subsidiaries, or affiliates, as well as one (1) additional employee technical representative for each Party, or its parents, subsidiaries, or affiliates, who need to be consulted by, and at the direction of such Outside Counsel. Persons designated under this subsection shall not be involved in U.S. or foreign patent prosecution relating to alpha-andrenergic anatagonists for the treatment of dysuria, including any alfuzosin products (and their

generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review), or business decision-making relating to any alfuzosin product, or the scientific development of any alfuzosin product.

**3.2 Access to material designated "Outside-Counsel-Only Confidential Information"**: Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Outside-Counsel-Only Confidential Information" to persons identified under (a) through (e) of Subsection 3.1.

**3.3 Persons for Whom a Signed Declaration and Agreement to be Bound by Protective Order Is Required**: Prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the party desiring to disclose Protected Information to such a person shall have complied with the notification procedure set forth in this Section:

a. Outside Counsel for the Receiving Party seeking to disclose such information to a person under this Subsection shall obtain from such person a written Declaration and Agreement to be Bound by Protective Order attached hereto as Exhibit A.

b. Outside Counsel obtaining said executed Declaration and Agreement to be Bound by Protective Order shall maintain all original copies of same until, at a minimum, the Termination of the Action, and copies of the same shall be sent to counsel for the Producing Party.

**3.4 Notification Required Prior to Disclosure to Independent Experts, Technical Consultants, Non-Technical Consultants and In-House Counsel**: In addition to complying

with Section 3.3, prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the following conditions must first be met:

a. Outside Counsel for the Receiving Party wishing to disclose Protected Information to such person shall, at least five (5) business days in advance of the proposed disclosure, notify the Producing Party's counsel, in writing, of the intent to disclose such information. The notice must include;

i. a copy of an executed Declaration and Agreement to be Bound by Protective Order as provided in Exhibit A. and in compliance with Subsection 3.3;

ii. if such person is identified under Subsection 3.1(b):

(1) a true and accurate copy of such person's current curriculum vitae or resume;

(2) a statement indicating whether or not such person was an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party;

(3) in the event that such person is not a natural person, but an entity such as a firm retained to provide consulting services in the Action, such entity shall provide a statement indicating whether or not the entity (or a predecessor or related entity of same) has ever been engaged by the Producing Party, including a statement indicating whether or not any employee of the entity who is expected to provide such consulting services on behalf of the entity has ever been an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party in the

Action, as well as a Declaration and Agreement to be Bound by Protective Order executed as required under Subsection 3.3 by an authorized representative of such entity.

b. No disclosure of Protected Information shall be made to such person identified under Subsection 3.1(b) until at least five (5) business days after all of the requirements set forth under (a) of this Subsection have been met. If the Producing Party objects in writing within said five (5) business day period, no disclosure of Protected Information shall be made to that person pending the resolution of the objection. Such written objection shall set forth in sufficient detail the grounds on which the objection is based.

c. If the Producing Party objects to the disclosure under Subsection 3.4(b), the Producing Party and the Receiving Party wishing to make the disclosure must meet and confer to try to resolve the matter. If the parties in good faith are unable to reach an agreement, the Producing Party may seek an Order from the Court requesting that the proposed disclosure not be permitted, the Producing Party carrying the burden to show that the disclosure should not be made. Such motion must be filed and served within seven (7) business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen (14) days after the written objection to disclosure is received by the Receiving Party, whichever is longer, but in no event longer than twenty-one (21) days after the written objection is received. Failure to so move within this stated period will be deemed a waiver of the Producing Party's objection, upon which the Receiving Party may then proceed with the disclosure of the Protected Information to such extent permitted by this Protective Order.

## 4. MARKING PROTECTED MATERIAL

All documents produced by any Producing Party shall, to the extent possible, be numbered using a prefix bearing the Party's name or an abbreviation thereof. The prefix should be used on a consistent basis and in a manner which makes clear the identity of the Producing Party.

a. **Documents:** Any document produced during discovery or otherwise disclosed in the Action, and any information contained therein, may be properly designated as "Confidential Information" or "Outside-Counsel-Only Confidential Information" by affixing the respective legends "CONFIDENTIAL" and "OUTSIDE-COUNSEL-ONLY CONFIDENTIAL" upon every page of the document that contains Protected Information, including the first page, in a conspicuous manner.

b. **Documents on Electronic Media**: Where a document containing Protected Information is produced in an electronic medium such as on a hard drive, compact disc, or a digital versatile disk (DVD), or other media of electronic storage, it shall be marked with the appropriate legend. To the extent possible, the information or documents contained therein shall also be appropriately marked. The parties shall further negotiate the format for such designations as part of their meet and confers on electronic discovery.

c. **Tangible Items**: Where a physical exhibit or other tangible item is produced, designation shall be made by marking the item in a prominently visible location with the appropriate designation if practicable, or, if not practicable, by affixing the marking on a package or container associated with the item.

d. **Discovery Responses and Testimonial Documents**: Where Protected Information is incorporated into correspondence, written answers to interrogatories,

document requests, responses to requests for admission, or other discovery requests and responses, a designation shall be made by placing the appropriate legend on the first page of the document.

e. **Originals**: Where original files are produced for inspection, no markings need be made by the Producing Party in advance of the inspection. For the purpose of inspection, all documents produced shall be considered designated as "Outside-Counsel-Only Confidential Information." Thereafter, upon selection of specific documents for copying, the Producing Party shall mark the copies of such documents with the appropriate designation in accordance with the provisions of this Protective Order.

f. **Court Filings**: Any document, pleading, or tangible item containing Protected Information, if filed or submitted to the Court, shall be properly designated as provided in this Protective Order and filed under seal pursuant to the provisions of the Local Rules of the Court. The Clerk of the Court is directed to maintain under seal in accordance with the Local Rules of the Court any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, under the categories provided in this Protective Order.

In the event that a Party wishes to use any Protected Information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper to be filed with the Court, such paper shall be filed under seal in accordance with the Local Rules of the Court and the Court's electronic filing procedures if applicable.

g. **Deposition Testimony:** Designation of portions or the entirety of deposition transcripts (including attached exhibits) as Confidential Information or

Outside-Counsel-Only Confidential Information shall be made by a statement to such effect on the record in the course of the deposition, or upon review of the deposition transcript by Counsel for the Producing Party within five (5) business days after Counsel's receipt of the transcript. All information disclosed during a deposition shall be treated as Outside-Counsel-Only Confidential Information until at least five (5) business days after a transcript of the deposition is received by counsel for each Party. Upon designation of the transcript or a portion thereof on the record during the deposition, the Producing Party shall be allowed to exclude, for the portion of the deposition likely to elicit Protected Information, all persons to whom access to Protected Information has not been granted under the terms of this Protective Order. The Court Reporter or other person recording the proceeding may only furnish copies of any portion of the deposition transcript that has been stated to contain Protected Information designated "Outside-Counsel-Only Confidential Information" in a sealed envelope to: the deponent as required by law, the Court, and the Outside Counsel for the Party to the deposition. Designations made within the five (5) business day period after receipt of a deposition transcript shall be made by sending written notices to the Court Reporter, to counsel for the Parties to the Action, and to any other person known to have a copy of said transcript. The notice shall reference this Protective Order and identify the pages, lines and/or exhibits of the transcript so designated. All copies of transcripts thus designated shall be marked with a notice indicating the confidentiality of the material therein, and the distribution of said transcript shall be governed by the terms of this Protective Order.

h. Any Protected Information not reduced to documentary or physical form, which cannot be conveniently labeled shall be designated by a Party serving a written notification of the designation on the Receiving Party.

## 5. SCOPE OF PROTECTIVE ORDER AND USE OF PROTECTED INFORMATION

**5.1** Protected Information shall not be made available to anyone other than as provided in this Protective Order.

**5.2** The restrictions set forth in this Protective Order will not apply to information that is in the lawful possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party by the Producing Party and not otherwise subject to a confidentiality agreement. Similarly, the restrictions set forth in this Protective Order will not apply to information that becomes known to the public after the date of its transmission to the Receiving Party, and not otherwise subject to a confidentiality agreement, provided that such information does not become publicly known by any act or omission of or attributable to the Receiving Party, its employees, or agents, which act or omission is in violation of this Protective Order or any other confidentiality agreement.

**5.3** A Receiving Party shall use Protected Information solely for the purpose of the Action, and not for any other purpose or for any other legal, regulatory, commercial or business purpose, including the pursuit of intellectual property rights, and cannot be used in any or cited within any citizens petitions or any other submission to FDA or other regulatory bodies, including but not limited to the United States Pharmacopeia.

**5.4** Nothing in this Protective Order shall restrict a Producing Party from using its own Protected Information for any purpose.

**5.5** This Protective Order also applies to all copies, summaries, translations, abstracts or similar compilations containing information, documents or things derived from a designating Party's trade secret or other confidential research, development, or commercial information.

**5.6** A Party's designation under the provisions of this Protective Order shall constitute a representation that counsel for the Producing Party believes in good faith that the designation is appropriate under the standards set forth herein.

**5.7** This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Protected Information. This Protective Order shall not limit a Party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive Protected Information under the terms of this Protective Order, so long as such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as demonstrated by the Protected Information itself or by foundation testimony during a deposition, hearing or trial.

**5.8** Protected Information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the Party who produced such Protected Information and (b) the Protected Information was in existence during the period of his or her service or employment.

**5.9** Only persons qualified to receive Protected Information under Section 3 of this Protective Order, including counsel, the deponent, translators, the court reporter, and the videographer, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

**5.10** Should any Protected Information be disclosed by a Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) within three (3) business days of the discovery of the disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party in a written notice; (b) use its best efforts to obtain the prompt return of any such Protected

Information and to bind such person to the terms of this Protective Order; and (c) request such person to sign Declaration and Agreement to be Bound by Protective Order, Exhibit A attached hereto. The executed Declaration and Agreement to be Bound by Protective Order shall be served upon counsel of record for the Producing Party within three (3) business days of its execution.

**5.11** In the event that a Receiving Party desires to provide access to Protected Information to any person not entitled to such access under this Protective Order, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing Party refuses to enter into such an agreement within ten (10) business days, the Receiving Party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to Protected Information after first signing an undertaking in the form of Exhibit A attached hereto, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the parties to the Action may agree or the Court may order.

**5.12** No Party shall be responsible to another Party for any use made of information that was produced and not designated as Protected Information.

**5.13** In the event that a new party is added, substituted, or brought into the Action or a coordinated action, this Protective Order shall be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of the Protective Order.

**5.14** Nothing in this Protective Order shall prejudice the right of any Party to bring before the Court at any time the question of whether any greater or lesser restriction should be placed upon the disclosure of any Protected Information.

**5.15** This Protective Order may be amended as need may arise by written agreement of the Parties without leave of the Court.

**5.16 Drafts of Expert Reports:** The Parties agree that no Party or testifying Independent Expert or Technical Consultant witness is required to maintain or produce drafts of Independent Expert reports or communications with Counsel relating to the captioned matter, or notes taken during the preparation of Independent Expert reports. In all other respects, however, the Parties and their Independent Expert, Technical Consultants, and Non-Technical Consultants shall fully comply with the disclosure requirements of Rule 26(a)(2) of the Fed. R. Civ. P.

## 6. PROCEDURES GOVERNING HANDLING OF PROTECTED INFORMATION

Protected Information must be stored and maintained by a Receiving Party or Third Party at a secure location and in a secure manner at all times to ensure that access is limited to persons authorized under this Protective Order. Upon the Termination of the Action, a Receiving Party or Third Party must comply with the provisions of Section 13 of this Protective Order.

## 7. CORRECTION OF INADVERTENT FAILURE TO DESIGNATE

The disclosure and/or production of any information, document or tangible item without one of the designations provided by this Protective Order shall constitute a waiver of any claim of confidentiality, except where such undesignated disclosure or production resulted from inadvertence or mistake on the part of the Producing Party and such inadvertence or mistake is brought to the attention of the Receiving Party promptly after its discovery. Along with the notice of such inadvertence or mistaken undesignated disclosure or production, the Producing Party shall provide properly designated documents and/or tangible items if applicable. Upon receipt of such notice and properly designated documents and/or tangible items if applicable, the Receiving Party shall substitute properly designated copies for those previously received and

treat the information contained in or derived from said replaced documents and/or tangible items as Protected Information.

**8. CHALLENGES TO PROTECTED INFORMATION DESIGNATION**

A Receiving Party's acceptance of Protected Information from a Producing Party shall not constitute an admission, or create an inference that the material is in fact confidential as designated. This Protective Order shall not foreclose any Party from moving for an order that materials designated Protected Information are not confidential within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P. Prior to bringing such a motion, however, the Receiving Party shall first request in writing that the Producing Party change or remove its designation. If the Producing Party refuses to change its confidentiality designation within ten (10) business days, the Receiving Party may move for an order changing or removing the designation. On such motion, the Producing Party shall have the burden of proving that the material it designated Protected Information embodies its trade secrets or other confidential information within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P.

**9. PROTECTED INFORMATION RECEIVED FROM THIRD PARTIES**

If, in responding to a discovery request, subpoena or other legal process or otherwise, a Third Party discloses Protected Information belonging to or owned by a Party, the information disclosed by the Third Party shall be accorded the same protection as if it were received from a Producing Party under this Protective Order. In such an event, a Party, in good faith believing the information disclosed to be its Protected Information, may designate such information pursuant to this Protective Order. Likewise, a Third Party disclosing its own or a Party's Protected Information may do so under the terms of this Protective Order.

**10. DISCOVERY REQUESTS RECEIVED FROM THIRD PARTIES**

In the event that any Protected Information in the possession, custody or control

of any Receiving Party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the Receiving Party to whom the process or discovery request is directed shall: (1) give written notice of such process or discovery request, together with a copy thereof, to counsel for the Producing Party, and request an agreement to make the requested disclosure; (2) refuse to produce any Protected Information as long as permitted under law until such a time that the Producing Party has had a reasonable opportunity to object, which reasonable time to object shall not be less than ten (10) business days from the date of receipt of the notice under (1); and (3) in the event that the Producing Party objects as provided under (2) and the parties fail to reach an agreement to make the requested disclosure, the Producing Party may move the Court for an order that the disclosure not be made. An agreement in the form of Exhibit A must be obtained from all persons to whom disclosure is made under this section, or under such other conditions to which the Producing Party may agree or that the Court may order.

## 11. DISCOVERY OF INFORMATION RESTRICTED BY CONFIDENTIALITY AGREEMENTS WITH THIRD PARTIES

If discovery in the Action calls for the production of information, documents or tangible items that a Party cannot produce because its disclosure would breach an existing confidentiality obligation to a Third Party to maintain such information in confidence, the Producing Party shall, no less than ten (10) business days before the date scheduled for production, give written notice to the Third Party that its information is subject to discovery in the Action and provide the Third Party with a copy of this Protective Order. In addition to written notice, the Producing Party shall advise the Party requesting discovery of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the Third Party. The Producing Party shall use all reasonable efforts to secure permission from the Third Party to produce said Third Party's information, documents, or tangible items in the possession of the Producing Party, and shall not impede discovery by the Receiving Party of said Third Party's information, documents or tangible items in the possession

of the Producing Party.

## 12. DISCOVERY OF INFORMATION PROTECTED BY EUROPEAN UNION PRIVACY DIRECTIVE OR MEMBER STATE

In the event that a Party believes in good faith that it is legally precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in sufficient detail to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. To the extent that a Producing Party discovers that information already produced to a Receiving Party must be returned in order to comply with the EU Privacy Directive, the Producing Party shall promptly notify the Receiving Party in writing of the specific documents to be returned and the basis for the return.

Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return, sequester or destroy any documents or tangible items identified. The Receiving Party shall also sequester or destroy all copies or summaries of, or notes relating to any such documents. The Producing Party shall also identify the documents with sufficient detail as described above. If the Parties are unable to resolve the issue informally, the Producing Party seeking to withhold the document shall within five (5) days of the conclusion of the parties' meet and confer on this issue, seek protection from the Court and shall have the burden of establishing that the document cannot be produced. The same procedure shall apply to the extent that documents are not initially produced under this section. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicably jurisdiction.

## 13. HANDLING PROTECTED INFORMATION AFTER TERMINATION OF THE ACTION

**13.1** The provisions of this Protective Order shall survive and remain in full force and effect after the Termination of the Action (including any appeals).

**13.2** Within ninety (90) days after the Termination of the Action (including any appeals), each document and other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the Producing Party or (b) destroyed with a representation of such destruction being made to the attorney of record for the Receiving Party. The provisions of this Protective Order insofar as it restricts disclosure, communication, and use of Protected Information produced hereunder to a Receiving Party, shall continue to be binding on such Receiving Party after the Termination of the Action. Notwithstanding the foregoing, outside counsel for a Receiving Party may retain one (1) file copy of all court filings, discovery, correspondence, expert reports and exhibits, and deposition transcripts and exhibits, as well as Protected Information to the extent such Protected Information is contained in counsel's work product or in any materials filed with the Court.

**13.3** The Court retains jurisdiction even after the Termination of the Action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate.

## 14. ATTORNEY ADVICE TO CLIENT

Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to the Action and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any Protected Information if such disclosure would be contrary to the provisions of this Protective

Order.

**15. INADVERTENT PRODUCTION OF PRIVILEGED DOCUMENTS OR WORK-PRODUCTS**

If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in the Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice or otherwise constitute a waiver of any claim of privilege or immunity for such information, provided that the Producing Party, within five (5) business days of the date on which it becomes aware, makes a good faith representation that such production was inadvertent or mistaken and takes remedial action to withdraw the disclosure. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information. The Producing Party shall retain copies of all returned documents and tangible items for further disposition. Within five (5) days of the return of any documents or tangible items, the Producing Party shall provide a privilege log with entries for all returned documents and tangible items.

**16. SEEKING RELIEF FROM, MODIFICATION OR ENFORCEMENT OF THIS PROTECTIVE ORDER**

This Protective Order shall not prevent any Party from applying to the Court for relief therefrom, or from applying to the Court for further additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court.

**17. NO LIMITATION ON OTHER RIGHTS**

Nothing in this Protective Order shall prejudice the right of any Party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality. Further, nothing in this Protective Order prevents a Party from disclosing its own documents and information as it sees fit.

SO ORDERED this _____ day of March, 2008

The Honorable Andrea M. Simonton
United States Magistrate Judge

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,
Defendants. /

**PROTECTIVE ORDER**

WHEREAS discovery in the above captioned action may involve the disclosure of certain documents, things and information in the possession, custody or control of the plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), the defendants, Apotex Inc. and Apotex Corp. (collectively "Defendants"), or other persons, that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order to advance this Action and prevent unnecessary dissemination or disclosure of such secret or other confidential research, development, or commercial information; and

WHEREAS the parties have established good cause for entry of this Protective

Order ("Protective Order");

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in the Action:

**DEFINITIONS**

**1.**

**1.1** "Action" refers to the above-captioned matter.

**1.2** The term "Protected Information" shall mean any document or other tangible thing or oral testimony that contains or reveals what a party considers to be its trade secret, business confidential, or proprietary information. In designating information as "Protected Information," a party shall designate only its trade secrets, information that it has maintained in confidence, or information in which it has a proprietary interest. Each party shall act in good faith in designating information as "Protected Information."

**1.3** "Party" shall mean any party to the Action, including all its officers, directors, and employees, and its outside counsel retained by that party for the Action, including such counsel's support staff.

**1.4** "Document" shall mean all information, documents or things within the scope of Rule 34 of the Fed. R. Civ. P.

**1.5** "Outside Counsel" shall mean attorneys who are not employees of a Party and whose firm has entered an appearance in any or all of the Action.

**1.6** "In-House Counsel" shall mean attorneys who are employees of a Party, or its parents, subsidiaries, or affiliates, to the Action.

**1.7** "Producing Party" shall mean a Party that produces and/or designates documents or testimony pursuant to the categories allowed under this Protective Order.

**1.8** "Receiving Party" shall mean a Party that receives documents or other things in the Action.

**1.9** "Third Party" shall mean any person or entity not a Party as defined in this Protective Order.

**1.10** "Independent Expert" or "Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the subject matter of this Action solely for the purpose of assisting in the Action to furnish expert or consulting services or to give expert testimony with regard to the Action.

**1.11** "Non-Technical Consultant" shall mean a person, not an employee of a Party, retained by counsel or a Party in connection with the Action solely for the purpose of assisting in the Action to furnish expert services that is not based on the subject matter of the Action, such as a jury consultant, interpreter, or translator.

**1.12** "Termination of the Action" shall mean the earlier of either (a) final settlement in the Action with respect to all causes of action, or (b) a final judgment ending the Action which judgment is not subject to appeal.

**2. DESIGNATION OF PROTECTED INFORMATION**

**2.1** This Protective Order establishes two categories of Protected Information. Information in the higher category is referred to as "Outside-Counsel-Only Confidential Information." Protected Information in the lower category is referred to as "Confidential Information."

**2.2 "Outside-Counsel-Only Confidential Information":** A Producing Party may in good faith invoke the designation "Outside-Counsel-Only Confidential Information" only for highly sensitive information:

a. Information appropriate for designation as Outside-Counsel-Only Confidential Information shall presumptively include, but is not limited to:

i. Information relating to customer, supplier, distributor, licensee, licensor or partner identities; agreements with customers, suppliers, distributors, licensees, licensors or partners;

ii. Financial projections, sales volumes, pricing, costs, profit margins, marketing materials and plans, strategy documents relating to business plans, and financial trade secrets, and the calculation of same;

iii. Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration;

iv. Information relating to research, development, product development reports, formulation, testing or studies on proposed potential, un-marketed, or future products or new indications including testing on inactive ingredients;

v. Trade secrets;

vi. Information relating to pending and unpublished patent applications;

vii. Technical notebooks, or similar documents, and records for any

current or proposed future products, including schematic diagrams, technical reference manuals, operation manuals, or other like, non-public, sensitive information including process formulation data and chemical synthesis routes.

viii. Correspondence and communications with active pharmaceutical ingredient suppliers and excipient suppliers.

ix. Any and all Drug Master Files and Amendments.

b. Disputes regarding the propriety in designating particular Protected Information as "Outside-Counsel-Only Confidential Information" shall be resolved in accordance with Section 8 of this Protective Order.

**2.3 "Confidential Information":** A Producing Party may in good faith only invoke the designation "Confidential Information" with respect to other information that is not publicly known and which the Producing Party would not normally reveal to Third Parties or if disclosed, would require such Third Parties to maintain in confidence.

**2.4 Copies and Derivative Works from Protected Information:** All copies, derivative abstracts, summaries, or notes that refer to Protected Information shall be entitled to the same designation as the original source of the information contained therein.

**2.5 Restraint In Designation:** Each Producing Party agrees to designate Protected Information on a good faith basis and not to harass the Receiving Party or unnecessarily restrict access to information concerning the lawsuit. Each Producing Party must take care to designate for protection only those documents or testimony that qualify. A Producing Party shall further have the duty to notify the Receiving Party whenever it comes to light that the Producing Party has mistakenly or improperly invoked a designation.

**3. PERSONS WITH ACCESS TO PROTECTED INFORMATION**

**3.1 Access to material designated "Confidential Information":** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Confidential Information" to:

a. A Receiving Party's Outside Counsel of record in the Action, as well as employees of said Outside Counsel working solely in legal, secretarial, clerical, and paralegal capacities and who are assisting attorneys in the Action, as well as other persons working for outsourced litigation support services, including, without limitation, translation, interpreter, reprographic, and electronic discovery services, for the purpose of the Action, however, each such person is prohibited from involvement in either U.S. or foreign patent prosecution relating to alpha-andrenergic antagonists for the treatment of dysuria, including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review);

b. Any Independent Expert, Technical Consultant or Non-Technical Consultant. All such Independent Experts, Technical Consultants and Non-Technical Consultants shall be instructed not to disclose the Protected Information to any person, except as may be necessary within such person's organization to research, test, investigate or perform tasks associated solely with the Action. Disclosure of Protected Information to any Independent Expert, Technical Consultant or Non-Technical Consultant shall be

made pursuant to Subsections 3.3 or 3.4, as may be applicable.

c. Authors, creators, addressees and other recipients of Protected Information, who, prior to the commencement of the Action, lawfully received or had access to the Protected Information;

d. Licensed stenographers, videographers, and their support staff, retained for the Action;

e. the Court and its personnel; and

f. Three (3) In-House Counsels or other personnel responsible for overseeing Outside Counsel in connection with the Action for each Party, or its parents, subsidiaries, or affiliates, as well as one (1) additional employee technical representative for each Party, or its parents, subsidiaries, or affiliates, who need to be consulted by, and at the direction of such Outside Counsel. Persons designated under this subsection shall not be involved in U.S. or foreign patent prosecution relating to alpha-andrenergic anatagonists for the treatment of dysuria, including any alfuzosin products (and their generic equivalents), the uses of alfuzosin products (and their generic equivalents), or the method of manufacturing alfuzosin products (and their generic equivalents) for a period of two (2) years after the final disposition of this action (including appeals and petitions for review), or business decision-making relating to any alfuzosin product, or the scientific development of any alfuzosin product.

**3.2 Access to material designated "Outside-Counsel-Only Confidential Information":** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may only disclose any Protected Information designated as "Outside-

Counsel-Only Confidential Information" to persons identified under (a) through (e) of Subsection 3.1.

**3.3 Persons for Whom a Signed Declaration and Agreement to be Bound by Protective Order Is Required:** Prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the party desiring to disclose Protected Information to such a person shall have complied with the notification procedure set forth in this Section:

a. Outside Counsel for the Receiving Party seeking to disclose such information to a person under this Subsection shall obtain from such person a written Declaration and Agreement to be Bound by Protective Order attached hereto as Exhibit A.

b. Outside Counsel obtaining said executed Declaration and Agreement to be Bound by Protective Order shall maintain all original copies of same until, at a minimum, the Termination of the Action, and copies of the same shall be sent to counsel for the Producing Party.

**3.4 Notification Required Prior to Disclosure to Independent Experts, Technical Consultants, Non-Technical Consultants and In-House Counsel:** In addition to complying with Section 3.3, prior to disclosure of any Protected Information to any person identified in Subsections 3.1(b) or 3.1(f), the following conditions must first be met:

a. Outside Counsel for the Receiving Party wishing to disclose Protected Information to such person shall, at least five (5) business days in advance of the proposed disclosure, notify the Producing Party's counsel, in writing, of the intent to disclose such information. The notice must include;

i. a copy of an executed Declaration and Agreement to be Bound by Protective Order as provided in Exhibit A. and in compliance with Subsection 3.3;

ii. if such person is identified under Subsection 3.1(b):

(1) a true and accurate copy of such person's current curriculum vitae or resume;

(2) a statement indicating whether or not such person was an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party;

(3) in the event that such person is not a natural person, but an entity such as a firm retained to provide consulting services in the Action, such entity shall provide a statement indicating whether or not the entity (or a predecessor or related entity of same) has ever been engaged by the Producing Party, including a statement indicating whether or not any employee of the entity who is expected to provide such consulting services on behalf of the entity has ever been an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party in the Action, as well as a Declaration and Agreement to be Bound by Protective Order executed as required under Subsection 3.3 by an authorized representative of such entity.

b. No disclosure of Protected Information shall be made to such person identified under Subsection 3.1(b) until at least five (5) business days after all of the requirements set forth under (a) of this Subsection have been met. If the Producing Party objects in writing within said five (5) business day period, no disclosure of Protected Information shall be made to that person pending the resolution of the objection. Such written objection shall set forth in sufficient detail the grounds on which the objection is based.

c. If the Producing Party objects to the disclosure under Subsection 3.4(b), the Producing Party and the Receiving Party wishing to make the disclosure must meet and confer to try to resolve the matter. If the parties in good faith are unable to reach an agreement, the Producing Party may seek an Order from the Court requesting that the proposed disclosure not be permitted, the Producing Party carrying the burden to show that the disclosure should not be made. Such motion must be filed and served within seven (7) business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen (14) days after the written objection to disclosure is received by the Receiving Party, whichever is longer, but in no event longer than twenty-one (21) days after the written objection is received. Failure to so move within this stated period will be deemed a waiver of the Producing Party's objection, upon which the Receiving Party may then proceed with the disclosure of the Protected Information to such extent permitted by this Protective Order.

**4. MARKING PROTECTED MATERIAL**

All documents produced by any Producing Party shall, to the extent possible, be numbered using a prefix bearing the Party's name or an abbreviation thereof. The prefix should be used on a consistent basis and in a manner which makes clear the identity of the Producing Party.

a. **Documents:** Any document produced during discovery or otherwise disclosed in the Action, and any information contained therein, may be properly designated as "Confidential Information" or "Outside-Counsel-Only Confidential Information" by affixing the respective legends "CONFIDENTIAL" and "OUTSIDE-COUNSEL-ONLY CONFIDENTIAL" upon every page of the document that contains Protected Information, including the first page, in a conspicuous manner.

b. **Documents on Electronic Media:** Where a document containing Protected Information is produced in an electronic medium such as on a hard drive, compact disc, or a digital versatile disk (DVD), or other media of electronic storage, it shall be marked with the appropriate legend. To the extent possible, the information or documents contained therein shall also be appropriately marked. The parties shall further negotiate the format for such designations as part of their meet and confers on electronic discovery.

c. **Tangible Items:** Where a physical exhibit or other tangible item is produced, designation shall be made by marking the item in a prominently visible

location with the appropriate designation if practicable, or, if not practicable, by affixing the marking on a package or container associated with the item.

d. **Discovery Responses and Testimonial Documents:** Where Protected Information is incorporated into correspondence, written answers to interrogatories, document requests, responses to requests for admission, or other discovery requests and responses, a designation shall be made by placing the appropriate legend on the first page of the document.

e. **Originals:** Where original files are produced for inspection, no markings need be made by the Producing Party in advance of the inspection. For the purpose of inspection, all documents produced shall be considered designated as "Outside-Counsel-Only Confidential Information." Thereafter, upon selection of specific documents for copying, the Producing Party shall mark the copies of such documents with the appropriate designation in accordance with the provisions of this Protective Order.

f. **Court Filings:** Any document, pleading, or tangible item containing Protected Information, if filed or submitted to the Court, shall be properly designated as provided in this Protective Order and filed under seal pursuant to the provisions of the Local Rules of the Court. The Clerk of the Court is directed to maintain under seal in accordance with the Local Rules of the Court any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, under the categories provided in this Protective Order.

In the event that a Party wishes to use any Protected Information in any

pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper to be filed with the Court, such paper shall be filed under seal in accordance with the Local Rules of the Court and the Court's electronic filing procedures if applicable.

g. **Deposition Testimony:** Designation of portions or the entirety of deposition transcripts (including attached exhibits) as Confidential Information or Outside-Counsel-Only Confidential Information shall be made by a statement to such effect on the record in the course of the deposition, or upon review of the deposition transcript by Counsel for the Producing Party within five (5) business days after Counsel's receipt of the transcript. All information disclosed during a deposition shall be treated as Outside-Counsel-Only Confidential Information until at least five (5) business days after a transcript of the deposition is received by counsel for each Party. Upon designation of the transcript or a portion thereof on the record during the deposition, the Producing Party shall be allowed to exclude, for the portion of the deposition likely to elicit Protected Information, all persons to whom access to Protected Information has not been granted under the terms of this Protective Order. The Court Reporter or other person recording the proceeding may only furnish copies of any portion of the deposition transcript that has been stated to contain Protected Information designated "Outside-Counsel-Only Confidential Information" in a sealed envelope to: the deponent as required by law, the Court, and the Outside Counsel for the Party to the deposition. Designations made within the five (5) business day period after receipt of a deposition transcript shall be made by sending written notices to the Court Reporter, to counsel for the Parties to the

Action, and to any other person known to have a copy of said transcript. The notice shall reference this Protective Order and identify the pages, lines and/or exhibits of the transcript so designated. All copies of transcripts thus designated shall be marked with a notice indicating the confidentiality of the material therein, and the distribution of said transcript shall be governed by the terms of this Protective Order.

h. Any Protected Information not reduced to documentary or physical form, which cannot be conveniently labeled shall be designated by a Party serving a written notification of the designation on the Receiving Party.

**5. SCOPE OF PROTECTIVE ORDER AND USE OF PROTECTED INFORMATION**

**5.1** Protected Information shall not be made available to anyone other than as provided in this Protective Order.

**5.2** The restrictions set forth in this Protective Order will not apply to information that is in the lawful possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party by the Producing Party and not otherwise subject to a confidentiality agreement. Similarly, the restrictions set forth in this Protective Order will not apply to information that becomes known to the public after the date of its transmission to the Receiving Party, and not otherwise subject to a confidentiality agreement, provided that such information does not become publicly known by any act or omission of or attributable to the Receiving Party, its employees, or agents, which act or omission is in violation of this Protective Order or any other confidentiality agreement.

**5.3** A Receiving Party shall use Protected Information solely for the purpose of the

Action, and not for any other purpose or for any other legal, regulatory, commercial or business purpose, including the pursuit of intellectual property rights, and cannot be used in any or cited within any citizens petitions or any other submission to FDA or other regulatory bodies, including but not limited to the United States Pharmacopeia.

**5.4** Nothing in this Protective Order shall restrict a Producing Party from using its own Protected Information for any purpose.

**5.5** This Protective Order also applies to all copies, summaries, translations, abstracts or similar compilations containing information, documents or things derived from a designating Party's trade secret or other confidential research, development, or commercial information.

**5.6** A Party's designation under the provisions of this Protective Order shall constitute a representation that counsel for the Producing Party believes in good faith that the designation is appropriate under the standards set forth herein.

**5.7** This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Protected Information. This Protective Order shall not limit a Party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive Protected Information under the terms of this Protective Order, so long as such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as demonstrated by the Protected Information itself or by foundation testimony during a deposition, hearing or trial.

**5.8** Protected Information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the Party who produced such Protected

Information and (b) the Protected Information was in existence during the period of his or her service or employment.

**5.9** Only persons qualified to receive Protected Information under Section 3 of this Protective Order, including counsel, the deponent, translators, the court reporter, and the videographer, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

**5.10** Should any Protected Information be disclosed by a Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) within three (3) business days of the discovery of the disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party in a written notice; (b) use its best efforts to obtain the prompt return of any such Protected Information and to bind such person to the terms of this Protective Order; and (c) request such person to sign Declaration and Agreement to be Bound by Protective Order, Exhibit A attached hereto. The executed Declaration and Agreement to be Bound by Protective Order shall be served upon counsel of record for the Producing Party within three (3) business days of its execution.

**5.11** In the event that a Receiving Party desires to provide access to Protected Information to any person not entitled to such access under this Protective Order, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing Party refuses to enter into such an agreement within ten (10) business days, the Receiving Party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to Protected Information after first

signing an undertaking in the form of Exhibit A attached hereto, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the parties to the Action may agree or the Court may order.

**5.12** No Party shall be responsible to another Party for any use made of information that was produced and not designated as Protected Information.

**5.13** In the event that a new party is added, substituted, or brought into the Action or a coordinated action, this Protective Order shall be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of the Protective Order.

**5.14** Nothing in this Protective Order shall prejudice the right of any Party to bring before the Court at any time the question of whether any greater or lesser restriction should be placed upon the disclosure of any Protected Information.

**5.15** This Protective Order may be amended as need may arise by written agreement of the Parties without leave of the Court.

**5.16 Drafts of Expert Reports:** The Parties agree that no Party or testifying Independent Expert or Technical Consultant witness is required to maintain or produce drafts of Independent Expert reports or communications with Counsel relating to the captioned matter, or notes taken during the preparation of Independent Expert reports. In all other respects, however, the Parties and their Independent Expert, Technical Consultants, and Non-Technical Consultants shall fully comply with the disclosure requirements of Rule 26(a)(2) of the Fed. R. Civ. P.

**6. PROCEDURES GOVERNING HANDLING OF PROTECTED INFORMATION**

Protected Information must be stored and maintained by a Receiving Party or Third Party at a secure location and in a secure manner at all times to ensure that access is limited to persons authorized under this Protective Order. Upon the Termination of the Action, a Receiving Party or Third Party must comply with the provisions of Section 13 of this Protective Order.

**7. CORRECTION OF INADVERTENT FAILURE TO DESIGNATE**

The disclosure and/or production of any information, document or tangible item without one of the designations provided by this Protective Order shall constitute a waiver of any claim of confidentiality, except where such undesignated disclosure or production resulted from inadvertence or mistake on the part of the Producing Party and such inadvertence or mistake is brought to the attention of the Receiving Party promptly after its discovery. Along with the notice of such inadvertence or mistaken undesignated disclosure or production, the Producing Party shall provide properly designated documents and/or tangible items if applicable. Upon receipt of such notice and properly designated documents and/or tangible items if applicable, the Receiving Party shall substitute properly designated copies for those previously received and treat the information contained in or derived from said replaced documents and/or tangible items as Protected Information.

**8. CHALLENGES TO PROTECTED INFORMATION DESIGNATION**

A Receiving Party's acceptance of Protected Information from a Producing Party shall not constitute an admission, or create an inference that the material is in fact confidential as designated. This Protective Order shall not foreclose any Party from moving for an order that

materials designated Protected Information are not confidential within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P. Prior to bringing such a motion, however, the Receiving Party shall first request in writing that the Producing Party change or remove its designation. If the Producing Party refuses to change its confidentiality designation within ten (10) business days, the Receiving Party may move for an order changing or removing the designation. On such motion, the Producing Party shall have the burden of proving that the material it designated Protected Information embodies its trade secrets or other confidential information within the meaning of Rule 26(c)(1)(G) of the Fed. R. Civ. P.

**9. PROTECTED INFORMATION RECEIVED FROM THIRD PARTIES**

If, in responding to a discovery request, subpoena or other legal process or otherwise, a Third Party discloses Protected Information belonging to or owned by a Party, the information disclosed by the Third Party shall be accorded the same protection as if it were received from a Producing Party under this Protective Order. In such an event, a Party, in good faith believing the information disclosed to be its Protected Information, may designate such information pursuant to this Protective Order. Likewise, a Third Party disclosing its own or a Party's Protected Information may do so under the terms of this Protective Order.

**10. DISCOVERY REQUESTS RECEIVED FROM THIRD PARTIES**

In the event that any Protected Information in the possession, custody or control of any Receiving Party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the Receiving Party to whom the process or discovery request is directed shall: (1) give written notice of such process or discovery request, together with a copy thereof, to counsel for the Producing Party, and request an

agreement to make the requested disclosure; (2) refuse to produce any Protected Information as long as permitted under law until such a time that the Producing Party has had a reasonable opportunity to object, which reasonable time to object shall not be less than ten (10) business days from the date of receipt of the notice under (1); and (3) in the event that the Producing Party objects as provided under (2) and the parties fail to reach an agreement to make the requested disclosure, the Producing Party may move the Court for an order that the disclosure not be made. An agreement in the form of Exhibit A must be obtained from all persons to whom disclosure is made under this section, or under such other conditions to which the Producing Party may agree or that the Court may order.

**11. DISCOVERY OF INFORMATION RESTRICTED BY CONFIDENTIALITY AGREEMENTS WITH THIRD PARTIES**

If discovery in the Action calls for the production of information, documents or tangible items that a Party cannot produce because its disclosure would breach an existing confidentiality obligation to a Third Party to maintain such information in confidence, the Producing Party shall, no less than ten (10) business days before the date scheduled for production, give written notice to the Third Party that its information is subject to discovery in the Action and provide the Third Party with a copy of this Protective Order. In addition to written notice, the Producing Party shall advise the Party requesting discovery of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the Third Party. The Producing Party shall use all reasonable efforts to secure permission from the Third Party to produce said Third Party's information, documents, or tangible items in the possession of the Producing Party, and shall not impede discovery by the Receiving Party of said Third Party's information, documents or tangible items in the possession of the Producing Party.

**12. DISCOVERY OF INFORMATION PROTECTED BY EUROPEAN UNION PRIVACY DIRECTIVE OR MEMBER STATE**

In the event that a Party believes in good faith that it is legally precluded from producing a discoverable document by virtue of the EU Privacy Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data) as implemented in the applicable member-state, the Producing Party shall identify the document in sufficient detail to enable the would be Receiving Party to appreciate the nature of the document (including information typically included in a privilege log entry) and the basis for the withholding Party's belief that it is subject to the applicable implementation of the EU Privacy Directive and cannot be produced in this litigation. To the extent that a Producing Party discovers that information already produced to a Receiving Party must be returned in order to comply with the EU Privacy Directive, the Producing Party shall promptly notify the Receiving Party in writing of the specific documents to be returned and the basis for the return.

Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return, sequester or destroy any documents or tangible items identified. The Receiving Party shall also sequester or destroy all copies or summaries of, or notes relating to any such documents. The Producing Party shall also identify the documents with sufficient detail as described above. If the Parties are unable to resolve the issue informally, the Producing Party seeking to withhold the document shall within five (5) days of the conclusion of the parties' meet and confer on this issue, seek protection from the Court and shall have the burden of establishing that the document cannot be produced. The same procedure shall apply to the extent that documents are not initially produced under this section. Nothing in this section shall preclude a would-be receiving party from filing a motion to compel the production of such documents subject to the meet and confer requirements of the applicably jurisdiction.

**13. HANDLING PROTECTED INFORMATION AFTER TERMINATION OF THE ACTION**

**13.1** The provisions of this Protective Order shall survive and remain in full force and effect after the Termination of the Action (including any appeals).

**13.2** Within ninety (90) days after the Termination of the Action (including any appeals), each document and other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the Producing Party or (b) destroyed with a representation of such destruction being made to the attorney of record for the Receiving Party. The provisions of this Protective Order insofar as it restricts disclosure, communication, and use of Protected Information produced hereunder to a Receiving Party, shall continue to be binding on such Receiving Party after the Termination of the Action. Notwithstanding the foregoing, outside counsel for a Receiving Party may retain one (1) file copy of all court filings, discovery, correspondence, expert reports and exhibits, and deposition transcripts and exhibits, as well as Protected Information to the extent such Protected Information is contained in counsel's work product or in any materials filed with the Court.

**13.3** The Court retains jurisdiction even after the Termination of the Action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate.

**14. ATTORNEY ADVICE TO CLIENT**

Nothing in this Protective Order shall bar or otherwise restrict an attorney herein

from rendering advice to his or her client with respect to the Action and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any Protected Information if such disclosure would be contrary to the provisions of this Protective Order.

**15. INADVERTENT PRODUCTION OF PRIVILEGED DOCUMENTS OR WORK-PRODUCTS**

If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in the Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice or otherwise constitute a waiver of any claim of privilege or immunity for such information, provided that the Producing Party, within five (5) business days of the date on which it becomes aware, makes a good faith representation that such production was inadvertent or mistaken and takes remedial action to withdraw the disclosure. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information. The Producing Party shall retain copies of all returned documents and tangible items for further disposition. Within five (5) days of the return of any documents or tangible items, the Producing Party shall provide a privilege log with entries for all returned documents and tangible items.

**16. SEEKING RELIEF FROM, MODIFICATION OR ENFORCEMENT OF THIS PROTECTIVE ORDER**

This Protective Order shall not prevent any Party from applying to the Court for relief therefrom, or from applying to the Court for further additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court.

**17. NO LIMITATION ON OTHER RIGHTS**

Nothing in this Protective Order shall prejudice the right of any Party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality. Further, nothing in this Protective Order prevents a Party from disclosing its own documents and information as it sees fit.

SO ORDERED this 21st day of March, 2008

Andrea M. Simonton

The Honorable Andrea M. Simonton
United States Magistrate Judge

**EXHIBIT A**

**DECLARATION AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

I, _____ , declare under penalty of perjury that:

I have read and understand the annexed Protective Order that has been signed and entered in the Action.

I have been retained by [Party] _____ as a [role] _____ for the Action,

I hereby agree to be bound by and comply with the terms of the Protective Order, and not to disseminate or disclose any information subject to the Protective Order that I either review or about which I am told, to any person, entity, party, or agency for any reason, except in accordance with the terms of this Protective Order.

I am aware that if I violate the provisions of this Protective Order, the Court may order the entry of contempt sanctions against me.

I further agree to submit to the jurisdiction of this Court for the purpose of enforcing the terms of this Protective Order.

Dated this _____ day of _____, 20____.

_____
(Signature)

_____
(Typed Name)

_____
(Title)

REC'D by _____ D.C.
INTAKE
MAR 18 2008
CLARENCE MADDOX
CLERK U.S. DIST. CT.
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KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

(212) 446-4800

www.kirkland.com

Facsimile:
(212) 446-4900
Dir. Fax: (212) 446-4900

Gerald J. Flattmann, Jr.
To Call Writer Directly:
(212) 446-4720
gflattmann@kirkland.com

March 17, 2008

**VIA FEDERAL EXPRESS**

Clerk of Court
United States District Court
District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Lock Box 18
Wilmington, DE 19801

Clerk of Court
United States District Court
Southern District of Florida
United States District Court Clerks Office
301 North Miami Avenue, Rm 150
Miami, FL 33128

Re: *Sanofi-aventis et al. v. Actavis South Atl. LLC et al.*, No. 1:07-CV-00572-GMS-MPT (D. Del.);
*Sanofi-aventis et al. v. Barr Laboratories Inc.*, 1:07-CV-00574-GMS-MPT (D. Del.);
*Sanofi-aventis et al. v. Apotex Inc. et al.*, 1:07-CV-00792-GMS-MPT (D. Del.);
*Sanofi-aventis et al. v. Wockhardt Ltd. et al.*, 1:08-CV-00150 (D. Del.); and
*Sanofi-aventis et al. v. Apotex Inc. et al.*, 1:07-CV-61800-FAM-AMS (S.D. Fla.)

Clerk of the Court:

Please be advised that sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") filed today with the Judicial Panel on Multidistrict Litigation a Notice Of Related Action with respect to *In re Alfuzosin Hydrochloride Patent Litigation,* MDL #1941. A copy of sanofi-aventis's notice is enclosed. Please do not hesitate to call if you have any questions.

Very truly yours,

Gerald J. Flattmann, Jr.

Enclosures

Case 1:08-cv-00347-GMS Document 110-33 Filed 06/23/2008 Page 2 of 8

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

## NOTICE OF RELATED ACTION

Pursuant to Rule 7.5(e) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation (the "Panel"), sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis") hereby notify the Clerk of the Panel of the related action listed on the attached Schedule Of Related Action, and state as follows:

1. On February 1, 2008 sanofi-aventis filed a motion to transfer and consolidate for pretrial proceeding in the above-captioned MDL. The motion has been fully briefed and is currently under consideration by the Panel.

2. An additional related action filed on March 14, 2008, is now pending in the District of Delaware as *sanofi-aventis et al. v. Wockhardt Ltd. et al.*, Civil Action No. 08-150. (Complaint and docket entry attached hereto as Exhibit 1). This action and the actions currently under consideration by the Panel in the above-captioned MDL involve common questions of fact and law.

Dated: March 17, 2008

Respectfully submitted,

John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

Case 1:08-cv-00347-GMS Document 110-33 Filed 06/23/2008 Page 4 of 8

**Before the Judicial Panel on Multidistrict Litigation**
**MDL 1941- *In re Alfuzosin Hydrochloride Patent Litigation***

**SCHEDULE OF RELATED ACTION**

| Case Caption | Court | Civil Action No. | Judge |
|---|---|---|---|
| | | | |
| **Plaintiffs:**<br>Sanofi-aventis and sanofi-aventis U.S. LLC<br>**Defendant:**<br>Wockhardt Ltd. and Wockhardt USA, Inc. | D. Delaware | 08-150 | Currently Unassigned |

**BEFORE THE JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| | |
|---|---|
| **IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION** | **MDL Docket No. 1941** |

**CERTIFICATE OF SERVICE**

In accordance with Rule 5.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, I hereby certify that true and correct copies of the foregoing NOTICE OF RELATED ACTION and accompanying papers were served this 17th day of March, 2008, by depositing such copies with Federal Express, on each of the following parties:

**Judicial Panel on Multidistrict Litigation - Panel Attorney Service List** Page 1

Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation
Status: Pending on / /
Transferee District: Judge: Printed on 02/15/2008

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Cohen, Eric C.<br>KATTEN MUCHIN ROSENMAN<br>525 West Monroe Street<br>Suite 1600<br>Chicago, IL 60661-3693 | =>Phone: (312) 902-5200 Fax: (312) 902-1061 Email: eric.cohen@kattenlaw.com<br>Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries, Ltd. |
| Feldman, Steven E.<br>WELSH & KATZ LTD<br>120 South Riverside Plaza<br>22nd Floor<br>Chicago, IL 60606 | =>Phone: (312) 526-1551 Fax: (312) 655-1501 Email: sefeldman@welshkatz.com<br>Apotex Corp.*; Apotex, Inc.* |
| Flattmann, Jr, Gerald J.<br>KIRKLAND & ELLIS LLP<br>Citicorp Center<br>153 East 53rd Street<br>New York, NY 10022 | =>Phone: (212) 445-4800 Fax: (212) 446-4900 Email: gflattmann@kirkland.com<br>Sanofi Aventis*; Sanofi-Aventis, US, LLC* |
| Kratz, Timothy H.<br>MCGUIREWOODS LLP<br>1170 Peachtree Street, N.E.<br>Suite 2100<br>Atlanta, GA 30309 | =>Phone: (404) 443-5500 Fax: (404) 443-5784 Email: tkratz@mcguirewoods.com<br>Mylan Pharmaceuticals, Inc.* |
| Olson, Darrell L.<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 Main Street<br>14th Floor<br>Irvine, CA 92614 | =>Phone: (949) 760-0404 Fax: (949) 760-9502 Email: dolson@kmob.com<br>Ranbaxy Laboratories, Ltd.; Ranbaxy, Inc. |
| Ongman, John Will<br>AXINN VELTROP & HARKRIDER LLP<br>1330 Connecticut Avenue, NW<br>Washington, DC 20036 | =>Phone: (202) 912-4700 Fax: (202) 912-4701 Email: jwo@avhlaw.com<br>Actavis South Atlantic, LLC*; PAR Pharmaceutical, Inc.* |
| Parr, Keith D.<br>LOCKE LORD BISSELL & LIDDELL LLP<br>111 South Wacker Drive<br>Chicago, IL 60606-4410 | =>Phone: (312) 443-0497 Fax: (312) 896-6497 Email: kparr@lockelord.com<br>Torrent Pharma, Inc.*; Torrent Pharmaceuticals, Ltd.* |
| Poulaos, Ivan M.<br>WINSTON & STRAWN LLP<br>35 West Wacker Drive<br>Chicago, IL 60601 | =>Phone: (312) 558-5600 Fax: (312) 558-5700 Email: ipoulaos@winston.com<br>Barr Laboratories, Inc.* |
| Schuman, Mark D.<br>CARLSON CASPERS VANDENBURGH & LINDQUIST<br>225 South Sixth Street<br>Suite 3200<br>Minneapolis, MN 55402 | =>Phone: (612) 436-9600 Fax: (612) 436-9605 Email: mschuman@ccvl.com<br>Teva Pharmaceuticals USA, Inc.* |

Note: Please refer to the report title page for complete report scope and key.

| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Siwik, Christine J.<br>RAKOCZY MOLINO MAZZOCHI SIWIK LLP<br>6 West Hubbard Street<br>Suite 500<br>Chicago, IL 60610 | =>Phone: (312) 222-6304 Fax: (312) 222-6324<br>Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc. |

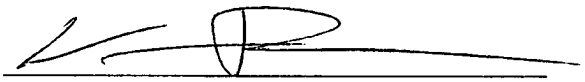
| ATTORNEY - FIRM | REPRESENTED PARTY(S) |
|---|---|
| Brij Khera, Ph.D.<br>Wockhardt Limited<br>135 Route 202-206<br>Bedminster, NJ 07921 | **Phone: (908) 719-1281 Fax: (908) 719-1282 Email: bkhera@wockhardtin.com**<br>Wockhardt Limited; Wockhardt USA, Inc. |

I further certify that I caused true and correct copies of the foregoing documents to be filed with the Clerk of the United States District Court for the District of Delaware, on this 17th day of March, 2008, by depositing such copies with Federal Express.

I further certify that I caused true and correct copies of the foregoing documents to be filed with the Clerk of the United States District Court for the Southern District of Florida on this 17th day of March, 2008, by depositing such copies with Federal Express.

Dated: March 17, 2008

Respectfully submitted,



John M. Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

*Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,<br>Plaintiffs,<br><br>v.<br><br>WOCKHARDT LIMITED and WOCKHARDT USA, INC.,<br>Defendants. | C.A. No. _____ |

**COMPLAINT**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Wockhardt Limited and Wockhardt USA, Inc., hereby allege as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Wockhardt USA, Inc. is a Delaware Corporation, and a wholly-owned subsidiary and agent of Wockhardt Limited, having a principal place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

4. Upon information and belief, Defendant Wockhardt Limited is an Indian Corporation having a place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra

(East), Mumbai - 400 051. Upon information and belief, Defendant Wockhardt Limited manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Wockhardt USA, Inc.

**Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 6,149,940 ("the '940 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Wockhardt USA, Inc. by virtue of the fact that, *inter alia,* Wockhardt USA, Inc. is a Delaware Corporation.

9. This Court has personal jurisdiction over Defendant Wockhardt Limited by virtue of, *inter alia*, (1) its presence in Delaware through its subsidiary and agent Wockhardt USA, Inc.; and (2) its systematic and continuous contact with Delaware, including through its subsidiary and agent Wockhardt USA, Inc.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**The '940 Patent**

11. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

**Acts Giving Rise to this Action**
**Infringement of the '940 Patent by Defendants**

12. Upon information and belief, Wockhardt Limited, through its subsidiary and agent Wockhardt USA, Inc., submitted Abbreviated New Drug Application ("ANDA") 90-221 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 90-221 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

13. Wockhardt Limited alleged in ANDA 90-221 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of

sanofi-aventis's Uroxatral® brand product. Plaintiffs received written notification of ANDA 90-221 on or about February 20, 2008.

14. Wockhardt Limited's submission of ANDA 90-221 to the FDA, through Wockhardt USA, Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt Limited's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

15. Wockhardt USA, Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Wockhardt USA, Inc. participated in, contributed to, aided, abetted and/or induced Wockhardt Limited's submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Wockhardt USA, Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Wockhardt USA, Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis's Uroxatral® brand product would infringe the '940 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Wockhardt Limited and Wockhardt USA, Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 90-221 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

18. Plaintiffs will be irreparably harmed by Wockhardt Limited's and Wockhardt USA, Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Prayer for Relief**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '940 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Wockhardt Limited's ANDA identified in this Complaint shall not be earlier than the expiration date of the '940 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis's Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com
*Attorneys for Plaintiffs*
*sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022
(212) 446-4800

March 14, 2008

JS 44 (Rev. 11/04)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**
sanofi-aventis and
sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

**DEFENDANTS**
Wockhardt Limited and
Wockhardt USA, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**CIVIL RIGHTS**
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

**FORFEITURE/PENALTY**
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

**V. ORIGIN** (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
35 U.S.C. § 271
Brief description of cause: patent infringement

**VII. REQUESTED IN COMPLAINT:** ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☐ Yes ☒ No

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE Sleet DOCKET NUMBER 07-572, 07-574 and 07-792

DATE March 14, 2008 SIGNATURE OF ATTORNEY OF RECORD Jack B. Blumenfeld

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 11/04)

# INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

**III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V. Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

**VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

PATENT

**U.S. District Court**
**District of Delaware (Wilmington)**
**CIVIL DOCKET FOR CASE #: 1:08-cv-00150-UNA**

Sanofi-Aventis et al v. Wockhardt Limited et al
Assigned to: Unassigned Judge
Related Cases: 1:07-cv-00572-GMS-MPT
1:07-cv-00574-GMS-MPT
1:07-cv-00792-GMS-MPT
Cause: 35:271 Patent Infringement

Date Filed: 03/14/2008
Jury Demand: None
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Sanofi-Aventis**

represented by **Jack B. Blumenfeld**
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: jbbefiling@mnat.com
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**Sanofi-Aventis US LLC**

represented by **Jack B. Blumenfeld**
(See above for address)
*LEAD ATTORNEY*
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Wockhardt Limited**

**Defendant**

**Wockhardt USA Inc.**

| Date Filed | # | Docket Text |
|---|---|---|
| 03/14/2008 | 1 | COMPLAINT filed against Wockhardt Limited, Wockhardt USA Inc. - ( Filing fee $ 350, receipt number 3110000000000423830.) - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibit A, # 2 Civil Cover Sheet)(els) (Entered: 03/14/2008) |
| 03/14/2008 | 2 | Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (els) (Entered: 03/14/2008) |
| 03/14/2008 | | Summons Issued as to Wockhardt Limited on 3/14/2008; Wockhardt USA Inc. on 3/14/2008. (els) (Entered: 03/14/2008) |

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| 03/14/2008 | 3 | Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis US LLC identifying Corporate Parent Sanofi-Aventis for Sanofi-Aventis US LLC. (els) (Entered: 03/14/2008) |
| 03/14/2008 | 4 | Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number (s) 6,149,940; (els) (Entered: 03/14/2008) |

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO COMPEL DISCOVERY RESPONSES AND INCORPORATED MEMORANDUM OF LAW**

The Apotex Defendants move pursuant to Fed. R. Civ. P. 37 and Local Rule 26.1 (H) for an order compelling Sanofi to produce documents responsive to Defendants' First Requests for Production and Things to Plaintiff. Sanofi, the plaintiff, has refused to provide any substantive discovery responses to move this case forward to prepare for trial. As the Magistrate Judge recognized, "Sanofi was scheduled to being producing documents on February 18, 2008, and the discovery deadlines and trial dates are **rapidly approaching**." (Dkt. 51 at 4.) To date Sanofi has failed to produce one scrap of paper or one byte of data. Having failed in its explicit request to put off the trial, Sanofi is now trying to put off the trial date unilaterally by refusing to participate in discovery.

Sanofi's main argument for denying Apotex discovery is that it would prefer to wait until its pending motions to stay or transfer this case to Delaware (including its pending 28 U.S.C. §1407 motion before the Judicial Panel on Multidistrict Litigation) are resolved. Thus, Sanofi objects that any discovery in this case is "premature" and "untimely." Sanofi's timeliness objections fly in the face of the Court's January 23, 2008 scheduling order (Dkt. 23), which requires the parties to be proceeding with discovery towards a discovery cut-off date of August, 2008. Sanofi's objections also are contrary to law.

Nothing in the Federal Rules of Civil Procedure permit a plaintiff to refuse to produce documents until it decides it is ready for the case to go forward. Regarding the sequence and timing of discovery, the rules say to proceed apace once the parties have conferred as required by Rule 26(f), which the parties did long ago. FED. R. CIV. PROC. 26(d)(1). The rules also specifically decry "unnecessary delay" as an "improper purpose" and a violation of the signature requirement in discovery. FED. R. CIV. PROC. 26(g)(1)(B)(i). One of the overriding purposes of the Federal Rules is to secure the "speedy . . . determination of every action and proceeding." FED. R. CIV. PROC. 1. The rules so go.

Nothing in the rules of the Judicial Panel on Multidistrict Litigation ("MDL") says that a party seeking to escape from the venue where it filed suit should refuse to participate in discovery until the MDL panel rules. To the contrary, the MDL rules tell the parties to proceed. *See* JPML Rule 1.5 ("The pendency of a motion, order to show cause, conditional transfer order or conditional remand order before the Panel concerning transfer or remand of an action pursuant to 28 U.S.C. §1407 **does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending** and does not in any way limit the pretrial jurisdiction of that court.") (emphasis added).

Nothing in the statutory scheme governing patent litigation over generic pharmaceutical products suggests that the patentee/brand manufacturer can refuse to participate in discovery in the lawsuit it filed in the forum it selected. To the contrary, the act requires the parties to cooperate in expediting the action. 21U.S.C.§355(j)(5)(B)(iii) (parties required to "reasonably cooperate in expediting the action."); *see also In re Barr Labs., Inc.,* 930 F.2d 72, 76 (D.C. Cir. 1991) (noting Congress enacted the Hatch-Waxman Act to "get generic drugs into the hands of patients at reasonable prices – fast").

Sanofi also objected to producing documents because no protective order governing discovery had been entered in the case to protect confidential documents. This objection is now moot in light of the fact that the Magistrate Judge entered a Protective Order in the case on March 21 (Dkt. 76).

Trial in this case is set for October, 2008. It is both unfair and highly prejudicial to Apotex for Sanofi to opt out of discovery at this stage in the proceedings. Apotex is diligently trying to get its case ready for trial and needs discovery now to meet the Court's deadlines.

**SANOFI'S OBJECTIONS ARE DILATORY AND LACK MERIT**

Since early January, Apotex has requested Sanofi to produce copies of core documents with obvious relevance to this litigation such as Sanofi's New Drug Applications, lab notebooks, research notes, data and memoranda underlying the development of the drug product and method that are the subjects of Sanofi's patents in suit. Sanofi has steadfastly refused to produce anything.

Apotex served Sanofi with formal document requests on January 18, 2008. On February 19, 2008. Rather than producing documents, Sanofi responded to Apotex's document requests with 51 pages of objections. *See Plaintiffs' Responses and Objections to Defendants' First Request for Production of Documents and Things to Plaintiff* attached hereto as Exhibit A.

**LOCAL RULE 26.2 STATEMENT OF ITEMS SOUGHT**

For most of the request, Sanofi repeats most of the following boilerplate objection:

> Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

(Plaintiffs' Responses And Objections To Defendants' First Request For Production Of Documents And Things To Plaintiff, *passim*.) For each repetition of this same, stale objection, Apotex's gives as its reasons assigned as supporting the motion the following points, more fully explained above:

- The request is not premature, for the reasons stated *supra*.

- By claiming all right, title, and interest to enforce the patents-in-suit, Sanofi is estopped to deny authority to produce relevant material in the possession of its co-patentee Jagotec AG.
- The possible inclusion of third-party, confidential information is not a proper objection or grounds for refusing to provide discovery, but instead a basis for entering the protective order required by Apotex.

Other reasons assigned as supporting the motion as it relates to each specific item requested are as follows:

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| **Request** | **"1. All documents concerning any proposal, consideration or decision by Plaintiff to draft and/or file the patents at issue."** |
| Objections | "Sanofi-aventis "also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'proposal' and 'consideration.'" |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents recounting the genesis of the asserted patents are highly relevant in this patent infringement suit.<br>• The terms "proposal" and "consideration" have their ordinary and customary meaning, and are not so imprecise as to permit no answer. |
| **Request** | **"2. All documents reviewed and/or relied on by Plaintiff in making the determination to seek patent protection for the subject matter of the patents at issue."** |
| Objections | Sanofi recites only its boilerplate objection. |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents recounting the genesis of the asserted patents are highly relevant in this patent infringement suit. |
| **Request** | **"3. All documents which are relevant to establishing a date of invention by Plaintiff, or any person associated with Plaintiff, earlier than the filing date for each of the patents at issue."** |
| Objections | Sanofi recites only its boilerplate objection. |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The date of invention is highly relevant and can be critically important for identifying available prior art under 35 U.S.C. § 102(a). |
| **Request** | **"4. All documents and communications that refer or relate to the preparation and/or prosecution of the patents at issue and/or any U.S. applications or foreign applications that constitute or are based in whole or in part on, or which claim priority from, or are the basis of priority for, any of the applications in the family of patent applications leading to the patents at issue and any related oppositions, re-examinations, and/or reissue proceedings including, without limitation:**<br>**"a. all documents that provided the bases for any of said applications or proceedings;**<br>**"b. all files in Plaintiff s possession, custody or control regarding the patents at issue, the patent applications for the patents at issue, or any related U.S. or foreign patents or applications;**<br>**"c. all disclosures of the subject matter of any of said applications or proceedings;**<br>**"d. all communications between the alleged inventor and his patent attorney(s) or agent(s) concerning the subject matter described or claimed in any of said applications or proceedings;**<br>**"e. all documents referring or relating to any information used or supplied by the alleged inventor in connection with the preparation or prosecution of any of said applications or proceedings including invention disclosure prepared by or for the inventor;**<br>**"f. all drafts of any said applications or proceedings;** |

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| | **"g. all patents, publications, references or prior art, and all records or documents referring or relating to any prior art or possible prior art, and all records or documents referring or relating to any prior art or any possible ground of unpatentability and/or invalidity, submitted, cited, discussed or considered in connection with any of said applications or proceedings;**<br>**"h. all documents referring or relating to the citation of, decision not to cite, or failure to cite, any references and/or prior art to the PTO or other patent office or patent authority in connection with said applications or proceedings; and**<br>**"i. all copies (including drafts) of responses to Office Actions, amendments, affidavits, declarations and other communications or submissions of any kind with or to the PTO or other patent office, or patent authority with respect to any of said applications or proceedings."** |
| Objections | "Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts, as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'possible prior art.'" |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • This requests generally concerns papers relating to the prosecution of the patents in suit. It is reasonably calculated to lead to the discovery of admissible evidence concerning, inter alia, infringement and validity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit.<br>• Documents relating to foreign counterparts claiming related subject matter are likely to disclose prior art relevant to the patents in suit and are reasonably calculated to lead to the discovery of admissible evidence.<br>• The term in the phrase "possible prior art" have their ordinary and customary meaning, and are not so imprecise as to permit no answer. |
| **Request** | **"5. All documents and communications concerning any search, investigation, analysis, review, opinion or study relating to the scope, novelty, nonobviousness, patentability, validity, enforceability, value and/or infringement of any claim of the patents at issue, including without limitation:**<br>**"a. all documents and communications, samples, prototypes and the like that refer or relate to the first public disclosure, first public use, first advertisement, first offer for sale, and/or the first sale of the alleged invention of the patents at issue in any country, including but not limited to, disclosures, advertisements, offers for sale, and sales of products prior to the priority date, filing date and/or bar date of the patents at issue and concerning use of the subject matter claimed in the patents at issue on or before the respective filing dates(s) whether or not you contend such use was not public or was experimental;**<br>**"b. all documents and communications concerning the scope and content of the prior art for the patents at issue and any foreign counterparts and all documents identified, found, described, or considered with regard to this prior art, regardless of whether such documents are considered prior art with regard to the patents at issue;**<br>**"c. all documents and communications referring or relating to the scope of the 'art' and/or the level of skill in the 'art,' as the term 'art' is used in 35 U.S.C. § 103, of the subject** |

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| | **matters described and claimed in the patents at issue, including all documents concerning the levels of education and experience of persons working in the field, the types of problems encountered in the art, the activities of others, prior art solutions to the problems encountered by the inventor, and the sophistication of the technology at issue;**<br>**"d. all documents and communications that refer or relate to seminars, speeches, presentations, lectures, or talks (including without limitation, texts, drafts and notes thereof) given by any person employed or retained by, or otherwise affiliated with, or under authority or grant from Sanofi (or any predecessor in interest with regard to the patents at issue) concerning alfuzosin formulations or methods of treatment using alfuzosin formulations;**<br>**"e. all documents and communications that refer or relate to any papers, articles, or other publications by any person employed or retained by, or otherwise affiliated with, or under the authority or grant by Sanofi, regarding alfuzosin or methods of treatment using alfuzosin formulations, including without limitation all drafts of any such materials and any memoranda or correspondence between co-authors or others concerning either the work reflected in the materials or the publications themselves;**<br>**"f. all opinions of counsel concerning the validity, enforceability or infringement of the patents at issue or any foreign counterparts;**<br>**"g. all documents and communications that (i) concern, (ii) support or tend to establish and/or otherwise support or (iii) refute or tend to refute any allegation that Apotex or any other person infringed the patents at issue or any foreign counterparts; and**<br>**"h. all documents and communications that refer or relate to any oral or written statement made by Sanofi, or any other person or entity, that Sanofi, or any other person, was, is or might be infringing the patents at issue, or that any product made, used or sold by or for Sanofi, or any other person, was is, or might be infringing the patents at issue."** |
| Objections | "Sanofi-aventis also objects to this request, and in particular to the over-breadth of subsection 'd', as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'and the like.' Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to its request for 'prior art ... regardless of whether such documents are considered prior art with regard to the patents at issue.' Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts or documents related to the first public disclosure, first public use, first advertisement, first offer for sale and/or the first sale "in any country", as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • This request covers prior art, which is highly relevant to the issue of validity.<br>• Public statements regarding the patented subject matter (subpart d) is reasonably calculated to lead to the discovery of admissible evidence on issues in suit including but not limited to prior art and level of ordinary skill in the art.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit. |

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| | • The terms and phrases including "and the like" and ""prior art ... regardless of whether such documents are considered prior art with regard to the patents at issue" have their ordinary and customary meaning, and are not so imprecise as to permit no answer.<br>• Documents concerning foreign counterparts or documents related to the first public disclosure, first public use, first advertisement, first offer for sale and/or the first sale "in any country" are reasonably calculated to lead to the discovery of admissible evidence. Some such documents may themselves disclose prior art, and others may reasonably be expected to suggest lines of inquiry to identify admissible prior art in this country where applicable.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"6. All documents and communications concerning secondary factors or objective indicia of non-obviousness with regard to the patents at issue, including without limitation:**<br>**"a. all documents and communications concerning any commercial success of products covered by the patents at issue and any asserted nexus with the claimed invention;**<br>**"b. all documents and communications concerning any long-felt need in the art that was satisfied by the invention claimed in the patents at issue;**<br>**"c. all documents and communications concerning whether or not others had tried, but failed to solve the problem solved by the invention claimed in the patents at issue;**<br>**"d. all documents and communications concerning simultaneous or near simultaneous invention by others;**<br>**"e. all documents and communications concerning whether others have copied the invention claimed in the patents at issue;**<br>**"f. all documents and communications concerning any alleged superior, surprising or unexpected results achieved by the invention claimed in the patents at issue; and**<br>**"g. all documents and communications concerning whether others have accepted licenses under patents in suit."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requests all concern so called "secondary factors" that the Court may consider in assessing obviousness under 35 U.S.C. § 103 under the leading case *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966) and its progeny.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit. |
| **Request** | **"7. All documents and memos concerning or referring to any term extension of the patents at issue."** |
| Objections | "Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The availability of any term extension is relevant to determine the scope of any remedy available.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit. |
| **Request** | **"8. All documents and communications concerning the alleged conception, reduction to practice and development of the alleged invention or inventions claimed by the patents at issue, including without limitation:** |

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| | **"a. all documents concerning any research, development, testing (both animal and human), and/or refinement of the subject matter of the patents at issue;**<br>**"b. all documents referring or relating to any research, development, testing (both animal and human) and/or refinement of any commercial embodiments of the subject matter of the patents at issue;**<br>**"c. all documents referring or relating to the conception and/or reduction to practice of the alleged invention of the patents at issue;**<br>**"d. all documents referring or relating to any Sanofi product that is believed to be covered literally, or under the doctrine of equivalents, by any claim of the patents at issue; and**<br>**"e. all documents concerning, created by, or created under the direction of the inventor named on the face of the patents at issue concerning alfuzosin or method of treatment using alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested, including but not limited to all documents and things concerning the testing of Uroxatral®. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'refinement.' Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Conception and reduction to practice are terms of art in patent law which define the date of invention, if the patentee claims a date of invention earlier than the filing date of the application, and hence are highly relevant and reasonably calculated to lead to the discovery of admissible evidence.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• The term "refinement" has its ordinary and customary meaning, and is not so imprecise as to permit no answer. |
| **Request** | **"9. All documents and communications that refer or relate to any contemplated, proposed or actual license, or offers for or inquiries regarding license, of any patents, trade secrets or proprietary technology relating to Sanofi' s UROXATRAL® products, including without limitation:**<br>**"a. all documents and communications concerning any request, offer, acquisition or denial of any right (including any forbearance to assert a right), license, agreement, immunity, release, option, title or interest in, to or under the patents at issue, including all documents concerning why an agreement was not consummated (if not consummated), whether any agreement has been terminated, and any documents relating to the transfer and/or assignment of the patents at issue; and**<br>**"b. all documents that refer or relate to any licensing policy(ies) of Sanofi and its predecessors-in-interest with regard to the patents at issue and products believed to be covered by the patents at issue."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested." |

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| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The patentee's licensing practice, although not providing a categorical basis for denying injunctive relief, may be relevant to the scope of the remedy available and the question of whether the patentee, even if it prevails, is entitled to a permanent injunction under the standards explained in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), and may also be relevant to questions of ownershipl<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only some documents instead of all documents, and its objection on that grounds is without merit. |
| **Request** | **"10. All document and communications or opinions concerning the value, strategic or pecuniary, of the patents at issue and commercial embodiments of the alleged invention of the patents at issue, including annual marketing reports, actual and estimated sales figures and the like."** |
| Objections | "Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'strategic,' 'pecuniary' and 'and the like.' Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested information may be relevant as secondary factors on the question of obviousness and may be relevant to the availability of a permanent injunction or other remedy.<br>• Have their ordinary and customary meaning, and are not so imprecise as to permit no answer terms "strategic," "pecuniary" and "and the like."<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"11. All documents that compare any element, aspect or attribute of pharmaceutical tablets containing alfuzosin with any element, aspect or attribute of any other product sold anywhere in the world."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'element,' 'aspect,' and 'attribute.' Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • This request is reasonably calculated to lead to the discovery of admissible evidence concerning possible prior art, for comparative products in existence before the invention of the subject matter claimed, and for claim construction, among other things.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The terms "element," "aspect," and "attribute" have their ordinary and customary meaning, and are not so imprecise as to permit no answer.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or |

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| | preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"12. All documents concerning requests or desires to develop a pharmaceutical tablet containing alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'requests' and 'desires.'. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Motivation to develop the subject matter claimed is relevant to the issue of non-obviousness.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The terms "requests" and "desires" have their ordinary and customary meaning, and are not so imprecise as to permit no answer.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"13. All documents concerning requests or desires to develop a method of treatment for dysuria using alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'requests' and 'desires'." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Same as 12 |
| **Request** | **"14. All documents and communications concerning Sanofi's corporate structure and organizational policies, including without limitation:**<br>**"a. organizational charts that identify all persons involved in research, development, manufacturing, processing, marketing, sales or promotion of UROXATRAL® manufactured, marketed or sold by Sanofi;**<br>**"b. all documents that constitute, refer or relate to any document retention policy program of Sanofi;**<br>**"c. a copy of each of Sanofi's annual reports from its inception to the present; and**<br>**"d. all documents and communications concerning development, manufacture, marketing, research and planning concerned with the subject matter of the patents at issue."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. . . . Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it does not restrict the date range for the documents or things concerning the categories requested. Sanofi-aventis objects to this |

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| | request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'processing.' Sanofi-aventis also objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacture, production, or distribution of Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The documents requested are reasonably calculated to lead to the discovery of admissible evidence by, for example, providing context necessary to understand other documents and evidence produced, to evaluate the scope of any admissions identified, and also documents directly relevant the development of the patented pharmaceutical in issue.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The term "processing" has its ordinary and customary meaning, and is not so imprecise as to permit no answer.<br>• If Sanofi chooses to identify particular documents as publicly available or outside the time period it considers relevant Apotex would consider whether to narrow its request or obtain documents from public sources, but the objections as stated to do not excuse response.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"15. All documents relating or referring to Sanofi's contemplation or, decision to bring and maintain, a patent infringement lawsuit against Apotex, including without limitation:**<br>**"a. all documents constituting or relating to communications with actual or potential purchasers of UROXATRAL® , or any third party other than an actual or potential purchaser of UROXATRAL® relating in anyway to (i) Apotex, (ii) the patents at issue, or (iii) this lawsuit;**<br>**"b. all meeting minutes of Sanofi's Board of Directors or any committee of such Board of Directors, and all studies and reports submitted thereto that refer or relate to the Board's authorization to commence litigation charging infringement of the patents at issue, or its consideration of any claims or defenses relating to such litigation;**<br>**"c. all documents reflecting Sanofi's knowledge of or belief in, the invalidity and/or enforceability of the patents at issue at the time this action was commenced or at any time thereafter; and**<br>**"d. all documents reflecting knowledge by Sanofi and/or any attorney employed or retained by Sanofi who was involved in prosecuting the applications that ultimately led to the patents at issue or any document or pre-filing activity that constituted or could constitute prior art."** |
| Objections | Sanofi recites only its boilerplate. |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern questions of infringement, validity, ownership, and other issues in suit, and are reasonably calculated to lead to the discovery of admissible evidence. |
| **Request** | **"16. All documents, communications, and submissions made by Sanofi or its predecessors-in-interest with regard to the FDA as part of its INDA, NDA and those portions of the supporting Drug Master File for UROXATRAL® products, including but without limitation:**<br>**"a. all documents and submissions which contain the product specifications and processing information for the manufacture of UROXATRAL®, including documents reflecting all starting materials and intermediates, test protocols and certificates of analysis;**<br>**"b. all documents and submissions which describe the composition, function and use of UROXATRAL®;**<br>**"c. all documents and submissions which relate to all treatment indications and/or use of UROXATRAL®, including proposed labeling, proposed package inserts and all other information relating or referring to any proposed or actual clinical use of** |

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| | **UROXATRAL®;**<br>**"d. all documents and submissions relating to the composition, formulation, chemistry, functionality or excipients, or other inactive or active ingredients testing and manufacture of UROXATRAL®; and**<br>**"e. all documents, records, descriptions, agreements, results and product samples relating to the clinical testing of UROXATRAL® or earlier versions and formulations of alfuzosin products including all documents and product samples concerning or used in clinical trials resulting in side-effects descried in the package insert."** |
| Objections | "Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings."<br>*It further indicates that it will produce only **excerpts** of responsive documents, instead of the entire documents.* |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern patentee's embodiment of its product and are reasonably calculated to lead to the discovery of admissible evidence on issues including claim construction, infringement, and invalidity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• A litigant cannot shield a document from discovery in U.S. litigation by filing it with a foreign regulatory authority. If that authority imposes conditions of confidentiality then those concerns can be adequately addressed by a suitable protective order such as the one Apotex has proposed in this litigation.<br>• Sanofi is not entitled to pick and choose which excerpts from responsive, discoverable documents it will produce, and any confidentiality concerns are adequately addressed by entry of a suitable protective order such as the form proposed by Apotex. |
| **Request** | **"17. NDA 21-287 and all documents and communications concerning NDA 21-287 including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA, and all amendments to such NDA."** |
| Objections | "Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings."<br>*It further indicates that it will produce only **excerpts** of responsive documents, instead of the documents themselves.* |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern patentee's embodiment of its product and are reasonably calculated to lead to the discovery of admissible evidence on issues including claim construction, infringement, and invalidity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• A litigant cannot shield a document from discovery in U.S. litigation by filing it with a foreign regulatory authority. If that authority imposes conditions of confidentiality then those concerns can be adequately addressed by a suitable protective order such as the one Apotex has proposed in this litigation.<br>• Sanofi is not entitled to pick and choose which excerpts from responsive, discoverable documents it will produce, and any confidentiality concerns are adequately addressed by entry of a suitable protective order such as the form proposed by Apotex. |
| **Request** | **"18. All NDAs for any other dosage form or drug product containing alfuzosin submitted to the FDA and all documents and communications concerning such NDAs, including but not limited to all communications and correspondence with the FDA concerning such NDA, all** |

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| | **clinical testing, protocols and results contained in or referred to in such NDA and all amendments to such NDA."** |
| Objections | "Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by NDA 21-287 and/or ANDA 79-013. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings."<br>Sanofi further does not identify **any** documents it will produce in response to this request. |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern patentee's embodiment of its product and are reasonably calculated to lead to the discovery of admissible evidence on issues including claim construction, infringement, and invalidity.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxtral® or NDA 21-287 or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• A litigant cannot shield a document from discovery in U.S. litigation by filing it with a foreign regulatory authority. If that authority imposes conditions of confidentiality then those concerns can be adequately addressed by a suitable protective order such as the one Apotex has proposed in this litigation. |
| **Request** | **"19. All documents comprising Plaintiffs Investigation New Drug application ('INDA') for UROXATRAL® or any other products containing alfuzosin and all documents and/or communications concerning or referring to that INDA, including but not limited to all clinical testing, protocols and results contained in or referred to in such INDA and all amendments to such INDA."** |
| Objections | "Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by INDA 51,200. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings."<br>*It further indicates that it will produce only **excerpts** of responsive documents, instead of the documents themselves.* |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern patentee's embodiment of its product and are reasonably calculated to lead to the discovery of admissible evidence on issues including claim construction, infringement, and invalidity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxatral® or INDA 51,200 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• A litigant cannot shield a document from discovery in U.S. litigation by filing it with a foreign regulatory authority. If that authority imposes conditions of confidentiality then those concerns can be adequately addressed by a suitable protective order such as the one Apotex has proposed in this litigation. |
| **Request** | **"20. All documents concerning a transfer of any rights or interest in commercial** |

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| | **embodiments of the patents at issue from that patents' respective date of conception to the present."** |
| Objections | "Sanofi-aventis further objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested documents concern patentee's embodiment of its product and are reasonably calculated to lead to the discovery of admissible evidence on issues including claim construction, ownership, infringement, and invalidity.<br>• The scope of the patent in suit is not necessarily limited to the patentee's commercial or preferred embodiment, and even documents unrelated to Uroxatral® or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"21. All documents and communications evidencing the educational background and qualifications for each or the named inventors of the patents at issue including but not limited to curriculum vitaes, resumes, publications, accreditations, honors, awards and/or certificates of recognition."** |
| Objections | "All documents and communications evidencing the educational background and qualifications for each or the named inventors of the patents at issue including but not limited to curriculum vitaes, resumes, publications, accreditations, honors, awards and/or certificates of recognition. . . . Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The requested information is reasonably calculated to lead to the discovery of admissible evidence concerning level of ordinary skill in the art, which is relevant to issues including claim construction and obviousness.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• To the extent plaintiff would identify publicly available sources for responsive documents in its possession custody or control Apotex could consider whether collecting such allegedly publicly available information was reasonable, but to the extent the material requested is already in the possession, custody or control of patentee its production is likely to be less burdensome than identification in publicly available sources. |
| **Request** | **"22. All documents that relate to the research, development and manufacture of pharmaceutical tablets containing alfuzosin, including without limitation;**<br>**"a. all documents constituting or relating to 'any contemplated, proposed or implemented studies, measurements, evaluations, analyses, testing or other compilations of data;**<br>**"b. all laboratory notebooks, memoranda, summaries, progress and research reports, meeting minutes, comparative tests or studies;**<br>**"c. all documents relating or referring to each actual or proposed change in formulation, composition or process of manufacture of alfuzosin pharmaceutical tablets, from initial stages of development to the present;"**<br>**"d. all documents relating or referring to each process or method for making pharmaceutical tablets containing alfuzosin, that has been considered, tested, used, or proposed for use by Plaintiff, including but not limited to the process or method by which Plaintiff, or any person or entity acting under Plaintiffs direction or with Plaintiff s authority manufacture pharmaceutical tablets."** |
| Objections | "Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of |

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| | documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis also objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacturing process, or production of Uroxatral® or a treatment for dysuria." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Research and development documents related to the products covered by the patents in suit reasonably calculated to lead to the discovery of issues including infringement, invalidity and claim construction.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"23. All documents and communications concerning the research and/or development of any medicines containing alfuzosin in pharmaceutical tablets, including but not limited to laboratory notebooks, invention records, research results, studies, tests, memoranda, project status reports, forecasts and projections."** |
| Objections | "Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "medicines." Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents related to research and development of medicines containing alfuzosin in pharmaceutical tablets is relevant to the validity of the patents at issue.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• The term "medicines" has its ordinary and customary meaning, and is not so imprecise as to permit no answer. |
| **Request** | **"24. All documents in Plaintiff s possession, custody or control which discuss pharmaceutical tablets containing alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents relating to pharmaceutical tablets containing alfuzosin are relevant to the validity of the patents at issue.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit. |

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| | • The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to produce documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit. |
| **Request** | **"25. All documents in Plaintiffs possession, custody or control which discuss a method for treatment of dysuria using alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents related to treatment of dysuria using alfuzosin are relevant to validity of the patents at issue.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to produce documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit. |
| **Request** | **"26. All documents or communications concerning, discussing or expressing any complaints, concerns or dissatisfaction with any aspect, element or feature of any products or formulations containing alfuzosin."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms 'complaints,' 'concerns,' 'dissatisfaction.'. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • This request relates to the products covered by the patents in suit and the predecessors to the product and to issues including non-obviousness.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the |

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| | documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit.<br>• The terms "complaints," " concerns," and "dissatisfaction" has their ordinary and customary meaning, and are not so imprecise as to permit no answer. |
| **Request** | **"27. All communications by and between Jagotec AG and Sanofi relating to pharmaceutical tablets containing alfuzosin including but not limited to documents relating to the '940 patent."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents relating to communications between Sanofi and Jagotec AG are related to the ownership of the patents at issue.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"28. All documents and communications by and between Synthelabo, SanofiSynthelabo, Jagotec AG, Jagotec AB, and Sanofi-Aventis, including but not limited to all assignments and any other documents referring to the assignments or to which the assignments refer."** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents related to assignments of rights are relevant to the ownership of the patents at issue.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"29. All documents that refer or relate to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled release of alfuzosin or a** |

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| | **salt thereof."** |
| Objections | "Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• Documents related to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled release of alfuzosin or a salt thereof is relevant to claim construction and validity of the patent at issue.<br>• The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"30. All documents referring or relating to a method for treating humans or nonhuman animals for dysuria comprising administering an effective dysuria controlling non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human, including the development and efficacy of such method**." |
| Objections | "Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Documents relating to a method for treating humans or nonhuman animals for dysuria are relevant to the claim construction of the patent at issue and the issue of validity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to produce documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit. |
| **Request** | **"31. Please provide all documents concerning, analyzing, evaluating or referring to any and all of the following documents:**<br>**"a. Cavero et aI., *Br. J. Pharmacol.,* Vol. 81, *Aljuzosin (SL* 77,499), *A new Antihypertensive Agent with A Peripheral Site ofAction: II. In Vitro Pharmacological Studies;***<br>**"b. Cavero et al., *Fed. Proc.,* Vol. 43, No.3, *Alfuzosin, Antihypertensive Agent With a-Adrenoceptor Antagonist Properties,* abstract 2627 (1984);**<br>**"c. Hedlund et al., *The Journal of Urology,* Vol. 133, *Effects ofPrazosin in Patients With Benign Prostatic Obstruction,* Pgs 275-78 (1983);**<br>**"d. Ronchi et al., *Urological Research,* Vol. 10, No.3, *Symptomatic Treatment of Benign Prostatic Obstruction with Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation,* pgs. 131-34 (1982);**<br>**"e. Whitefield et al., *Br. J. Pharmacol,* Vol. 47, *the Effect ofAdrenergic Blocking Drugs on Outflow Resistance,* Pgs. 823-27 (1976)"** |
| Objections | "Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks 'all' |

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| | documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'evaluating'." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The documents identified in Request No. 31 are prior art and any documents Sanofi has analyzing, evaluating or referring to the prior art are relevant to the question of validity.<br>• The patentee gives no reason it should be allowed to produce fewer than all of the documents in the stated categories, nor why it should be permitted to pick and choose only **some** documents instead of **all** documents, and its objection on that grounds is without merit.<br>• Apotex continues its own search for publicly available documents, but whether Sanofi chooses to produce documents as kept in the ordinary course of business or organized by category of request, the relation of particular pieces of possible prior art to the patent in suit is reasonably calculated to lead to the discovery of admissible evidence on the issues in suit.<br>• The term "evaluating" has its ordinary and customary meaning, and is not so imprecise as to permit no answer. |
| **Request** | **"32. All documents produced or to be produced by Sanofi to opposing parties in any and all earlier filed or pending litigations relating to the patents at issue, including but not limited to documents produced by Sanofi in connection with the following cases: *Sanofi-Aventis et al v. Actavis South Atlantic LLC, et al* (Case No.1 :07-cv-00572); and *Sanofi-Aventis et al v. Barr Laboratories Inc.* (l:07-cv-00574)."** |
| Objections | "Sanofi-aventis also objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013." |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • The scope of the patent in suit is not necessarily limited to the patentees commercial or preferred embodiment, and even documents unrelated to Uroxtral® or dysuria or ANDA 79-013 are reasonably likely to lead to the discovery of admissible evidence regarding the validity of the patent in suit. |
| **Request** | **"33. All documents that have been disclosed or provided to any individual by, any scientist and/or consultant retained by Plaintiff in connection with the above-captioned action."** |
| Objections | "Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'scientist.'" |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Pursuant to Federal Rule of Civil Procedure 26(b) Documents disclosed to individuals by Plaintiff in connection with the above-captioned action are discoverable as preparation by a trial expert.<br>• The term "scientist" has its ordinary and customary meaning, and is not so imprecise as to permit no answer. |
| **Request** | **"34. All documents relating to any investigation or test conducted by any scientist and/or consultant retained by Plaintiff in the above-captioned action."** |
| Objections | "Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term 'scientist.'" |
| Grounds | Apotex knows of no grounds assigned but not apparent from the objection. |
| Reasons to Support Motion | • Pursuant to Federal Rule of Civil Procedure 26(b) Documents relating to any investigation or test conducted by scientist or consultants retained by Plaintiff in the above-captioned action is discoverable as preparation by a trial expert.<br>• The term "scientist" has its ordinary and customary meaning, and is not so imprecise as to permit no answer. |

## CONCLUSION

For the foregoing reasons, Apotex's Motion to Compel should be granted together with such other relief is just and proper under the circumstances.

Dated: March 24, 2008

/s/ Robert B. Breisblatt
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

March 25, 2008

___/s/ Robert B. Breisblatt_____
*Attorney for Defendants*

# EXHIBIT A

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' RESPONSES AND OBJECTIONS TO DEFENDANTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFF**

Pursuant to Federal Rules of Civil Procedure 26 and 34 and Local Rules 26.1 and 34.1 for the Southern District of Florida, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") make the following objections and responses to Defendants Apotex Inc. and Apotex Corp.'s (collectively "Apotex") First Request For Production Of Documents And Things To Plaintiff.

Pursuant to Federal Rule of Civil Procedure 26(e), sanofi-aventis reserves the right to supplement its responses and objections as discovery and its investigation continues.

**PLAINTIFFS' GENERAL OBJECTIONS TO DEFENDANTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFFS**

Sanofi-aventis makes the following general objections to Defendants' First Request For Production Of Documents And Things To Plaintiff ("General Objections"), which General

Objections are hereby incorporated by reference and made part of its response to each such request:

1. Sanofi-aventis objects to each request to the extent that it seeks to impose requirements or obligations on sanofi-aventis in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

2. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

3. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to alter the plain meaning or scope of any request, on the ground that such alteration renders the request vague, ambiguous and uncertain.

4. Sanofi-aventis objects to Apotex's definition of "Parties" as overly broad to the extent that it purports to include individuals, corporations or entities over which sanofi-aventis has no control or are not otherwise parties to the present action.

5. Sanofi-aventis objects to Apotex's definition of "Communication" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

6. Sanofi-aventis objects to Apotex's definitions of "Concern(s)," "Concerning," "Concerned with," "Relate(s)," and "Relating to" as vague and ambiguous and, to the extent understood, to the extent that they purport to impose obligations or requirements in addition to or

different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

7. Sanofi-aventis objects to Apotex's definition of "Date" as overly broad and unduly burdensome and unlikely to lead to the discovery of admissible evidence, and to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

8. Sanofi-aventis objects to Apotex's definition of "Document" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

9. Sanofi-aventis objects to Apotex's definition of "Person" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

10. Sanofi-aventis objects to Apotex's "rules of construction" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

11. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as overly broad and unduly burdensome to the extent that they seek "All," "Each," or "Any" document or thing requested, and thus purport to impose obligations in addition to, or different from, those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

12. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are

protected by the attorney-client privilege, attorney work-product doctrine, or any other applicable privilege or immunity. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any such applicable privilege or immunity.

13. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not in sanofi-aventis's possession, custody or control.

14. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are in the possession, custody or control of Jagotec AG.

15. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents and things that contain confidential information of third parties.

16. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that the requests are duplicative in nature.

17. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as vague, ambiguous and uncertain to the extent that they seek information, documents or things that are not described with reasonable particularity.

18. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not relevant to the claims or defenses of any party, nor reasonably calculated to lead to the discovery of admissible evidence.

19. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are subject to either the European Union and/or member states privacy directives.

20. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they purport to seek documents, things or information generated after June 12, 2007, the date upon which sanofi-aventis first received written notification that an Abbreviated New Drug Application had been filed with the FDA seeking FDA approval for the commercial manufacture, use, offer for sale and sale of a generic version of sanofi-aventis's Uroxatral® brand product. Except for information related to secondary indicia of non-obviousness, sanofi-aventis will not provide any information generated after June 12, 2007 unless and until Apotex demonstrates the purported relevance of such information and/or how it is reasonably calculated to lead to the discovery of admissible evidence.

21. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to: this Court's decisions on sanofi-aventis's Motion to Transfer or Stay, Motion for Protective Order and Apotex's Motion for Entry of a Protective Order; the Judicial Panel on Multidistrict Litigation's decision on sanofi-aventis's Motion to Transfer and Consolidate for Pretrial Proceedings; and/or the Delaware Court's decision on Apotex's Motion to Transfer in Favor of Pending Florida Jurisdiction or in the Alternative Stay the Delaware Litigation (collectively "the currently pending motions").

22. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they seek information, documents or things that contain trade secret or other confidential, research, development or commercial information prior

to the entry of an agreed upon Protective Order in this action. Sanofi-aventis further objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to the Court's decision on Apotex's Motion for Entry of a Protective Order.

**REQUEST NO. 1:**

All documents concerning any proposal, consideration or decision by Plaintiff to draft and/or file the patents at issue.

**RESPONSE TO REQUEST NO. 1:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "proposal" and "consideration.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 2:**

All documents reviewed and/or relied on by Plaintiff in making the determination to seek patent protection for the subject matter of the patents at issue.

**RESPONSE TO REQUEST NO. 2:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 3:**

All documents which are relevant to establishing a date of invention by Plaintiff, or any person associated with Plaintiff, earlier than the filing date for each of the patents at issue.

**RESPONSE TO REQUEST NO. 3:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 4:**

All documents and communications that refer or relate to the preparation and/or prosecution of the patents at issue and/or any U.S. applications or foreign applications that constitute or are based in whole or in part on, or which claim priority from, or are the basis of priority for, any of the applications in the family of patent applications leading to the patents at issue and any related oppositions, re-examinations, and/or reissue proceedings including, without limitation:

a. all documents that provided the bases for any of said applications or proceedings;

b. all files in Plaintiff's possession, custody or control regarding the patents at issue, the patent applications for the patents at issue, or any related U.S. or foreign patents or applications;

c. all disclosures of the subject matter of any of said applications or proceedings;

d. all communications between the alleged inventor and his patent attorney(s) or agent(s) concerning the subject matter described or claimed in any of said applications or proceedings;

e. all documents referring or relating to any information used or supplied by the alleged inventor in connection with the preparation or prosecution of any of said applications or proceedings including invention disclosure prepared by or for the inventor;

f. all drafts of any said applications or proceedings;

g. all patents, publications, references or prior art, and all records or documents referring or relating to any prior art or possible prior art, and all records or documents referring or relating to any prior art or any possible ground of unpatentability and/or invalidity, submitted, cited, discussed or considered in connection with any of said applications or proceedings;

h. all documents referring or relating to the citation of, decision not to cite, or failure to cite, any references and/or prior art to the PTO or other patent office or patent authority in connection with said applications or proceedings; and

i. all copies (including drafts) of responses to Office Actions, amendments, affidavits, declarations and other communications or submissions of any kind with or to the PTO or other patent office, or patent authority with respect to any of said applications or proceedings.

**RESPONSE TO REQUEST NO. 4:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts, as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "possible prior art."

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 5:**

All documents and communications concerning any search, investigation, analysis, review, opinion or study relating to the scope, novelty, nonobviousness, patentability, validity, enforceability, value and/or infringement of any claim of the patents at issue, including without limitation:

a. all documents and communications, samples, prototypes and the like that refer or relate to the first public disclosure, first public use, first advertisement, first offer for sale, and/or the first sale of the alleged invention of the patents at issue in any country, including but not limited to, disclosures, advertisements, offers for sale, and sales of products prior to the priority date, filing date and/or bar date of the

patents at issue and concerning use of the subject matter claimed in the patents at issue on or before the respective filing dates(s) whether or not you contend such use was not public or was experimental;

b. all documents and communications concerning the scope and content of the prior art for the patents at issue and any foreign counterparts and all documents identified, found, described, or considered with regard to this prior art, regardless of whether such documents are considered prior art with regard to the patents at issue;

c. all documents and communications referring or relating to the scope of the 'art' and/or the level of skill in the 'art,' as the term 'art' is used in 35 U.S.C. § 103, of the subject matters described and claimed in the patents at issue, including all documents concerning the levels of education and experience of persons working in the field, the types of problems encountered in the art, the activities of others, prior art solutions to the problems encountered by the inventor, and the sophistication of the technology at issue;

d. all documents and communications that refer or relate to seminars, speeches, presentations, lectures, or talks (including without limitation, texts, drafts and notes thereof) given by any person employed or retained by, or otherwise affiliated with, or under authority or grant from Sanofi (or any predecessor in interest with regard to the patents at issue) concerning alfuzosin formulations or methods of treatment using alfuzosin formulations;

e. all documents and communications that refer or relate to any papers, articles, or other publications by any person employed or retained by, or otherwise affiliated with, or under the authority or grant by Sanofi, regarding alfuzosin or methods of treatment using alfuzosin formulations, including without limitation all drafts of any such materials and any memoranda or correspondence between co-authors or others concerning either the work reflected in the materials or the publications themselves;

f. all opinions of counsel concerning the validity, enforceability or infringement of the patents at issue or any foreign counterparts;

g. all documents and communications that (i) concern, (ii) support or tend to establish and/or otherwise support or (iii) refute or tend to refute any allegation that Apotex or any other person infringed the patents at issue or any foreign counterparts; and

h. all documents and communications that refer or relate to any oral or written statement made by Sanofi, or any other person or entity, that Sanofi, or any other person, was, is or might be infringing the patents at issue, or that any product made, used or sold by or for Sanofi, or any other person, was is, or might be infringing the patents at issue.

**RESPONSE TO REQUEST NO. 5:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request, and in particular to the over-breadth of subsection "d", as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "and the like." Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to its request for "prior art . . . regardless of whether such documents are considered prior art with regard to the patents at issue." Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts or documents related to

the first public disclosure, first public use, first advertisement, first offer for sale and/or the first sale "in any country", as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 6:**

All documents and communications concerning secondary factors or objective indicia of non-obviousness with regard to the patents at issue, including without limitation:

a. all documents and communications concerning any commercial success of products covered by the patents at issue and any asserted nexus with the claimed invention;

b. all documents and communications concerning any long-felt need in the art that was satisfied by the invention claimed in the patents at issue;

c. all documents and communications concerning whether or not others had tried, but failed to solve the problem solved by the invention claimed in the patents at issue;

d. all documents and communications concerning simultaneous or near simultaneous invention by others;

e. all documents and communications concerning whether others have copied the invention claimed in the patents at issue;

f. all documents and communications concerning any alleged superior, surprising or unexpected results achieved by the invention claimed in the patents at issue; and

g. all documents and communications concerning whether others have accepted licenses under patents in suit.

**RESPONSE TO REQUEST NO. 6:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 7:**

All documents and memos concerning or referring to any term extension of the patents at issue.

**RESPONSE TO REQUEST NO. 7:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 8:**

All documents and communications concerning the alleged conception, reduction to practice and development of the alleged invention or inventions claimed by the patents at issue, including without limitation:

a. all documents concerning any research, development, testing (both animal and human), and/or refinement of the subject matter of the patents at issue;

b. all documents referring or relating to any research, development, testing (both animal and human) and/or refinement of any commercial embodiments of the subject matter of the patents at issue;

c. all documents referring or relating to the conception and/or reduction to practice of the alleged invention of the patents at issue;

d. all documents referring or relating to any Sanofi product that is believed to be covered literally, or under the doctrine of equivalents, by any claim of the patents at issue; and

e. all documents concerning, created by, or created under the direction of the inventor named on the face of the patents at issue concerning alfuzosin or method of treatment using alfuzosin.

**RESPONSE TO REQUEST NO. 8:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested, including but not limited to all documents and things concerning the testing of Uroxatral®. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "refinement." Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 9:**

All documents and communications that refer or relate to any contemplated, proposed or actual license, or offers for or inquiries regarding license, of any patents, trade secrets or proprietary technology relating to Sanofi's UROXATRAL® products, including without limitation:

a. all documents and communications concerning any request, offer, acquisition or denial of any right (including any forbearance to assert a right), license, agreement, immunity, release, option, title or interest in, to or under the patents at issue, including all documents concerning why an agreement was not consummated (if not consummated), whether any agreement has been terminated, and any documents relating to the transfer and/or assignment of the patents at issue; and

b. all documents that refer or relate to any licensing policy(ies) of Sanofi and its predecessors-in-interest with regard to the patents at issue and products believed to be covered by the patents at issue.

**RESPONSE TO REQUEST NO. 9:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to the licensing of the patents at issue and sanofi-aventis's licensing policies regarding the patents at issue, within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 10:**

All document and communications or opinions concerning the value, strategic or pecuniary, of the patents at issue and commercial embodiments of the alleged invention of the patents at issue, including annual marketing reports, actual and estimated sales figures and the like.

**RESPONSE TO REQUEST NO. 10:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "strategic," "pecuniary" and "and the like.". Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the marketing and sales of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 11:**

All documents that compare any element, aspect or attribute of pharmaceutical tablets containing alfuzosin with any element, aspect or attribute of any other product sold anywhere in the world.

**RESPONSE TO REQUEST NO. 11:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis

objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "element," "aspect," and "attribute." Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 12:**

All documents concerning requests or desires to develop a pharmaceutical tablet containing alfuzosin.

**RESPONSE TO REQUEST NO. 12:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the

production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires.". Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 13:**

All documents concerning requests or desires to develop a method of treatment for dysuria using alfuzosin.

**RESPONSE TO REQUEST NO. 13:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation

and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 14:**

All documents and communications concerning Sanofi's corporate structure and organizational policies, including without limitation:

a. organizational charts that identify all persons involved in research, development, manufacturing, processing, marketing, sales or promotion of UROXATRAL® manufactured, marketed or sold by Sanofi;

b. all documents that constitute, refer or relate to any document retention policy program of Sanofi;

c. a copy of each of Sanofi's annual reports from its inception to the present; and

d. all documents and communications concerning development, manufacture, marketing, research and planning concerned with the subject matter of the patents at issue.

**RESPONSE TO REQUEST NO. 14:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it does not restrict the date range for the documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous

and uncertain, particularly with respect to the undefined term "processing." Sanofi-aventis also objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacture, production, or distribution of Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce: representative organizational charts; documents sufficient to demonstrate sanofi-aventis's document retention policies; and relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the research, development, marketing, sales and promotion of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 15:**

All documents relating or referring to Sanofi's contemplation or, decision to bring and maintain, a patent infringement lawsuit against Apotex, including without limitation:

a. all documents constituting or relating to communications with actual or potential purchasers of UROXATRAL® , or any third party other than an actual or potential purchaser of UROXATRAL® relating in anyway to (i) Apotex, (ii) the patents at issue, or (iii) this lawsuit;

b. all meeting minutes of Sanofi's Board of Directors or any committee of such Board of Directors, and all studies and reports submitted thereto that refer or relate to the Board's authorization to commence litigation charging infringement of the patents at issue, or its consideration of any claims or defenses relating to such litigation;

c. all documents reflecting Sanofi's knowledge of or belief in, the invalidity and/or enforceability of the patents at issue at the time this action was commenced or at any time thereafter; and

d. all documents reflecting knowledge by Sanofi and/or any attorney employed or retained by Sanofi who was involved in prosecuting the applications that ultimately led to the patents at issue or any document or pre-filing activity that constituted or could constitute prior art.

**RESPONSE TO REQUEST NO. 15:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 16:**

All documents, communications, and submissions made by Sanofi or its predecessors-in-interest with regard to the FDA as part of its INDA, NDA and those portions of the supporting Drug Master File for UROXATRAL® products, including but without limitation:

a. all documents and submissions which contain the product specifications and processing information for the manufacture of UROXATRAL®, including documents reflecting all starting materials and intermediates, test protocols and certificates of analysis;

b. all documents and submissions which describe the composition, function and use of UROXATRAL®;

c. all documents and submissions which relate to all treatment indications and/or use of UROXATRAL®, including proposed labeling, proposed package inserts and all other information relating or referring to any proposed or actual clinical use of UROXATRAL®;

d. all documents and submissions relating to the composition, formulation, chemistry, functionality or excipients, or other inactive or active ingredients testing and manufacture of UROXATRAL®; and

e. all documents, records, descriptions, agreements, results and product samples relating to the clinical testing of UROXATRAL® or earlier versions and formulations of alfuzosin products including all documents and product samples concerning or used in clinical trials resulting in side-effects descried in the package insert.

**RESPONSE TO REQUEST NO. 16:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client

privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and/or NDA 21-287 and documents relating to INDA 51,200 and/or NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 17:**

NDA 21-287 and all documents and communications concerning NDA 21-287 including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA, and all amendments to such NDA.

**RESPONSE TO REQUEST NO. 17:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of NDA 21-287 and documents relating to NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 18:**

All NDAs for any other dosage form or drug product containing alfuzosin submitted to the FDA and all documents and communications concerning such NDAs, including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA and all amendments to such NDA.

**RESPONSE TO REQUEST NO. 18:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by NDA 21-287 and/or ANDA 79-013. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

**REQUEST NO. 19:**

All documents comprising Plaintiff's Investigation New Drug application ("INDA") for UROXATRAL® or any other products containing alfuzosin and all documents and/or communications concerning or referring to that INDA, including but not limited to all clinical testing, protocols and results contained in or referred to in such INDA and all amendments to such INDA.

**RESPONSE TO REQUEST NO. 19:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by INDA 51,200. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and documents relating to INDA 51,200 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 20:**

All documents concerning a transfer of any rights or interest in commercial embodiments of the patents at issue from that patents' respective date of conception to the present.

**RESPONSE TO REQUEST NO. 20:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 21**

All documents and communications evidencing the educational background and qualifications for each or the named inventors of the patents at issue including but not limited to curriculum vitaes, resumes, publications, accreditations, honors, awards and/or certificates of recognition.

**RESPONSE TO REQUEST NO. 21:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-

aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 22:**

All documents that relate to the research, development and manufacture of pharmaceutical tablets containing alfuzosin, including without limitation;

a. all documents constituting or relating to any contemplated, proposed or implemented studies, measurements, evaluations, analyses, testing or other compilations of data;

b. all laboratory notebooks, memoranda, summaries, progress and research reports, meeting minutes, comparative tests or studies;

c. all documents relating or referring to each actual or proposed change in formulation, composition or process of manufacture of alfuzosin pharmaceutical tablets, from initial stages of development to the present;

d. all documents relating or referring to each process or method for making pharmaceutical tablets containing alfuzosin, that has been considered, tested,

used, or proposed for use by Plaintiff, including but not limited to the process or method by which Plaintiff, or any person or entity acting under Plaintiff's direction or with Plaintiff's authority manufacture pharmaceutical tablets.

**RESPONSE TO REQUEST NO. 22:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis also objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacturing process, or production of Uroxatral® or a treatment for dysuria.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate the research and development of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 23:**

All documents and communications concerning the research and/or development of any medicines containing alfuzosin in pharmaceutical tablets, including but not limited to laboratory notebooks, invention records, research results, studies, tests, memoranda, project status reports, forecasts and projections.

**RESPONSE TO REQUEST NO. 23:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "medicines." Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 24:**

All documents in Plaintiff's possession, custody or control which discuss pharmaceutical tablets containing alfuzosin.

**RESPONSE TO REQUEST NO. 24:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 25:**

All documents in Plaintiff's possession, custody or control which discuss a method for treatment of dysuria using alfuzosin.

**RESPONSE TO REQUEST NO. 25:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 26:**

All documents or communications concerning, discussing or expressing any complaints, concerns or dissatisfaction with any aspect, element or feature of any products or formulations containing alfuzosin.

**RESPONSE TO REQUEST NO. 26:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "complaints," "concerns," "dissatisfaction.". Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control sufficient to show consumer complaints to the extent that such documents or excerpts do not include individual patient data that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 27:**

All communications by and between Jagotec AG and Sanofi relating to pharmaceutical tablets containing alfuzosin including but not limited to documents relating to the '940 patent.

**RESPONSE TO REQUEST NO. 27:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or

things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 28:**

All documents and communications by and between Synthelabo, Sanofi-Synthelabo, Jagotec AG, Jagotec AB, and Sanofi-Aventis, including but not limited to all assignments and any other documents referring to the assignments or to which the assignments refer.

**RESPONSE TO REQUEST NO. 28:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of

admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 29:**

All documents that refer or relate to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled release of alfuzosin or a salt thereof.

**RESPONSE TO REQUEST NO. 29:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within

its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 30:**

All documents referring or relating to a method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human, including the development and efficacy of such method.

**RESPONSE TO REQUEST NO. 30:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 31:**

Please provide all documents concerning, analyzing, evaluating or referring to any and all of the following documents:

a. Cavero et al., *Br. J. Pharmacol.*, Vol. 81, *Alfuzosin (SL 77,499), A new Antihypertensive Agent with A Peripheral Site of Action : II. In Vitro Pharmacological Studies* ;

b. Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, *Alfuzosin, Antihypertensive Agent With a-Adrenoceptor Antagonist Properties*, abstract 2627 (1984);

c. Hedlund et al., *The Journal of Urology*, Vol. 133, *Effects of Prazosin in Patients With Benign Prostatic Obstruction*, Pgs 275-78 (1983);

d. Ronchi et al., *Urological Research*, Vol. 10, No. 3, *Symptomatic Treatment of Benign Prostatic Obstruction with Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation*, pgs. 131-34 (1982);

e. Whitefield et al., *Br. J. Pharmacol*, Vol. 47, *the Effect of Adrenergic Blocking Drugs on Outflow Resistance*, Pgs. 823-27 (1976);

**RESPONSE TO REQUEST NO. 31:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or

things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "evaluating".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 32:**

All documents produced or to be produced by Sanofi to opposing parties in any and all earlier filed or pending litigations relating to the patents at issue, including but not limited to documents produced by Sanofi in connection with the following cases: *Sanofi-Aventis et al v. Actavis South Atlantic LLC, et al* (Case No. 1:07-cv-00572); and *Sanofi-Aventis et al v. Barr Laboratories Inc.* (1:07-cv-00574).

**RESPONSE TO REQUEST NO. 32:**

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as

irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 33:**

All documents that have been disclosed or provided to any individual by, any scientist and/or consultant retained by Plaintiff in connection with the above-captioned action.

**RESPONSE TO REQUEST NO. 33:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that re protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "scientist.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 34:**

All documents relating to any investigation or test conducted by any scientist and/or consultant retained by Plaintiff in the above-captioned action.

**RESPONSE TO REQUEST NO. 34:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that re protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "scientist.".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

**REQUEST NO. 35:**

All documents that Plaintiff may use as an exhibit in any trial, hearing, submission to the court or deposition in the above-captioned action.

**RESPONSE TO REQUEST NO. 35:**

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will identify documents it intends to use as exhibits: at hearing or trial in

accordance with the Scheduling Order set by the Court; in submissions to the Court when such submissions are made; and at depositions when such exhibits are formally marked as exhibits provided this request is not rendered moot by any of the currently pending motions.

Dated: February 19, 2008

Alfred J. Saikali (Fla. Bar No.: 178195)
asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

John M. Desmarais (jdesmarais@kirkland.com)
Gerald J. Flattmann, Jr. (gflattmann@kirkland.com)
William T. Vuk (wvuk@kirkland.com)
Alexis Gorton (agorton@kirkland.com)
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs*

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was faxed and served by U.S. mail this 19th day of February, 2008 to **Stephen J. Bronis, Esq.**, **Jennifer Coberly, Esq.**, Zuckerman Spaeder LLP, 201 South Biscayne Boulevard, Suite 900, Miami, FL 33131; and **Robert B. Breisblatt, Esq.**, Welsh & Katz, Ltd., 120 South Riverside Plaza, Chicago, IL 60606.

Respectfully submitted,

Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

DEFENDANTS' NOTICE OF COMPLIANCE WITH LOCAL RULE 7.1(A)(3)

The Apotex Defendants hereby submit this Notice of Compliance with Local Rule 7.1(A)(3) in connection with Defendants' Memorandum in Support of Motion to Compel Discovery Responses and Incorporated Memorandum of Law.

On January 18, 2008, Apotex served Sanofi with Defendants' First Set of Requests for Production of Documents and Things to Plaintiffs. Sanofi responded to Apotex's requests on February 19, 2008, with 51 pages of objections. Apotex immediately, conferred with Sanofi on February 20, 2008, by letter requesting that Sanofi produce responsive documents and offering to treat any confidential documents on an attorney's eyes only basis until a Protective Order is entered. Sanofi's response did not address Apotex's concerns over Sanofi's objections but rather only addressed the on-going negotiations for a Protective Order.

Apotex continued reasonable and good faith effort to confer with Sanofi and reach an agreement regarding the production of responsive and relevant documents. To date, Sanofi has refused to produce any documents.

Apotex has complied with the requirements of Local Rule 7.1(A)(3) with respect to its Memorandum in Support of Motion to Compel Discovery Responses and Incorporated Memorandum of Law.

Dated: March 24, 2008

/s/ Robert B. Breisblatt
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fl. Bar No. 145928
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606

*Attorneys for Apotex Corp and Apotex Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

Alfred John Saikali
asaikali@shb.com
Shook Hardy & Bacon
201 S Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611

March 25, 2008 ___/s/ Robert B. Breisblatt_____
*Attorney for Defendants*

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

**MOTION WITHDRAW AS COUNSEL FOR DEFENDANTS APOTEX INC. AND APOTEX CORP.**

Steve Bronis, Jennifer Coberly, Walter Tache, and the law firm Zuckerman Spaeder LLP hereby move to withdraw as counsel for Defendants Apotex Inc. and Apotex Corp. in case number 07-61800-CIV-Moreno, and states the following reason:

Movants Steve Bronis, Jennifer Coberly, and Walter Tache are relocating their law practice and will no longer be able to represent Defendants Apotex Inc. and Apotex Corp. upon relocation. The Miami office of Zuckerman Spaeder LLP will be closing its doors and Zuckerman Spaeder LLP will no longer have counsel in the Southern District of Florida to service Defendants Apotex Inc. and Apotex Corp. in this matter.

However, Defendants will continue to be represented in this matter by Robert B. Breisblatt, Steven E. Feldman and Sherry L. Rollo of WELSH & KATZ, LTD, 120 South Riverside Plaza, Chicago, Illinois 60606, who remain attorneys of record for case number 07-61800-CIV-Moreno. Mr. Breisblatt is a member of the Florida Bar and the United States District Court for the Southern District of Florida. Counsel for Defendants have advised that they no objection to the granting of this motion.

Respectfully submitted,

Dated: March 27, 2008
Miami, FL

*s/. Jennifer Coberly*
Stephen J. Bronis
sbronis@zuckerman.com
Fla. Bar No. 145970
Jennifer Coberly
jcoberly@zuckerman.com
Fla. Bar No. 930466
Walter J. Taché
Fla. Bar. No. 028850
ZUCKERMAN SPAEDER LLP
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131
Tel: 305-358-5000
Fax: 305-579-9749

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by mail on March 27th, 2008 on all counsel of record on the attached service list.

*s/. Jennifer Coberly*
Jennifer Coberly

SERVICE LIST
Case No. 07-61800-CIV-MORENO/SIMONTON

Alfred John Saikali
e-mail: asaikali@shb.com
Shook Hardy & Bacon
201 South Biscayne Blvd., Suite 2400
Miami, FL 33131
Tel: 305-358-5171
Fax: 305-358-7470

Gerald J. Flattmann, Jr.
gflattmarm@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
Kirkland & Ellis
153 E 53rd Street
New York, NY 10022-4611
Tel: 212-446-4800
Fax: 212-446-4900

*Attorneys for Plaintiffs,*
*Sanofi-Aventis and Sanofi-Aventis, U.S. LLC*

Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Steven E. Feldman
Sherry L. Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
Tel: 312-655-1500
Fax: 312-655-1501
*Attorneys for Apotex Corp and Apotex Inc.*

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

**ORDER ON MOTION TO WITHDRAW**

This matter having come before the Court upon the Motion to Withdraw of Steve Bronis, Jennifer Coberly, Walter Tache, and the law firm Zuckerman Spaeder LLP, and the Court having reviewed this matter, it is hereby

ORDERED and ADJUDGED that the Motion to Withdraw is hereby GRANTED, and that Steve Bronis, Jennifer Coberly, Walter Tache, and the law firm Zuckerman Spaeder LLP will be absolved of all further responsibility in this matter.

DONE and ORDERED in chambers in Miami, Florida, this _____ day of ____, 2008.

_____
Federico A. Moreno
United States District Judge

cc: All Counsel of Record

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

**PLAINTIFFS' NOTICE OF PENDENCY OF SIMILAR ACTION RELATING TO PLAINTIFFS' MOTION TO TRANSFER OR STAY**

Plaintiffs, sanofi-avenis and sanofi-aventis U.S. LLC ("Plaintiffs"), by and through their undersigned counsel, and pursuant to S. D. Fla. Rule 3.8, hereby file this Notice of Pendency of Similar Action. Attached hereto is a Complaint filed on March 14, 2008 in the District of Delaware in the matter of *sanofi-aventis et al v. Wockhardt Limited et al*., Civil Action No. 1:08cv150 (D.Del.). *See* Exhibit 1. The case is a civil action for the infringement of United States Patent No. 6,149,940 and has been designated as a related case to *sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT), *sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT), and *sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), also pending in the District of Delaware. All four cases have been assigned to Judge Gregory M. Sleet. The facts and issues in *sanofi-aventis et al v. Wockhardt Limited et al*. will relate directly to this case and Plaintiffs' Motion to Transfer or Stay (Dkt. 5), as it concerns infringement of a patent that Defendants have asserted noninfringement and



LAW OFFICES
SHOOK, HARDY & BACON LLP
MIAMI CENTER, SUITE 2400, 201 SOUTH BISCAYNE BOULEVARD, MIAMI, FLORIDA 33131-4332 •TELEPHONE (305) 358-5171

invalidity counterclaims on and is based on an ANDA for Uroxatral®, the same reference drug at issue in this case.

Date: March 27, 2008

Respectfully submitted,

/s/ Alfred J. Saikali
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on March 27, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali
Alfred J. Saikali
Florida Bar No.: 178195
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
Miami Center, Suite 2400
201 South Biscayne Boulevard
Miami, Florida 33131-4332
Tel: (305) 358-5171
Fax: (305) 358-7470

and

Gerald J. Flattmann, Jr.
gflattmann@kirkland.com
William T. Vuk
wvuk@kirkland.com
Alexis Gorton
agorton@kirkland.com
John M. Desmarais
jdesmarais@kirkland.com
Kirkland & Ellis LLP
153 E. 53rd Street
New York, NY 10022-4611
Tel: (212) 446-4800
Fax: (212) 446-4900

*Attorneys for Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC*

**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court**
**Southern District of Florida**
**(Miami Division)**

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Walter J. Tache, Esq.
ZUCKERMAN SPAEDER, LLP
*Attorneys for Apotex Corp. and Apotex, Inc.*
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

*VIA CM/ECF*

Sherry L. Rollo, Esq.
Steven E. Feldman, Esq.
Robert B. Breisblatt, Esq.
WELSH & KATZ, LTD
*Co-Counsel for Defendants*
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606-3912

*VIA CM/ECF*



LAW OFFICES
SHOOK, HARDY & BACON LLP
MIAMI CENTER, SUITE 2400, 201 SOUTH BISCAYNE BOULEVARD, MIAMI, FLORIDA 33131-4332 • TELEPHONE (305) 358-5171

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | |
|---|---|
| SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. WOCKHARDT LIMITED and WOCKHARDT USA, INC., Defendants. | C.A. No. _____ |

**COMPLAINT**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Wockhardt Limited and Wockhardt USA, Inc., hereby allege as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Wockhardt USA, Inc. is a Delaware Corporation, and a wholly-owned subsidiary and agent of Wockhardt Limited, having a principal place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

4. Upon information and belief, Defendant Wockhardt Limited is an Indian Corporation having a place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra

(East), Mumbai - 400 051. Upon information and belief, Defendant Wockhardt Limited manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Wockhardt USA, Inc.

**Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 6,149,940 ("the '940 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Wockhardt USA, Inc. by virtue of the fact that, *inter alia,* Wockhardt USA, Inc. is a Delaware Corporation.

9. This Court has personal jurisdiction over Defendant Wockhardt Limited by virtue of, *inter alia*, (1) its presence in Delaware through its subsidiary and agent Wockhardt USA, Inc.; and (2) its systematic and continuous contact with Delaware, including through its subsidiary and agent Wockhardt USA, Inc.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**The '940 Patent**

11. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

**Acts Giving Rise to this Action**
**Infringement of the '940 Patent by Defendants**

12. Upon information and belief, Wockhardt Limited, through its subsidiary and agent Wockhardt USA, Inc., submitted Abbreviated New Drug Application ("ANDA") 90-221 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 90-221 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

13. Wockhardt Limited alleged in ANDA 90-221 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of

sanofi-aventis's Uroxatral® brand product. Plaintiffs received written notification of ANDA 90-221 on or about February 20, 2008.

14. Wockhardt Limited's submission of ANDA 90-221 to the FDA, through Wockhardt USA, Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt Limited's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

15. Wockhardt USA, Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Wockhardt USA, Inc. participated in, contributed to, aided, abetted and/or induced Wockhardt Limited's submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Wockhardt USA, Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Wockhardt USA, Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis's Uroxatral® brand product would infringe the '940 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Wockhardt Limited and Wockhardt USA, Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 90-221 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

18. Plaintiffs will be irreparably harmed by Wockhardt Limited's and Wockhardt USA, Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Prayer for Relief**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '940 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Wockhardt Limited's ANDA identified in this Complaint shall not be earlier than the expiration date of the '940 patent, including any extensions;

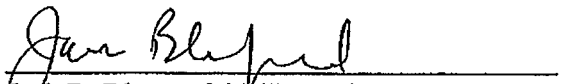
C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis's Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com
*Attorneys for Plaintiffs*
*sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel*:

John Desmarais
Gerald J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022
(212) 446-4800

March 14, 2008

# EXHIBIT A

US006149940A

# United States Patent [19]

Maggi et al.

[11] Patent Number: 6,149,940

[45] Date of Patent: Nov. 21, 2000

[54] TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE

[75] Inventors: Lauretta Maggi, Pavia; Ubaldo Conte, Busto Arisizio., both of Italy; Pascal Grenier; Guy Vergnault, both of Saint Louis, France; Alain Dufour, Paris, France; François Xavier Jarreau, Versailles, France; Clemence Rauch-Desanti, Ozoire la Ferrière, France

[73] Assignees: Synthelabo, Le Plessis-Robinson, France; Jagotec AB, Hergiswil, Switzerland

[21] Appl. No.: 09/147,581

[22] PCT Filed: Aug. 22, 1997

[86] PCT No.: PCT/FR97/01515

§ 371 Date: Apr. 26, 1999

§ 102(e) Date: Apr. 26, 1999

[87] PCT Pub. No.: WO98/08515

PCT Pub. Date: Mar. 5, 1998

[30] Foreign Application Priority Data

Aug. 29, 1996 [FR] France ..... 96 10551
Apr. 10, 1997 [FR] France ..... 97 04386

[51] Int. Cl.[7] ..... A61K 9/24; A61K 9/28; A61K 9/22

[52] U.S. Cl. ..... 424/472; 424/468; 424/474; 514/772.3; 514/777; 514/778; 514/779; 514/773; 514/781; 514/784; 514/785

[58] Field of Search ..... 424/468, 469, 424/470, 472, 474, 465

[56] References Cited

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 4,661,491 | 4/1987 | Regnier | 514/260 |
| 4,839,177 | 6/1989 | Colombo et al. | 424/482 |
| 5,422,123 | 6/1995 | Conte et al. | 424/479 |
| 5,589,190 | 12/1996 | Andrieu et al. | 424/462 |

FOREIGN PATENT DOCUMENTS

WO94/27582 12/1994 WIPO .

*Primary Examiner*—James M. Spear
*Attorney, Agent, or Firm*—Jacobson, Price, Holman & Stern, PLLC

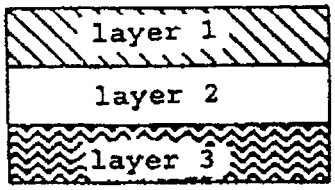
[57] ABSTRACT

Pharmaceutical tablet which consists of:

a) a first layer having the property of swelling considerably and quickly on contact with aqueous biological fluids, the first layer being produced by compression of a mixture or of a granulate comprising hydrophilic polymers, and

b) a second layer adjacent to the first layer being formulated with hydrophilic polymers and with other auxiliary substances in order to give the preparation suitable properties of compressibility and in order to allow the release of alfuzosin hydrochloride within a predetermined time period.

23 Claims, 2 Drawing Sheets



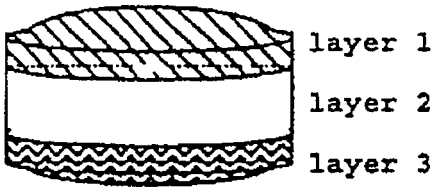






Fig. 1

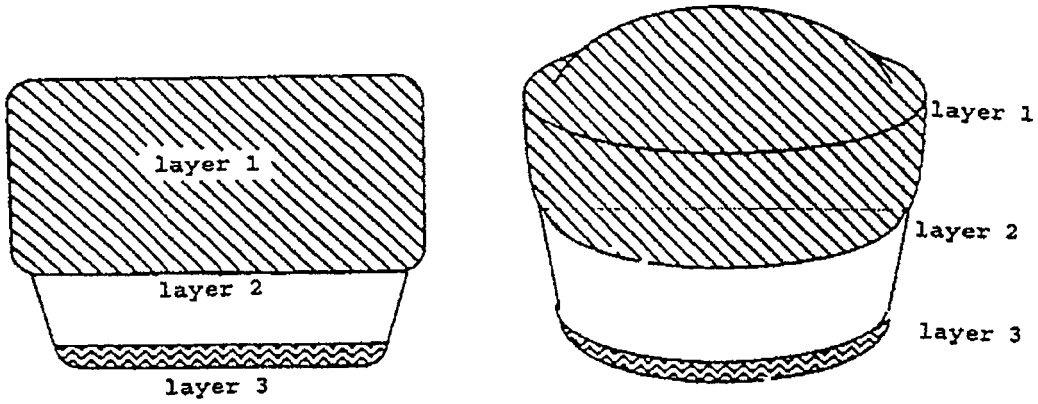



Fig. 2

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# TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE

This applicatin is a 371 of PCT/FR97/01515 filed Aug. 27, 1997.

The present invention relates to a tablet with controlled release of alfuzosin hydrochloride and to a pharmaceutical composition containing one or more tablets.

Alfuzosin hydrochloride is an active substance that is known in the treatment of benign hypertrophy of the prostate. There is a wealth of data and experimental studies regarding the activity of the product. In particular, there is a large amount of data regarding the bioavailability of the product and the pharmacokinetics of the active substance. Indeed, it is an active substance which has a relatively short half-life and a more intense absorption at the duodenum-jejunum level, but the size of which decreases along the intestinal tract. Consequently, for an optimum effect, the administration of alfuzosin hydrochloride as conventional tablets (with rapid disintegration and dissolution) must be carried out several times a day. For these reasons, alfuzosin hydrochloride is a candidate for the production of a pharmaceutical preparation with controlled release in the promixal upper parts of the tract (duodenum and jejunum).

In the pharmaceutical field, noteworthy progress has been made in recent years in the production of increasingly improved systems for the release of active substances, which are capable of releasing the active substances conveyed per se according to kinetics and modes of release designed to allow optimum therapeutic effects.

Prolonged-release forms (or delayed-effect preparations) are characterized in that they convey a markedly larger amount of medicinal product than traditional pharmaceutical preparations, so as to allow the dosage to be simplified. That is to say that the administration decreases from two, three or more times a day to only one administration of a pharmaceutical preparation (or therapeutic system) capable of providing satisfactory therapeutic cover throughout the day.

Preparations of this type have been used and marketed for a long time, among which mention should be made of: chronoids, microcapsules and micro-matrices, tablets generically defined as "delayed-effect" tablets, gastro-resistent tablets and more complex preparations such as hydrophilic matrices which break down and/or swell. Recently, more refined therapeutic systems have been produced, for example so-called "reservoir" systems and the Geomatrix® systems as described in U.S. Pat. Nos. 4,839,177 and 5,422,123.

Most of these novel therapeutic systems are capable of releasing the active substance conveyed per se, at a constant rate (that is to say according to zero-order kinetics) up to complete release of the active substance, independently of the pH conditions of the gastrointestinal tract, and thus uniformly along the gastrointestinal tract. It results therefrom that these systems may be applied widely in the case of administration of medicinal products that are absorbed uniformly in the gastrointestinal tract. However, these pharmaceutical systems may have major drawbacks in the case where active substances per se would be conveyed, such as alfuzosin, having a more intense absorption at the duodenum-jejunum level which decreases thereafter in the tract. Indeed, in this case, only a very limited amount of the active substance conveyed may be absorbed and thus exert the desired therapeutic activity, whereas most of the medicinal product released by the pharmaceutical preparation cannot be absorbed since, in lower portions of the gastrointestinal tract, the biological barriers are relatively incapable of allowing the medicinal product to pass.



The subject of the present patent application is a tablet with controlled release of alfuzosin hydrochloride, which overcomes the drawbacks mentioned above.

The invention consists of a pharmaceutical tablet containing two or three layers, characterized in that it has the following structure:

a) a first layer **1** having the property of swelling considerably and quickly on contact with aqueous biological fluids, the said layer being produced by compression of a mixture or of a granulate comprising hydrophilic polymers constituting from 5.0 to 90% and preferably from 10 to 85% of the weight of the layer,

b) a second layer **2** adjacent to the first layer, in which the alfuzosin hydrochloride is conveyed, this layer being formulated with hydrophilic polymers and with other auxiliary substances, in order to give the preparation suitable properties of compressibility and in order to allow the release of alfuzosin hydrochloride within a predetermined time period,

c) and optionally a third layer **3** obtained by compression and applied to the layer **2**, generally consisting in particular of hydrophilic polymers which gel and/or swell and which may then optionally be broken down and having a barrier function which modifies the release of the alfuzosin hydrochloride from the layer **2**, the layer **3** being primarily highly impervious to passage of the active substance.

The invention is characterized in that on contact with gastric juices, after rapid and considerable swelling of at least one of the layers **1** or **3**, as well as by the possible swelling of the layer **2**, the pharmaceutical preparation increases considerably in volume; thus, the pharmaceutical preparation remains in the stomach for longer. In this way, most of the alfuzosin hydrochloride contained may be absorbed in a controlled manner in that portion of the gastrointestinal tract which has the highest capacity for absorption.

The layers **1** and **3** may have an identical composition and identical functional properties or they may have a different composition and different properties.

When the layers **1** and **3** have identical functional properties and compositions, they may differ by their amounts and their thicknesses applied to the layer **2**.

At least one of the layers **1** and **3** acts as a barrier, that is to say that it is primarily highly impervious to passage of the alfuzosin hydrochloride contained in the layer **2** and at least one of the layers is characterized in that it swells quickly, that is to say that it quickly increases in volume.

Another embodiment of the pharmaceutical preparation is characterized in that the tablet containing **3** layers is formed of a first layer **1** as described above, that is to say that its sole function is to increase considerably in volume on contact with aqueous liquids, a second layer **2** conveying some of the alfuzosin hydrochloride which has to be released within a predetermined time period, and a third layer **3** in which some of the alfuzosin hydrochloride is conveyed, formulated such that it can be released immediately on contact with gastric juices.

The amount of alfuzosin hydrochloride carried in the tablet is between 2.5 and 50 mg.

The polymeric substances which are used in the layers **1** and **3**, and which may also be used in the layer **2**, are biocompatible and have hydrophilic properties. They are slowly soluble and/or slowly gelable and/or swell rapidly or at a different rate in aqueous liquids and then may optionally be broken down; they are chosen from the following group: hydroxymethylcellulose, hydroxyethyl-cellulose, hydroxypropylmethylcellulose having a molecular weight of

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from 1000 to 4,000,000, hydroxypropylcellulose having a molecular weight of from 2000 to 2,000,000, carboxyvinyl polymers, chitosans, mannans, galactomannans, xanthans, carrageenans, amylose, alginic acid, its salts and its derivatives, pectins, acrylates, methacrylates, acrylic/methacrylic copolymers, polyanhydrides, polyamino acids, poly(methyl vinyl ether/maleic anhydride) polymers, polyvinyl alcohols, glucans, scleroglucans, carboxymethylcellulose and its derivatives, ethylcellulose, methylcellulose and, in general, hydrophilic cellulose derivatives.

The content of hydrophilic polymers may range from 5 to 90% relative to the total weight of the layer, but preferably from 10 to 85% and more particularly from 20 to 80%.

In order to promote a rapid and considerable increase in the volume of the pharmaceutical preparation, during the preparation of the layers 1 and 3, with the hydrophilic polymers mentioned above, it is possible to use hydrophilic products and/or excipients capable of promoting wetting of the layers, in this way facilitating interaction between the components of the said layer and the biological fluids with which the layer comes into contact. These hydrophilic excipients are preferably chosen from the groups of so-called "super disintegrating" excipients comprising crosslinked polyvinylpyrrolidone, hydroxypropylcellulose and hydroxypropylmethylcellulose having a molecular weight form 1,000 to 100,000, crosslinked sodium carboxymethylcellulose, carboxymethyl starch and its salts, and divinylbenzene/potassium methacrylate copolymer.

These substances constitute from 1 to 50% of the weight of the layer and preferably from 10 to 30%.

It is moreover possible also to use surfactants (anionic, cationic and nonionic surfactants) which, by facilitating wetting, allow a more rapid interaction between the dissolution medium (or gastric fluid) and the tablet, thereby allowing much faster wetting and swelling of the pharmaceutical preparation, preferably of the layer in which this hydration-modifying component is conveyed. In the group of substances possessing these properties, mention may be made of products such as sodium lauryl sulphate, sodium ricinoleate, sodium tetradecyl sulphate, sodium dioctyl sulphosuccinate, cetomagrogol, poloxamer, glyceryl monostearate, polysorbates, sorbitan monolaurate, lecithins or any other pharmaceutically acceptable surfactant.

In addition, other hydration-modifying elements may be used, these being chosen from the following group of substances:

- hydrophilic diluents such as mannitol, lactose, starches of various origins, sorbitol, xylitol, microcrystalline cellulose and/or substances which, in general, promote the penetration of water or of aqueous fluids into the pharmaceutical preparation,
- hydrophobic diluents such as glyceryl monostearate, palmitates, hydrogenated or unhydrogenated plant oils such as hydrogenated castor oil, waxes, mono-, di- or trisubstituted glycerides, for slowing down the penetration of water or of aqueous fluids into the pharmaceutical preparation.

The technical preparation of the tablets may lead to introducing:

- lubricants such as magnesium stearate, stearic acid, glyceryl monostearate, polyoxyethylene glycols having a molecular weight of from 400 to 7,000,000, hydrogenated castor oil, glyceryl behenate, mono-, di- or trisubstituted glycerides,
- flow agents such as colloidal silica or any other silica,
- and binders, buffers, absorbing agents, as well as any other pharmaceutically acceptable additive.

The tablets of the invention may be produced in the following way: powders and/or granulates are mixed using current production technologies and thus with a production process which may be industrialized immediately.

The pharmaceutical tablet containing two or three layers is obtained according to tableting processes that are very commonly used and known to those skilled in the art.

For example, the tablets may be produced using rotary presses capable of producing "multi-layer" tablets.

Normally, the working compression force ranges from 7 to 50 KN (or kilonewtons) and, according to the processes which will be described in greater detail in the examples, tablets containing two or three layers having a cylindrical, lenticular, spheroidal or ovoid shape which makes them easy to administer and to swallow, are obtained.

Depending on the amount of active substance which is conveyed, each layer of the tablet may have a different thickness ranging from 0.2 to 8 mm, but preferably from 1 mm to 4 mm.

A coating made of polymer materials, whose aim is to afford simple protection or alternatively a slowing-down at the start of the release of the active substance conveyed in the pharmaceutical preparation, may also be applied to this pharmaceutical prepartion. The coating may be soluble in acidic solution or alternatively permeable, so t activation of the tablet (release of the active substance) only after a predetermined time period.

According to another embodiment of the invention, a soluble coating containing alfuzosin hydrochloride may be applied so as to allow immediate release of some of the active substance on contact with the gastric juices.

The coating may be applied by standard methods known to those skilled in the art using organic or aqueous solutions.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 presents an embodiment of the invention comprising a tablet with three layers as described above.

On contact with gastric juices and/or fluids of the gastrointestinal tract, the tablet rapidly increases in volume, taking the structure shown in FIG. 2.

This increase in volume may be determined and limited to a single layer or to several layers of the tablet; this increase in volume, as well as the rate at which this phenomenon takes place, may be monitored and evaluated precisely by direct measurement or by a video microscope coupled to a computer. The measurement is performed by a special video analysis programme.

The tablet is characterized in that the volume of at least one of the layers increases, at the end of 2 hours, by 1.5 times and preferably by at least 3 times relative to the initial volume.

By this method, it is possible to study the behaviour "in vitro" of various preparations (described in the examples of the Application) and thus to design pharmaceutical preparations capable of satisfying the required morphological qualities, as well as of optimizing the preparation of each of the said layers so as to obtain the morphological behaviour which satisfies the requested aim. This type of analysis thus makes it possible to model the "in vivo" behaviour of the pharmaceutical preparation on contact with biological fluids. It is also possible to program, within a determined time period, the release of the active substance conveyed in the pharmaceutical preparation.

The pharmaceutical compositions of the present invention may be in the form of tablets or small tablets or gelatin capsules comprising small tablets.

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At least two small tablets may also be combined in the same pharmaceutical composition. They may be packaged in a common envelope, for example in a wafer capsule or in a gelatin capsule.

When the pharmaceutical composition consists of small tablets, each of these may have a different or identical composition.

The examples which follow are intended to illustrate the invention.

EXAMPLE 1:

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

1A: Preparation of the granulate containing the active substance

A granulate is prepared, according to the process described below, which is used for the preparation of the layer 2 of FIG. 1 containing 10.0 mg of alfuzosin hydrochloride and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 10.00 mg |
| Mannitol | 10.00 mg |
| Hydroxypropylmethylcellulose USP 2208 | 10.00 mg |
| Polyvinylpyrrolidone | 3.20 mg |
| Microcrystalline cellulose | 65.00 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 1.25 mg |
| Total | 100.45 mg |

The manufacturing process consists in preparing a granulate by mixing together the amounts of active substance required, mannitol, microcrystalline cellulose and hydroxypropylmethylcellulose. The uniform powder mixture is moistened uniformly with an alcoholic solution based on 10% w/v polyvinyl-pyrrolidone and is then dried to a predetermined percentage of residual moisture in a fluidized-air bed at 40–45° C. The dried granulate is calibrated and placed in a powder mixer with magnesium stearate and colloidal silica and it is then mixed until homogeneous.

1B: Preparation of the granulate constituting layer 1 which swells

An amount of granulate required to obtain 5000 layers which swell, layer 1 of FIG. 1, were prepared, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 79.75% |
| Hydrogenated castor oil | 13.50% |
| Yellow iron oxide | 0.25% |
| Ethylcellulose | 5.00% |
| Magnesium stearate | 1.00% |
| Silica gel | 0.50% |
| Total | 100.00% |

The manufacturing process consists of the preparation of a granulate obtained by mixing the required amounts of hydroxypropylmethylcellulose, hydrogenated castor oil and iron oxide; the uniform powder mixture is moistened with an alcoholic solution based on 10% w/v ethylcellulose and the uniformly moistened mass is dried in a fluidized-air bed at 40–45° C. The granulate, dried to a predetermined percentage of moisture, is calibrated and placed in a powder mixer with magnesium stearate and colloidal silica and it is mixed until homogeneous.

1C: Preparation of the granulate constituting the third layer 3 which acts as a barrier

An amount of granulate required to obtain 5000 barrier layers is prepared, layer 3 of FIG. 1, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 76.00% |
| Hydrogenated castor oil | 18.60% |
| Polyvinylpyrrolidone | 3.15% |
| Yellow iron oxide | 0.10% |
| Magnesium stearate | 0.70% |
| Colloidal silica | 1.45% |
| Total | 100.00% |

The manufacturing process consists in mixing the required amounts of hydroxypropylmethylcellulose, hydrogenated castor oil and yellow iron oxide; the homogeneous powder mixture is moistened with a solution based on 10% w/v polyvinylpyrrolidone in ethanol and the wet mass is dried in a fluidized-air bed at 40–45° C. The granulate, dried to a predetermined percentage of residual moisture, is calibrated and placed in a powder mixer with magnesium stearate and colloidal silica and mixed until homogeneous.

1D: Preparation of tablets containing three layers (by compression)

The granulates obtained are loaded into the three supply hoppers of a rotary multi-layer press capable of producing three-layer tablets. The granulate described in point 1B is loaded into the first hopper, the granulate according to the description of point 1A is loaded into the second hopper and the granulate according to the description of point 1C is loaded into the third hopper; granulates 1B and 1C may be inverted in the hoppers.

The multi-layer press is equipped with flat circular bevelled punches having a diameter of 8 mm. The machine is adjusted to produce three-layer tablets consisting of a first amount of 100 mg of layer 1 for a thickness of about 1.7 mm, a second amount of 100.45 mg of granulate containing the active substance (equivalent to 10.0 mg of alfuzosin hydrochloride) and a third amount of 150 mg of layer 3 for a thickness of about 3.3 mm. Working according to the above description, three-layer tablets having an average weight of 350.45 mg and containing 10.0 mg of alfuzosin hydrochloride are produced.

1E: Dissolution test

In order to evaluate the release properties of the complete tablets, the vane machine (described in USP XXIII) is used, working at 100 rpm and using as dissolution liquid a 0.01M HCl solution at 37° C. The release of the active substance is monitored by UV spectrophotometric determination at 330 nm using a sampling and automatic reading system.

The results of the tests carried out are given in Table 1.

TABLE 1

| Time (hours) | % released |
|---|---|
| 1 | 16.0 |
| 2 | 25.0 |
| 3 | 32.0 |
| 4 | 37.0 |
| 6 | 48.0 |
| 8 | 57.0 |
| 10 | 66.0 |
| 12 | 74.0 |
| 16 | 88.0 |

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TABLE 1-continued

| Time (hours) | % released |
|---|---|
| 20 | 95.0 |
| 24 | 98.0 |

A controlled release of the active substance is obtained in about 20 hours.

1F: Swelling test

The test is carried out under the same experimental conditions as the dissolution test. The tablets are taken from the dissolution medium at regular intervals and their volume and the sizes of the various layers are measured with a video-microscope coupled to an image-analysis system. The results of the tests carried out are given in Table 2.

TABLE 2

| Swelling time (hours) | Volume (layer 2 + layer 3) (%) | Volume of layer 1 (%) |
|---|---|---|
| 0 | 100.0 | 100.0 |
| 0.5 | 142.0 | 211.1 |
| 1 | 152.7 | 271.0 |
| 1.5 | 175.2 | 302.6 |
| 2 | 161.8 | 399.5 |
| 3 | 182.7 | 483.7 |
| 4 | 196.0 | 534.0 |
| 5 | 199.4 | 609.8 |
| 6 | 195.7 | 727.9 |
| 7 | 166.8 | 809.9 |
| 8 | 138.9 | 851.0 |
| 10 | 139.9 | 937.5 |

It may be noted that, in the tablets, layer 1 increases considerably in volume, up to 9 times its initial volume. This phenomenon is very evident if it is related to the increase in volume of the other two layers, layer 2 and layer 3, which cumulatively swell to about 2-fold. In addition, layer 1 increases in volume at a rate which is considerably higher than that of the other layers.

## EXAMPLE 2

Preparation of a series of tablets (10,000) as reported in FIGS. 1 and 2, containing alfuzosin hydrochloride as active substance.

2A: Preparation of the granulate containing the active substance

A granulate is prepared, according to the process described in Example 1A, which is used in the preparation of the layer 2 of FIG. 1 containing 7.5 mg of alfuzosin hydrochloride, and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 7.50 mg |
| Mannitol | 10.00 mg |
| Hydroxypropylmethylcellulose | 10.00 mg |
| Polyvinylpyrrolidone | 3.20 mg |
| Microcrystalline cellulose | 65.00 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 1.25 mg |
| Total | 97.95 mg |

2B: Preparation of the granulate constituting the first layer 1 which swells

An amount of granulate required to obtain 10,000 layers which swell, layer 1 of FIG. 1, is prepared according to the process described in Example 1B, each layer having the following percentage unit composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 79.75% |
| Hydrogenated castor oil | 13.50% |
| Ethylcellulose | 5.00% |
| Iron oxide | 0.25% |
| Magnesium stearate | 1.00% |
| Colloidal silica | 0.50% |
| Total | 100.00% |

2C: Preparation of the granulate constituting the third layer 3

An amount of granulate required to obtain 10,000 barrier layers, layer 3 of FIG. 1, is prepared according to the process described in Example 1C, each layer having the following percentage unit composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 76.00% |
| Hydrogenated castor oil | 18.60% |
| Polyvinylpyrrolidone | 3.15% |
| Yellow iron oxide | 0.10% |
| Magnesium stearate | 1.45% |
| Colloidal silica | 0.70% |
| Total | 100.00% |

2D: Preparation of the three-layer tablets (by compression)

The granulates obtained according to Examples 2A, 2B and 2C are loaded into the three supply hoppers of a rotary press with respective amounts of 100 mg of granulate for layer 1 for a thickness of 1.75 mm, 97.95 mg of granulate containing the active substance (corresponding to 7.5 mg of alfuzosin hydrochloride) for layer 2 and 150 mg for layer 3 for a thickness of 3.3 mm. By working in the manner described above, three-layer tablets having an average weight of 347.95 mg and containing 7.5 mg of active substance are obtained.

2E: Dissolution test

The dissolution tests are carried out according to the process described in Example 1E.

The results are given in Table 3.

TABLE 3

| Time (hours) | % released |
|---|---|
| 1 | 15.1 |
| 2 | 24.4 |
| 4 | 37.7 |
| 6 | 48.0 |
| 8 | 57.6 |
| 10 | 66.0 |
| 12 | 74.2 |
| 14 | 82.2 |
| 16 | 89.1 |
| 18 | 94.8 |
| 20 | 98.6 |

It may be noted that the controlled release of the active substance takes place over about 20 hours.

2F: Swelling test

The swelling tests are carried out according to the process described in Example 1F. The results are given in Table 4.

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TABLE 4

| Time (hours) | Volume (layer 2 + layer 3) (%) | Volume of layer 1 (%) |
|---|---|---|
| 0 | 100.0 | 100.0 |
| 0.5 | 137.6 | 233.2 |
| 1 | 142.3 | 305.1 |
| 1.5 | 150.4 | 338.5 |
| 2 | 142.3 | 412.4 |
| 3 | 167.1 | 435.2 |
| 4 | 139.2 | 526.5 |
| 6 | 132.0 | 665.0 |
| 8 | 129.9 | 715.1 |

It may be noted that in the tablets prepared, the volume of layer 1 increases considerably, by up to 7 times the initial volume; layer 2 and layer 3 increase by up to one and a half times. In addition, layer 1 increases in volume at a rate which is very much higher than that of the other two layers.

## EXAMPLE 3

Preparation of a series of tablets (10,000) containing alfuzosin hydrochloride as active substance

3A: Preparation of the granulate containing the active substance.

A granulate used in the preparation of layer 2 is prepared according to the process described in Example 1A, this granulate containing 10.0 mg of alfuzosin hydrochloride and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 10.00 mg |
| Mannitol | 10.00 mg |
| Hydroxypropylmethylcellulose | 10.00 mg |
| Polyvinylpyrrolidone | 3.20 mg |
| Microcrystalline cellulose | 65.00 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 1.25 mg |
| Total | 100.45 mg |

3B: Preparation of the granulate constituting the first layer 1 which swells

An amount of granulate required to obtain 10,000 layers which swell, layer 1 of FIG. 1, is prepared according to the process described, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 75.00% |
| Glyceryl behenate | 13.40% |
| Polyvinylpyrrolidone | 5.00% |
| Iron oxide | 0.10% |
| Polyvinylpyrrolidone | 5.00% |
| Magnesium stearate | 1.00% |
| Colloidal silica | 0.50% |
| Total | 100.00% |

3C: Preparation of the granulate constituting the third layer 3

An amount of granulate required to obtain 10,000 layers, layer 3 of FIG. 1, is prepared according to the process described in Example 1C, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose | 76.00% |
| Hydrogenated castor oil | 18.60% |
| Polyvinylpyrrolidone | 3.15% |
| Yellow iron oxide | 0.10% |
| Magnesium stearate | 1.45% |
| Colloidal silica | 0.70% |
| Total | 100.00% |

3D: Preparation of three-layer tablets (by compression)

The granulates obtained as described in Examples 3A, 3B and 3C are loaded into the three supply hoppers of a rotary press with respective amounts of 100 mg of granulate for layer 1, 100.45 mg of granulate containing the active substance for layer 2 and 150 mg for layer 3. By working in the manner described above, three-layer tablets having an average weight of 350.45 mg and containing 10.0 mg of active substance are obtained.

3E: Dissolution test

The dissolution tests are carried out according to the process described in Example 1E.

The results of the tests carried out are given in Table 5.

TABLE 5

| Time (hours) | % released |
|---|---|
| 1 | 19.0 |
| 2 | 27.8 |
| 4 | 41.7 |
| 6 | 53.4 |
| 8 | 64.7 |
| 10 | 75.6 |
| 12 | 84.6 |
| 14 | 90.9 |
| 16 | 95.1 |
| 18 | 97.8 |
| 20 | 99.4 |

The controlled release of the active substance takes place over about 18 hours.

3F: Swelling test

The swelling tests are carried out according to the process described in Example 1F.

The results of the tests carried out are given in Table 6.

TABLE 6

| Time (hours) | Volume (layer 2 + layer 3) (%) | Volume of layer 1 (%) |
|---|---|---|
| 0 | 100.0 | 100.0 |
| 0.5 | 124.0 | 231.8 |
| 1 | 130.5 | 297.0 |
| 2 | 108.5 | 387.0 |
| 3 | 115.2 | 448.8 |
| 4 | 131.3 | 517.2 |
| 5 | 124.7 | 554.5 |
| 6 | 137.0 | 601.1 |
| 8 | 106.6 | 740.5 |

It may be noted that in the tablets prepared, the volume of layer 1 which swells increases considerably, by up to 7 times its initial volume; layer 2 and layer 3 only increase by 30–40% relative to the initial volume. In addition, the layer which swells increases in volume at a rate which is very much higher than that of the other two layers.

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EXAMPLE 4

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

4A: Preparation of the granulate containing the active substance

A granulate is prepared according to the process described below, which is used for the preparation of layer 2 of FIG. 1 containing 10.0 mg of alfuzosin hydrochloride and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 10.00 mg |
| Lactose | 60.30 mg |
| Hydroxypropylmethylcellulose USP 2208 | 25.00 mg |
| Polyvinylpyrrolidone | 3.20 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 0.50 mg |
| Total | 100.00 mg |

The manufacturing process consists in preparing a granulate by mixing the required amounts of active substance, of lactose, of polyvinylpyrrolidone and of hydroxypropylmethylcellulose. The uniform powder mixture is uniformly moistened with purified water and is then dried to a predetermined residual moisture percentage in a fluidized-air bed at 40–45° C. The dried granulate is calibrated and placed in a powder mixer with magnesium stearate and colloidal silica and is then mixed until homogeneous.

4B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose USP 2208 | 40.00% |
| Lactose | 39.75% |
| Glyceryl behenate | 13.50% |
| Yellow iron oxide | 0.25% |
| Polyvinylpyrrolidone | 5.00% |
| Magnesium stearate | 1.00% |
| Colloidal silica | 0.50% |
| Total | 100.00% |

The manufacturing process consists in preparing a granulate obtained by mixing together the required amounts of hydroxypropylmethylcellulose, of lactose, of glyceryl behenate, of polyvinylpyrrolidone and of iron oxide; the uniform powder mixture is moistened with purified water. The uniformly moistened mass is dried in a fluidized-air bed at 40–45° C. The granulate, dried to a predetermined moisture percentage, is calibrated and placed in a powder mixer with magnesium stearate and colloidal silica and it is mixed until homogeneous.

4C: Preparation of three-layer tablets (by compression)

The granulates obtained are loaded into the three supply hoppers of a rotary multilayer press capable of producing three-layer tablets. The granulate described in point 4B is loaded into the first and third hoppers; the granulate according to the description of point 4A is loaded into the second hopper.

The multi-layer press is equipped with flat circular bevelled punches having a diameter of 8 mm. The machine is adjusted to produce three-layer tablets consisting of a first amount of 100 mg of layer 1 or 3 for a thickness of about 1.7 mm, a second amount of 100 mg of granulate containing the active substance and a third amount of 100 mg of layer 1 or 3 for a thickness of about 1.7 mm. By working according to the above description, three-layer tablets having an average weight of 300 mg and containing 10.0 mg of alfuzosin hydrochloride are produced.

EXAMPLE 5

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

5A: Preparation of the granulate containing the active substance

A granulate is prepared according to the process described in Example 4A, this granulate being used in the preparation of layer 2 of FIG. 1 containing 15 mg of alfuzosin hydrochloride and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 15.00 mg |
| Lactose | 55.30 mg |
| Hydroxypropylmethylcellulose USP 2208 | 25.00 mg |
| Polyvinylpyrrolidone | 3.20 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 0.50 mg |
| Total | 100.00 mg |

5B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer corresponding to the composition and to the manufacturing process described in Example 4B.

5C: Preparation of three-layer tablets (by compression)

By working in the manner described above (Example 4C), three-layer tablets containing 15.0 mg of active substance are obtained with the granulates described in Examples 5A and 5B.

EXAMPLE 6

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

6A: Preparation of the granulate containing the active substance

A granulate is prepared according to the process described below, this granulate being used in the preparation of layer 2 of FIG. 1 containing 10 mg of alfuzosin hydrochloride and having the following unit composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 10.00 mg |
| Microcrystalline cellulose | 33.80 mg |
| Mannitol | 10.00 mg |
| Hydroxypropylmethylcellulose USP 2208 | 40.00 mg |
| Polyvinylpyrrolidone | 5.00 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 0.20 mg |
| Total | 100.00 mg |

The manufacturing process consists in preparing a granulate by mixing together the required amounts of active substance, of cellulose, of polyvinylpyrrolidone, of mannitol and of hydroxypropylmethylcellulose. The uniform powder mixture is moistened uniformly with purified water and is then dried to a predetermined residual moisture percentage in a fluidized-air bed at 40–50° C. The dried granulate is

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calibrated and placed in a powder mixer with magnesium stearate and colloidal silica until homogeneous.

6B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose USP 2208 | 45.00% |
| Lactose | 28.60% |
| Microcrystalline cellulose | 20.00% |
| Yellow iron oxide | 0.20% |
| Polyvinylpyrrolidone | 5.00% |
| Magnesium stearate | 1.00% |
| Colloidal silica | 0.20% |
| Total | 100.00% |

The manufacturing process is identical to that of Example 4B, the microcrystalline cellulose being added in place of the glyceryl behenate.

6C: Preparation of three-layer tablets (by compression)

By working in the manner described above (Example 4C), three-layer tablets containing 10.0 mg of active substance are obtained with 100 mg, for each of the layers, of granulates described in Examples 6A and 6B, layers 1 and 3 having a thickness of about 1.8 mm.

## EXAMPLE 7

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

7A: Preparation of the granulate containing the active substance

A granulate is prepared according to the process described below, this granulate being used in the preparation of layer 2 of FIG. 1 containing 15 mg of alfuzosin hydrochloride and having the following unti composition:

| | |
|---|---|
| Alfuzosin hydrochloride | 15.00 mg |
| Microcrystalline cellulose | 28.80 mg |
| Mannitol | 10.00 mg |
| Hydroxypropylmethylcellulose USP 2208 | 40.00 mg |
| Polyvinylpyrrolidone | 5.00 mg |
| Magnesium stearate | 1.00 mg |
| Colloidal silica | 0.20 mg |
| Total | 100.00 mg |

The manufacturing process is identical to that of Example 6A.

7B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer corresponding to the composition and to the manufacturing process described in Example 6B.

7C: Preparation of three-layer tablets (by compression)

By working in the manner described above (Example 6C), three-layer tablets containing 15.0 mg of active substance are obtained with the granulates described in Examples 7A and 7B.

## EXAMPLE 8

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

8A: Preparation of the granulate containing the active substance

A granulate is prepared, which is used in the preparation of layer 2 of FIG. 1, containing 10 mg of alfuzosin hydrochloride, with a composition identical to that described in Example 6A and according to the same process.

8B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer having the following percentage composition:

| | |
|---|---|
| Hydroxypropylmethylcellulose USP 2208 | 35.00% |
| Lactose | 34.50% |
| Microcrystalline cellulose | 23.90% |
| Yellow iron oxide | 0.40% |
| Polyvinylpyrrolidone | 5.00% |
| Magnesium stearate | 1.00% |
| Colloidal silica | 0.20% |
| Total | 100.00% |

The manufacturing process is identical to that of Example 6B.

8C: Preparation of three-layer tablets (by compression)

The granulates obtained are loaded into the three supply hoppers of a rotary multi-layer press capable of producing three-layer tablets. The granulate described in point 8B is loaded into the first and third hoppers; the granulate according to the description of point 8A is loaded into the second hopper.

The multi-layer press is equipped with flat circular bevelled punches having a diameter of 8 mm. The machine is adjusted to produce three-layer tablets whose outer layers consist of 100 mg and 150 mg of the granulate described in point 8B and corresponding respectively to a thickness of about 1.7 mm for one of them and 2.7 mm for the other. The inner layer is composed of 100 mg of granulate containing the active substance (equivalent to 10.0 mg of alfuzosin hydrochloride). By working according to the above description in point 7C, three-layer tablets having an average weight of 350 mg and containing 10.0 mg of alfuzosin hydrochloride are produced.

## EXAMPLE 9

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

9A: Preparation of the granulate containing the active substance

A granulate is prepared, which is used in the preparation of layer 2 of FIG. 1, containing 15 mg of alfuzosin hydrochloride, with a composition identical to that described in Example 7A and according to the same process.

9B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer corresponding to the composition and to the manufacturing process described in Example 8B.

9C: Preparation of the three-layer tablets (by compression)

By working in the manner described above (Example 8C), three-layer tablets containing 15.0 mg of active substance

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and having an average weight of 350 mg are obtained with 100 mg of granulate described in Example 9A and, for the outer layers, 100 and 150 mg of granulate described in point 9B corresponding respectively to a thickness of about 1.8 mm for one and 2.7 mm for the other.

EXAMPLE 10

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

10A: Preparation of the granulate containing the active substance

A granulate is prepared, which is used in the preparation of layer 2 of FIG. 1, containing 7.5 mg of alfuzosin hydrochloride, with a composition which is identical to that described in Example 2A and according to the same process.

10B: Preparation of the granulate constituting layers 1 and 3 which swell and form a barrier

An amount of granulate required to obtain 10,000 layers which swell and form a barrier, layers 1 and 3 of FIG. 1, is prepared, each layer corresponding to the composition and to the manufacturing process described in Example 4B.

10C: Preparation of the three-layer tablets (by compression)

By working in the manner described above (Example 8C), three-layer tablets containing 7.5 mg of active substance and having an average weight of 350 mg are obtained, with 100 mg of granulate described in Example 10A and, for the outer layers, 100 and 150 mg of granulate described in point 10B, corresponding respectively to a thickness of about 1.8 mm for one and 5 2.7 mm for the other.

EXAMPLE 11

Preparation of a series of tablets (5000) based on alfuzosin hydrochloride.

11A: Preparation of the granulate containing the active substance

A granulate containing 10 mg of alfuzosin hydrochloride is prepared, with a composition which is identical to that described in Example 4A and according to the same process.

11B: Preparation of the granulate constituting layer 1 which swells

An amount of granulate required to obtain 10,000 layers which swell is prepared. Each layer corresponds to the composition and to the manufacturing process described in Example 4B.

11C: Preparation of the two-layer tablets (by compression)

By working in the manner described above (Example 8C), the granulates obtained, 100 mg of granulate described in Example 10A and, for the outer layer, 150 mg of granulate described in point 10B, are loaded into two supply hoppers of a rotary multi-layer press capable of producing two-layer tablets.

What is claimed is:

1. A pharmaceutical tablet for oral administration and for the controlled release of alfuzosin hydrochloride into the proximal segments of the gastrointestinal tract, the tablet comprising:

a) a first layer having the property of swelling considerably and quickly on contact with aqueous biological fluids, the first layer being produced by compression of a mixture or of a granulate comprising a hydrophilic polymer constituting from 5.0 to 90% of the weight of the first layer,

b) a second layer adjacent to the first layer containing the alfuzosin hydrochloride, the second layer being formulated with a hydrophilic polymer and with an auxiliary substance to give the preparation suitable properties of compressibility and in order to allow the release of alfuzosin hydrochloride within a predetermined time period,

c) and optionally a third layer adjacent to the second layer comprising a hydrophilic polymer which gels and/or swells and which may optionally be broken down and has a barrier function which modifies the release of the alfuzosin hydrochloride from the second layer, the third layer being primarily highly impervious to passage of the active substance.

2. The tablet according to claim 1, wherein at least one of the layers comprises an hydrophilic product and/or an excipient.

3. The tablet according to claim 2, wherein the hydrophilic excipient is crosslinked polyvinylpyrrolidone, hydroxypropylcellulose or hydroxypropylmethylcellulose having a molecular weight from 1,000 to 100,000, crosslinked sodium carboxymethylcellulose, carboxymethyl starch or its salts, or divinylbenzene/potassium methyacrylate copolymer.

4. The tablet according to claim 2, wherein the hydrophilic excipient constitutes from 1 to 50% of the weight of the layer.

5. The tablet according to claim 1, wherein the third layer has an identical composition to that of the first layer and the same functional properties.

6. The tablet according to claim 5, wherein the first and third layers differ in the amount applied to the second layer and their thickness.

7. The tablet according to claim 1, wherein, on contact with an aqueous liquid, at least one of the layers of the tablet increases by at least 1.5 times relative to the initial volume after two hours.

8. Tablet according to claim 1, wherein the hydrophilic polymer is hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose having a molecular weight of from 1000 to 4,000,000, hydroxypropylcellulose having a molecular weight of from 2000 to 2,000,000, a carboxyvinyl polymer, a chitosan, a mannan, a galactomannan, a xanthan, a carrageenan, an amylose, an alginic acid, a pectin, an acrylate, a methacrylate, an acrylic/methacrylic copolymer, a polyanhydride, a polyamino acid, a poly(methyl vinyl ether/maleic anhydride) polymer, a polyvinyl alcohol, a glucan, a scleroglucan, a carboxymethylcellulose, an ethylcellulose, or a methylcellulose.

9. The tablet according to claim 1, wherein the second layer containing the active substance comprises 5 to 90% by weight of the hydrophilic polymer.

10. The tablet according to claim 1, wherein the third layer contains alfuzosin hydrochloride.

11. The tablet according to claim 1, wherein the amount of alfuzosin hydrochloride in the tablet ranges from 2.5 to 50 mg.

12. The tablet according to claim 1, further comprising a surfactant which is sodium lauryl, sulphate, sodium ricinoleate, sodium tetradecyl sulphate, sodium dioctyl, sulphosuccinate, cetomacrogol, poloxamer, glyceryl monostearate, a polysorbate, sorbitan monolaurate, or a lecithin.

13. The tablet according to claim 1, further comprising an hydrophilic diluent which is mannitol, lactose, a starch, sorbitol, xylitol, microcrystalline cellulose or a substance which promotes the penetration of water and/or an aqueous fluid into the layers.

14. The tablet according to claim 1, further comprising an hydrophobic diluent which is glyceryl monostearate, a palmitate, an hydrogenated plant oil or a wax used for

slowing down the penetration of water and/or of aqueous fluids into the second layer containing the active substance and into the first and third layers.

15. The tablet according to claim 1, wherein the layers of the tablet have different thicknesses ranging from 0.2 mm to 8 mm.

16. The tablet according to claim 1, wherein the tablet is compressed at a pressure that ranges from 7 to 50 KN.

17. The tablet according to claim 1, wherein the tablet is covered with a coating which may optionally contain alfuzosin hydrochloride.

18. A pharmaceutical composition comprising one or more tablets according to claim 1.

19. The tablet according to claim 1, wherein the hydrophilic polymer constitutes from 10 to 85% of the weight of the first layer.

20. The tablet according to claim 2, wherein the hydrophilic excipient constitutes from 10 to 30% of the weight of the layer.

21. The tablet according to claim 1, wherein, on contact with an aqueous liquid, at least one of the layers of the tablet increases by at least 3 times relative to the initial volume after two hours.

22. The tablet according to claim 1, wherein the second layer comprises 10 to 85% by weight of the hydrophilic polymer.

23. The tablet according to claim 1, wherein

a) the first layer consists of by weight:

| | |
|---|---|
| hydroxypropylmethylcellulose | 79.75% |
| hydrogenated castor oil | 13.50% |
| yellow iron oxide | 0.25% |
| ethylcellulose | 5.00% |
| magnesium stearate | 1.00% |
| silica gel | 0.50% |

b) the second layer consists of by weight:

| | |
|---|---|
| alfuzosin hydrochloride | 10.00 mg |
| mannitol | 10.00 mg |
| hydroxypropylmethylcellulose | 10.00 mg |
| polyvinylpyrrolidone | 3.20 mg |
| microcrystalline cellulose | 65.00 mg |
| magnesium stearate | 1.00 mg |
| colloidal silica | 1.25 mg |

c) and the third layer consists of by weight:

| | |
|---|---|
| hydroxypropylmethylcellulose | 76.00% |
| hydrogenated castor oil | 18.60% |
| polyvinylpyrrolidone | 3.15% |
| yellow iron oxide | 0.10% |
| magnesium stearate | 0.70% |
| colloidal silica | 1.45%. |

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION



PATENT NO. : 6,149,940
DATED : November 21, 2000
INVENTOR(S) : Maggi et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [73], correct the name of the Assignee from "**Jagotec AB**" to -- **Jagotec AG** --.

Signed and Sealed this

Thirtieth Day of April, 2002

*Attest:*

*Attesting Officer*

JAMES E. ROGAN
*Director of the United States Patent and Trademark Office*

JS 44 (Rev. 11/04)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**
sanofi-aventis and
sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

**DEFENDANTS**
Wockhardt Limited and
Wockhardt USA, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**CIVIL RIGHTS**
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

**FORFEITURE/PENALTY**
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

**V. ORIGIN** (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
35 U.S.C. § 271
Brief description of cause: patent infringement

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE Sleet DOCKET NUMBER 07-572, 07-574 and 07-792

DATE March 14, 2008
SIGNATURE OF ATTORNEY OF RECORD Jack Blumenfeld

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 11/04)

# INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

**III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V. Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

**VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.