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)
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Phillip D. Segrest, Jr.

(See above for address)
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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
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(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)
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John M. Desmarais
(See above for address)
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William T. Vuk
(See above for address)
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TERMINATED: 04/09/2008
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(See above for address)
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Walter J. Tache
(See above for address)
TERMINATED: 04/09/2008
ATTORNEY TO BE NOTICED

Counter Claimant

Apotex Corp. 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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(See above for address)
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(See above for address)
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ATTORNEY TO BE NOTICED

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(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)

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)

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

		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

		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)

		(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.

		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)

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

		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)

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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.
/

DECLARATION OF ALEXIS GORTON IN SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER OR STAY

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' Motion to Transfer or Stay. I have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 20 are true and accurate copies of Motion of Plaintiffs for Transfer to the District of Delaware Pursuant to 28 U.S.C. § 1407 and Brief in Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407, without exhibits, dated February 1, 2008 filed in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

2. Attached hereto as Exhibit 21 is a true and accurate copy of Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures dated January 17, 2008 and served in this action.

3. Attached hereto as Exhibit 22 are true and accurate copies of Defendants Apotex Inc.'s and Apotex Corp.'s Motion to Transfer, Or In the Alternative, to Stay and Opening Brief In Support of Motion to Transfer In Favor of Pending Florida Jurisdiction, Or In the Alternative to Stay the Delaware Litigation, without exhibits, dated January 24, 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.

4. Attached hereto as Exhibit 23 is a true and accurate copy of Plaintiffs' Answering Brief In Opposition to Defendants' Motion to Transfer In Favor of Pending Florida Jurisdiction, Or In the Alternative to Stay the Delaware Litigation, without exhibits, dated January 31, 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.

I declare under penalty of perjury that the foregoing is true and accurate.

s/ Alexis Gorton

Alexis Gorton

February 7, 2008
New York, New York

EXHIBIT 20

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

PLAINTIFFS' MOTION TO TRANSFER
AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 Laboratories, Inc.*, No. 07-574 (GMS) (MPT), pending in that District. A list of the four pending actions identifying all parties and the presiding judges is attached hereto as the Schedule of Actions.

In support of transfer and consolidation, sanofi-aventis avers the following, more fully set forth in the accompanying brief in support of this motion:

1. All four actions for which transfer and consolidation are proposed involve the infringement, validity and enforceability of the same two patents: U.S. Patent No. 4,661,491 ("the '491 patent") titled "Alfuzosine Compositions and Use" and U.S. Patent 6,149,940 ("the '940 patent") titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate." Sanofi-aventis is the current assignee of the '491 patent and a co-assignee, with Jagotec AG, of the '940 patent.

2. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets. The '491 and '940 patents cover this product, and have been submitted to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) as patents that claim an alfuzosin hydrochloride product. Based on that submission, both patents have been listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

3. 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)). Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed

generic alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents.

4. As part of each ANDA, the submitting entity or entities included one or more allegations under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") 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 of the proposed generic product. Each Paragraph IV Certification sets out the grounds on which the submitting entity or entities allege that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product defined by the ANDA. In many cases, the grounds on which the submitting entity or entities alleged that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product were identical or very similar. For example, each Paragraph IV Certification against the '491 patent alleges that the claims are invalid as obvious over varying combination of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. And in each Paragraph IV Certification alleging non-infringement of the '940 patent, the ANDA filer argues that there is no infringement because the proposed generic product does not meet the '940 patent's layer limitation.

5. Apotex Inc. sent sanofi-aventis a Paragraph IV Certification, dated August 14, 2007, with respect to the '940 patent. Apotex Inc. then sent sanofi-aventis a second Paragraph IV Certification, dated October 25, 2007, with respect to the '491 patent.

6. Each of these filings was an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

7. Given that personal jurisdiction could be exercised against all 15 potential defendants in the District of Delaware, 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 the 13 defendants it elected to sue at that time[1] for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[2]

8. The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are: Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

9. In response to Apotex Inc.'s second Paragraph IV Certification, dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent, sanofi-aventis 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. That action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge.

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[1] 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.

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

10. The three Delaware actions are in their early stages. All 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. In its answer, Apotex conceded that jurisdiction and venue were proper in Delaware. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay. Sanofi-aventis filed its opposition brief on January 31, 2008. As of the date of this application, Apotex has not served its rely brief and no decision has been issued.

11. 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. 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.

12. Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over all 15 defendants, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct, representations made in their respective Paragraph IV Certification letters, and/or refusals to consent to jurisdiction in Delaware.

13. The District of Delaware can properly exercise personal jurisdiction over all defendants. However, given the uncertain consequences surrounding the potential challenges to personal jurisdiction in Delaware, sanofi-aventis had no choice but to bring second-filed actions

in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. Sanofi-aventis brought such second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007[3] and against Apotex on December 10, 2007.

14. 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. It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware.

15. On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's Complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's Complaint in the Delaware action against Apotex, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. The Florida action is also at an early stage.[4]

16. One business day after answering the Florida Complaint, on January 2, 2008, Apotex answered the Complaint in the first-filed Delaware action – conceding that jurisdiction

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[3] Sanofi-aventis commenced the following four second-filed actions, all of which have been dismissed: (1) *Sanofi-aventis et al. v. Torrent Pharma Inc. et al*, Case No. 1:07-cv-969 (W.D. Mich.) (filed September 27, 2007; dismissed October 18, 2007); (2) *Sanofi-aventis et al. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 1:07CV139 IMK (N.D.W.V.) (filed October 5, 2007; dismissed October 18, 2007); (3) *Sanofi-aventis et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case: 2:07-cv-14355 (E.D. Mich.) (filed October 12, 2007; dismissed December 3, 2007); and (4) *Sanofi-aventis et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 07 CV 5807 (BMM) (N.D. Ill.) (filed October 12, 2007; dismissed January 17, 2008).

[4] The Florida action has not progressed significantly further than the Delaware actions despite the fact that the court has issued a scheduling order. Notably no significant discovery has occurred: Apotex has served its Rule 26(a) Initial Disclosures–insufficient in that it discloses only one individual and one document category at an undisclosed location–and a set of 35 document requests. Sanofi-aventis has not served or responded to any discovery requests. Neither party has produced any documents, nor has a protective order been entered.

and venue were proper in Delaware – and asserted the same counterclaims. Sanofi-aventis filed its reply to Apotex's counterclaims in Delaware on January 3, 2008.

17. Sanofi-aventis moved to transfer the Florida action to Delaware or to stay the action pending resolution of the venue issues in the first-filed Delaware action on January 8, 2008 in the interests of judicial economy and efficiency and the convenience of the parties and witnesses. Apotex filed its opposition brief on January 28, 2008. As of the date of this application, sanofi-aventis has not served its rely brief and no decision has been issued.

18. The three Delaware actions and the Florida action described above all focus on the infringement, validity, enforceability, claim construction and scope of the same sanofi-aventis patent(s), the '491 patent and/or the '940 patent. Thus, these cases involve one or more common questions of fact. 28 U.S.C. § 1407(a).

19. Transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, will be the most convenient for the parties. 28 U.S.C. § 1407(a).

20. Additionally, transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, is in the interests of judicial economy in that it will promote just and efficient resolution of the cases. 28 U.S.C. § 1407(a). Transfer will also promote the certainty of patent rights and prevent duplicative actions in multiple districts thereby avoiding the possibility of inconsistent rulings.

21. Sanofi-aventis respectfully requests that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

This motion is based on the BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407, the pleading and papers on file herein, and such other matters as may be presented to the Panel at the time of hearing.

Dated: February 1, 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

Before the Judicial Panel on Multidistrict Litigation
MDL-_____- In re Alfuzosin Patent Litigation

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Actavis South Atlantic LLC; Aurobindo Pharma Ltd.; Aurobindo Pharma USA 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 Limited	D. Delaware	07-572	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendant:** Barr Laboratories, Inc.	D. Delaware	07-574	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	D. Delaware	07-792	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	S.D. Florida Miami Division	07-61800	Federico A. Moreno

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION
FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407

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I. INTRODUCTION

Sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 against 13 defendants that have been pending in Delaware since September 2007, *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).[1]

Transfer and consolidation in this manner are warranted because all four actions involve numerous questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware.

II. BACKGROUND

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. 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.

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[1] The names of all parties to the pending actions, and the assigned judges, are set out in the Schedule of Actions attached to Plaintiffs' motion.

Sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." (Ex. A). It is also a current assignee of United States Patent No. 6,149,940 ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] (Ex. B). Sanofi-aventis U.S. LLC sells alfuzosin hydrochloride 10 mg extended release tablets, covered by both the '491 and '940 patents, throughout the United States for the treatment of the signs and symptoms of benign prostatic hyperplasia under the brand name Uroxatral®. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 relating to Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets and in conjunction with that NDA, submitted both the '491 and '940 patents to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) for listing in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book").

A. In the Summer of 2007, Nine Abbreviated New Drug Applications Were Filed Seeking FDA Approval to Market Copies of Sanofi-aventis's Uroxatral® Brand Alfuzosin Hydrochloride Product

In the Summer of 2007, nine separate Abbreviated New Drug Applications ("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)). Each of these ANDAs seeks the FDA approval necessary for the submitting entity or entities to engage in the commercial manufacture, use and sale of generic copies of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the submitting entity or entities included an allegation under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of

[2] Jagotec AG is also a current assignee of the '940 patent. Sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

the proposed generic products and the grounds for those allegations. Each of these filings was an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). The commercialization of the generic ANDA drug products would be further acts of infringement. *See* 35 U.S.C. § 271(a), (b) and (c).

B. Because Personal Jurisdiction Was Available Against All Defendants In The District Of Delaware, Sanofi-aventis First Filed Actions In That District Against Each Of The 15 Defendants

Because personal jurisdiction exists over all of the entities involved in the submission of the infringing ANDAs and Paragraph IV Certifications in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) (the "Actavis Dkt.") and 07-574 (GMS) (MPT) (the "Barr Dkt.") 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] *See* Complaints (Actavis Dkt. 1; Barr Dkt. 1).[4] At the time of the 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 did not file an action against Apotex for infringement of the '940 patent. 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 the first-filed action, Civil Action No. 07-792 (GMS) (MPT) (the "Apotex DE Dkt."), against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent.

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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.

[4] The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

See Complaint (Apotex DE Dkt. 1). On January 2, 2008, Apotex answered the complaint 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* Apotex Delaware Answer ¶ 7 (Apotex DE Dkt. 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.

In each of the three first-filed Delaware actions, sanofi-aventis alleges infringement of either the '491 patent and/or the '940 patent based on the filing of the ANDAs and any subsequent commercialization. All three actions are designated as related cases and are proceeding before the same Judge and the same Magistrate Judge. The actions are in their early stages. As of January 7, 2008, all 15 defendants had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay the action against it. Sanofi-aventis filed its opposition brief on January 31, 2008. Apotex has not yet served its reply brief and no decision has been issued.

C. Because A Number Of Defendants Threatened To Challenge Personal Jurisdiction In The District Of Delaware, Sanofi-aventis Was Forced To File Five Parallel Actions In The Southern District Of Florida, The Northern District Of Illinois, The Eastern District Of Michigan, The Western District Of Michigan And The Northern District Of West Virginia

To litigate under the protections of the Hatch-Waxman Act, sanofi-aventis was required to file an action against each ANDA submitting party or parties within forty-five days of receiving notice of the Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Abbott*

Labs. v. Mylan Pharm., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).[5] 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. Prior to filing the Delaware actions, however, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct and/or representations made in their respective Paragraph IV Certification letters. Sanofi-aventis's concerns appeared justified when Apotex, Aurobindo, Mylan, Sun, and Torrent refused to consent to jurisdiction in Delaware during sanofi-aventis's strict 45-day window in which to bring suit.

The law remains 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. The consequences of losing the protections of the Hatch-Waxman Act, however, are clear and 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) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate

[5] A compendium of unpublished cases cited herein is attached as Ex. C.

the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

The District of Delaware can properly exercise personal jurisdiction over all 15 defendants in the three first-filed Delaware actions. Given the uncertain consequences surrounding the unlikely, but possible dismissal of any defendant from one of the Delaware actions, sanofi-aventis had no choice but to bring second-filed actions in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. As a result, sanofi-aventis brought second-filed actions within the statutory 45-day window 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. The second-filed suits against Aurobindo, Mylan, Sun, and Torrent have each been dismissed, leaving Apotex as the lone outstanding second-filed suit. [6]

1. Sanofi-aventis Filed A Second-Filed Action In The Southern District Of Florida Against Apotex Because Sanofi-aventis Knew Apotex Would Not Contest Personal Jurisdiction In That District

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[7] 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. G,

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[6] The docket sheets for the second-filed suits against Aurobindo, Mylan, Sun, and Torrent are attached as Ex. D.

[7] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. *See* 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 3-4; 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. (Ex. E). In fact, Apotex has also availed itself of the Delaware court as a plaintiff. *See* Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4. (Ex. F).

12/06/07 W. Vuk ltr to B. Sherman.) It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware. (Ex. H, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo.) Thus, On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON (the "Apotex FL Dkt.") in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's complaint in the first-filed Delaware action, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. *See* Florida Complaint (Apotex FL Dkt. 1).

Similar to the Delaware actions, the Florida action is in its early stages.[8] Sanofi-aventis did not serve its Complaint, yet Apotex filed an Answer and Counterclaims on December 28, 2007; one business day before Apotex answered the Delaware complaint. Sanofi-aventis filed its Reply to Apotex's counterclaims on January 17, 2008 and, prior to filing that reply, on January, 8, 2008, sanofi-aventis moved to transfer the Florida action to Delaware or to stay the Florida action pending the disposition of any transfer issues raised by Apotex in Delaware. Apotex filed its opposition brief on January 28, 2008. Sanofi-aventis has not yet served its reply brief and no decision has been issued. In summary, sanofi-aventis argued that transfer or stay of the Florida action is appropriate in the interests of judicial economy and efficiency to avoid the need for two federal courts to assess the same issues thereby leading to a waste of time and resources on

[8] While the Florida court has issued a scheduling order setting the trial date for October 2008, the action has not truly progressed significantly further than the Delaware actions. The parties have not had their initial case management conference with the judge and Plaintiffs have asked the Florida court to set the trial for June 2009 in its status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Notably no significant discovery has occurred: Rule 26(a) Initial Disclosures have been exchanged and Apotex has served its document requests; sanofi-aventis has not served or responded to any discovery requests; and neither party has produced any documents, nor has a protective order been entered.

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.

III. SUMMARY OF THE ARGUMENT

Each of the four pending actions involves issues that are not just common, but are essentially identical. For example, the same sanofi-aventis patents are at the core of all four pending actions. Moreover, all defendants are trying to make generic versions of the same product and contend that the patents they certified against are either not infringed, invalid over prior art and/or unenforceable based upon essentially the same arguments. Thus, the claims, defenses and counterclaims in all four actions will involve consideration of the same documents, technology, testimony, and legal theories. Centralization is necessary here to eliminate duplicative proceedings and discovery, prevent inconsistent pretrial rulings and conserve judicial resources. Because none of the four actions is near trial, and no significant discovery has taken place, consolidation and centralization is favored and should be ordered now, before substantial pretrial proceedings take place.

IV. ARGUMENT

A. The Applicable Standard

Section 1407(a) of Title 28 of the United States Code provides:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

28 U.S.C. § 1407. Patent cases, as noted by Congress, are particularly appropriate for transfer and consolidation. *See* H.R. No. 90-1130, 1st Sess. (1968).

B. Sanofi-aventis's Four Actions Involve Multiple Common Questions Of Fact And Law

Section 1407 requires consideration of whether the actions sought to be consolidated involve common questions of fact, whether consolidation will promote a just and efficient resolution of the parties' dispute, and whether transfer and consolidation will best serve the convenience of the parties and witnesses. *See* 28 U.S.C. § 1407; *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) ("[W]e find that these three actions involve common questions of fact, and that centralization under Section 1407 in the [first-filed District] will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."). Because the present situation with respect to sanofi-aventis's four actions meets each of these criteria, as described below, transfer and consolidation is warranted.

Sanofi-aventis's four pending actions satisfy the first requirement of Section 1407(a) by having numerous questions of fact and law in common. Although 28 U.S.C. § 1407(a) is phrased in terms of common questions of fact, the Panel also considers common questions of law when applying this standard. *See, e.g.*, *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005) (stating that, because all three actions sought to be consolidated involved claims that generic products infringed one or more of the same patents, "[t]he actions can thus be expected to share factual and legal questions . . . .").

The Panel's decision in *In re Desloratadine* is instructive here. 502 F. Supp. 2d at 1355. In that case, the patentee filed a complaint alleging patent infringement based upon the submission of ANDAs to the FDA against 21 defendants in the District of New Jersey. *Id.* Several defendants threatened to, and eventually did, challenge jurisdiction; thus the patentee

was forced to bring second-filed actions in other districts. The patentee moved the Panel to consolidate the actions in the first-filed forum where the majority of defendants already were in front of the court. Only two defendants objected to the consolidation, arguing that it would delay the resolution of the second-filed action–which was only proceeding against them. The Panel ordered consolidation and transferred the cases to the first-filed court, noting that "assigning the present actions to a single judge who can formulate a pretrial program that ensures that all pretrial proceedings will be conducted in a just and expeditious manner." *Id.* Here, 15 defendants are in front the District of Delaware, the first-filed court, and only Apotex is attempting to proceed in a different forum. Consolidation in front of the first-filed court–the District of Delaware–here is even more compelling than in *In re Desloratadine* because Apotex has consented to jurisdiction and admitted that venue is proper in Delaware.

"[T]ransfer 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). Here, however, the common issues of law and fact will predominate because all four actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product, and many of the defendants have raised the same defenses and counterclaims. *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 at 1361 (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]."). The defendants may have slightly different formulations or base their obviousness arguments on different combinations of

prior art, but that is not justification for denying a request for transfer and consolidation. *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("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.").

Unless the four actions are consolidated for all pretrial purposes, both the Delaware and Florida courts will be required to independently conduct the same complex analyses relating to claim construction, infringement, and patent validity issues. *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (noting that related patent infringement actions share factual and legal issues concerning validity and related questions.); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (same). For example, both courts would be required to construe terms from the claims of both patents. Thus, each court would have to consider the language of the claims, analyze the specification and study the file histories of both patents. These common considerations warrant consolidation. *Id.* (granting order to transfer and consolidate where multiple actions alleged infringement of patent by generic pharmaceutical products).

Similarly, because the validity of both patents are challenged in each case, both 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. Again, these factors warrant 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 Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998) (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin Patent Litig.*, MDL

No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (J.P.M.L. Feb. 5, 2001) (ordering transfer where four actions involved "validity of the same complex pharmaceutical patent").

Here, a more specific common issue stems from the fact that each ANDA filer, except Barr Laboratories, asserts the same non-infringement argument in their '940 patent Paragraph IV Certifications, namely that the proposed generic products do not meet the '940 patent's layer limitation. Absent centralization, both courts will be required to assess this claim construction issue in light of the language of the claims, specification and file history of the '940 patent, and will be required to consider the same extrinsic evidence such as expert testimony. Additionally, the common asserted defense of obviousness with respect to the '491 patent raised by every ANDA filer–including Apotex–that filed a '491 patent Paragraph IV Certification, also presents common issues. Each ANDA filer argues that that the '491 patent is invalid as obvious over combinations of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. Accordingly, it is clear that the four actions will involve common issues of obviousness with respect to the '491 patent and, absent centralization, both judges will be required to learn the technology behind the '491 patent and the state of the art in a complex pharmaceutical field involving technology, research and development that dates back nearly 30 years.

In sum, given the numerous questions of fact and law that are common to all four actions, transfer and consolidation under Section 1407(a) is appropriate and should be granted. *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 re Acacia Media Techs. Corp.*, 360 F. Supp. 2d at 1379.

C. Consolidation Will Promote A Just And Efficient Resolution Of Sanofi-aventis's Actions

Transfer and consolidation of the actions will also promote the just and efficient conduct of the actions, satisfying the second requirement of Section 1407(a) . As the Supreme Court noted, "Patent infringement litigation often raises difficult technical issues that are unfamiliar to the average trial judge." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank.*, 527 U.S. 627, 651 (1999). Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency. *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.'").

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. Without consolidation, each judge would not only need to learn the science underlying the patented method of treatment, the patented formulations, the prior art, and the prosecution histories of the '491 and the '940 patents, but also apply that understanding in construing the asserted patent claims and ruling on pretrial motions. The complexity of the issues coupled with the number of common defenses and counterclaims make these actions ripe for transfer and consolidation. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim

construction; and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Second, consolidation will prevent inconsistent pretrial rulings. For example, consolidation will prevent inconsistent claim construction rulings. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the judge to decide). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming. Without consolidation, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings. This is precisely the scenario that Section 1407 was designed to avoid. *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).

Third, consolidation will result in a more efficient discovery schedule for the parties and the court, avoiding duplicative written discovery, document productions, discovery motions and the like. Given that the same patents are at issue in all four of sanofi-aventis's 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 the four actions. *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").

Finally, consolidation is particularly desirable here because all four actions are in their early stages. As noted above, the parties have not exchanged any discovery, although Apotex has served a set of document requests, and no court has construed the claims or received claim construction briefs from the parties.

D. The Panel's Transfer And Consolidation Of Sanofi-aventis's Actions Will Best Serve The Convenience Of The Parties And Witnesses

Transfer and consolidation of the actions will be most convenient for the parties and witnesses. Consolidation will serve as a cost-saving measure to the parties by avoiding duplicative discovery and other pretrial burdens in relation to common issues. *See 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). Transfer and consolidation will "ensure that discovery will transpire but once and, at the same time, will also streamline the rest of the pretrial process through the involvement and supervision of only a single judge in a single district." *In re Celotex Corp. "Technifoam" Prods. Liab. Litig.*, 68 F.R.D. 502, 504 (J.P.M.L. 1975).

If discovery were to proceed in two courts in parallel, sanofi-aventis would be required to seek and provide the same discovery twice. Sanofi-aventis would also be forced to litigate claim construction issues and go through the summary judgment process twice. That would not

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 will also avoid subjecting witnesses to multiple depositions on identical subject matter. *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."). Sanofi-aventis expects that the parties will require at least 100 fact depositions.[9] Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications that may impact their ability to travel for deposition. 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.

These advantages outweigh any minor burdens placed on the parties by consolidation. For example, it is unlikely that Apotex–which conceded that jurisdiction and venue were proper in Delaware–can demonstrate any significant prejudice as a result of the transfer and consolidation of the actions for pretrial proceedings in the District of Delaware. Indeed, this is especially true given that Apotex admitted that its lone knowledgeable employee and sole

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9 It is likely that the parties will seek deposition testimony from the eight inventors named on the patents and a variety of other witnesses with knowledge of the alleged prior art, Uroxatral®, the proposed generic product, including the decision to file, the preparation and submission of each of the nine ANDAs, the research, development and formulation pertaining to the proposed generic products, and marketing and regulatory issues.

category of documents related to its claims and defenses are located in Canada, not Florida. *See* Initial Disclosures (Ex. I). Furthermore, both Apotex Inc. and Apotex Corp. have litigated in the Delaware court on at least five separate occasions. (Ex. E, F). In any case, because consolidation by the Panel would be for pretrial proceedings only, the consolidation will not necessarily require Apotex's witnesses 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).

Defendants' counsel would also not be adversely affected by consolidation. Apotex's lead counsel is located in Chicago and would have to travel if the action proceeded in Delaware or Florida. In any case, the burden on counsel is of little importance when compared to the significant burden of duplicative discovery responsibilities on sanofi-aventis and its witnesses, including multiple depositions of the same witnesses on the same topics. Furthermore, any burden on counsel can be easily overcome. *See, e.g., In re Cygnus Telecommunications Tech., LLC*, 177 F. Supp. 2d 1375, 1376 (J.P.M.L. 2001) ("the judicious use of liaison counsel and lead counsel will eliminate the need for most counsel ever to travel to the transferee district.").

In sum, any burden on the defendants would be minimal and would be far outweighed by the prejudice to sanofi-aventis and its witnesses if required to conduct parallel litigation in two separate forums. Accordingly, this factor weighs strongly in favor of transfer and consolidation.

E. Coordinated Pretrial Proceedings Should Proceed In The United States District Court For The District Of Delaware

Once the Panel determines that centralization within a single forum is appropriate, the actions should be consolidated in the district that will best "serve the convenience of the parties and witnesses and promote the just and efficient conduct of th[e] litigation." *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has previously recognized the advantage of consolidating cases in a district where one of the actions is pending. *See, e.g., In re*

Mirtazapine Patent Litig., 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, 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 California*, 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. *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.

F. Consolidating The Actions For Pretrial Proceedings Would Serve The Purposes Of The Hatch-Waxman Act

Transfer and consolidation in this action is also consistent with the purposes of the Hatch-Waxman Act. Indeed, the Panel has recognized that "actions involving the validity of pharmaceutical patents, in which the entry of generic versions of drugs into the market is also at issue, are well-suited for transfer under Section 1407." *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has also noted that transfer and consolidation under Section 1407 is consistent with the "expedited" nature of ANDA litigation under the Hatch-Waxman Act. *Id.* (ordering transfer and consolidation of ANDA litigations and stating that the transfer "will have

the salutary effect of assigning the present actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious manner."); *see also In re Gabapentin*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (transferring and consolidating ANDA actions and dismissing as "misplaced" the defendants' argument that "transfer will engender further delays in a litigation in which time is of the essence"); *In re Nabumetone*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (same).

Further, consolidation of the pretrial proceedings against all defendants will ensure that the intent of Congress in enacting the Hatch-Waxman Act is not frustrated because all defendants will be placed on an equal footing in their bid to market a generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product. The Hatch-Waxman Act provides 180 days of exclusivity against competing generic manufacturers to the first filer of an ANDA that challenges the validity, enforceability or infringement of a patent listed in connection with a pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). In the present case, 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. In these circumstances, the Hatch-Waxman Act is intended to provide each of these "first-filers" with equal rights and opportunities to market their generic version of the drug.

For that reason, it is appropriate that the actions against all defendants proceed in the same district to provide a level playing field for each generic manufacturer in their bid to manufacture a generic version of sanofi-aventis's Uroxatral® brand drug product. Allowing a second-filed action related to just one ANDA to proceed in a different district would run counter to the purpose of the Hatch-Waxman Act, and could potentially prejudice the rights of the other defendants, particularly in circumstances where they cannot participate in the parallel actions.

Thus, the policy of the Hatch-Waxman Act also favors consolidation of all four actions in the District of Delaware where the first-filed actions are already pending against all defendants.

V. 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: February 1, 2008.

Respectfully submitted,

Gerald J. Flattmann, Jr. /AG

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

EXHIBIT 21

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

EXHIBIT 22

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

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

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

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APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

OPENING BRIEF IN SUPPORT OF MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE ALTERNATIVE TO STAY THE DELAWARE LITIGATION

Richard L. Horwitz (#2246)
Kenneth L. Dorsney (#3726)
POTTER ANDERSON & CORROON LLP
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 24, 2008
844301 / 32533

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Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") request that the Court transfer this litigation, pursuant to 28 U.S.C. § 1404 (a), to the Southern District of Florida where an identical lawsuit already is underway and trial is scheduled to occur there less than nine months from now.

Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") sued Apotex in the Southern District of Florida, Apotex answered that complaint and counterclaimed against Sanofi in Florida, and Sanofi has replied to Apotex's Florida counterclaim. *See Sanofi's Florida Complaint* attached hereto as Exhibit A and *Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Amended Counterclaims* attached hereto as Exhibit B.

The Florida Court already has set a discovery schedule and has scheduled trial for a two-week period beginning on **October 6, 2008**. *See* January 22, 2008 Revised Scheduling Order (Judge Moreno) attached hereto as Exhibit C.[1] The parties in Florida already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and discovery has begun in the case. By contrast, other than initial pleadings, the Delaware action has not yet begun. There has been no Fed. R. Civ. P. 26(f) conference. No discovery has been served. No trial date has been set.

One of the primary purposes of the *Hatch-Waxman* Act is to expedite resolution of patent disputes involving drug products in order to facilitate the public's access to less expensive generic drugs. *See In re Barr Labs., Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991) (explaining that

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[1] The Florida Court's original scheduling order (dated January 3, 2008) had set trial for May 2008. The revised scheduling order was entered in response to Sanofi's Motion to Continue Pretrial Deadlines and Trial, wherein Sanofi sought to delay the trial date until **September 2009**. At the time the Florida Court entered its revised scheduling order, Sanofi also had filed a motion in the Florida Court seeking to transfer that case to Delaware or to stay it, which motion Apotex is opposing. Although Sanofi's motion is still pending before the Florida Court, that Court was aware that Sanofi was seeking transfer of that action to Delaware when it entered its revised scheduling order.

Congress enacted the Hatch-Waxman Act for to "get generic drugs into the hands of patients at reasonable prices – fast."); 21 U.S.C. § 355(j)(5)(B)(iii) (parties required to "reasonably cooperate in **expediting** the action." (emphasis added)). Transferring this case to Florida will accomplish that goal. It is unlikely the parties will proceed at anything near this speed in the District of Delaware.

Florida also is a much more convenient and logical forum for this action. One of the Defendants, Apotex Corporation, which will market and sell the allegedly infringing drug product, has its headquarters in Florida. (McIntire Decl. at ¶4[2]). Sanofi has alleged that Apotex Corp. is "jointly and severally liable" for Apotex, Inc.'s alleged infringement of the '491 patent, and has further accused Apotex Corp. of participating in, aiding and abetting, inducing and contributing to "Apotex Inc.'s submission of ANDA 79-013 and its §505(j)(2)(A)(vii)(IV) allegation to the FDA." Del. Compl. ¶15 (Dkt.1). While Apotex denies these allegations (or even that they state a claim for infringement), the situs of these alleged acts, and any related Apotex Corp. documents and witnesses, necessarily would be Florida, where Apotex Corp. is located.

None of the parties have active operations in Delaware. Apotex Corp.'s operations are located in Florida. Apotex, Inc., whose act of filing an abbreviated new drug application ("ANDA") to market a generic version of an approved drug is the alleged act of infringement under 35 U.S.C. § 271(e)(2), is a Canadian company whose operations are based in Canada. (Tao Decl. at ¶¶4, 6[3]). According to Sanofi's complaint, Sanofi-Aventis U.S., which presently markets the drug at issue here, is located in New Jersey. Del. Compl. ¶2. Its parent, Sanofi-

[2] All references to "McIntire Decl." are to the Declaration of Tammy McIntire, submitted concurrently herewith.

[3] All references to "Tao Decl." are to the Declaration of Jeremy Tao, submitted concurrently herewith.

Aventis, which purports to own the patents in suit, is located in France. Del. Compl. ¶1. None of the acts accused of infringement here have any connection to Delaware. None of the documents necessary as evidence for this matter are located in Delaware. ((McIntire Decl. at ¶7; Tao Decl. at ¶9). None of the potential witnesses are located in Delaware. (McIntire Decl. at ¶ 6; Tao Decl. at ¶8).

The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C., which courts have recognized is not a dispositive factor in the 28 U.S.C § 1404 analysis – indeed state of incorporation is not listed in § 1404 as a factor to consider in determining an appropriate forum. 28 U.S.C. § 1404; *see also Mentor Graphics Corp. v. Quickturn Design Systems, Inc.,* 77 F. Supp. 2d 505, 509 n. 6 (D. Del. 1999) ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive.").

Accordingly, the Court should transfer this litigation to Florida, or in the alternative, the Court should stay this litigation until a resolution is reached in Florida.

BACKGROUND

Sanofi brought this lawsuit under the Hatch-Waxman Act alleging Apotex infringes one of their patents under 35 U.S.C. § 271(e)(2) by submitting an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA"). The Hatch-Waxman Act was enacted to promote and expedite the public's access to lower priced generic drugs. H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at p. 28, *reprinted in* 1984 U.S.C.C.A.C. 2647.

I. STATUTORY AND REGULATORY BACKGROUND

To obtain FDA approval to sell a drug that has not been previously approved, a company generally must file a new drug application ("NDA"). 21 U.S.C. § 355(b). The Hatch-Waxman Act requires NDA holders, such as Sanofi, to submit a list of all patents that cover their approved drugs. 21 U.S.C. § 355(b)(1). These patents are published in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" also known as "the Orange Book."

Generic companies wishing to market a drug covered by a NDA are permitted to file an ANDA, which substitutes bioequivalence data for the safety and efficacy studies in a NDA. In cases where the generic manufacturer seeks approval to market the generic pharmaceuticals before the expiration of the patents, the generic must submit a "paragraph IV" certification to the FDA that the applicable patents listed in the Orange Book are invalid or will not be infringed by the manufacture, use, or sale of the drug covered by the ANDA. 21 C.F.R. § 314.94(a)(12)(i)(A). Additionally, the generic must notify the brand manufacturer in writing, per a Paragraph IV letter, that such certification was made. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. 314.95(c)(6).

The submission of a paragraph IV ANDA constitutes a "highly artificial" act of infringement, establishing subject matter jurisdiction for the Court to determine whether the patents identified in the Paragraph IV letter are valid and would be infringed by the sale and manufacture of the proposed generic drug product identified in the ANDA, even though the generic drug product itself has not yet been sold. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). After receiving a Paragraph IV letter, brand manufacturers are given 45 days to bring a suit for patent infringement under 35 U.S.C. § 271 (e)(2); 21 U.S.C. § 355(j)(5)(B)(iii). The mere act of filing within 45 days prevents the FDA from approving the generic's ANDA for thirty (30) months unless the generic prevails on the merits at the District Court level before that

time. 21 U.S.C. § 355(j)(5)(B)(iii). Until a final decision is reached, the brand manufacturer enjoys unchallenged exclusivity in the marketplace. In exchange for this automatic 30-month stay, Congress also imposed the express statutory requirements that all parties "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.,* 403 F.Supp.2d 484, 490 (E.D. Va. 2005) ("Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, 'each of the parties shall reasonably cooperate in expediting the action.'" (quoting analogous provision of 21 U.S.C. § 355(c)(3)(C))), *rev'd on other grounds*, 499 F.3d 1299 (Fed. Cir. 2007) (reversing the grant of summary judgment of infringement on the merits).

Under these statutory regulations, as the Court is well aware, the generic is entitled to expeditious judicial resolution of this matter to get its less expensive generic equivalents to market. Any delay in resolution significantly favors the brand pharmaceutical company, which gets to maintain its monopoly profits and higher prices until the patent dispute is resolved.

II. STATEMENT OF FACTS

Apotex, Inc. submitted its ANDA No. 79-013 seeking FDA approval to market and sell a generic version of Sanofi's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product before the patents that Sanofi has listed with the FDA as covering that product expire. (Exh. B at Answer ¶ 12). The ANDA was prepared in Canada, where Apotex, Inc. is located. (Exh. B at Answer ¶ 3). Apotex, Inc. provided Sanofi with Paragraph IV notice of its ANDA No. 79-013, certifying that Sanofi's U.S. Patent Nos. 4,661,491 and 6,149,940 ("the '491 patent" and "the '940 patent" respectively) were not infringed or invalid. (Exh. B at Counterclaim Paragraphs ¶¶15, 16). After receiving Apotex's notice letters, Sanofi filed two identical lawsuits naming Apotex, Inc. and Apotex Corp. as parties. Sanofi filed the first lawsuit on December 6, 2007

(Dkt. 1) in this District ("the Delaware litigation") and the second, days later, on December 10, 2007, in the Southern District of Florida ("the Florida litigation"). *See* Exh. A, Florida Complaint. On December 28, 2007, the Apotex parties answered, counterclaimed and consented to proceed in the Southern District of Florida. *See* Exh. B, Florida Answer/Counterclaims. Since that date, the Apotex parties have answered and counterclaimed in the Delaware litigation, but preserved its position that this matter should be transferred to the Southern District of Florida and joined with the co-pending litigation. (Del. Answer ¶ 10 (Dkt. 7)). Sanofi has now answered Apotex's counterclaim in Florida. The parties also have begun discovery there, having exchanged initial disclosures, and Apotex also has served discovery requests on Sanofi in the Florida action in accordance with the Florida court's discovery schedule, which sets a discovery cut-off date of August 6, 2008 (for both fact and expert testimony) and a trial date of October 6, 2008. (Exh. C).

ARGUMENT

I. PROCEEDING IN FLORIDA WOULD EXPEDITE RESOLUTION OF THIS ACTION

As noted above, the Hatch-Waxman Act requires the parties to an ANDA action to cooperate with each other in expediting the resolution of the action. 21 U.S.C. § 355(j)(5)(B)(iii) ("In such an action, each of the parties shall reasonably cooperate in expediting the action."). Apotex now asks the Court to enforce the intent of the Hatch-Waxman Act and allow this litigation to proceed in the most expeditious fashion, which means transferring this case to Florida.

There can be no dispute that a transfer to Florida would expedite this litigation. On January 22, 2008, the Florida Court entered a revised scheduling Order setting trial for October, 2008 and a discovery cut-off of August 6, 2008 and a summary judgment deadline of August 20,

2008. Exh. C. The parties already have exchanged Rule 26(a)(1) disclosures, and Apotex already has served discovery requests. It is highly unlikely that the Delaware action will proceed towards resolution as quickly as the Florida action. Sanofi filed suit in Delaware against 13 other ANDA holders also seeking to market alfuzosin hydrochloride extended release tablets, for the alleged infringement of the '491 patent. Sanofi also sued several of these companies for infringement of the '940 patent. Although Sanofi has not yet sued Apotex for infringement of the '940 patent, Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe that patent because Apotex's proposed drug product is different from what is claimed in the '940 patent. Given Sanofi's disparate treatment of Apotex's ANDA product as compared with many of the other generic competitors that it sued in Delaware on the '940 patent, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Delaware defendants, and that the Delaware litigation against Apotex – whether alone or in combination with other ANDA holders – will not be in a position where discovery would be done less than seven months from now, and trial would occur less than nine months from now.[4]

Because of these differences, there is no evidentiary overlap and nothing to be gained from consolidation on the infringement issues. Indeed, consolidation on the infringement issues likely will cause delay, as the parties and the Court sort out the issues of competitive sensitivity and confidentiality amongst the other generic defendants and their competing ANDA products. All of this delay would be avoided if the present case is transferred down to Florida.

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[4] Although Apotex's ANDA product does not infringe Sanofi's '940 patent, because Sanofi listed the '940 patent in the Orange Book it remains a cloud over Apotex's ANDA product, and is delaying Apotex's ability to get to market. *See Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). Accordingly, Apotex has counterclaimed against Sanofi seeking patent certainty and a judicial declaration that the '940 patent also is not infringed by its ANDA product. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

To be sure there may be overlap between the Delaware parties' invalidity arguments and those of Apotex. But the evidence and arguments raised also may be significantly different, as each party determines its strongest defenses. To the extent that the invalidity or other issues in the case overlap, the remaining Delaware cases will benefit from the work already done on those issues in Florida. And the rulings in Florida, while not binding, will surely be instructive and also will help to narrow if not resolve the issues remaining here to everyone's benefit.

II. THE LOCATION OF EVIDENCE, CONVENIENCE OF PARTIES AND WITNESSES, AND THE INTERESTS OF JUSTICE WEIGH IN FAVOR OF TRANSFER

The factors dictated by 28 U.S.C. § 1404 also favor transferring this case to Florida. *Jumara v. State Farm Ins. Co.* 55 F.3d 873, 879 (3d Cir. 1995) ("While there is no definitive formula or list of the factors to consider, courts have considered many variants of the private and public interests protected by the language of § 1404(a)." (internal citations omitted)). Specifically, § 1404 requires the Court to consider the location of evidence, the convenience of the parties, the convenience of the witnesses and the interests of justice. Additional public and private interest factors are outlined in the Third Circuit's decision in *Jumara v. State Farm Inc. Co.* 55 F.3d 873, 879 (3d Cir. 1995):

> The private interests have included: plaintiff's forum preference as manifested in the original choice, 1A PT.2 MOORE'S P 0.345[5], at 4363; the defendant's preference, id. § 3848, at 385; whether the claim arose elsewhere, 15 WRIGHT ET AL. § 3848; the convenience of the parties as indicated by their relative physical and financial condition, id. § 3849, at 408; the convenience of the witnesses -- but only to the extent that the witnesses may actually be unavailable for trial in one of the fora, id. § 3851, at 420-22; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum), id. § 3853.
>
> The public interests have included: the enforceability of the judgment, 1A PT.2 MOORE'S P 0.345[5], at 4367; practical considerations that could make the trial easy, expeditious, or inexpensive, id.; the relative administrative difficulty in the two fora resulting from court congestion, id., at 4373; 15 WRIGHT ET AL. §

> 3854; the local interest in deciding local controversies at home, 1A PT.2 MOORE'S ¶ 0.345[5], at 4374; the public policies of the fora, see 15 WRIGHT ET AL. § 3854; and the familiarity of the trial judge with the applicable state law in diversity cases. id.

Weighing these interests renders Florida the more appropriate forum. With respect to the public's interest, the public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). The above-quoted sections of the Hatch-Waxman Act dealing with the parties' obligation to expedite resolution of this matter further dictate that Florida is the appropriate forum for this action. As explained above, any arguments by Sanofi concerning conservation of judicial resources through combining this action with the other cases pending here will prove illusory.

The private interests also dictate that the case should be transferred to Florida. The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C. Neither company has active operations in Delaware. Apotex Corp.'s headquarters is located in Florida and Apotex, Inc. is located in Canada. Sanofi-Aventis U.S. is located in New Jersey and its parent, Sanofi-Aventis is located in France. Although the Defendants' state of incorporation is not irrelevant to a transfer inquiry, it certainly is not dispositive. *Mentor Graphics,* 77 F. Supp. 2d at 509 ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive.").

The operative facts giving rise to this litigation are centered in Canada, France, New Jersey and Florida, *not* Delaware. 17 Moore's Federal Practice 3d, § 111.13(1)(d) at 111-71 ("If none of the operative events in the lawsuit took place in the district in which the action was

originally filed, a motion to transfer to the district in which the events occurred is likely to succeed…."). None of the alleged infringing activities took place in Delaware. (McIntire Decl. at ¶ 6-8). The filing of the ANDA with Paragraph IV certification was the purported act of infringement prompting this litigation and was initiated from Canada. (McIntire Decl. at ¶ 5-7; Tao Decl. at ¶ 6-9). None of the documents relevant to this litigation are in Delaware. (McIntire Decl. at ¶ 7; Tao Decl. at ¶ 9). The ANDA filing, Paragraph IV Certification, and further correspondence with the FDA are the operative facts and documents relevant to this litigation, all of which originated from or are located in Canada or Florida.

The convenience of the witnesses also favors transfer to Florida. All persons knowledgeable about the contents of Apotex's ANDA, and therefore potential witnesses, are located in Florida or Canada. Accordingly, Florida is a more convenient and logical forum for this litigation.

On January 8, 2008, Sanofi filed a motion to transfer the Florida action in favor of this litigation, explaining that it filed the Florida action as a protective measure because it feared the Delaware action would be dismissed for lack of personal jurisdiction. Far from being a persuasive reason to continue this litigation here, Sanofi's professed reason for suing in Florida is indicative that Florida "is clearly the better forum, as all parties agree that both jurisdiction and venue lie here." *Aventis,* 403 F.Supp.2d at 490; *see also Bristol-Myers Squibb Co. v . Andrx Pharms., LLC*, No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (rejecting argument that second-filed lawsuit in the Southern District of Florida should not proceed because patentee only filed there out of fear that the situs of the first filed action would not have jurisdiction over one of the parties). As the *Aventis* court explained neither the law nor logic support Sanofi's position:

> While Plaintiffs strongly urge Defendants' letter necessitated a "protective suit," however, they do not explain why or if the statutory framework requires such a "protective measure." **They point to no case or regulation indicating that "protective actions" are necessary or encouraged in ANDA cases.** They **do not maintain that "protective actions" "expedite the action" as the statute commands. See *21 U.S.C. § 355(c)(3)(C).*** They provide nothing to convince this Court they could not pursue this action in solely in Maryland instead of also filing an identical action in this District. According to Plaintiffs, "the basis for personal jurisdiction over defendant Lupin India in Maryland is particularly strong," yet a "protective suit" is necessary in the event the Maryland court determines it lacks jurisdiction over Lupin Ltd., the India company. Pl.'s Mot. for Stay at 9. This Court cannot accept such a contradictory argument. **If the Maryland forum is in any way questionable in order to necessitate a "protective filing" as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here.** Plaintiffs have therefore failed to justify the need for a stay by "clear and convincing circumstances," as required by *Williford, 715 F.2d at 127*.

Aventis, 403 F. Supp. 2d at 490. (emphasis added).

Similarly, in *Bristol-Myers*, the court rejected the protective filing argument, placing particular reliance on the fact that the defendant company was located in Florida and that the "locus of operative facts" was centered there. *Bristol-Myers*, 2003 WL 22888804 at *5. Here, regardless of whether Sanofi's lawsuit in Florida was protective, Florida is the more logical and convenient forum, where the situs of many of the alleged acts of infringement took place, and where the Apotex Corp. documents and witnesses are located, and where a trial date has already been set for October of this year. Accordingly, Florida is where this case should be litigated.

III. THE FIRST FILED RULE DOES NOT APPLY WHERE A PLAINTIFF FILES BOTH SUITS; HERE, FLORIDA IS THE MORE CONVENIENT FORUM

To the extent that Sanofi seeks to rely on this lawsuit having been filed a few days before the Florida case as a basis for this Court retaining this litigation, that reliance is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues. *Aventis*, 403 F. Supp.2d at 489 (E.D. Va. 2005) (explaining that the first-filed rule does not apply where the "Plaintiffs filed the same case against the same

Defendants in two different courts."); *Employers Reins. Corp. v. MSK Ins., Ltd.*, No. Civ. 01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003) (declining to apply first-to-file rule, noting rule applies to "*party* who files first"); *see also Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-CV-04700-HAA-ES (D.N.J.) Dkt. No. 14, Nov. 16, 2006 Order at 2) (Exhibit D). Rather, it most often applies to situations where two opposing parties race to different courthouses to file suits against each other, a situation not present here. *See, e.g., Serco Serv. Co. L.P., v. Kelley Co., Inc.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995); *Aventis,* 403 F. Supp. 2d at 489-90 (E.D. Va. 2005).

In any event, the first filed rule is not absolute, and is subsidiary to the balancing of convenience and other interests. *Id.* ("Thus, 'the trial court's discretion tempers the preference for the first-filed suit, when such preference should yield to the forum in which all interests are best served.'" (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993)). For example, in *Aventis*, in rejecting the plaintiffs' first filed argument, the court explained that "its primary concern is to 'expedite the action' as directed by 21 U.S.C. § 355(c)(3)(C)." *Aventis*, 403 F. Supp. 2d at 490. There, the appropriate venue was determined to be the location (Virginia) where the person who was designated to accept service of process in the Paragraph IV certification letter was located. *Id.* at 488. Similarly here, Apotex, Inc.'s paragraph IV letters designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf. (Tao Decl. ¶9).

Adams similarly holds that the first-filed rule has no place in a situation such as this, where the ANDA filer was sued in two different jurisdictions by the same patentee. There, the patentee (like Sanofi here), filed identical patent infringement actions against the ANDA-filer in both New Jersey and Pennsylvania. The ANDA-filer immediately answered and counterclaimed

in Pennsylvania and consented to proceed there. The patentee objected. Invoking the first-filed rule, the patentee moved to stay the Pennsylvania action that it voluntarily filed and asked the New Jersey Court to enjoin the Pennsylvania court from proceeding. The patentee's arguments were rejected and the second-filed Pennsylvania action was permitted to continue.

> The "first-filed rule' is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient.

Id.

The court in the second filed Pennsylvania action similarly rejected the patentee's arguments seeking to stay or transfer the action, explaining:

> . . . I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which the Plaintiff almost exclusively relies – applies in the unique circumstances presented here . . . . I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial.

Adams Resp. Therap. v. Mutual Pharm. Holdings, No. 2:06-cv-04418-PD (E.D. Pa.), Dkt. No. 31, Nov. 2, 2006 (Order at 2) (Exhibit E).

Even if the first-filed rule had some application here, the fact remains that the Delaware and Florida litigations were filed within a few days of each other, so there is no prejudice to Sanofi with proceeding with that action over the Delaware case. By filing the second lawsuit in Southern District of Florida, and availing themselves of that forum, Plaintiffs accepted the possibility of having to litigate this case in Florida. No claimed hardship, as a result of dismissal in favor of the Florida litigation, should be recognized by this Court.

CONCLUSION

For the foregoing reasons, the Delaware litigation should be transferred in favor of proceeding with the Florida litigation, or in the alternative stayed until final resolution of the Florida litigation.

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
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 24, 2008
844301 / 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

EXHIBIT 23

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE ALTERNATIVE TO STAY THE DELAWARE ACTION

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett (#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
jdesmarais@kirkland.com
gflattmann@kirkland.com
wvuk@kirkland.com

January 31, 2008

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Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") submit this brief in opposition to Defendants Apotex Corp. and Apotex Inc.'s (collectively "Apotex") 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. As Apotex has failed to show that balancing the *Jumara* factors favors transfer from Delaware—the first-filed forum and Plaintiff's forum of choice—to Florida, the Court should retain this action for coordinated proceedings with two related cases pending before the Court against 13 other defendants.

NATURE AND STAGE OF THE PROCEEDINGS

This is an action brought 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. The pleading stage of this action is complete and the parties await an order setting the initial case management conference from the Court.

SUMMARY OF THE ARGUMENT

Apotex has not met its burden of demonstrating that the balance of the interests of justice and the convenience of the parties and witnesses favors transfer to Florida. Delaware is Plaintiffs' forum of choice and the first-filed forum, not only for the suit against Apotex, but also for their claims against 13 other defendants. Plaintiffs would not have even filed the second action in Florida if Apotex had timely confirmed what it has now admitted in its pleadings — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in this forum. Contrary to Apotex's assertion, plaintiffs' choice of forum and the first-filed rule apply even where the plaintiff filed both actions and courts have now widely recognized the necessity of filing so-called "protective suits" in ANDA cases in response to the ambiguities surrounding jurisdictional challenges under the Hatch-Waxman regime.

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. Apotex has failed to identify a single witness or document located in Florida. Instead, Apotex admits that it prepared and filed its ANDA from its offices in Canada. Moreover, 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 judicial resources as well as the resources of the parties 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. Apotex's strategy would not only impact the parties in this case, but also the 13 additional defendants now before the Court where sanofi-aventis's other related patent infringement actions will proceed regardless of what happens with respect to sanofi-aventis's claims against Apotex. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and retain this case so that all claims for patent infringement against all 15 defendants may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

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* D.I. 1 ¶ 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* D.I. 7 ¶ 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 a current assignee of United States Patent No. 6,149,940 (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.

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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' Answering Brief In Opposition To Defendants' Motion To Transfer In Favor Of Pending Florida Jurisdiction, Or In The Alternative To Stay The Delaware Action.

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.

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 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.

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.

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

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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.

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, 12/06/07 W. Vuk ltr to B. Sherman. 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.

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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**.**

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before Your Honor and Magistrate Judge Thynge. 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.

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)).[5] 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

[5] Ex. T is a compendium of unreported cases cited herein.

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.[6] Ex. M, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

> Plaintiff's 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. M ¶ 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 this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. N, Plaintiff's Florida Motion To Transfer Or Stay.

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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.

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. O, Florida Answer And Counterclaims; Ex. P, 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 even though the Florida court has not held its initial case management conference and the parties have only exchanged initial disclosures. Ex. Q, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. R, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. S, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1). Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. Q. 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 been rejected.

ARGUMENT

I. All Relevant Factors Favor Proceeding In Delaware In Coordination 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

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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. O ¶ 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.

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 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. *Jumara v. State Farm Ins. Co.*, 55 F. 3d 873, 879 (3d Cir. 1995). In the Third Circuit, courts consider both private and public interests in this balancing:

> The private interests have included: plaintiff's forum preference as manifested in the original choice, the defendant's preference, whether the claim arose elsewhere, the convenience of the parties as indicated by their relative physical and financial condition, the convenience of the witnesses-but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum).
>
> The public interests have included: the enforceability of judgment, practical considerations that could make the trial easy, expeditious, or inexpensive, the relative administrative difficulty in the two fora resulting from court congestion, the local interest in deciding local controversies at home, the public policies of the fora, and the familiarity of the trial judge with the applicable state law in diversity cases.

Id. at 879-80 (internal citations omitted). As the moving party, Apotex bears a heavy burden: unless the balance of these factors is in strong favor of transfer, a plaintiff's choice of forum should prevail. *See id.* at 879*; ZF Meritor LLC v. Eaton Corp.,* Civ. No. 06-623-SLR, slip op. at 2-3 (D. Del. June 13, 2007).

The parties do not dispute that this action could proceed either in this jurisdiction, where Apotex has agreed that it will not contest jurisdiction and that venue is appropriate, or in the Southern District of Florida. The only issue for the Court to decide is whether the balance of the *Jumara* factors heavily favors transfer to Florida. According to Apotex, transfer is warranted because (1) plaintiff's choice of forum and the first-filed rule do not apply when the plaintiff brought both actions against the same defendant; (2) transfer will "enforce the intent" of the Hatch-Waxman Act of getting inexpensive generic drugs into the hands of consumers as soon as

possible because the Florida action will be tried in October 2008; and (3) Florida is the more convenient forum and the locus of operative events. Apotex fails to meet its burden for each of these arguments under the relevant law and facts.

A. Both the Plaintiffs' Choice of Forum and the First-Filed Rule Favor Delaware

Plaintiff's choice of forum weighs against transfer and should not be disturbed if the relevant factors are evenly balanced or weigh only slightly in favor of the transfer. *Cont'l Cas. Co. v. Am. Home. Assurance Co.*, 61 F. Supp. 2d 128, 131 (D. Del. 1999). In fact, "plaintiff's choice of forum is of paramount consideration," even if that jurisdiction is not considered the party's "home turf." *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.,* No. CIV 06-505-SLR, 2006 WL 3755452, at *2 (D. Del. Dec. 19, 2006). Retention of this case also comports with the Third Circuit's "first-filed" rule, which has been applied to "protective suits" brought under the Hatch-Waxman Act in this district. *Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007). Under that standard, based on the principles of comity, 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. *EEOC v. University of Pennsylvania,* 850 F.2d 969, 971 (3d Cir. 1988).[8]

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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 Florida one business day before filing them in this District. *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).

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. Sanofi-aventis had a rational and legitimate reason to choose the District of Delaware because it was the district where Plaintiffs could bring each of the 15 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. *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 plaintiff had a rational and legitimate reason to sue defendants in the forum because, *inter alia*, all parties were subject to personal jurisdiction in that forum); *see also Joint Stock Soc'y v. Heublein, Inc.,* 936 F. Supp. 177, 187 (D. Del. 1996). This District is also where two of the parties, Apotex Corp. and sanofi-aventis U.S. LLC, are incorporated. *See Auto. Techs.*, 2006 WL 3783477 at *2.

Apotex argues that these time-honored rules should be ignored where the "plaintiff chooses to file two identical lawsuits against the same party in two different venues" to support its spurious allegation that Plaintiffs cannot claim hardship because they chose to file a second action in Florida. *See* D.I. 11 at 11, 13. Apotex has not cited any authority that would support the application of such a mechanical limitation on the first-filed rule in this jurisdiction; in fact it would be contrary to the efficient administration of justice through the principles of comity which form the basis of the rule. Moreover, Apotex's proposed carve-out completely ignores the specific jurisdictional issues inherent to ANDA litigations that various district courts have

recognized force patentees to file protective suits to ensure that they will be entitled to the benefit of a 30-month stay under the Hatch-Waxman Act.

For example, 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 its second-filed "protective action" based on the "first-filed" rule. No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007). ANDA filer Sun opposed 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. *Id.* 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. (emphasis added). "[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.*; *Abbott*, 2006 WL 850916 at *8 ("The [Hatch-Waxman Act] is silent, and the courts have not clarified, whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired.").

Courts in the Third Circuit have made similar findings. For example, in *Celgene Corp. v. Abrika Pharm., Inc.,* plaintiffs brought suit for patent infringement under the Hatch-Waxman Act against defendants in the District of New Jersey. No. 06-5818, 2007 WL 1456156, at *1 (D.N.J. May 17, 2007). Plaintiffs filed a nearly identical action two days later in the District of Delaware. *Id.* 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." *Id* at *4*; see also 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."); *cf. Medpointe Healthcare Inc. v. Cobalt Pharm. 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). The court went on to note that plaintiffs had filed the New Jersey action first, and as here, had not served the complaint in the second-filed Delaware action, "indicating a clear preference that the case move forward in New Jersey." *Id.* Judge Robinson agreed and dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'" *Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007).

The facts here are identical in all relevant respects to those in *PDL* and *Celgene.* Sanofi-aventis was forced by Apotex's 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 Florida. *See, e.g.,* Ex. H; Ex. M ¶ 19. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex Corp.'s incorporation here and 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. G; D.I. 7. Apotex can hardly argue that sanofi-aventis's filing of parallel actions are motivated by bad faith or forum shopping. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should move forward with this action in Plaintiffs' forum of choice and not allow Apotex's gamesmanship to dictate where Plaintiffs' claims will proceed.

None of the cases cited by Apotex to support its argument are binding or even persuasive authority. In *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, the Virginia court based its ruling on the erroneous holding that the first-filed rule was limited to the race-to-the-courthouse situation, and did not apply to two suits filed by the same plaintiff. 403 F. Supp. 2d 484, 489-90 (E.D. Va. 2005). Moreover, it stated that plaintiffs in that case did "not explain why or if the [Hatch-Waxman Act] requires such a 'protective measure.'" *Id.* at 490.

This case is readily distinguishable from *Lupin.* As an initial matter, precedent from this District clearly shows that the first-filed rule is certainly not subject to the mechanical limitation imposed by the *Lupin* court. *See, e.g., Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007); *see also 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 Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants). Moreover, defendants in *Lupin* contested jurisdiction in the first-filed forum; here, Apotex has stated that it will not contest jurisdiction in Delaware. *Aventis*, 403 F. Supp. 2d at 490; D.I. 7 ¶¶ 7-8, 10. And here, there are related actions pending in this first-filed forum that will proceed regardless of where the Apotex case is tried—a key fact not at issue in *Lupin.* Finally, Plaintiffs have made clear that their sole reason for filing in Florida was to protect their rights due to the ambiguities concerning personal jurisdiction challenges in ANDA cases. Ex. M ¶ 19. District courts post-*Lupin*, such the *PDL*, *Celgene*, and *Abbott* courts discussed above, have clearly recognized the need for filing protective suits under the Hath-Waxman Act and have expressly rejected the Virginia court's limitation on the first-filed rule. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.,* No. 1:07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (refusing to apply the *Aventis* court's "mechanical limitation" and noting "the harsh outcome should [the first-filed forum] dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay" of the second-filed action).

Apotex also relies on a letter opinion from *Adams Respiratory Therapy v. Mutual Pharmaceutical Holdings*, Civil Action No. 06-4418 HAA, slip op. (D.N.J. Nov. 16, 2006), to support its position. D.I. 11 at 12-13. The primary concern of the *Adams* court, however, was judge shopping. D.I. 11-2 at Ex. D at 2. Here, Plaintiffs were not judge shopping, but were merely trying to ensure that their claims would go forward if Apotex successfully challenged personal jurisdiction in Delaware. Plaintiff's intention was clear—they sought Apotex's consent

to jurisdiction in Delaware prior to filing the Florida action and never served the Florida complaint on Apotex. Exs. H, M ¶ 19. And as in *Lupin*, the judge in *Adams* did not appreciate the specific jurisdictional issues relevant to ANDA actions and the serious consequences patentees face due to the ambiguities in the statute and case law concerning those issues if they do not file second, "protective" suits in certain circumstances. Moreover, the *Adams* opinion has not been followed in the issuing forum as the *Celgene* decision discussed above shows. [9]

B. The Interests of Justice Can Only Be Served By Litigating In Delaware Where All Others Claims Concerning The Patents Are Pending

Alternatively, Apotex argues that the Court should transfer under an exception to the first-filed rule to expedite the resolution of the parties' claims and to the serve the convenience of its witnesses. D.I. 11 at 12. As discussed below, there is little support for either of these arguments and they are greatly outweighed by the interests of justice in litigating the patent claims against all 15 defendants in the same forum.

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 Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997). Courts have found that the interests of justice are best served when all of a patentees' claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Apotex brushes aside these significant considerations with general claims that the generic products and defenses in the related Delaware actions may

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9 The other cases cited by Apotex are no more persuasive. *See* D.I. 11 at 12. They do not address ANDA patent litigations or protective suits, but instead addressed issues concerning anticipatory declaratory judgment actions—a well-known exception to the first-filed rule. *See Employers Reinsurance Corp. v. MSK Ins., Ltd.*, No. Civ.A.01-2608-CM, 2003 WL 21143105, at *6-7 (D. Kan. Mar. 31, 2003); *Serco Services Co., L.P. v. Kelley Co., Inc.*, 51 F. 3d 1037, 1039 (Fed. Cir. 1995).

be different. Such unsupported hand waving does not obscure the fact that if the Apotex case proceeds in Florida, both this Court and the Florida court will have to manage discovery, pretrial proceedings such as claim construction, and eventually trial based on allegations of infringement and validity of the same patents for proposed generic products all referencing the same innovator product and its approved indication. The case law, and logic, demonstrate that the benefit of avoiding such duplication is hardly "illusory" as Apotex claims. *See* D.I. 11 at 9.

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 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. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 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 that support proceeding in this Court are even more compelling here where sanofi-aventis has multiple suits pending in Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to this action against Apotex, there are two other related cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of where the Apotex claims are tried. Each of these actions is pending before the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order and coordinated pretrial activities in all three pending cases to avoid duplicative discovery efforts and serve judicial efficiency.

By retaining this action for coordination with the other Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. Apotex's attempt to argue that these efficiencies have no bearing on this case because there may be differences between its products and the other generics as well as the invalidity

arguments advanced by each defendant are unpersuasive. *See* D.I. 11 at 7-8. 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. As the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer would lead to 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 defendants may seek discovery. Additionally, transfer would likely lead to duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Florida would force two courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products. *See Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (staying second-filed action pending resolution of jurisdictional issues in first-filed court, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary" where claims against 19 other ANDA defendants were pending in the first-filed forum).

Finally, retaining this case 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. This factor is especially important with respect to claim construction, where inconsistent rulings could result in the same claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MLR, 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 Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors

Apotex's only public interest counterargument is that under the Hatch-Waxman regime a "generic is entitled to expeditious judicial resolution of this matter to get its less expensive generic equivalents to market" and that Florida will reach resolution fastest. D.I. 11 at 5. As an initial matter, Apotex's evidence that the Florida action will reach resolution faster than this case is minimal at best. Although the Florida court has issued a scheduling order setting the trial date for October 2008, the parties have not had their initial case management conference with the judge and Plaintiffs will ask the Florida court to set a 2009 trial in the parties' joint status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Moreover, no meaningful discovery has taken place in Florida. The parties have merely exchanged their initial disclosures and Apotex has served a set of document requests. *See* Exs. Q-S.

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, this case will take a significant amount of time to resolve regardless of where it proceeds. Any additional time spent litigating does not necessitate transfer from Plaintiffs' choice of forum in light of the juridical economy and witnesses convenience benefits to retaining the case in this District for coordination with the other two related cases.

Moreover, getting low-cost drugs to market is not the only goal of the Hatch-Waxman Act. Rather, "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). 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.*, 302 F. Supp. 2d at 343; *Ben Venue Labs.,* 146 F. Supp. 2d at 579. Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple forums, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market. This result would run counter to the intent of Congress and frustrate 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 the Florida action while seeking to delay this case 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' Uroxatral® without competition from the other defendants.[10] 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 purposes to espouse. Indeed, the resolution of Plaintiffs' claims will best be expedited under the Hatch-Waxman Act through cooperation between Plaintiffs and all 15 defendants to conduct discovery and other pretrial proceedings in an efficient and coordinated manner.

D. Apotex's Unsupported Convenience Arguments Do Not Favor Transfer Under *Jumara*

Finally, 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 that district. D.I. 11 at 2, 10; D.I. 7 ¶ 10; Ex. P ¶ 19. As the moving party, Apotex bears the burden of demonstrating that this factor, in the balance of the *Jumara* standard, so strongly favors transfer that Plaintiffs' choice of forum should be disturbed. Apotex doesn't even come close.

Apotex states that Apotex Corp., located in Florida, "will market and sell the allegedly infringing product" citing the declaration of Apotex Corp.'s president, Tammy McIntire, in

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[10] Apotex's delay is even evidenced by the timing of its present motion. Apotex first alerted the Court that it preferred the Southern District of Florida in its Answer and Counterclaims on January 2, 2008. D.I. 7 ¶ 10. Apotex then confirmed during a meet and confer with Plaintiffs on January 7 that it would move to transfer the present action to Florida. Ex. L. But Apotex waited another three weeks before filing this motion to transfer, after the parties exchanged their local rule disclosures in Florida and after Apotex was entitled to serve document requests in that action.

support. D.I. 11 at 2. Nothing in Ms. McIntire's barely 2-page declaration, however, supports this allegation. D.I. 13. In fact, the declaration does not identify a single event, witness, or document with any connection to Florida that is relevant to this case. Instead, Ms. McIntire merely says that :

> To the extent any Apotex Corp. employees are knowledge about ANDA NO. 79-013 they are employed at the Florida location.
>
> To the extent Apotex Corp. has any documents relevant to ANDA No. 79-013 they are located at Apotex Corp.'s Florida location.

Id. ¶¶ 5, 6. The declaration submitted by Apotex Inc.'s director of regulatory affairs, Bernice Tao, does not say much more. D.I. 12. The sole link to Florida provided by Ms. Tao is that Apotex listed Ms. McIntire in Weston, Florida as the agent for service in Apotex Inc.'s paragraph IV certification letters. *Id.* ¶ 9.

None of these facts weigh in favor of transfer under the *Jumara* convenience factors. Although Apotex has failed to name any witnesses or identify their locations in Florida, it is reasonable to assume that any such witnesses are likely employees of Apotex and could be made available for trial in either Florida or Delaware. *See Jumara,* 55 F. 3d at 879 (stating that the convenience of witnesses is only considered "to the extent that the witnesses may actually be unavailable for trial in one of the fora."); *Pernod,* 2006 WL 3755452 at *3; *Auto. Techs.,* 2006 WL 3783477, at *2 ("Further, as this court has previously held, a flight to Delaware is not an onerous task warranting transfer."); *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."). To the extent Apotex contends there are third parties with relevant knowledge in Florida, it has made no showing of who those witnesses are or that they would be unwilling or unable to travel to Delaware for trial; obviously, the parties can work together on a discovery schedule that

minimizes the travel burdens placed on third parties to the extent they must be deposed prior to trial. Likewise, the location of any documents in Florida does not favor transfer as Apotex has made now showing as to why those documents could not be produced in Delaware. *Jumara,* 55 F. 3d at 879*; Auto. Techs.,* 2006 WL 3783477, at *2 ("Here, the Defendants do not suggest that their documents could not be produced in Delaware, especially in this day and age where large-scale 'document' products are reduced to digitized records that parties transfer via electronic media. Accordingly, this factor does not weigh in favor of granting transfer.").

Moreover, these unsupported facts cited by Apotex to not establish that Florida was the situs of operative events that lead to the litigation. D.I. 11 at 10-11. Apotex admits that the Canadian company, Apotex Inc., prepared and filed the ANDA from its offices in Canada. D.I. 12 ¶ 5. Apotex does not allege that any of the research and development, patent prosecution, or marketing activities with respect to the reference drug Uroxatral took place in Florida. *Compare Alcon Mfg., Ltd. v. Apotex Inc.,* No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026, at *2-3 (S.D. Ind. Mar. 14, 2007) (finding that operative events took places where Apotex prepared its ANDA and where plaintiffs conducted research and development) *to Bristol-Myers Squibb Co. v. Andrx Pharms., LLC,* No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (noting that the design and development of the allegedly infringing product occurred in the second-filed forum). To the extent that any of Apotex Corp.'s acts to induce or contribute to Apotex Inc.'s infringement occurred in Florida, this factor may marginally support transfer, but is vastly outweighed by Plaintiffs' choice of forum, the first filed-rule, the interests of judicial economy, and the convenience of the parties and witnesses.

Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations, including at least one as a plaintiff, without moving

to transfer. *See, e.g., ZF Meritor LLC v. Eaton Corp.,* Civ. No. 06-623-SLR, slip op. at 3, (D. Del. June 13, 2007) (refusing to transfer where "[d]efendant is a billion-dollar company with nationwide operations that has litigated in Delaware on multiple occasions."); *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, Civil Action No. 03-1047 GMS, slip op. at 4 (D. Del. Mar. 5, 2004) ("Moreover, short of invoking judicial estoppel, the court finds many of the Defendants' arguments in favor of these factors to be disingenuous considering that [one of Defendants] have brought infringement actions in the District of Delaware on five previous occasions in the last three years."); *see also 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). In addition, Apotex Corp. is a Delaware corporation. Having enjoyed the benefits of doing business under Delaware law, it cannot complain about proceeding in this judicial forum. Based on these facts, Apotex can surely be expected to bear any minimal, unsupported inconvenience of proceeding in Delaware as it would be greatly outweighed by the burden on sanofi-aventis of proceeding in two separate fora for discovery and other pretrial proceedings, as well as the burden on sanfoi-aventis's and third party witnesses who will likely be called for deposition by Apotex in Florida and by the other 13 defendants in Delaware.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to the Southern District of Florida. *See Alcon*, 2007 WL 854026 at *2-3. The *Alcon* court rejected Apotex's arguments, including its convenience claims. 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.*

The facts here are analogous to those in *Alcon* with a significant addition—there are related actions pending in this District that will proceed regardless of where Plaintiffs' claims against Apotex are litigated. If this case is transferred to Florida, both this Court and the Florida court will have to become experts in the technology-in-suit, construe the claims of the patents-in-suit, rule on summary judgment and generally manage discovery on identical issues. Additionally, sanofi-aventis will be forced to conduct the same pretrial activities in each forum while its witnesses and those of third parties are needlessly forced to appear for deposition in multiple actions. These public and private burdens substantially outweigh any claimed inconvenience to Apotex. [11]

II. As the First-Filed Forum, This Court Should Decide The Issue Of Venue And Not Stay This Case Pending Final Resolution Of The Florida Action

Apotex provides absolutely no argument or authority in support of its request that the Court stay this action—while the two related cases in this forum proceed—pending final resolution of the Florida action. D.I. 11 at 3, 14. Plaintiffs respectfully request that the Court

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[11] Balancing the remaining *Jumara* factors does not favor transfer as Apotex has made no showing that (1) either Florida or Delaware would not be able to enforce a judgment against any of the parties; (2) Florida has any specialized interest in resolving a federal patent dispute concerning drugs that are or would be sold throughout the country; (3) the public policies of Florida and Delaware differ with respect to the enforcement of patent rights or in balancing the competing interests of the Hatch-Waxman Act; or (4) that there are any state law issues that either the Florida or Delaware courts have more familiarity with.

retain this action for coordinated proceedings with the two related cases pending before it. Staying this action pending final resolution of the Florida case would mean that two courts will have to deal with the same issues if Plaintiffs must proceed in two fora at the same time. Plaintiffs have moved the Florida court to transfer the action before it to this District, or in the alternative, to stay that action pending this Court's resolution of the parties' venue disputes. Plaintiffs expect that the Florida court will transfer the case before it to this District or defer to this Court under the first-filed rule on deciding where this case should proceed.

CONCLUSION

For all the foregoing reasons, sanofi-aventis requests that the Court deny Defendants' motion to transfer this action to the Southern District of Florida or to stay this case pending final resolution of that second-filed case.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
James W. Parrett (#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
jdesmarais@kirkland.com
gflattmann@kirkland.com
wvuk@kirkland.com

January 31, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 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
Kenneth L. Dorsney, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on January 31, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
Kenneth L. Dorsney, 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/ Maryellen Noreika

Maryellen Noreika (#3208)

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

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

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER DENYING AS MOOT DEFENDANTS' MOTION FOR EXTENSION OF TIME AND PLAINTIFFS' MOTION TO FILE SCHEDULING REPORT

THIS CAUSE came before the Court upon Defendants' Motion for Extension of Time to Comply with Requirements of Local Rule 16.1 or, in the Alternative to File Unilateral Scheduling Report and Proposed Scheduling Order **(D.E. No. 29)**, filed on **January 31, 2008**, and Plaintiffs' Motion to File Scheduling Report and Proposed Scheduling Order **(D.E. No. 30)** filed on **February 1, 2008**.

THE COURT has considered the motions and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motions are DENIED as moot as the Court issued a scheduling order in this case on **January 3, 2008**.

DONE AND ORDERED in Chambers at Miami, Florida, this 8th day of February, 2008.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

FILING FEE
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974666
Clarence Maddox, Clerk

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. /

FILED by D.C.
FEB - 7 2008
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

MOTION FOR LIMITED APPEARANCE, CONSENT TO DESIGNATION AND REQUEST TO ELECTRONICALLY RECEIVE NOTICES OF FILING

In accordance with Local Rule 4B of the Special Rules Governing the Admission and Practice of Attorneys of the United States District Court for the Southern District of Florida, the undersigned respectfully moves for the admission of John M. Desmarais, of the firm Kirkland & Ellis LLP, for the purposes of limited appearance as co-counsel on behalf of sanofi-aventis and sanofi-aventis U.S. LLC herein, in the above-styled case only, and pursuant to Rule 2B, Southern District of Florida, CM/ECF Administrative Procedures, to permit John M. Desmarais to receive electronic filings in this case, and in support thereof states as follows:

1. John M. Desmarais is not admitted to practice in the Southern District of Florida and is a member in good standing of the Bar of the State of the New York.

2. Movant, Alfred J. Saikali, Esquire, of the law firm of Shook Hardy & Bacon is a member in good standing of the Florida Bar and the United States District Court for the Southern

District of Florida, maintains an office in this State for the practice of law, and is authorized to file through the Court's electronic filing system. Movant consents to be designated as a member of the Bar of this Court with whom the Court and opposing counsel may readily communicate regarding the conduct of the case, upon whom filings shall be served, who shall be required to electronically file all documents and things that may be filed electronically, and who shall be responsible for filing documents in compliance with the CM/ECF Administrative Procedures, See Section 2B of the CM/ECF Administrative Procedures.

3. In accordance with the local rules of this Court, John M. Desmarais has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. John M. Desmarais, by and through designated counsel and pursuant to Section 2B, Southern District of Florida, CM/ECF Administrative Procedures, hereby requests the Court to provide Notice of Electronic Filings to John M. Desmarais at email address: jdesmarais@kirkland.com.

WHEREFORE, Alfred J. Saikali moves this Court to enter an Order permitting John M. Desmarais to appear before this Court on behalf of sanofi-aventis and sanofi-aventis U.S. LLC for all purposes relating to the proceedings in the above-styled matter and directing the Clerk to provide notice of electronic filings to John M. Desmarais.

Dated: February 7, 2008

LAW OFFICES
SHOOK, HARDY & BACON L.L.P.
MIAMI CENTER, SUITE 2400, 201 SOUTH BISCAYNE BOULEVARD, MIAMI, FLORIDA 33131-4332 •TELEPHONE (305) 358-5171

Respectfully submitted,

Alfred J. Saikali (Fla. Bar No. 178195)
asaikali@shb.com
SHOOK HARDY & BACON, LLP
Miami Center
201 S. Biscayne Blvd., Suite 2400
Miami, FL 33131-4332
Telephone: (305)358-5171
Facsimile: (305)358-7470
Attorney for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a copy of the foregoing was faxed and mailed this 7th day of February, 2008 to **Stephen J. Bronis, Esq.** and **Jennifer Coberly, Esq.**, ZUCKERMAN SPAEDER LLP, *Attorneys for Defendants*, 201 S. Biscayne Blvd., Suite 900, Miami, FL 33131.

BY_____
ALFRED J. SAIKALI
FL. Bar No. 178195

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. /

CERTIFICATION OF JOHN M. DESMARAIS

John M. Desmarais, Esquire, pursuant to Rule 4B of the Special Rules Governing the Admission and Practice of Attorneys, hereby certifies that (1) I have studied the Local Rules of the United States District Court for the Southern District of Florida; and (2) I am a member in good standing of the Bar of the State of New York.

Dated: January 18, 2008

John M. Desmarais
jdesmarais@kirkland.com
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022-4611
(212) 446-4800

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. /

ORDER GRANTING MOTION FOR LIMITED APPEARANCE OF JOHN M. DESMARAIS, CONSENT TO DESIGNATION AND REQUEST TO ELECTRONICALLY RECEIVE NOTICES OF ELECTRONIC FILINGS

THIS CAUSE having come before the Court on the motion for Limited Appearance of John M. Desmarais and Consent to Designation, requesting, pursuant to Rule 4B of the Special Rules Governing the Admission and Practice of Attorneys in the United States District Court for the Southern District of Florida, permission for a limited appearance of John M. Desmarais in this matter and request to electronically receive notice of electronic filings. This Court having considered the motion and all other relevant factors, it is hereby

ORDERED and ADJUDGED that:

The Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Electronic Filings is GRANTED. John M. Desmarais is granted to appear and participate in this action on behalf of sanofi-aventis and sanofi-aventis U.S. LLC. The Clerk shall provide electronic notification of all electronic filings to John M. Desmarais at: jdesmarais@kirkland.com.

DONE AND ORDERED in Chambers at _____, Florida this _____ day of _____, 2008.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Alfred J. Saikali, Esq.
asaikali@shb.com
SHOOK HARDY & BACON LLP
Miami Center, Suite 2400
201 S. Biscayne Blvd.
Miami, Florida 33131
Tel: 305-358-5171
Fax: 305-358-7470

Stephen J. Bronis
sbronis@zuckerman.com
Jennifer Coberly
jcoberly@zuckerman.com
ZUCKERMAN SPAEDER LLP
201 South Biscayne Blvd., Suite 900
Miami, FL 33131
Tel: 305-358-5000
Fax: 305-579-9749

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' OPPOSITION TO DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully oppose Defendants Apotex Corp. and Apotex Inc.'s (collectively "Apotex") Motion For Entry of a Protective Order. D.I. 25-1. Sanofi-aventis agrees that the parties' exchange of confidential information should eventually be made under a Protective Order. Entry of such an order would be premature at this time, however, as two motions to transfer and/or stay this action are currently pending before the Court, and sanofi-aventis has moved the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer this action to the District of Delaware and consolidate it with three related actions pending in that district for pretrial purposes. *See* D.I. 5, Plaintiffs' Motion to Stay or Transfer, D.I. 32, Plaintiffs' Emergency Motion to Stay Pending JPML Decision; Ex. 1, Plaintiffs' JPML Motion and Brief.[1] In the likely event, in view of the motion practice before this Court, the Delaware court, and the Panel, that sanofi-aventis's claims

[1] True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of Alexis Gorton in Support of Plaintiffs' Opposition to Defendants' Motion For Entry of a Protective Order.

proceed against Apotex in Delaware, the parties will have to negotiate with the 13 additional defendants in the related Delaware actions on an appropriate Protective Order. Consequently, any order entered by this Court will likely be reconsidered or vacated in Delaware, especially if the order fails to provide adequate safeguards to protect the parties' confidential information, as Apotex's proposal so clearly does. Moreover, the parties will be unduly burdened by the cost of reviewing and processing for production hundreds of thousands, if not millions, of pages of documents under protective orders entered by this Court and the Delaware court with potentially different or even conflicting standards. Accordingly, the Court should not enter a Protective Order at this time, but should revisit the issue in the event that this action is not stayed or transferred to the District of Delaware.

I. The Court Is Currently Considering Two Motions To Transfer And/Or Stay This Action That Would Render Apotex's Protective Order Motion Moot

This is a second-filed action based on Apotex's infringement of United States Patent No. 4,661,491 ("the '491 patent"), a patent assigned to Plaintiff sanofi-aventis and listed in the FDA's Orange Book for Plaintiff sanofi-aventis U.S. LLC's drug Uroxatral®, by Apotex's Abbreviated New Drug Application ("ANDA") which seeks FDA approval for the commercial manufacture, sale and use of a generic version of that drug. A parallel first-filed action, involving the same claims, defenses, and counterclaims, is pending against Apotex in the District of Delaware. [2]

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[2] This suit is brought under the Hatch-Waxman Act, which provides a patentee with a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed. *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 enjoys the benefits of a suit under the Act, including a 30-month stay of generic approval during patent litigation (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 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. Sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent and designated it as related to two earlier-filed complaints against 13 other ANDA defendants. Ex. 2, Apotex Delaware Complaint; Ex. 3, Actavis *et al.* Delaware Complaint; Ex. 4, Barr Delaware Complaint. Sanofi-

(Continued…)

Two related actions are also pending in Delaware against 13 other defendants for infringement of the '491 patent and/or United States Patent No. 6,149,940 ("the '940 patent"), another patent listed in the Orange Book for Uroxatral® for which Plaintiff sanofi-aventis is an assignee and which is the subject of Apotex's counterclaims in both the Delaware and Florida actions. All three Delaware cases are assigned to the same Judge and Magistrate Judge.

In the interests of judicial economy and the convenience of the parties and witnesses, sanofi-aventis moved to transfer this second-filed action to the District of Delaware on January 8, 2008. D.I. 5. In the alternative, sanofi-aventis requested that the Court stay this action pending resolution of any venue issues raised by Apotex in Delaware. *Id.* Briefing on the motion was completed on February 7. Since sanofi-aventis filed its motion, Apotex has in fact moved to transfer the Delaware action to this District or to stay it indefinitely pending the final resolution of this action. Sanofi-aventis opposed Apotex's motion and Apotex filed its reply today.

Additionally, on February 1, 2008, sanofi-avenis submitted for filing with the Panel a motion for transfer and consolidation pursuant to 28 U.S.C. § 1407. Ex. 1. In that motion, sanofi-aventis requested that the Panel transfer this action to the District of Delaware and consolidate it with the three actions currently pending in that district, including sanofi-aventis's

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aventis only brought the present action because Apotex would not consent to jurisdiction in Delaware before sanofi-aventis's 45-day window to bring suit expired. *See* D.I. 1 ¶ 19; Ex. 5, 12/06/07 W. Vuk ltr to B. Sherman. As courts have acknowledged, without a second-filed "protective" suit, sanofi-aventis may have been barred from bringing any suit against Apotex under the Act, and thus lost its right to a 30-month stay, if Apotex successfully challenged jurisdiction in Delaware. *See, e.g., PDL*, 2007 WL 2261386, at *2; *Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007); *Celgene Corp. v. Abrika Pharms., Inc.,* No. 06-5818, 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007). Apotex has since confirmed that it will not contest jurisdiction in Delaware, and sanofi-aventis has moved to transfer this action to that district. Ex. 6, Apotex Delaware Answer, ¶¶ 7-8, 10; D.I. 5. Sanofi-aventis refers the Court to D.I. 5 for a more thorough description of the procedural history of this action and the three related Delaware actions.

case against Apotex, for coordinated pretrial proceedings. Sanofi-aventis argues that transfer and consolidation are warranted because all four actions involve numerous common questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware. The motion was docketed by the Panel on February 5 and assigned MDL No. 1941, *In re Alfuzosin Patent Litigation*, and all 15 ANDA defendants must file their responses by February 25. The Panel's prior decisions from factually similar ANDA or patent actions demonstrate that the Panel is likely to grant sanofi-aventis's motion. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) (ordering transfer and consolidation of three ANDA actions to promote the just and efficient conduct of the litigations and to serve the convenience of the parties and witnesses); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005); *In re Mirtazapine Patent Litig.*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002); *In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976); *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999). Furthermore, sanofi-aventis filed an emergency motion with the Court on February 7 to stay this acting pending the Panel's decision. D.I. 32.

II. Entry Of A Protective Order At This Time That Will Be Reconsidered Or Vacated By The Transferee Court, Would Unduly Prejudice The Parties And Waste The Time And Resources Of This Court

Contrary to Apotex's implication, litigation in this forum is not well underway. To date the parties have merely exchanged initial disclosures and Apotex has served document requests and interrogatories. The parties have not held their initial case management conference with the Court and are continuing to meet and confer on issues such as the form of electronic production. And while Apotex chides sanofi-aventis for not producing documents, it fails to mention that Apotex has not produced a single document in this action or in the Delaware case—not even the portions of its ANDA that were provided to sanofi-aventis under Apotex's offer of confidential

access in their first Paragraph IV notification letter—though sanofi-aventis agreed to treat any documents produced by Apotex on an outside counsels eyes only basis.

Sanofi-aventis does not contend that discovery is "optional" or that a Protective Order is unnecessary, but believes that now is not the appropriate time for the parties to finalize or for the Court to enter such an order. Should the Court transfer this action or the Panel grant sanofi-aventis's motion to consolidate the four pending Uroxatral® actions in a single district, sanofi-aventis and all 15 ANDA defendants will have to negotiate the terms of a Protective Order that will adequately protect the confidentiality interests of all 17 concerned parties. Thus, the transferee court will likely reconsider or vacate any Protective Order entered here as the 13 other defendants in the Delaware actions will have had no input into the order. *See Astarte Shipping Co. v. Allied Steel & Export Serv.*, 767 F.2d 86, 87 (5th Cir. 1985) (noting that "[t]he transferee district court has the power and the obligation to modify or rescind any orders in effect in the transferred case which it concluded are incorrect."); *In re Upjohn Co. Antibiotic Cleocin Prods. Liab. Litig.,* 664 F.2d 114, 115 (6th Cir. 1981) (holding that the MDL transferee court had the power to vacate or modify protective orders issued by a transferor court); *see also Factory Mut. Ins. Co. v. Insteel Indus., Inc.*, 212 F.R.D. 301,303 (M.D.N.C. 2002) (". . . a transferee court has the authority to modify or to lift protective orders signed by another district court judge."). Consequently, the Court should not expend judicial resources familiarizing itself with the Protective Order issues in this case until there is a decision on where the action will proceed. *See Bankers Life & Cas. Co., v. Case,* No. 05 C 6532, 2005 WL 3542523, *1, 5 (N.D. Ill. Dec. 23, 2005) (considering, and granting, motion to transfer though motion for protective order to preserve evidence was also pending); *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) ("If the MDL motion is granted, all of the Court's time, energy, and acquired knowledge regarding this action and its pretrial procedures will be wasted."); *cf. Enplanar, Inc. v. Marsh*, 11 F.3d 1284, 1291 (5th Cir. 1994) ("The district court did not abuse its discretion in refusing to allow discovery concerning [Plaintiff's claims] pending the grant of the Defendants' change of venue motion regarding these claims.");

McDonnell Douglas Corp. v. Polin, 429 F.2d 30, 31 (3d Cir. 1970) (holding that non-transfer related discovery should only go forward after transfer issue was decided); *Sawgrass Sys. Inc. v. BASF Corp.,* 50 U.S.P.Q.2d 1692, 1693 (D.S.C. 1999) (holding that first-filed court should determine where action should proceed and that "discovery on the merits of the action should not be ordered before issues of venue and jurisdiction have been decided."); *Datasouth Comp. Corp. v. Three Dimensional Techs.*, *Inc.*, 719 F. Supp. 446, 454 (W.D.N.C. 1989) (transferring action and denying defendants' motion for a discovery protective order as "this discovery matter should be taken up with the district court [in the transferee forum].").

Moreover, to the extent the Protective Orders in this District and Delaware differ, sanofi-aventis will be prejudiced by having to provide discovery, not only on multiple occasions, but with the added cost and burden of having to review, process, and produce that information under different and potentially conflicting standards. This harm to sanofi-aventis is substantial as it expects, based on its investigation-to-date, to review hundreds of thousands, if not millions of pages, of documents for production. *See Am. Seafood v. Magnolia Processing, Inc.*, Nos. 92-1030, 92-1086, 1992 WL 102762, at *2 (E.D. Pa. May 7, 1992) (holding that "[t]he duplicative motion practice and discovery proceedings demonstrate that judicial economy and prejudice … weigh heavily in favor of [a] stay"). Apotex will face the same burden as it will have to abide by whatever Protective Order is entered in the transferee forum. There is little to weigh against this burden as sanofi-aventis has already represented that it will treat any documents produced by Apotex on an outside counsels eyes only basis until a Protective Order is issued in whichever forum this case proceeds.

III. Apotex's Proposed Order Fails To Adequately Safeguard The Parties' Interests

Furthermore, the Court should not enter Apotex's order as it will not adequately safeguard the confidential information likely to be exchanged between the parties and any relevant third parties in this case. For example, the description of information presumptively entitled to outside counsels eyes only treatment is incomplete as it fails to include various categories of information concerning financial data, third party agreements, and the research and

development of proposed future products or indications. D.I. 25-2 ¶ 4. Failure to include these categories could needlessly lead to disputes between the parties concerning the designation of their documents. Nor does the proposed order limit the individuals who may be present at a deposition in which confidential information is used or elicited from the deponent. *See id.* Additionally, sanofi-aventis, and potentially third parties, will likely be asked to disclose information that may be subject to the EU Privacy Directive and other member state privacy regulations, but the proposed order fails to include any provision for the return of such information in the event consent to disclosure is revoked or the Directive and regulations otherwise require return.[3] *See id.*

Despite these deficiencies, Apotex insists that sanofi-aventis should agree to its proposed order because ***counsel*** for sanofi-aventis agreed to a similar order in a completely unrelated action in which it represents a completely unrelated party. *See* D.I. 25-1 at 1, 3. Not surprisingly, Apotex cites to no authority that would bind a party in one case to the terms of a Protective Order agreed to by its counsel in another case for a different client. In the event that this case moves forward in this District, the Court should enter a Protective Order that addresses

[3] The proceeding discussion addresses only a subset of the problems with Apotex's proposal. The proposed order also, *inter alia*: (1) fails to provide for the disclosure of confidential and outside counsels eyes only information to translation, reprographic, and electronic discovery vendors which the parties must use to prepare for and conduct trial in this action (D.I. 25-2 ¶ 6); (2) improperly shifts the burden on the party seeking to disclose confidential information to an expert or technical consultant of moving the Court to resolve any disputes concerning the disclosure (*Id.* ¶ 6(d)(ii)); (3) unfairly limits the disclosure of confidential information to only one in-house attorney or business person and provides no framework for the parties to object to the receiving parties' designation of such a person or to make substitutions in good faith (*Id.* ¶ 6(b),(c)); and (4) fails to clearly define whether references to CONFIDENTIAL INFORMATION throughout the document refer to CONFIDENTIAL INFORMATION and/or OUTSIDE COUNSELS EYES ONLY information (*Id.* throughout).

the specific confidentiality concerns of the parties to this case.[4] For the reasons discussed above, Apotex's proposal is not that order.

CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Court deny the Defendants' Motion For Entry of a Protective Order.

Dated: February 11, 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

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

[4] In the event that the Court believes that a Protective Order is necessary at this time, sanofi-aventis will promptly negotiate with Apotex on the terms of a fair and comprehensive Protective Order that adequately safeguards the parties' confidentiality interests.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 11, 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

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.
/

DECLARATION OF ALEXIS GORTON IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER

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' Opposition to Defendants' Motion For Entry of a Protective Order. I have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 are true and accurate copies of Motion of Plaintiffs for Transfer to the District of Delaware Pursuant to 28 U.S.C. § 1407 and Brief in Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407, without exhibits, in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

2. Attached hereto as Exhibit 2 is a true and accurate copy of the Complaint, without exhibits, dated December 6, 2007 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 the Complaint, without exhibits, dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC*, *et al.*, Civil Action No. 07-572 (GMS) (MJT), in the District Court for the District of Delaware.

4. Attached hereto as Exhibit 4 is a true and accurate copy of the Complaint, without exhibits, dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Barr Laboratories, Inc.*, Civil Action No. 07-574 (GMS) (MJT), in the District Court for the District of Delaware.

5. Attached hereto as Exhibit 5 is a true and accurate copy of a letter dated December 6, 2007 from William T. Vuk to Dr. Bernard Sherman and Tammy McIntyre.

6. Attached hereto as Exhibit 6 is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Counterclaims dated January 2, 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.

I declare under penalty of perjury that the foregoing is true and accurate.

s/ Alexis Gorton

Alexis Gorton

February 11, 2008
New York, New York

EXHIBIT 1

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

PLAINTIFFS' MOTION TO TRANSFER
AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 Laboratories, Inc.*, No. 07-574 (GMS) (MPT), pending in that District. A list of the four pending actions identifying all parties and the presiding judges is attached hereto as the Schedule of Actions.

In support of transfer and consolidation, sanofi-aventis avers the following, more fully set forth in the accompanying brief in support of this motion:

1. All four actions for which transfer and consolidation are proposed involve the infringement, validity and enforceability of the same two patents: U.S. Patent No. 4,661,491 ("the '491 patent") titled "Alfuzosine Compositions and Use" and U.S. Patent 6,149,940 ("the '940 patent") titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate." Sanofi-aventis is the current assignee of the '491 patent and a co-assignee, with Jagotec AG, of the '940 patent.

2. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets. The '491 and '940 patents cover this product, and have been submitted to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) as patents that claim an alfuzosin hydrochloride product. Based on that submission, both patents have been listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

3. 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)). Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed

generic alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents.

4. As part of each ANDA, the submitting entity or entities included one or more allegations under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") 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 of the proposed generic product. Each Paragraph IV Certification sets out the grounds on which the submitting entity or entities allege that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product defined by the ANDA. In many cases, the grounds on which the submitting entity or entities alleged that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product were identical or very similar. For example, each Paragraph IV Certification against the '491 patent alleges that the claims are invalid as obvious over varying combination of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. And in each Paragraph IV Certification alleging non-infringement of the '940 patent, the ANDA filer argues that there is no infringement because the proposed generic product does not meet the '940 patent's layer limitation.

5. Apotex Inc. sent sanofi-aventis a Paragraph IV Certification, dated August 14, 2007, with respect to the '940 patent. Apotex Inc. then sent sanofi-aventis a second Paragraph IV Certification, dated October 25, 2007, with respect to the '491 patent.

6. Each of these filings was an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

7. Given that personal jurisdiction could be exercised against all 15 potential defendants in the District of Delaware, 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 the 13 defendants it elected to sue at that time[1] for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[2]

8. The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are: Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

9. In response to Apotex Inc.'s second Paragraph IV Certification, dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent, sanofi-aventis 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. That action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge.

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[1] 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.

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

10. The three Delaware actions are in their early stages. All 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. In its answer, Apotex conceded that jurisdiction and venue were proper in Delaware. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay. Sanofi-aventis filed its opposition brief on January 31, 2008. As of the date of this application, Apotex has not served its rely brief and no decision has been issued.

11. 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. 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.

12. Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over all 15 defendants, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct, representations made in their respective Paragraph IV Certification letters, and/or refusals to consent to jurisdiction in Delaware.

13. The District of Delaware can properly exercise personal jurisdiction over all defendants. However, given the uncertain consequences surrounding the potential challenges to personal jurisdiction in Delaware, sanofi-aventis had no choice but to bring second-filed actions

in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. Sanofi-aventis brought such second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007[3] and against Apotex on December 10, 2007.

14. 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. It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware.

15. On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's Complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's Complaint in the Delaware action against Apotex, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. The Florida action is also at an early stage.[4]

16. One business day after answering the Florida Complaint, on January 2, 2008, Apotex answered the Complaint in the first-filed Delaware action – conceding that jurisdiction

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[3] Sanofi-aventis commenced the following four second-filed actions, all of which have been dismissed: (1) *Sanofi-aventis et al. v. Torrent Pharma Inc. et al*, Case No. 1:07-cv-969 (W.D. Mich.) (filed September 27, 2007; dismissed October 18, 2007); (2) *Sanofi-aventis et al. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 1:07CV139 IMK (N.D.W.V.) (filed October 5, 2007; dismissed October 18, 2007); (3) *Sanofi-aventis et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case: 2:07-cv-14355 (E.D. Mich.) (filed October 12, 2007; dismissed December 3, 2007); and (4) *Sanofi-aventis et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 07 CV 5807 (BMM) (N.D. Ill.) (filed October 12, 2007; dismissed January 17, 2008).

[4] The Florida action has not progressed significantly further than the Delaware actions despite the fact that the court has issued a scheduling order. Notably no significant discovery has occurred: Apotex has served its Rule 26(a) Initial Disclosures–insufficient in that it discloses only one individual and one document category at an undisclosed location–and a set of 35 document requests. Sanofi-aventis has not served or responded to any discovery requests. Neither party has produced any documents, nor has a protective order been entered.

and venue were proper in Delaware – and asserted the same counterclaims. Sanofi-aventis filed its reply to Apotex's counterclaims in Delaware on January 3, 2008.

17. Sanofi-aventis moved to transfer the Florida action to Delaware or to stay the action pending resolution of the venue issues in the first-filed Delaware action on January 8, 2008 in the interests of judicial economy and efficiency and the convenience of the parties and witnesses. Apotex filed its opposition brief on January 28, 2008. As of the date of this application, sanofi-aventis has not served its rely brief and no decision has been issued.

18. The three Delaware actions and the Florida action described above all focus on the infringement, validity, enforceability, claim construction and scope of the same sanofi-aventis patent(s), the '491 patent and/or the '940 patent. Thus, these cases involve one or more common questions of fact. 28 U.S.C. § 1407(a).

19. Transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, will be the most convenient for the parties. 28 U.S.C. § 1407(a).

20. Additionally, transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, is in the interests of judicial economy in that it will promote just and efficient resolution of the cases. 28 U.S.C. § 1407(a). Transfer will also promote the certainty of patent rights and prevent duplicative actions in multiple districts thereby avoiding the possibility of inconsistent rulings.

21. Sanofi-aventis respectfully requests that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

This motion is based on the BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407, the pleading and papers on file herein, and such other matters as may be presented to the Panel at the time of hearing.

Dated: February 1, 2008

Respectfully submitted,

Gerald J. Flattmann, Jr./AG

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

Before the Judicial Panel on Multidistrict Litigation
MDL-_____- In re Alfuzosin Patent Litigation

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Actavis South Atlantic LLC; Aurobindo Pharma Ltd.; Aurobindo Pharma USA 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 Limited	D. Delaware	07-572	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendant:** Barr Laboratories, Inc.	D. Delaware	07-574	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	D. Delaware	07-792	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	S.D. Florida Miami Division	07-61800	Federico A. Moreno

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION
FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407

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I. INTRODUCTION

Sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 against 13 defendants that have been pending in Delaware since September 2007, *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).[1]

Transfer and consolidation in this manner are warranted because all four actions involve numerous questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware.

II. BACKGROUND

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. 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.

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[1] The names of all parties to the pending actions, and the assigned judges, are set out in the Schedule of Actions attached to Plaintiffs' motion.

Sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." (Ex. A). It is also a current assignee of United States Patent No. 6,149,940 ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] (Ex. B). Sanofi-aventis U.S. LLC sells alfuzosin hydrochloride 10 mg extended release tablets, covered by both the '491 and '940 patents, throughout the United States for the treatment of the signs and symptoms of benign prostatic hyperplasia under the brand name Uroxatral®. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 relating to Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets and in conjunction with that NDA, submitted both the '491 and '940 patents to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) for listing in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book").

A. In the Summer of 2007, Nine Abbreviated New Drug Applications Were Filed Seeking FDA Approval to Market Copies of Sanofi-aventis's Uroxatral® Brand Alfuzosin Hydrochloride Product

In the Summer of 2007, nine separate Abbreviated New Drug Applications ("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)). Each of these ANDAs seeks the FDA approval necessary for the submitting entity or entities to engage in the commercial manufacture, use and sale of generic copies of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the submitting entity or entities included an allegation under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of

[2] Jagotec AG is also a current assignee of the '940 patent. Sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

the proposed generic products and the grounds for those allegations. Each of these filings was an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). The commercialization of the generic ANDA drug products would be further acts of infringement. *See* 35 U.S.C. § 271(a), (b) and (c).

B. Because Personal Jurisdiction Was Available Against All Defendants In The District Of Delaware, Sanofi-aventis First Filed Actions In That District Against Each Of The 15 Defendants

Because personal jurisdiction exists over all of the entities involved in the submission of the infringing ANDAs and Paragraph IV Certifications in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) (the "Actavis Dkt.") and 07-574 (GMS) (MPT) (the "Barr Dkt.") 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] *See* Complaints (Actavis Dkt. 1; Barr Dkt. 1).[4] At the time of the 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 did not file an action against Apotex for infringement of the '940 patent. 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 the first-filed action, Civil Action No. 07-792 (GMS) (MPT) (the "Apotex DE Dkt."), against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent.

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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.

[4] The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

See Complaint (Apotex DE Dkt. 1). On January 2, 2008, Apotex answered the complaint 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* Apotex Delaware Answer ¶ 7 (Apotex DE Dkt. 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.

In each of the three first-filed Delaware actions, sanofi-aventis alleges infringement of either the '491 patent and/or the '940 patent based on the filing of the ANDAs and any subsequent commercialization. All three actions are designated as related cases and are proceeding before the same Judge and the same Magistrate Judge. The actions are in their early stages. As of January 7, 2008, all 15 defendants had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay the action against it. Sanofi-aventis filed its opposition brief on January 31, 2008. Apotex has not yet served its reply brief and no decision has been issued.

C. Because A Number Of Defendants Threatened To Challenge Personal Jurisdiction In The District Of Delaware, Sanofi-aventis Was Forced To File Five Parallel Actions In The Southern District Of Florida, The Northern District Of Illinois, The Eastern District Of Michigan, The Western District Of Michigan And The Northern District Of West Virginia

To litigate under the protections of the Hatch-Waxman Act, sanofi-aventis was required to file an action against each ANDA submitting party or parties within forty-five days of receiving notice of the Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Abbott*

Labs. v. Mylan Pharm., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).[5] 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. Prior to filing the Delaware actions, however, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct and/or representations made in their respective Paragraph IV Certification letters. Sanofi-aventis's concerns appeared justified when Apotex, Aurobindo, Mylan, Sun, and Torrent refused to consent to jurisdiction in Delaware during sanofi-aventis's strict 45-day window in which to bring suit.

The law remains 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. The consequences of losing the protections of the Hatch-Waxman Act, however, are clear and 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) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate

[5] A compendium of unpublished cases cited herein is attached as Ex. C.

the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

The District of Delaware can properly exercise personal jurisdiction over all 15 defendants in the three first-filed Delaware actions. Given the uncertain consequences surrounding the unlikely, but possible dismissal of any defendant from one of the Delaware actions, sanofi-aventis had no choice but to bring second-filed actions in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. As a result, sanofi-aventis brought second-filed actions within the statutory 45-day window 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. The second-filed suits against Aurobindo, Mylan, Sun, and Torrent have each been dismissed, leaving Apotex as the lone outstanding second-filed suit. [6]

1. Sanofi-aventis Filed A Second-Filed Action In The Southern District Of Florida Against Apotex Because Sanofi-aventis Knew Apotex Would Not Contest Personal Jurisdiction In That District

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[7] 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. G,

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[6] The docket sheets for the second-filed suits against Aurobindo, Mylan, Sun, and Torrent are attached as Ex. D.

[7] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. *See* 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 3-4; 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. (Ex. E). In fact, Apotex has also availed itself of the Delaware court as a plaintiff. *See* Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4. (Ex. F).

12/06/07 W. Vuk ltr to B. Sherman.) It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware. (Ex. H, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo.) Thus, On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON (the "Apotex FL Dkt.") in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's complaint in the first-filed Delaware action, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. *See* Florida Complaint (Apotex FL Dkt. 1).

Similar to the Delaware actions, the Florida action is in its early stages.[8] Sanofi-aventis did not serve its Complaint, yet Apotex filed an Answer and Counterclaims on December 28, 2007; one business day before Apotex answered the Delaware complaint. Sanofi-aventis filed its Reply to Apotex's counterclaims on January 17, 2008 and, prior to filing that reply, on January, 8, 2008, sanofi-aventis moved to transfer the Florida action to Delaware or to stay the Florida action pending the disposition of any transfer issues raised by Apotex in Delaware. Apotex filed its opposition brief on January 28, 2008. Sanofi-aventis has not yet served its reply brief and no decision has been issued. In summary, sanofi-aventis argued that transfer or stay of the Florida action is appropriate in the interests of judicial economy and efficiency to avoid the need for two federal courts to assess the same issues thereby leading to a waste of time and resources on

[8] While the Florida court has issued a scheduling order setting the trial date for October 2008, the action has not truly progressed significantly further than the Delaware actions. The parties have not had their initial case management conference with the judge and Plaintiffs have asked the Florida court to set the trial for June 2009 in its status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Notably no significant discovery has occurred: Rule 26(a) Initial Disclosures have been exchanged and Apotex has served its document requests; sanofi-aventis has not served or responded to any discovery requests; and neither party has produced any documents, nor has a protective order been entered.

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.

III. SUMMARY OF THE ARGUMENT

Each of the four pending actions involves issues that are not just common, but are essentially identical. For example, the same sanofi-aventis patents are at the core of all four pending actions. Moreover, all defendants are trying to make generic versions of the same product and contend that the patents they certified against are either not infringed, invalid over prior art and/or unenforceable based upon essentially the same arguments. Thus, the claims, defenses and counterclaims in all four actions will involve consideration of the same documents, technology, testimony, and legal theories. Centralization is necessary here to eliminate duplicative proceedings and discovery, prevent inconsistent pretrial rulings and conserve judicial resources. Because none of the four actions is near trial, and no significant discovery has taken place, consolidation and centralization is favored and should be ordered now, before substantial pretrial proceedings take place.

IV. ARGUMENT

A. The Applicable Standard

Section 1407(a) of Title 28 of the United States Code provides:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

28 U.S.C. § 1407. Patent cases, as noted by Congress, are particularly appropriate for transfer and consolidation. *See* H.R. No. 90-1130, 1st Sess. (1968).

B. Sanofi-aventis's Four Actions Involve Multiple Common Questions Of Fact And Law

Section 1407 requires consideration of whether the actions sought to be consolidated involve common questions of fact, whether consolidation will promote a just and efficient resolution of the parties' dispute, and whether transfer and consolidation will best serve the convenience of the parties and witnesses. *See* 28 U.S.C. § 1407; *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) ("[W]e find that these three actions involve common questions of fact, and that centralization under Section 1407 in the [first-filed District] will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."). Because the present situation with respect to sanofi-aventis's four actions meets each of these criteria, as described below, transfer and consolidation is warranted.

Sanofi-aventis's four pending actions satisfy the first requirement of Section 1407(a) by having numerous questions of fact and law in common. Although 28 U.S.C. § 1407(a) is phrased in terms of common questions of fact, the Panel also considers common questions of law when applying this standard. *See, e.g., In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005) (stating that, because all three actions sought to be consolidated involved claims that generic products infringed one or more of the same patents, "[t]he actions can thus be expected to share factual and legal questions . . . .").

The Panel's decision in *In re Desloratadine* is instructive here. 502 F. Supp. 2d at 1355. In that case, the patentee filed a complaint alleging patent infringement based upon the submission of ANDAs to the FDA against 21 defendants in the District of New Jersey. *Id.* Several defendants threatened to, and eventually did, challenge jurisdiction; thus the patentee

was forced to bring second-filed actions in other districts. The patentee moved the Panel to consolidate the actions in the first-filed forum where the majority of defendants already were in front of the court. Only two defendants objected to the consolidation, arguing that it would delay the resolution of the second-filed action–which was only proceeding against them. The Panel ordered consolidation and transferred the cases to the first-filed court, noting that "assigning the present actions to a single judge who can formulate a pretrial program that ensures that all pretrial proceedings will be conducted in a just and expeditious manner." *Id.* Here, 15 defendants are in front the District of Delaware, the first-filed court, and only Apotex is attempting to proceed in a different forum. Consolidation in front of the first-filed court–the District of Delaware–here is even more compelling than in *In re Desloratadine* because Apotex has consented to jurisdiction and admitted that venue is proper in Delaware.

"[T]ransfer 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). Here, however, the common issues of law and fact will predominate because all four actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product, and many of the defendants have raised the same defenses and counterclaims. *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 at 1361 (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]."). The defendants may have slightly different formulations or base their obviousness arguments on different combinations of

prior art, but that is not justification for denying a request for transfer and consolidation. *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("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.").

Unless the four actions are consolidated for all pretrial purposes, both the Delaware and Florida courts will be required to independently conduct the same complex analyses relating to claim construction, infringement, and patent validity issues. *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (noting that related patent infringement actions share factual and legal issues concerning validity and related questions.); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (same). For example, both courts would be required to construe terms from the claims of both patents. Thus, each court would have to consider the language of the claims, analyze the specification and study the file histories of both patents. These common considerations warrant consolidation. *Id.* (granting order to transfer and consolidate where multiple actions alleged infringement of patent by generic pharmaceutical products).

Similarly, because the validity of both patents are challenged in each case, both 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. Again, these factors warrant 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 Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998) (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin Patent Litig.*, MDL

No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (J.P.M.L. Feb. 5, 2001) (ordering transfer where four actions involved "validity of the same complex pharmaceutical patent").

Here, a more specific common issue stems from the fact that each ANDA filer, except Barr Laboratories, asserts the same non-infringement argument in their '940 patent Paragraph IV Certifications, namely that the proposed generic products do not meet the '940 patent's layer limitation. Absent centralization, both courts will be required to assess this claim construction issue in light of the language of the claims, specification and file history of the '940 patent, and will be required to consider the same extrinsic evidence such as expert testimony. Additionally, the common asserted defense of obviousness with respect to the '491 patent raised by every ANDA filer–including Apotex–that filed a '491 patent Paragraph IV Certification, also presents common issues. Each ANDA filer argues that that the '491 patent is invalid as obvious over combinations of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. Accordingly, it is clear that the four actions will involve common issues of obviousness with respect to the '491 patent and, absent centralization, both judges will be required to learn the technology behind the '491 patent and the state of the art in a complex pharmaceutical field involving technology, research and development that dates back nearly 30 years.

In sum, given the numerous questions of fact and law that are common to all four actions, transfer and consolidation under Section 1407(a) is appropriate and should be granted. *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 re Acacia Media Techs. Corp.*, 360 F. Supp. 2d at 1379.

C. Consolidation Will Promote A Just And Efficient Resolution Of Sanofi-aventis's Actions

Transfer and consolidation of the actions will also promote the just and efficient conduct of the actions, satisfying the second requirement of Section 1407(a) . As the Supreme Court noted, "Patent infringement litigation often raises difficult technical issues that are unfamiliar to the average trial judge." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank.*, 527 U.S. 627, 651 (1999). Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency. *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.'").

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. Without consolidation, each judge would not only need to learn the science underlying the patented method of treatment, the patented formulations, the prior art, and the prosecution histories of the '491 and the '940 patents, but also apply that understanding in construing the asserted patent claims and ruling on pretrial motions. The complexity of the issues coupled with the number of common defenses and counterclaims make these actions ripe for transfer and consolidation. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim

construction; and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Second, consolidation will prevent inconsistent pretrial rulings. For example, consolidation will prevent inconsistent claim construction rulings. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the judge to decide). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming. Without consolidation, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings. This is precisely the scenario that Section 1407 was designed to avoid. *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).

Third, consolidation will result in a more efficient discovery schedule for the parties and the court, avoiding duplicative written discovery, document productions, discovery motions and the like. Given that the same patents are at issue in all four of sanofi-aventis's 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 the four actions. *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").

Finally, consolidation is particularly desirable here because all four actions are in their early stages. As noted above, the parties have not exchanged any discovery, although Apotex has served a set of document requests, and no court has construed the claims or received claim construction briefs from the parties.

D. The Panel's Transfer And Consolidation Of Sanofi-aventis's Actions Will Best Serve The Convenience Of The Parties And Witnesses

Transfer and consolidation of the actions will be most convenient for the parties and witnesses. Consolidation will serve as a cost-saving measure to the parties by avoiding duplicative discovery and other pretrial burdens in relation to common issues. *See 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). Transfer and consolidation will "ensure that discovery will transpire but once and, at the same time, will also streamline the rest of the pretrial process through the involvement and supervision of only a single judge in a single district." *In re Celotex Corp. "Technifoam" Prods. Liab. Litig.*, 68 F.R.D. 502, 504 (J.P.M.L. 1975).

If discovery were to proceed in two courts in parallel, sanofi-aventis would be required to seek and provide the same discovery twice. Sanofi-aventis would also be forced to litigate claim construction issues and go through the summary judgment process twice. That would not

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 will also avoid subjecting witnesses to multiple depositions on identical subject matter. *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."). Sanofi-aventis expects that the parties will require at least 100 fact depositions.[9] Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications that may impact their ability to travel for deposition. 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.

These advantages outweigh any minor burdens placed on the parties by consolidation. For example, it is unlikely that Apotex–which conceded that jurisdiction and venue were proper in Delaware–can demonstrate any significant prejudice as a result of the transfer and consolidation of the actions for pretrial proceedings in the District of Delaware. Indeed, this is especially true given that Apotex admitted that its lone knowledgeable employee and sole

9 It is likely that the parties will seek deposition testimony from the eight inventors named on the patents and a variety of other witnesses with knowledge of the alleged prior art, Uroxatral®, the proposed generic product, including the decision to file, the preparation and submission of each of the nine ANDAs, the research, development and formulation pertaining to the proposed generic products, and marketing and regulatory issues.

category of documents related to its claims and defenses are located in Canada, not Florida. *See* Initial Disclosures (Ex. I). Furthermore, both Apotex Inc. and Apotex Corp. have litigated in the Delaware court on at least five separate occasions. (Ex. E, F). In any case, because consolidation by the Panel would be for pretrial proceedings only, the consolidation will not necessarily require Apotex's witnesses 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).

Defendants' counsel would also not be adversely affected by consolidation. Apotex's lead counsel is located in Chicago and would have to travel if the action proceeded in Delaware or Florida. In any case, the burden on counsel is of little importance when compared to the significant burden of duplicative discovery responsibilities on sanofi-aventis and its witnesses, including multiple depositions of the same witnesses on the same topics. Furthermore, any burden on counsel can be easily overcome. *See, e.g., In re Cygnus Telecommunications Tech., LLC*, 177 F. Supp. 2d 1375, 1376 (J.P.M.L. 2001) ("the judicious use of liaison counsel and lead counsel will eliminate the need for most counsel ever to travel to the transferee district.").

In sum, any burden on the defendants would be minimal and would be far outweighed by the prejudice to sanofi-aventis and its witnesses if required to conduct parallel litigation in two separate forums. Accordingly, this factor weighs strongly in favor of transfer and consolidation.

E. Coordinated Pretrial Proceedings Should Proceed In The United States District Court For The District Of Delaware

Once the Panel determines that centralization within a single forum is appropriate, the actions should be consolidated in the district that will best "serve the convenience of the parties and witnesses and promote the just and efficient conduct of th[e] litigation." *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has previously recognized the advantage of consolidating cases in a district where one of the actions is pending. *See, e.g., In re*

Mirtazapine Patent Litig., 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, 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 California*, 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. *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.

F. Consolidating The Actions For Pretrial Proceedings Would Serve The Purposes Of The Hatch-Waxman Act

Transfer and consolidation in this action is also consistent with the purposes of the Hatch-Waxman Act. Indeed, the Panel has recognized that "actions involving the validity of pharmaceutical patents, in which the entry of generic versions of drugs into the market is also at issue, are well-suited for transfer under Section 1407." *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has also noted that transfer and consolidation under Section 1407 is consistent with the "expedited" nature of ANDA litigation under the Hatch-Waxman Act. *Id.* (ordering transfer and consolidation of ANDA litigations and stating that the transfer "will have

the salutary effect of assigning the present actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious manner."); *see also In re Gabapentin*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (transferring and consolidating ANDA actions and dismissing as "misplaced" the defendants' argument that "transfer will engender further delays in a litigation in which time is of the essence"); *In re Nabumetone*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (same).

Further, consolidation of the pretrial proceedings against all defendants will ensure that the intent of Congress in enacting the Hatch-Waxman Act is not frustrated because all defendants will be placed on an equal footing in their bid to market a generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product. The Hatch-Waxman Act provides 180 days of exclusivity against competing generic manufacturers to the first filer of an ANDA that challenges the validity, enforceability or infringement of a patent listed in connection with a pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). In the present case, 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. In these circumstances, the Hatch-Waxman Act is intended to provide each of these "first-filers" with equal rights and opportunities to market their generic version of the drug.

For that reason, it is appropriate that the actions against all defendants proceed in the same district to provide a level playing field for each generic manufacturer in their bid to manufacture a generic version of sanofi-aventis's Uroxatral® brand drug product. Allowing a second-filed action related to just one ANDA to proceed in a different district would run counter to the purpose of the Hatch-Waxman Act, and could potentially prejudice the rights of the other defendants, particularly in circumstances where they cannot participate in the parallel actions.

Thus, the policy of the Hatch-Waxman Act also favors consolidation of all four actions in the District of Delaware where the first-filed actions are already pending against all defendants.

V. 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: February 1, 2008.

Respectfully submitted,

Gerald J. Flattmann, Jr. /AG

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

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 07-702

FILED
CLERK, U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2007 DEC -6 PM 3:02

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Apotex Inc. and Apotex Corp., 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, 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.

manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

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.

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.*

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 Apotex Inc. by virtue of, *inter alia,* its systematic and continuous contacts with Delaware, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Defendant Apotex Corp. by virtue of the fact that, *inter alia*, it is a Delaware corporation.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

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®.

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.

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.

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.

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) allegations to the FDA.

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.

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.

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.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '491 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 patent, including any extensions;

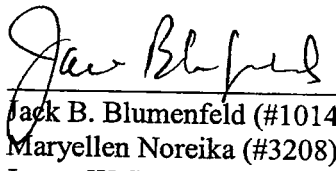
C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 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 (#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
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022

December 6, 2007

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, vs. ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA 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 LIMITED, Defendants.	C.A. No. - 07 - 572

FILED
2007 SEP 21 PM 4:02
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd. ("Aurobindo Ltd."), Aurobindo Pharma USA Inc. ("Aurobindo Inc."), Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc. ("Par"), Ranbaxy Inc., Ranbaxy Laboratories Limited ("Ranbaxy Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva"), Torrent Pharma Inc. ("Torrent Inc.") and Torrent Pharmaceuticals Ltd. ("Torrent Ltd."), 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, Defendant Actavis is a Delaware limited liability company having a place of business at 13800 NW 2nd Street, Ste-190, Fort Lauderdale, Florida 33325.

4. Upon information and belief, Defendant Aurobindo Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

5. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Aurobindo Inc.

6. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, Defendant Par is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

8. Upon information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Ltd., having a place of business at 600 College Road East, Princeton, New Jersey 08540.

9. Upon information and belief, Defendant Ranbaxy Ltd. is an Indian corporation having a place of business at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Upon information and belief, Defendant Ranbaxy Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Ranbaxy Inc.

10. Upon information and belief, Defendant Sun Inc. was a Michigan corporation, and the wholly-owned subsidiary and agent of Defendant Sun Ltd., having a place of business at 29714 Orion CT, Farmington Hills, Michigan 48334 at the time it submitted its Abbreviated New Drug Application. Upon information and belief, Sun Inc. dissolved as a corporation on or about July 15, 2007. Upon information and belief, Defendant Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

11. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., itself and through its wholly-owned subsidiary and agent Defendant Sun Inc., manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Teva is a Delaware corporation having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

13. Upon information and belief, Defendant Torrent Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Torrent Ltd., having a place of business at 3585 Bellflower Drive, Portage, Michigan 49024.

14. Upon information and belief, Defendant Torrent Ltd. is an Indian company having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India. Upon information and belief, Defendant Torrent Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Torrent Inc.

Nature of the Action

15. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940 patent") (Exhibit B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. 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.

18. This Court has personal jurisdiction over Defendant Actavis by virtue of the fact that, *inter alia*, Actavis is a Delaware limited liability company.

19. This Court has personal jurisdiction over Defendant Aurobindo Inc. by virtue of the fact that, *inter alia*, Aurobindo Inc. is a Delaware corporation.

20. This Court has personal jurisdiction over Defendant Aurobindo Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Aurobindo Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Aurobindo Inc.

21. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

22. This Court has personal jurisdiction over Defendant Par by virtue of the fact that, *inter alia*, Par is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Ranbaxy Inc. by virtue of the fact that, *inter alia*, Ranbaxy Inc. is a Delaware corporation.

24. This Court has personal jurisdiction over Defendant Ranbaxy Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy Inc.

25. This Court has personal jurisdiction over Defendant Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

26. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Sun Inc.

27. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

28. This Court has personal jurisdiction over Defendant Torrent Inc. by virtue of the fact that, *inter alia*, Torrent Inc. is a Delaware corporation.

29. This Court has personal jurisdiction over Defendant Torrent Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Torrent Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Torrent Inc.

30. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents

31. 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®.

32. 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 Orange Book for Uroxatral®.

Acts Giving Rise to this Action

Count I – Infringement of the '491 Patent by Defendants Actavis and Par

33. Upon information and belief, Actavis submitted Abbreviated New Drug Application ("ANDA") 79-055 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 79-055 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.

34. Actavis alleged in ANDA 79-055 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 ANDA 79-055 on or about August 17, 2007.

35. Actavis' submission of ANDA 79-055 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). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

36. Par is jointly and severally liable for Actavis' infringement of the '491 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

37. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 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, Par's

commercial manufacture, use, offer for sale or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

38. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '491 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

39. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement of the '940 Patent by Defendants Actavis and Par

40. ANDA 79-055 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 '940 patent.

41. Actavis has alleged in ANDA 79-055 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' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

42. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

43. Par is jointly and severally liable for Actavis' infringement of the '940 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or

induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

44. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 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). Par's commercial manufacture, use, offer for sale or sale of its proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

45. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '940 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

46. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count III – Infringement of the '491 Patent by Defendants Aurobindo Ltd. and Aurobindo Inc.

47. Upon information and belief, Aurobindo Ltd., through its subsidiary and agent Aurobindo Inc., submitted ANDA 79-060 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 79-060 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.

48. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

49. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

50. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '491 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

51. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 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, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

52. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

53. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IV – Infringement of the '940 Patent by Defendants Aurobindo Ltd. and Aurobindo Inc.

54. ANDA 79-060 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 '940 patent.

55. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

56. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo 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). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

57. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '940 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

58. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 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, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

59. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

60. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count V – Infringement of the '491 Patent by Defendant Mylan

61. Upon information and belief, Mylan submitted ANDA 79-014 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 79-014 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.

62. Mylan alleged in ANDA 79-014 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 ANDA 79-014 on or about August 27, 2007.

63. Mylan's submission of ANDA 79-014 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). Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

64. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '491 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

65. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VI – Infringement of the '940 Patent by Defendant Mylan

66. ANDA 79-014 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 '940 patent.

67. Mylan alleged in ANDA 79-014 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' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

68. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Mylan has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-014. However, given Mylan's claim of bioequivalence contained within ANDA 79-014, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation

or discovery that will demonstrate that Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

69. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '940 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

70. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VII – Infringement of the '940 Patent by Defendants Ranbaxy Ltd. and Ranbaxy Inc.

71. Upon information and belief, Ranbaxy Ltd., through its subsidiary and agent Ranbaxy Inc., submitted ANDA 79-006 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 79-006 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 '940 patent.

72. Ranbaxy Ltd. alleged in ANDA 79-006 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' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-006 on or about August 14, 2007.

73. Ranbaxy Ltd.'s submission of ANDA 79-006 to the FDA, through Ranbaxy 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). Ranbaxy Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

74. Ranbaxy Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted and/or induced Ranbaxy Ltd.'s submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

75. Ranbaxy Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-006 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, Ranbaxy Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

76. This is an exceptional case under 35 U.S.C. § 285 because Ranbaxy Ltd. and Ranbaxy Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-006 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

77. Plaintiffs will be irreparably harmed by Defendant Ranbaxy Ltd.'s and Defendant Ranbaxy Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VIII – Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.

78. Upon information and belief, Sun Inc. acting as a subsidiary and agent of Sun Ltd., submitted ANDA 79-057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 79-057 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 79-057 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 '940 patent.

79. Sun Inc. alleged in ANDA 79-057 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' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-057 on or about September 6, 2007.

80. Sun Inc.'s submission of ANDA 79-057 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Inc. has provided no information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-057. However, given Sun Inc.'s claim of bioequivalence contained within ANDA 79-057, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Sun Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

81. Sun Ltd. is jointly and severally liable for Sun Inc.'s infringement of the '940 patent. Upon information and belief, Sun Ltd. participated in, contributed to, aided, abetted and/or induced Sun Inc.'s submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

82. Sun Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-057 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). Sun Ltd.'s

commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

83. This is an exceptional case under 35 U.S.C. § 285 because Sun Inc. and Sun Ltd. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-057 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

84. Plaintiffs will be irreparably harmed by Defendant Sun Inc.'s and Defendant Sun Ltd.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IX – Infringement of the '491 Patent by Defendant Teva

85. Upon information and belief, Teva submitted ANDA 79-056 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 79-056 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.

86. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

87. Teva's submission of ANDA 79-056 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). Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

88. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '491 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

89. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count X – Infringement of the '940 Patent by Defendant Teva

90. ANDA 79-056 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 '940 patent.

91. Teva alleged in ANDA 79-056 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' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

92. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Teva has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-056. However, given Teva's claim of bioequivalence contained within ANDA 79-056, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or

discovery that will demonstrate that Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

93. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '940 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

94. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XI – Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.

95. Upon information and belief, Torrent Ltd., through its subsidiary and agent Torrent Inc., submitted ANDA 79-054 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 79-054 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.

96. Torrent Ltd. alleged in ANDA 79-054 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 ANDA 79-054 on or about August 16, 2007.

97. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its

proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

98. Torrent Inc. is jointly and severally liable for any infringement of the '491 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced Torrent Ltd.'s submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

99. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 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). Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

100. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

101. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XII – Infringement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.

102. ANDA 79-054 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 '940 patent.

103. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid and not

infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

104. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent 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). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

105. Torrent Inc. is jointly and severally liable for Torrent Ltd.'s infringement of the '940 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

106. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 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, Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

107. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

108. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent 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 Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Inc. and Torrent Ltd. have infringed the '491 patent;

B. That all Defendants have infringed the '940 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs identified in this Complaint shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;

D. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Ltd. and Torrent Inc., 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 versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

E. 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 versions of sanofi-aventis' 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;

F. That this case is exceptional under 35 U.S.C. § 285;

G. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

H. 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
KIRKLAND & ELLIS, LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022
(212) 446-4800

Dated: September 21, 2007

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	C.A. No. - 07 - 574 -

FILED
2007 SEP 21 PM 4:
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendant Barr Laboratories, Inc. ("Barr"), 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, Defendant Barr is a Delaware corporation having a place of business at 2 Quaker Road, Pomona, New York 10970.

Nature of the Action

4. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940

patent") (Exhibit B). This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Barr by virtue of the fact that, *inter alia*, Barr is a Delaware corporation.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents

8. 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 *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

9. 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

AG has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.

Count I – Infringement of the '491 Patent

10. Upon information and belief, Defendant Barr submitted Abbreviated New Drug Application ("ANDA") 79-052 to the United States Food and Drug Administration ("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 alfusozin hydrochloride per tablet. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfusozin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

11. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

12. Defendant Barr's submission of ANDA 79-052 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). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

13. This is an exceptional case. Barr was aware of the existence of the '491 patent at the time of the submission of ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

14. Plaintiffs will be irreparably harmed by Defendant Barr's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement of the '940 Patent

15. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfusozin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

16. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 the § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

17. Defendant Barr's submission of ANDA 79-052 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

18. This is an exceptional case under 35 U.S.C. § 285 because Barr was aware of the existence of the '940 patent at the time of the submission of ANDA 79-052 and its § 505 (j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

19. Plaintiffs will be irreparably harmed by Defendant Barr'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 Defendant Barr has infringed the '491 patent and the '940 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Barr's ANDA 79-052 shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;

C. That Defendant Barr, its 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 its proposed generic version of sanofi-aventis' Uroxatral® brand product, and any other product that infringes or induces or contributes to the infringement of the '491 patent or the '940 patent, prior to the expiration of those patents, 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 in 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

Dated: September 21, 2007

EXHIBIT 5

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

William T. Vuk
To Call Writer Directly:
212 446-4757
wvuk@kirkland.com

December 6, 2007

By Federal Express
and Electronic Mail

Dr. Bernard Sherman
Chairman & C.E.O.
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9
bsherman@apotex.com

Tammy McIntyre
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326
tmcintyre@apotex.com

Re: Apotex Inc.'s ANDA 79-013

Dear Dr. Sherman and Ms. McIntyre:

Enclosed are (1) a courtesy copy of the Complaint filed today by sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") against Apotex Inc. and Apotex Corp. (collectively "Apotex") in the United States District Court for the District of Delaware, and (2) copies of two Complaints from related cases previously filed by sanofi-aventis in the District of Delaware with respect to other generic challengers of Uroxatral®.

Please let me know by noon on Monday December 10, 2007 if Apotex will consent to jurisdiction in Delaware.

Sincerely,

William T. Vuk/ng

William T. Vuk

enclosures
cc by email:
Bernice Tao (btao@apotex.com)
Apotex Inc.

Jack Blumenfeld, Esq.
Morris Nichols Arsht & Tunnell

EXHIBIT 6

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)
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

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' OPPOSITION TO PLAINTIFFS' EMERGENCY MOTION TO STAY PENDING JPML DECISION AND SUPPORTING MEMORANDUM OF LAW

Sanofi's "emergency" motion for a stay of this action pending a decision by JPML on its 28 U.S.C. §1407 motion to transfer should be denied. There is no emergency here. Only a sense of déjà vu. Sanofi already has filed multiple similar motions seeking to stay this case or to otherwise slow it down. The Court has rejected each of Sanofi's proposals (including most recently in an order entered just last week) and has maintained its discovery and trial schedule in place since January. It should do so again here.

THE ONLY PARTY THAT BENEFITS FROM A STAY IS SANOFI

Filing of a JPML transfer motion does not require this action to be stayed, and certainly does not make this an "emergency". JPML Rule 1.5 expressly says so.

> 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.

JPML Rule 1.5 (emphasis added).

Reading this JPML rule in conjunction with the Hatch-Waxman Act, which requires ANDA cases such as this to be decided quickly and for the parties to cooperate in expediting the action, militates against a stay here. *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"); 21 U.S.C. § 355 (j)(5)(B)(iii)("In such an action, each of the parties shall reasonably cooperate in expediting the action.").

In deciding whether to stay an action, courts consider and weigh the following factors: (1) potential prejudice to the non-moving party; (2) hardship and inequity to the moving party if the action is not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases are in fact consolidated."). *E.g., Baxa Corp. v. ForHealth Techs.,* 2006 U.S. Dist. LEXIS 28583 (M.D. Fla. 2006); *Rivers v. Walt Disney Co.,* 980 F. Supp. 1358, 1360 (C.D. Cal. 1997). Each of these factors weigh against a stay.

Apotex will be prejudiced by a stay of this proceeding. This Court already entered a scheduling order and set a trial date for October, 2008. Any significant delay of discovery will potentially impact this trial date and thus Apotex's ability to get its generic alfuzosin product to market sooner. Discovery already is well underway – with initial disclosures already having been served, document production and interrogatory requests pending, and a motion for entry of a Protective Order already on file. Apotex has made every effort to proceed expeditiously in accordance with the requirements of the Hatch-Waxman Act and this Court's scheduling orders. Sanofi already has tried numerous tactics to slow down this litigation, and thus preserve its monopoly on the alfuzosin market, with corresponding prejudice to Apotex's ability to get generic alfuzosin to market.

Sanofi will not be burdened in any significant way by proceeding with this litigation. Sanofi complains that without a stay it will be subjected to duplicative discovery if its 28 U.S.C. §1407 motion ultimately is granted by the JPML. (Sanofi br. at 15). Regardless of whether a stay is issued, the parties will engage in the same discovery. Whether it happens now or later, there will not be duplication. There is no reason to delay the inevitable discovery that will take place.

Continuing with the pretrial activities, many of which are already in progress, will not waste judicial resources. To the contrary, any discovery in this case will be conducted regardless of what district this matter proceeds in. To the extent that any other pretrial activities or rulings occur, any other court presiding over the matter (should this case be transferred) will benefit from the work already done on those issues in this Court. And the rulings in this Court will help to narrow if not resolve the issues remaining to everyone's benefit.

CONCLUSION

For the foregoing reasons, Sanofi's motion to stay pending JPML decision should be denied together with such other relief is just and proper under the circumstances.

Dated: February 13, 2008

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 February 13, 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

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

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

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER GRANTING MOTION FOR LIMITED APPEARANCE, CONSENT TO DESIGNATION AND REQUEST TO ELECTRONICALLY RECEIVE NOTICES OF FILING

THIS CAUSE came before the Court upon Plaintiff's Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing **(D.E. No. 38)**, filed on **February 11, 2008**.

THE COURT has considered the motion and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motion is GRANTED and John M. Desmarais is permitted to appear before this Court on behalf of Plaintiffs in the above-styled matter.

DONE AND ORDERED in Chambers at Miami, Florida, this 14th day of February, 2008.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and 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' EMERGENCY MOTION TO STAY PENDING JPML DECISION

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this reply brief in further support of their emergency motion to stay this action pending the decision of the Judicial Panel on Multidistrict Litigation ("the Panel") on sanofi-aventis's motion for transfer and consolidation. The headline of Defendants Apotex Inc. and Apotex Corp.'s (collectively "Apotex") opposition—"The Only Party That Benefits From A Stay Is Sanofi"—demonstrates Apotex's complete disregard for the fact that the present action is only one of four related suits involving 17 total parties in two separate courts. *See* D.I. 41-1 at 1. A stay is necessary to conserve judicial resources, avoid inconsistent rulings, prevent witnesses from being deposed multiple times on identical issues and ensure that all 15 ANDA defendants proceed on equal footing as well as to prevent sanofi-aventis from having to conduct duplicative discovery and other pretrial activities in separate fora. These significant benefits can only be

achieved with the limited stay requested by sanofi-aventis and vastly outweigh any alleged burden claimed by Apotex.[1]

I. STAYS ROUTINELY GRANTED BY COURTS PENDING PANEL DECISIONS ARE COMPLETELY CONSISTENT WITH THE GOALS OF THE HATCH WAXMAN ACT

Apotex correctly notes that a motion pending before the Panel does not automatically stay the district court litigations, however, nothing in the Panel's rules preclude a party from seeking or a court from granting a stay. *See* D.I. 41-1 at 1. Indeed, courts do routinely stay actions subject to transfer and consolidation to preserve judicial resources and avoid undue burden to the parties and witnesses. D.I. 32 at 10-11. In fact, this Court has recognized that it is "common practice" to grant such stays to "increase efficiency and consistency, particularly when the transferor court believes that a transfer order is likely and when the pending motions raise issues likely to be raised in other cases as well." *Bonenfant v. R. J. Reynolds Tobacco Co.*, No. 07-60301-CIV, 2007 WL 2409980, at *1 (S.D. Fla. July 31, 2007); *see also Rivers v. Walt Disney Co.*, 980 F. Supp. 1358, 1362 (C.D. Cal. 1997) ("[I]t appears that a majority of courts have concluded that it is often appropriate to stay preliminary pretrial proceedings while a motion to transfer and consolidate is pending with the MDL Panel because of the judicial resources that are conserved."). As explained in sanofi-aventis's motion, and completely ignored by Apotex, the Panel is likely to transfer this action to Delaware for consolidated pretrial

[1] In mocking sanofi-aventis for filing its motion on an "emergency" basis (D.I. 41-1 at 1), Apotex ignores the underlying considerations which provide good cause for treating this motion under S.D. Fla. L.R. 7.1.E. *See* D.I. 32 at 17-18. By waiving the time requirements of S.D. Fla. L.R. 7.1 and holding an immediate hearing on the issues addressed in the motion, the Court will avoid wasting judicial resources in deciding other pending motions and prevent undue burden to sanofi-aventis of having to conduct duplicative discovery in this District and Delaware under potentially different standards and confidentiality obligations that may have to be redone once the actions are consolidated in a single district for pretrial proceedings. *Id.* These concerns are immediate and warrant emergency treatment.

proceedings because: (1) all four actions share common issues of law and fact; (2) transfer and consolidation will promote judicial efficiency and avoid inconsistent rulings; and (3) transfer and consolidation will serve the convenience of the parties and witnesses. D.I. 32 at 11-13 Moreover, and contrary to Apotex's unsupported claims, a brief stay pending the Panel's decision is not prejudicial, as this Court has recognized. *Republic of Venez. v. Philip Morris Cos., Inc.*, No. 99-0586-Civ, 1999 WL 33911677, at *1 (S.D. Fla. Apr. 28, 1999).

Apotex is absolutely wrong when it reads the Panel's rules and the Hatch-Waxman Act to mandate that ANDA cases "must be decided quickly" and should not be subject to a stay pending a Panel decision. *See* D.I. 41-1 at 2. In fact, the court in *Schering Corp. v. Caraco Pharmaceutical Laboratories, Ltd.* recently came to exactly the opposite conclusion. No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007). In that case, the patentee brought an ANDA action against 21 defendants in New Jersey and a protective suit against two of those defendants in Michigan. *Id.* at *1. The patentee moved to stay the Michigan action to allow the New Jersey court to resolve the defendants' pending jurisdictional challenge. *Id.* Before the court ruled on that motion, the patentee filed a motion with the Panel to consolidate the Michigan and New Jersey actions. *Id.* The Michigan court stayed the second-filed case "pending a final determination by the JPML regarding consolidation of the cases." *Id.* at *3. In granting the motion, the court found that continuing the case would be unfairly prejudicial to the patentee and misuse the limited resources of the judiciary. *Id.* The same concerns that motivated the court in *Schering* are present here. If this action is not stayed, sanofi-aventis will be unfairly prejudiced and scarce judicial resources will be wasted.

There is no support for Apotex's repeated assertions that ANDA cases must be tried quickly with no regard to any other interests of the courts, the parties, and the witnesses. Cooperating to expedite under the Hatch-Waxman Act does not mean that the case should proceed as quickly as possible at all costs. As an initial matter, 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 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. Moreover, the Act expressly provides for a 30-month stay of FDA approval to afford the parties adequate time to litigate ANDA infringement actions 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, 578 (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.

Moreover, Apotex's conduct in the litigation to date, both here and in 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.[2] 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. Staying this action will place the ANDA defendants on equal footing. Indeed, the 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.

II. THE SIGNIFICANT BENEFITS OF THE REQUESTED STAY TO THE COURTS, WITNESSES AND OTHER PARTIES OUTWEIGH ANY ALLEGED BURDEN CLAIMED BY APOTEX

In its haste to argue that sanofi-aventis is merely acting to delay the litigation, Apotex fails to address the significant benefits that the requested limited stay would provide the courts, the witnesses and the parties.[3] First, a stay will promote judicial efficiency because if the Panel

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2 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* D.I. 31 at Ex. 10 ¶ 10. Apotex then confirmed during a meet and confer with Plaintiffs on January 7 that it would move to transfer the Delaware action to this District. *See* D.I. 6 at Ex. 14. But Apotex waited another three weeks before filing its motion to transfer, after the parties exchanged their local rule disclosures in Florida and after Apotex was entitled to serve document requests in this action. *See* D.I. 31 at Ex. 12. 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.

3 Contrary to Apotex's suggestion, sanofi-aventis's motion practice before the Court and the Panel has been motivated by a desire to avoid duplicative litigation and inconsistent rulings, not to "slow it down." *See* D.I. 41-1 at 1. In fact, sanofi-aventis would not have even brought this second-filed action if Apotex had timely confirmed that it would not contest jurisdiction in the first-filed Delaware court. D.I. 32 at 7-9. Furthermore, Apotex's assertion that the "Court has rejected each of Sanofi's proposals" is simply incorrect. D.I. 41-1 at 1. The Court has already extended the schedule once in response to sanofi-aventis's request (D.I. 23) and has not ruled on sanofi-aventis's motion to transfer or stay.

determines that this case should be transferred, as it likely will, a single district court will preside over all pretrial proceedings for all four Uroxatral® matters. D.I. 32 at 13-15. Without a stay, this Court will invest substantial time and energy in making pretrial rulings that may be reconsidered or vacated if the case is transferred to a different forum. *See 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) (granting motion to stay and noting that "[i]f the MDL motion is granted, all of the Court's time, energy, and acquired knowledge regarding this action and its pretrial procedures will be wasted.").

For example, absent a stay, this Court would have to enter a protective order, handle all discovery disputes, and conduct a Markman hearing. In the likely event that the Panel transfers this action, the transferee court will not "benefit from the work already done" in this District as Apotex suggests. D.I. 41-1 at 3. Rather, this Court's time and resources will have been wasted because the transferee court will likely modify or rescind any issued orders as they would be made without participation by the 13 other ANDA defendants in the related Delaware actions. *See Astarte Shipping Co. v. Allied Steel & Exp. Serv.*, 767 F.2d 86, 87 (5th Cir. 1985) (noting that "[t]he transferee district court has the power and the obligation to modify or rescind any orders in effect in the transferred case which it concludes are incorrect); *In re Upjohn Co. Antibiotic Cleocin Prods. Liab. Litig.,* 664 F.2d 114, 115 (6th Cir. 1981) (holding that the MDL transferee court had the power to vacate or modify protective orders issued by a transferor court); *see also Factory Mut. Ins. Co. v. Insteel Indus., Inc.*, 212 F.R.D. 301, 303 (M.D.N.C. 2002) ("[A]

transferee court has the authority to modify or to lift protective orders signed by another district court judge.").[4]

Second, Apotex does not address the fact that without a stay, witnesses will be subject to multiple depositions on identical subject matter. D.I. 32 at 15-16. All 15 ANDA defendants are likely to seek deposition testimony from the same witnesses: sanofi-aventis, its employees, and third-parties, many of whom reside outside of the United States and may not even be within the power of the federal courts. This means that the witnesses may be forced to travel and appear for deposition twice on identical subject matter if this action is not stayed. *See Anderson v. Merck & Co. Inc.*, 417 F.Supp.2d 842, 849 (E.D. Ky. 2006) (staying proceedings to "'provide for the convenience of the parties and witnesses and ... promote the just and efficient conduct' of complex matters") (quoting 28 U.S.C. § 1407).

Finally, a stay will prevent the parties from having to seek and provide discovery both in this Court and in the District of Delaware, where sanofi-aventis has claims pending against both the Apotex defendants as well as 13 other ANDA defendants. D.I. 32 at 15; *see Am. Seafood v. Magnolia Processing, Inc.*, Civ. A. Nos. 92-1030, 92-1086, 1992 WL 102762, at *2 (E.D. Pa. May 7, 1992) (holding that "[t]he duplicative motion practice and discovery proceedings demonstrate that judicial economy and prejudice … weigh heavily in favor of [a] stay"); *cf. Enplanar, Inc. v. Marsh*, 11 F.3d 1284, 1291 (5th Cir. 1994) ("The district court did not abuse its discretion in refusing to allow discovery concerning [Plaintiff's claims] pending the grant of the

[4] Similarly, without a stay, there is a risk that this Court and the Delaware court will issue inconsistent pretrial rulings that will again have to be modified or vacated after consolidation. *See Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft*, 48 F.Supp.2d 37, 43 (D.D.C. 1999); *Weinke v. Microsoft Corp.*, 84 F.Supp.2d 989, 990 (E.D. Wis. 2000) (granting motion to stay "in the interest of judicial economy and to avoid inconsistent results"); *D's Pet Supplies, Inc. v. Microsoft Corp.*, No. 99-76056, 99-76086, 99-76202, 00-70481, 2000 WL 34423492, at *1 (E.D. Mich. May 19, 2000) (staying proceedings to serve the interests of justice and minimize the risk of inconsistent rulings).

Defendants' change of venue motion regarding these claims."); *McDonnell Douglas Corp. v. Polin,* 429 F.2d 30, 31 (3d Cir. 1970) (holding that non-transfer related discovery should only go forward after transfer issue was decided); *Sawgrass Sys. Inc. v. BASF Corp.,* 50 U.S.P.Q.2d 1692, 1693 (D.S.C. 1999) (holding that first-filed court should determine where an action should proceed and that "discovery on the merits of the action should not be ordered before issues of venue and jurisdiction have been decided."). Sanofi-aventis will fully participate in discovery, but believes that discovery should occur in the forum where this action will actually proceed. Apotex's assertion that there is no risk of duplicative discovery completely ignores the existence of the related Delaware actions involving 13 other defendants. D.I. 41-1 at 3. Based on its investigation to date, sanofi-aventis expects to review hundreds of thousands, if not millions, of pages of documents for production. If this action is not stayed, sanofi-aventis runs the risk of having to produce its documents in different forms and under different confidentiality designations as agreed to by the parties or otherwise ordered by the courts in each action. Moreover, certain of the discovery requests served by Apotex in this case may be revised or eliminated altogether if the transferee court requires all of the ANDA defendants to propound both common and individual discovery requests.

Conversely, the burden to Apotex from a limited stay is minimal, if not nonexistent. The stay that sanofi-aventis requests will be in effect only until the Panel issues its decision. The defendants' responses in that matter are due on February 25 and sanofi-aventis will reply by March 3. Thus, there will be no indefinite delay in the litigation.

As the Court has recognized, a brief stay pending the Panel's decision is not prejudicial. *Republic of Venez.*, 1999 WL 33911677, at *1. Additionally, the short duration of the stay is particularly harmless here in light of the fact that this action is at an early stage. For example, 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. Moreover, the parties will continue to litigate their claims and defenses in Delaware along with the 13 other ANDA defendants appearing in that forum while the limited stay of this action is in force. Any burden Apotex may claim after accounting for these facts is outweighed by the benefits to the courts, other parties, and the witnesses as discussed above.

CONCLUSION

For the foregoing reasons, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully request that the Court enter an order staying all proceedings in this action until the Judicial Panel on Multidistrict Litigation decides Plaintiffs' motion for transfer and consolidation pursuant to 28 U.S.C. § 1407.

Dated: February 14, 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

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 14, 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.
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.
/

PLAINTIFFS' MOTION FOR PROTECTIVE ORDER
AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully move the Court to enter a Protective Order 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 decisions on sanofi-aventis's motions to transfer or stay and the Judicial Panel on Multidistrict Litigation's ("the Panel") decision on sanofi-aventis's motion for transfer and consolidation under 28 U.S.C. § 1407. Without a Protective Order, sanofi-aventis will be unduly burdened as it will be forced to provide discovery on multiple occasions in different fora, and under potentially different standards and confidentiality designations. Moreover, witnesses, many residing outside of the United States, will be subject to multiple depositions on identical subject matter. And two courts will be forced to manage discovery and address any disputes between the parties on these issues. There is little if any burden to Apotex to weigh against these considerations as the Protective Order can immediately

be lifted, if necessary, once the Court and the Panel decide sanofi-aventis's motions. Moreover, the parties will continue to litigate their claims and defenses in the District of Delaware in coordination with 13 other ANDA defendants in the related actions pending in that district.

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 Plaintiffs' Motion for Protective Order.

MEMORANDUM OF LAW

I. Motions To Transfer Or Stay Are Pending Before This Court And The Panel

This is a second-filed action based on Apotex's infringement of United States Patent No. 4,661,491 ("the '491 patent"), a patent assigned to Plaintiff sanofi-aventis and listed in the FDA's Orange Book for Plaintiff sanofi-aventis U.S. LLC's drug Uroxatral®, by Apotex's Abbreviated New Drug Application ("ANDA") which seeks FDA approval for the commercial manufacture, sale and use of a generic version of that drug. A parallel, first-filed action, involving the same claims, defenses, and counterclaims, is pending against Apotex in the District of Delaware. Two related actions are also pending in Delaware against 13 other defendants for infringement of the '491 patent and/or United States Patent No. 6,149,940 ("the '940 patent"), another patent listed in the Orange Book for Uroxatral® for which Plaintiff sanofi-aventis is an assignee and which is the subject of Apotex's counterclaims in both the Delaware and Florida actions. All three Delaware cases are assigned to the same Judge and Magistrate Judge.[1]

[1] Sanofi-aventis refers the Court to its Motion to Transfer or Stay (D.I. 5) for a complete account of the procedural history concerning these four actions.

In the interests of judicial economy and the convenience of the parties and witnesses, sanofi-aventis moved to transfer this second-filed action to the District of Delaware on January 8, 2008. D.I. 5. In the alternative, sanofi-aventis requested that the Court stay this action pending resolution of any venue issues raised by Apotex in Delaware. *Id.* Briefing on sanofi-aventis's motion was completed on February 7. Since sanofi-aventis filed its motion, Apotex has in fact moved to transfer the Delaware action to this District or to stay it indefinitely pending the final resolution of this action. Briefing on Apotex's motion was completed on February 11.

Additionally, on February 1, 2008, sanofi-avenis submitted for filing with the Panel a motion for transfer and consolidation pursuant to 28 U.S.C. § 1407. Ex. 1, JPML Motion and Brief.[2] In that motion, sanofi-aventis requested that the Panel transfer this action to the District of Delaware and consolidate it with the three actions currently pending in that district, including sanofi-aventis's case against Apotex, for coordinated pretrial proceedings. Sanofi-aventis argues that transfer and consolidation are warranted because all four actions involve numerous common questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware. The motion was docketed by the Panel on February 5 and assigned MDL No. 1941, *In re Alfuzosin Patent Litigation*, and all 15 ANDA defendants

[2] True and correct copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk In Support of Plaintiffs' Motion for Protective Order.

must file their responses by February 25.[3] Additionally, sanofi-aventis filed an emergency motion with the Court on February 7 to stay this action pending the Panel's decision. D.I. 32. Briefing on the emergency motion will be completed today.

II. Apotex Has Served Discovery Requests Concerning The Merits Of The Parties' Dispute Even Though The Court And The Panel Have Not Ruled On The Motions To Transfer Or Stay

Though motions to transfer or stay are pending before the Court and the Panel, Apotex has served both document requests and interrogatories on sanofi-aventis. Ex. 2, Apotex's Requests for Production; Ex. 3, Apotex's Interrogatories. Apotex's discovery requests concern the merits of the parties' patent dispute, such as claim construction, infringement, and validity, and not issues related to the venue motions. *See, e.g.,* Ex. 2 at Request Nos. 1-4 (patent prosecution), 6 (prior art), 8, 22 (research and development), 9 (licenses), and 16-19 (regulatory filings); Ex. 3 at Interrogatory Nos. 4 (claim construction), 5-6, 8-10 (validity), and 7 (infringement). Apotex has not otherwise sought discovery in support of its motion to transfer the Delaware action or in support of its opposition to sanofi-aventis's motions to transfer or stay in this Court.

III. The Court Should Issue A Protective Order To Stay Discovery On The Merits Pending Decisions On The Motions To Transfer Or Stay By The Court And The Panel

The Court should enter a Protective Order staying discovery on the merits of the parties' dispute until the Court and the Panel rule on sanofi-aventis's motions to transfer or stay. The

[3] The Panel's prior decisions from factually similar ANDA or patent actions demonstrate that the Panel is likely to grant sanofi-aventis's motion. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) (ordering transfer and consolidation of three ANDA actions to promote the just and efficient conduct of the litigations and to serve the convenience of the parties and witnesses); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005); *In re Mirtazapine Patent Litig.*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002); *In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976); *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999).

Protective Order will 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. Likewise, a Protective Order will conserve judicial resources and prevent potentially inconsistent rulings as only one court will need to address any disputes between sanofi-aventis and all 15 ANDA defendants concerning the scope and form of discovery. Apotex will not suffer as a result; the Protective Order can immediately be lifted, if necessary, when the Court and the Panel decide sanofi-aventis's motions. Moreover, the parties will continue to litigate their claims and defenses in Delaware in coordination with the 13 other ANDA defendants in that district while the Protective Order in this Court remains in force.

The Court has the power to limit the scope of discovery with a Protective Order pending the resolution of preliminary matters, such as motions to transfer. As an initial matter, "trial courts have broad powers to regulate or prevent discovery and such powers have always been freely exercised." *See, e.g.*, *Simons-Eastern Co. v. United States*, 55 F.R.D. 88, 89 (N.D. Ga. 1972) (internal citations omitted); *Dolgow v. Anderson*, 53 F.R.D. 661, 664 (E.D.N.Y. 1971). Under Rule 26(c), the Court may enter a Protective Order to limit or preclude discovery "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. Civ. P. 26(c); *see also Harris v. Amoco Prod. Co.*, 768 F.2d 669, 684 (5th Cir. 1985) (finding that Protective Orders should be granted upon a showing of good cause); *Glick v. McKesson & Robbins, Inc.*, 10 F.R.D. 477, 479 (W.D. Mo. 1950) (noting that the existence of good cause for a Protective Order "is a factual matter to be determined from the nature and character of the information sought by deposition or interrogatory weighed in the balance of the factual issues involved in each action."). The Rule further permits the Court to enter an order

"forbidding . . . discovery" and/or "specifying terms, including time and place, for . . . discovery." Fed. R. Civ. P. 26(c)(1)(A)-(B).

In particular, trial courts have the authority to grant a Protective Order or otherwise stay discovery pending a motion to transfer. *Enplanar, Inc. v. Marsh*, 11 F.3d 1284, 1291 (5th Cir. 1994) ("The district court did not abuse its discretion in refusing to allow discovery concerning [Plaintiff's claims] pending the grant of the Defendants' change of venue motion regarding these claims."); *McDonnell Douglas Corp. v. Polin,* 429 F.2d 30, 31 (3d Cir. 1970) (holding that non-transfer related discovery should only go forward after transfer issue was decided); *Sawgrass Sys. Inc. v. BASF Corp.,* 50 U.S.P.Q.2d 1692, 1693 (D.S.C. 1999) (holding that first-filed court should determine where an action should proceed and that "discovery on the merits of the action should not be ordered before issues of venue and jurisdiction have been decided."); *Narco Avionics, Inc. v. Sportsman's Mkt., Inc.,* No. 90-8056, 1991 WL 255669, *2 (E.D. Pa. Nov. 27, 1991) (staying discovery with the exception of a "limited number of properly targeted interrogatories" concerning jurisdiction pending motions to transfer and dismiss based on jurisdictional challenges); *cf. Chudasama v. Mazda Motor Corp.,* 123 F.3d 1353, 1367-70 (11th Cir. 1997) (holding that a district court abused its discretion by not staying discovery on the merits pending a motion to dismiss).[4]

[4] As discussed in Plaintiffs' Emergency Motion to Stay Pending JPML Decision (D.I. 32), the Court has recognized that it is "common practice" to stay actions pending a Panel decision to "increase [] efficiency and consistency, particularly when the transferor court believes that a transfer order is likely and when the pending motions raise issues likely to be raised in other cases as well." *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 Pharmaceutical Laboratories, Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich June 6, 2007) (staying second-filed ANDA action pending a Panel decision); *Anderson v. Merck & Co. Inc.*, 417 F.Supp.2d 842, 849 (E.D.Ky. Feb. 28, 2006) (staying proceedings to "'provide for the convenience of the parties and witnesses and ... promote the just and efficient conduct' of complex matters") (quoting 28 U.S.C. § 1407); *U.S. Bank v. Royal Indem. Co.*, No. CIV.A.3:02-

Here, there is good cause for entry of a Protective Order staying discovery on the merits pending decisions on the motions to transfer or stay. First, without a Protective Order, sanofi-aventis will be forced to respond to discovery requests both in this Court and in the District of Delaware, where it has claims pending against Apotex defendants and 13 other ANDA defendants. Second, in addition to having to produce its documents twice, sanofi-aventis runs the risk of having to produce in different forms and under different confidentiality designations as agreed to by the parties or otherwise ordered by the courts in each action. This is particularly true if the transferee forum has guidelines for the parties to use in their discussions concerning electronic discovery. *See* 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 Feb. 14, 2008). This burden is especially acute in the present action as sanofi-aventis, based on its investigation to date, expects to review hundreds of thousands, if not millions, of pages of documents for production. *Cf. Chudasama,* 123 F.3d at 1367 (recognizing cost burdens associated with responding to discovery requests); *Dolgow*, 53 F.R.D. at 664 ("A trial court has a duty, of special significance in lengthy and complex cases, ... to supervise and limit discovery to protect parties and witnesses from annoyance and excessive expense."). Third, Apotex's current document requests and interrogatories may be revised or eliminated altogether if the transferee court requires all of the ANDA defendants to propound both common and individual discovery requests. Fourth, all 15 ANDA defendants are likely to seek deposition testimony from sanofi-aventis, its employees, or third-parties, many of whom reside outside of the United States and

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CV-0853-P, 2002 WL 31114069, at *2 (N.D. Tex. Sept. 23, 2002) (granting motion to stay and noting that "[i]f the MDL motion is granted, all of the Court's time, energy, and acquired knowledge regarding this action and its pretrial procedures will be wasted.").

may not even be within the power of the federal courts, meaning that without a Protective Order the witnesses may be forced to travel and appear for deposition twice on identical subject matter.[5] *Enplanar,* 11 F.3d at 1291 (recognizing convenience to witnesses as a factor in holding that discovery on the merits proceed in transferee forum).

Finally, both this Court and the Delaware court will be required to rule on discovery disputes between the parties, and consequently be forced to become experts in the technology and other facts relevant to those disputes. Such duplicative efforts would waste judicial resources and may lead to inconsistent rulings between the two courts. As the court in *McDonnell Douglas* stated:

> Judicial economy requires that another district court should not burden itself with the merits of the action until it is decided that a transfer should be effected and such consideration additionally requires that the court which ultimately decides the merits of the action should also decide the various questions which arise during the pendency of the suit instead of considering it in two courts.

429 F.2d at 30; *see also Am. Seafood Inc. v. Magnolia Processing, Inc.*, Nos. 92-1030, 92-1086, 1992 WL 102762, at *2 (E.D. Pa. May 7, 1992) (holding that "[t]he duplicative motion practice and discovery proceedings demonstrate that judicial economy and prejudice … weigh heavily in favor of [a] stay"). Moreover, any orders issued by this Court concerning discovery will likely be reconsidered or vacated in the transferee court if the Panel grants sanofi-aventis's motion for transfer and consolidation as they would not have been made in consideration of the interests of the 13 other ANDA defendants in the related actions. *See Astarte Shipping Co. v. Allied Steel & Export Serv.*, 767 F.2d 86, 87 (5th Cir. 1985) (noting that "[t]he transferee district court has the power and the obligation to modify or rescind any order in effect in the transferred case which it

[5] It is likely that Apotex and the 13 additional ANDA defendants in Delaware will seek deposition testimony from the eight inventors named on the patents-in-suit and a variety of other witnesses with knowledge of the alleged prior art, research and development of Uroxatral®, as well as marketing and regulatory issues.

concludes are incorrect). The Court should, therefore, stay discovery on the merits at this time in the interest of judicial economy, to prevent inconsistent rulings, and to avoid undue burden on sanofi-aventis and the witnesses.

Apotex will undoubtedly repeat its allegation that sanofi-aventis is motivated by its belief that discovery is "optional;" that is simply not the case. Sanofi-aventis will fully participate in discovery, and expects Apotex to do the same, but believes that discovery should occur in the forum where this action will ultimately proceed to avoid the burdens discussed above. There is little, if any, burden to Apotex to weigh against these considerations. The Protective Order may be lifted immediately, if necessary, once the Court and the Panel decide sanofi-aventis's motions to transfer or stay. *See Enplanar, Inc. v. Marsh*, 11 F.3d at 1291; *Republic of Venez. v. Phillip Morris Cos., Inc.*, No. 99-0582-Civ, 1999 WL 33911677, at *1 (S.D. Fla. Apr. 28, 1999) (holding that a stay pending a Panel decision is not prejudicial); *Capital Eng'g & Mfg. Co., Inc. v. Weinberger*, No. 87-1623 JHP, 1988 WL 13272, *1 (D.D.C. Feb. 5, 1988). In the meantime, the parties will continue to litigate their claims and defenses in Delaware in coordination with the 13 other ANDA defendants there.

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: February 14, 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 February 14, 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.
/

[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION FOR PROTECTIVE ORDER

THIS CAUSE is before the Court on Plaintiffs' Motion for Protective Order, filed on February 14, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiffs' Motion for Protective Order is GRANTED. Discovery on the merits of this Civil Action is hereby STAYED until the Court decides Plaintiffs' Motion to Transfer or Stay (D.I. 5) and Plaintiffs' Emergency Motion to Stay Pending JPML Decision (D.I. 32) and the Judicial Panel on Multidistrict Litigation decides sanofi-aventis's motion for transfer and consolidation in MDL 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of February, 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.
/

DECLARATION OF WILLIAM T. VUK 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 sanofi-aventis and sanofi-aventis U.S. LLC in this action. I submit this declaration in support of Plaintiffs' Motion for Protective Order. I have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 are true and accurate copies of Motion of Plaintiffs for Transfer to the District of Delaware Pursuant to 28 U.S.C. § 1407 and Brief in Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407, without exhibits, in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

2. Attached hereto as Exhibit 2 is a true and accurate copy of Defendants' First Request For Production of Documents and Things to Plaintiff.

3. Attached hereto as Exhibit 3 is a true and accurate copy of Defendants' First Set of Interrogatories to Plaintiff.

s/ William T. Vuk

William T. Vuk

February 14, 2008
New York, New York

EXHIBIT 1

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

PLAINTIFFS' MOTION TO TRANSFER
AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 Laboratories, Inc.*, No. 07-574 (GMS) (MPT), pending in that District. A list of the four pending actions identifying all parties and the presiding judges is attached hereto as the Schedule of Actions.

In support of transfer and consolidation, sanofi-aventis avers the following, more fully set forth in the accompanying brief in support of this motion:

1. All four actions for which transfer and consolidation are proposed involve the infringement, validity and enforceability of the same two patents: U.S. Patent No. 4,661,491 ("the '491 patent") titled "Alfuzosine Compositions and Use" and U.S. Patent 6,149,940 ("the '940 patent") titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate." Sanofi-aventis is the current assignee of the '491 patent and a co-assignee, with Jagotec AG, of the '940 patent.

2. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets. The '491 and '940 patents cover this product, and have been submitted to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) as patents that claim an alfuzosin hydrochloride product. Based on that submission, both patents have been listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

3. 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)). Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed

generic alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents.

4. As part of each ANDA, the submitting entity or entities included one or more allegations under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") 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 of the proposed generic product. Each Paragraph IV Certification sets out the grounds on which the submitting entity or entities allege that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product defined by the ANDA. In many cases, the grounds on which the submitting entity or entities alleged that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product were identical or very similar. For example, each Paragraph IV Certification against the '491 patent alleges that the claims are invalid as obvious over varying combination of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. And in each Paragraph IV Certification alleging non-infringement of the '940 patent, the ANDA filer argues that there is no infringement because the proposed generic product does not meet the '940 patent's layer limitation.

5. Apotex Inc. sent sanofi-aventis a Paragraph IV Certification, dated August 14, 2007, with respect to the '940 patent. Apotex Inc. then sent sanofi-aventis a second Paragraph IV Certification, dated October 25, 2007, with respect to the '491 patent.

6. Each of these filings was an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

7. Given that personal jurisdiction could be exercised against all 15 potential defendants in the District of Delaware, 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 the 13 defendants it elected to sue at that time[1] for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[2]

8. The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are: Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

9. In response to Apotex Inc.'s second Paragraph IV Certification, dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent, sanofi-aventis 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. That action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge.

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[1] 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.

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

10. The three Delaware actions are in their early stages. All 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. In its answer, Apotex conceded that jurisdiction and venue were proper in Delaware. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay. Sanofi-aventis filed its opposition brief on January 31, 2008. As of the date of this application, Apotex has not served its rely brief and no decision has been issued.

11. 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. 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.

12. Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over all 15 defendants, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct, representations made in their respective Paragraph IV Certification letters, and/or refusals to consent to jurisdiction in Delaware.

13. The District of Delaware can properly exercise personal jurisdiction over all defendants. However, given the uncertain consequences surrounding the potential challenges to personal jurisdiction in Delaware, sanofi-aventis had no choice but to bring second-filed actions

in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. Sanofi-aventis brought such second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007[3] and against Apotex on December 10, 2007.

14. 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. It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware.

15. On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's Complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's Complaint in the Delaware action against Apotex, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. The Florida action is also at an early stage.[4]

16. One business day after answering the Florida Complaint, on January 2, 2008, Apotex answered the Complaint in the first-filed Delaware action – conceding that jurisdiction

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[3] Sanofi-aventis commenced the following four second-filed actions, all of which have been dismissed: (1) *Sanofi-aventis et al. v. Torrent Pharma Inc. et al*, Case No. 1:07-cv-969 (W.D. Mich.) (filed September 27, 2007; dismissed October 18, 2007); (2) *Sanofi-aventis et al. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 1:07CV139 IMK (N.D.W.V.) (filed October 5, 2007; dismissed October 18, 2007); (3) *Sanofi-aventis et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case: 2:07-cv-14355 (E.D. Mich.) (filed October 12, 2007; dismissed December 3, 2007); and (4) *Sanofi-aventis et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 07 CV 5807 (BMM) (N.D. Ill.) (filed October 12, 2007; dismissed January 17, 2008).

[4] The Florida action has not progressed significantly further than the Delaware actions despite the fact that the court has issued a scheduling order. Notably no significant discovery has occurred: Apotex has served its Rule 26(a) Initial Disclosures–insufficient in that it discloses only one individual and one document category at an undisclosed location–and a set of 35 document requests. Sanofi-aventis has not served or responded to any discovery requests. Neither party has produced any documents, nor has a protective order been entered.

and venue were proper in Delaware – and asserted the same counterclaims. Sanofi-aventis filed its reply to Apotex's counterclaims in Delaware on January 3, 2008.

17. Sanofi-aventis moved to transfer the Florida action to Delaware or to stay the action pending resolution of the venue issues in the first-filed Delaware action on January 8, 2008 in the interests of judicial economy and efficiency and the convenience of the parties and witnesses. Apotex filed its opposition brief on January 28, 2008. As of the date of this application, sanofi-aventis has not served its rely brief and no decision has been issued.

18. The three Delaware actions and the Florida action described above all focus on the infringement, validity, enforceability, claim construction and scope of the same sanofi-aventis patent(s), the '491 patent and/or the '940 patent. Thus, these cases involve one or more common questions of fact. 28 U.S.C. § 1407(a).

19. Transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, will be the most convenient for the parties. 28 U.S.C. § 1407(a).

20. Additionally, transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, is in the interests of judicial economy in that it will promote just and efficient resolution of the cases. 28 U.S.C. § 1407(a). Transfer will also promote the certainty of patent rights and prevent duplicative actions in multiple districts thereby avoiding the possibility of inconsistent rulings.

21. Sanofi-aventis respectfully requests that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

This motion is based on the BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407, the pleading and papers on file herein, and such other matters as may be presented to the Panel at the time of hearing.

Dated: February 1, 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

Before the Judicial Panel on Multidistrict Litigation
MDL-_____- In re Alfuzosin Patent Litigation

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Actavis South Atlantic LLC; Aurobindo Pharma Ltd.; Aurobindo Pharma USA 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 Limited	D. Delaware	07-572	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendant:** Barr Laboratories, Inc.	D. Delaware	07-574	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	D. Delaware	07-792	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC **Defendants:** Apotex Inc. and Apotex Corp.	S.D. Florida Miami Division	07-61800	Federico A. Moreno

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	**MDL Docket No.**

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION
FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407

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I. INTRODUCTION

Sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating 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 against 13 defendants that have been pending in Delaware since September 2007, *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).[1]

Transfer and consolidation in this manner are warranted because all four actions involve numerous questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware.

II. BACKGROUND

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. 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.

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[1] The names of all parties to the pending actions, and the assigned judges, are set out in the Schedule of Actions attached to Plaintiffs' motion.

Sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." (Ex. A). It is also a current assignee of United States Patent No. 6,149,940 ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] (Ex. B). Sanofi-aventis U.S. LLC sells alfuzosin hydrochloride 10 mg extended release tablets, covered by both the '491 and '940 patents, throughout the United States for the treatment of the signs and symptoms of benign prostatic hyperplasia under the brand name Uroxatral®. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 relating to Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets and in conjunction with that NDA, submitted both the '491 and '940 patents to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) for listing in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book").

A. In the Summer of 2007, Nine Abbreviated New Drug Applications Were Filed Seeking FDA Approval to Market Copies of Sanofi-aventis's Uroxatral® Brand Alfuzosin Hydrochloride Product

In the Summer of 2007, nine separate Abbreviated New Drug Applications ("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)). Each of these ANDAs seeks the FDA approval necessary for the submitting entity or entities to engage in the commercial manufacture, use and sale of generic copies of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the submitting entity or entities included an allegation under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of

[2] Jagotec AG is also a current assignee of the '940 patent. Sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

the proposed generic products and the grounds for those allegations. Each of these filings was an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). The commercialization of the generic ANDA drug products would be further acts of infringement. *See* 35 U.S.C. § 271(a), (b) and (c).

B. Because Personal Jurisdiction Was Available Against All Defendants In The District Of Delaware, Sanofi-aventis First Filed Actions In That District Against Each Of The 15 Defendants

Because personal jurisdiction exists over all of the entities involved in the submission of the infringing ANDAs and Paragraph IV Certifications in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) (the "Actavis Dkt.") and 07-574 (GMS) (MPT) (the "Barr Dkt.") 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] *See* Complaints (Actavis Dkt. 1; Barr Dkt. 1).[4] At the time of the 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 did not file an action against Apotex for infringement of the '940 patent. 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 the first-filed action, Civil Action No. 07-792 (GMS) (MPT) (the "Apotex DE Dkt."), against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent.

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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.

[4] The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

See Complaint (Apotex DE Dkt. 1). On January 2, 2008, Apotex answered the complaint 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* Apotex Delaware Answer ¶ 7 (Apotex DE Dkt. 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.

In each of the three first-filed Delaware actions, sanofi-aventis alleges infringement of either the '491 patent and/or the '940 patent based on the filing of the ANDAs and any subsequent commercialization. All three actions are designated as related cases and are proceeding before the same Judge and the same Magistrate Judge. The actions are in their early stages. As of January 7, 2008, all 15 defendants had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay the action against it. Sanofi-aventis filed its opposition brief on January 31, 2008. Apotex has not yet served its reply brief and no decision has been issued.

C. Because A Number Of Defendants Threatened To Challenge Personal Jurisdiction In The District Of Delaware, Sanofi-aventis Was Forced To File Five Parallel Actions In The Southern District Of Florida, The Northern District Of Illinois, The Eastern District Of Michigan, The Western District Of Michigan And The Northern District Of West Virginia

To litigate under the protections of the Hatch-Waxman Act, sanofi-aventis was required to file an action against each ANDA submitting party or parties within forty-five days of receiving notice of the Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Abbott*

Labs. v. Mylan Pharm., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).[5] 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. Prior to filing the Delaware actions, however, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct and/or representations made in their respective Paragraph IV Certification letters. Sanofi-aventis's concerns appeared justified when Apotex, Aurobindo, Mylan, Sun, and Torrent refused to consent to jurisdiction in Delaware during sanofi-aventis's strict 45-day window in which to bring suit.

The law remains 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. The consequences of losing the protections of the Hatch-Waxman Act, however, are clear and 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) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate

[5] A compendium of unpublished cases cited herein is attached as Ex. C.

the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

The District of Delaware can properly exercise personal jurisdiction over all 15 defendants in the three first-filed Delaware actions. Given the uncertain consequences surrounding the unlikely, but possible dismissal of any defendant from one of the Delaware actions, sanofi-aventis had no choice but to bring second-filed actions in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. As a result, sanofi-aventis brought second-filed actions within the statutory 45-day window 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. The second-filed suits against Aurobindo, Mylan, Sun, and Torrent have each been dismissed, leaving Apotex as the lone outstanding second-filed suit. [6]

1. Sanofi-aventis Filed A Second-Filed Action In The Southern District Of Florida Against Apotex Because Sanofi-aventis Knew Apotex Would Not Contest Personal Jurisdiction In That District

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[7] 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. G,

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[6] The docket sheets for the second-filed suits against Aurobindo, Mylan, Sun, and Torrent are attached as Ex. D.

[7] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. *See* 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 3-4; 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. (Ex. E). In fact, Apotex has also availed itself of the Delaware court as a plaintiff. *See* Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4. (Ex. F).

12/06/07 W. Vuk ltr to B. Sherman.) It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware. (Ex. H, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo.) Thus, On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON (the "Apotex FL Dkt.") in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's complaint in the first-filed Delaware action, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. *See* Florida Complaint (Apotex FL Dkt. 1).

Similar to the Delaware actions, the Florida action is in its early stages.[8] Sanofi-aventis did not serve its Complaint, yet Apotex filed an Answer and Counterclaims on December 28, 2007; one business day before Apotex answered the Delaware complaint. Sanofi-aventis filed its Reply to Apotex's counterclaims on January 17, 2008 and, prior to filing that reply, on January, 8, 2008, sanofi-aventis moved to transfer the Florida action to Delaware or to stay the Florida action pending the disposition of any transfer issues raised by Apotex in Delaware. Apotex filed its opposition brief on January 28, 2008. Sanofi-aventis has not yet served its reply brief and no decision has been issued. In summary, sanofi-aventis argued that transfer or stay of the Florida action is appropriate in the interests of judicial economy and efficiency to avoid the need for two federal courts to assess the same issues thereby leading to a waste of time and resources on

[8] While the Florida court has issued a scheduling order setting the trial date for October 2008, the action has not truly progressed significantly further than the Delaware actions. The parties have not had their initial case management conference with the judge and Plaintiffs have asked the Florida court to set the trial for June 2009 in its status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Notably no significant discovery has occurred: Rule 26(a) Initial Disclosures have been exchanged and Apotex has served its document requests; sanofi-aventis has not served or responded to any discovery requests; and neither party has produced any documents, nor has a protective order been entered.

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.

III. SUMMARY OF THE ARGUMENT

Each of the four pending actions involves issues that are not just common, but are essentially identical. For example, the same sanofi-aventis patents are at the core of all four pending actions. Moreover, all defendants are trying to make generic versions of the same product and contend that the patents they certified against are either not infringed, invalid over prior art and/or unenforceable based upon essentially the same arguments. Thus, the claims, defenses and counterclaims in all four actions will involve consideration of the same documents, technology, testimony, and legal theories. Centralization is necessary here to eliminate duplicative proceedings and discovery, prevent inconsistent pretrial rulings and conserve judicial resources. Because none of the four actions is near trial, and no significant discovery has taken place, consolidation and centralization is favored and should be ordered now, before substantial pretrial proceedings take place.

IV. ARGUMENT

A. The Applicable Standard

Section 1407(a) of Title 28 of the United States Code provides:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

28 U.S.C. § 1407. Patent cases, as noted by Congress, are particularly appropriate for transfer and consolidation. *See* H.R. No. 90-1130, 1st Sess. (1968).

B. Sanofi-aventis's Four Actions Involve Multiple Common Questions Of Fact And Law

Section 1407 requires consideration of whether the actions sought to be consolidated involve common questions of fact, whether consolidation will promote a just and efficient resolution of the parties' dispute, and whether transfer and consolidation will best serve the convenience of the parties and witnesses. *See* 28 U.S.C. § 1407; *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) ("[W]e find that these three actions involve common questions of fact, and that centralization under Section 1407 in the [first-filed District] will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."). Because the present situation with respect to sanofi-aventis's four actions meets each of these criteria, as described below, transfer and consolidation is warranted.

Sanofi-aventis's four pending actions satisfy the first requirement of Section 1407(a) by having numerous questions of fact and law in common. Although 28 U.S.C. § 1407(a) is phrased in terms of common questions of fact, the Panel also considers common questions of law when applying this standard. *See, e.g., In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005) (stating that, because all three actions sought to be consolidated involved claims that generic products infringed one or more of the same patents, "[t]he actions can thus be expected to share factual and legal questions . . . .").

The Panel's decision in *In re Desloratadine* is instructive here. 502 F. Supp. 2d at 1355. In that case, the patentee filed a complaint alleging patent infringement based upon the submission of ANDAs to the FDA against 21 defendants in the District of New Jersey. *Id.* Several defendants threatened to, and eventually did, challenge jurisdiction; thus the patentee

was forced to bring second-filed actions in other districts. The patentee moved the Panel to consolidate the actions in the first-filed forum where the majority of defendants already were in front of the court. Only two defendants objected to the consolidation, arguing that it would delay the resolution of the second-filed action–which was only proceeding against them. The Panel ordered consolidation and transferred the cases to the first-filed court, noting that "assigning the present actions to a single judge who can formulate a pretrial program that ensures that all pretrial proceedings will be conducted in a just and expeditious manner." *Id.* Here, 15 defendants are in front the District of Delaware, the first-filed court, and only Apotex is attempting to proceed in a different forum. Consolidation in front of the first-filed court–the District of Delaware–here is even more compelling than in *In re Desloratadine* because Apotex has consented to jurisdiction and admitted that venue is proper in Delaware.

"[T]ransfer 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). Here, however, the common issues of law and fact will predominate because all four actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product, and many of the defendants have raised the same defenses and counterclaims. *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 at 1361 (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]."). The defendants may have slightly different formulations or base their obviousness arguments on different combinations of

prior art, but that is not justification for denying a request for transfer and consolidation. *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("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.").

Unless the four actions are consolidated for all pretrial purposes, both the Delaware and Florida courts will be required to independently conduct the same complex analyses relating to claim construction, infringement, and patent validity issues. *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (noting that related patent infringement actions share factual and legal issues concerning validity and related questions.); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (same). For example, both courts would be required to construe terms from the claims of both patents. Thus, each court would have to consider the language of the claims, analyze the specification and study the file histories of both patents. These common considerations warrant consolidation. *Id.* (granting order to transfer and consolidate where multiple actions alleged infringement of patent by generic pharmaceutical products).

Similarly, because the validity of both patents are challenged in each case, both 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. Again, these factors warrant 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 Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998) (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin Patent Litig.*, MDL

No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (J.P.M.L. Feb. 5, 2001) (ordering transfer where four actions involved "validity of the same complex pharmaceutical patent").

Here, a more specific common issue stems from the fact that each ANDA filer, except Barr Laboratories, asserts the same non-infringement argument in their '940 patent Paragraph IV Certifications, namely that the proposed generic products do not meet the '940 patent's layer limitation. Absent centralization, both courts will be required to assess this claim construction issue in light of the language of the claims, specification and file history of the '940 patent, and will be required to consider the same extrinsic evidence such as expert testimony. Additionally, the common asserted defense of obviousness with respect to the '491 patent raised by every ANDA filer–including Apotex–that filed a '491 patent Paragraph IV Certification, also presents common issues. Each ANDA filer argues that that the '491 patent is invalid as obvious over combinations of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. Accordingly, it is clear that the four actions will involve common issues of obviousness with respect to the '491 patent and, absent centralization, both judges will be required to learn the technology behind the '491 patent and the state of the art in a complex pharmaceutical field involving technology, research and development that dates back nearly 30 years.

In sum, given the numerous questions of fact and law that are common to all four actions, transfer and consolidation under Section 1407(a) is appropriate and should be granted. *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 re Acacia Media Techs. Corp.*, 360 F. Supp. 2d at 1379.

C. Consolidation Will Promote A Just And Efficient Resolution Of Sanofi-aventis's Actions

Transfer and consolidation of the actions will also promote the just and efficient conduct of the actions, satisfying the second requirement of Section 1407(a) . As the Supreme Court noted, "Patent infringement litigation often raises difficult technical issues that are unfamiliar to the average trial judge." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank.*, 527 U.S. 627, 651 (1999). Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency. *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.'").

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. Without consolidation, each judge would not only need to learn the science underlying the patented method of treatment, the patented formulations, the prior art, and the prosecution histories of the '491 and the '940 patents, but also apply that understanding in construing the asserted patent claims and ruling on pretrial motions. The complexity of the issues coupled with the number of common defenses and counterclaims make these actions ripe for transfer and consolidation. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim

construction; and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Second, consolidation will prevent inconsistent pretrial rulings. For example, consolidation will prevent inconsistent claim construction rulings. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the judge to decide). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming. Without consolidation, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings. This is precisely the scenario that Section 1407 was designed to avoid. *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).

Third, consolidation will result in a more efficient discovery schedule for the parties and the court, avoiding duplicative written discovery, document productions, discovery motions and the like. Given that the same patents are at issue in all four of sanofi-aventis's 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 the four actions. *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").

Finally, consolidation is particularly desirable here because all four actions are in their early stages. As noted above, the parties have not exchanged any discovery, although Apotex has served a set of document requests, and no court has construed the claims or received claim construction briefs from the parties.

D. The Panel's Transfer And Consolidation Of Sanofi-aventis's Actions Will Best Serve The Convenience Of The Parties And Witnesses

Transfer and consolidation of the actions will be most convenient for the parties and witnesses. Consolidation will serve as a cost-saving measure to the parties by avoiding duplicative discovery and other pretrial burdens in relation to common issues. *See 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). Transfer and consolidation will "ensure that discovery will transpire but once and, at the same time, will also streamline the rest of the pretrial process through the involvement and supervision of only a single judge in a single district." *In re Celotex Corp. "Technifoam" Prods. Liab. Litig.*, 68 F.R.D. 502, 504 (J.P.M.L. 1975).

If discovery were to proceed in two courts in parallel, sanofi-aventis would be required to seek and provide the same discovery twice. Sanofi-aventis would also be forced to litigate claim construction issues and go through the summary judgment process twice. That would not

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 will also avoid subjecting witnesses to multiple depositions on identical subject matter. *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."). Sanofi-aventis expects that the parties will require at least 100 fact depositions.[9] Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications that may impact their ability to travel for deposition. 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.

These advantages outweigh any minor burdens placed on the parties by consolidation. For example, it is unlikely that Apotex–which conceded that jurisdiction and venue were proper in Delaware–can demonstrate any significant prejudice as a result of the transfer and consolidation of the actions for pretrial proceedings in the District of Delaware. Indeed, this is especially true given that Apotex admitted that its lone knowledgeable employee and sole

9 It is likely that the parties will seek deposition testimony from the eight inventors named on the patents and a variety of other witnesses with knowledge of the alleged prior art, Uroxatral®, the proposed generic product, including the decision to file, the preparation and submission of each of the nine ANDAs, the research, development and formulation pertaining to the proposed generic products, and marketing and regulatory issues.

category of documents related to its claims and defenses are located in Canada, not Florida. *See* Initial Disclosures (Ex. I). Furthermore, both Apotex Inc. and Apotex Corp. have litigated in the Delaware court on at least five separate occasions. (Ex. E, F). In any case, because consolidation by the Panel would be for pretrial proceedings only, the consolidation will not necessarily require Apotex's witnesses 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).

Defendants' counsel would also not be adversely affected by consolidation. Apotex's lead counsel is located in Chicago and would have to travel if the action proceeded in Delaware or Florida. In any case, the burden on counsel is of little importance when compared to the significant burden of duplicative discovery responsibilities on sanofi-aventis and its witnesses, including multiple depositions of the same witnesses on the same topics. Furthermore, any burden on counsel can be easily overcome. *See, e.g., In re Cygnus Telecommunications Tech., LLC*, 177 F. Supp. 2d 1375, 1376 (J.P.M.L. 2001) ("the judicious use of liaison counsel and lead counsel will eliminate the need for most counsel ever to travel to the transferee district.").

In sum, any burden on the defendants would be minimal and would be far outweighed by the prejudice to sanofi-aventis and its witnesses if required to conduct parallel litigation in two separate forums. Accordingly, this factor weighs strongly in favor of transfer and consolidation.

E. Coordinated Pretrial Proceedings Should Proceed In The United States District Court For The District Of Delaware

Once the Panel determines that centralization within a single forum is appropriate, the actions should be consolidated in the district that will best "serve the convenience of the parties and witnesses and promote the just and efficient conduct of th[e] litigation." *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has previously recognized the advantage of consolidating cases in a district where one of the actions is pending. *See, e.g., In re*

Mirtazapine Patent Litig., 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, 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 California*, 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. *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.

F. Consolidating The Actions For Pretrial Proceedings Would Serve The Purposes Of The Hatch-Waxman Act

Transfer and consolidation in this action is also consistent with the purposes of the Hatch-Waxman Act. Indeed, the Panel has recognized that "actions involving the validity of pharmaceutical patents, in which the entry of generic versions of drugs into the market is also at issue, are well-suited for transfer under Section 1407." *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has also noted that transfer and consolidation under Section 1407 is consistent with the "expedited" nature of ANDA litigation under the Hatch-Waxman Act. *Id.* (ordering transfer and consolidation of ANDA litigations and stating that the transfer "will have

the salutary effect of assigning the present actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious manner."); *see also In re Gabapentin*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (transferring and consolidating ANDA actions and dismissing as "misplaced" the defendants' argument that "transfer will engender further delays in a litigation in which time is of the essence"); *In re Nabumetone*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (same).

Further, consolidation of the pretrial proceedings against all defendants will ensure that the intent of Congress in enacting the Hatch-Waxman Act is not frustrated because all defendants will be placed on an equal footing in their bid to market a generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product. The Hatch-Waxman Act provides 180 days of exclusivity against competing generic manufacturers to the first filer of an ANDA that challenges the validity, enforceability or infringement of a patent listed in connection with a pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). In the present case, 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. In these circumstances, the Hatch-Waxman Act is intended to provide each of these "first-filers" with equal rights and opportunities to market their generic version of the drug.

For that reason, it is appropriate that the actions against all defendants proceed in the same district to provide a level playing field for each generic manufacturer in their bid to manufacture a generic version of sanofi-aventis's Uroxatral® brand drug product. Allowing a second-filed action related to just one ANDA to proceed in a different district would run counter to the purpose of the Hatch-Waxman Act, and could potentially prejudice the rights of the other defendants, particularly in circumstances where they cannot participate in the parallel actions.

Thus, the policy of the Hatch-Waxman Act also favors consolidation of all four actions in the District of Delaware where the first-filed actions are already pending against all defendants.

V. 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: February 1, 2008.

Respectfully submitted,

Gerald J. Flattmann, Jr. /AG

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

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' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTFF

Pursuant to Federal Rules of Civil Procedure 26 and 34, 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 and produce documents and things for inspection and copying at the offices of Welsh & Katz, LTD, 120 S. Riverside Plaza, Chicago, Illinois 60606, within thirty (30) days of the date of service of this request.

A Protective Order has not yet been entered in this case. Apotex agrees to treat all documents produced 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. **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.

H. The following **rules of construction** apply to these discovery requests, 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.

I. Each request to produce documents shall be construed to request documents within your possession, custody, or control. Separately for each Request, if any document responsive to that Request once was in your possession, custody, or

control but has been lost, discarded, destroyed, or is otherwise presently not within your possession, custody, or control:

i. identify the unavailable document;

ii. identify any and all persons who lost, discarded, or destroyed the document or caused the document to become otherwise unavailable;

iii. identify any and all persons likely to have knowledge concerning the circumstances by which the document was lost, discarded, destroyed, or otherwise became unavailable;

iv. identify any and all persons likely to have knowledge concerning the contents of the document that was lost, discarded, or otherwise became unavailable.

J. When producing documents, Plaintiff should produce the documents as they are kept in the ordinary course of business or organize and label them to correspond with the numbered categories in this Request.

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

L. If Plaintiff objects to any request or part of any request, the reason(s) for the objection shall be stated in full. If an objection is made to any request, production should be made of all documents or things to which the objection does not relate.

M. If any information, document or thing responsive to any of the following production requests is 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.

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

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

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

REQUESTS

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

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

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.

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 disclosures 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.

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 date(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.

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 the patents in suit.

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

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.

9. All documents and communications that refer or relate to any contemplated, proposed or actual licenses, 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.

10. All documents 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.

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.

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

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

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.

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 (1) 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.

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 described in the package insert.

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.

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.

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.

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.

21. All documents and communications evidencing the educational background and qualifications for each of 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.

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.

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.

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

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

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.

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.

28. All documents and communications by and between Sythelabo, Sanofi-Synthelabo, Jagotec AG, Jagotech 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.

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.

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.

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 α-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);

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).

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.

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

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.

Dated: January 18, 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.

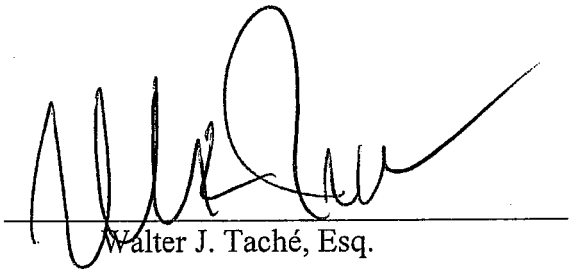
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by hand on January 18, 2008, to:

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

and by fax and mail to:

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



Walter J. Taché, Esq.

EXHIBIT 3

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.

Case 0:07-cv-61890-WJZ Document 145-4 Entered on FLSD Docket 02/14/2008 Page 12 of 12

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
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' REQUEST FOR ORAL ARGUMENT ON
PLAINTIFFS' MOTION FOR PROTECTIVE ORDER

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC, pursuant to S.D. Fla. L.R. 7.1B, respectfully request oral argument on Plaintiffs' Motion for Protective Order. Plaintiffs' motion addresses the complex factual and procedural history that lead to Plaintiffs filing of this action as well as their motion with the Judicial Panel on Multidistrict Litigation. Oral argument would be helpful as it would provide the parties with an opportunity to address these issues, and respond to the Court's questions on them, as well as the burdens faced by sanofi-aventis, the witnesses, and the Court in proceeding with discovery on the merits prior to ruling on the pending motions to transfer or stay.

Plaintiffs anticipate that the parties will require 10-15 minutes per side for oral argument.

Dated: February 14, 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 14, 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
Case No. 07-61800-CIV-MORENO/SIMONTON

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

DEFENDANTS' REPLY TO PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER

Sanofi admits that this case needs a protective order. It just does not want one in place now so that it can use the lack of protective order as a way to avoid having to participate in discovery in this case. Sanofi complains that it has filed several motions to transfer or otherwise stay this litigation, but none of those have been granted, and the reality is that the Court has set this case for trial on October 6, 2008 with a discovery cut-off of August 6, 2008. The Court has reiterated these dates in several orders (even with Sanofi's motions to transfer/stay pending), including most recently in an order of February 8, 2008 (Dkt. 36) rejecting Sanofi's proposal for a much more lengthy and delayed discovery and trial schedule. Although Sanofi wishes it were otherwise, this case is proceeding to trial. A protective order is needed. The one that Apotex proposed is one that Sanofi's lawyers have agreed to (indeed proposed) in a similar ANDA litigation. It should be entered.

I. Apotex's Proposed Protective Order is Not Premature.

Sanofi complains that a protective order in this case is premature. It is not. The parties have had their Rule 26(f) conference. Initial disclosures have been exchanged. Sanofi's responses to Apotex's document production requests are due February 18, 2008. A protective order is necessary to allow discovery to proceed uninterrupted.

Apotex's proposed protective order is a typical ANDA-litigation protective order. Apotex's proposed protective order has provisions for the parties to designate as confidential a document or tangible item that comprises or contains trade secrets or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c). The proposed protective order also has a provision for the parties to designate highly sensitive materials as "confidential, outside counsel eyes only." In short, it adequately safeguards the parties' legitimate interests. To the extent that Sanofi had concerns about the content of this protective order, it had every opportunity to suggest revisions or changes. Instead, although Sanofi is plaintiff, it has chosen to stand on the sidelines and has refused to participate in negotiating a protective order in this case.

The concerns that Sanofi does express in its brief are hypothetical at best and Sanofi has not provided a single concrete example to support its position. For example, Sanofi asserts that "sanofi-aventis, and *potentially* third parties, will *likely* be asked to disclose information that may be subject to the EU Privacy Directive and other member state privacy regulations…" *Id.* Sanofi has been in possession of Apotex's first set of document production requests for almost a month and yet has not identified one document subject to the EU Privacy Directive or some interest of a third party. Apotex's document requests seek such core discovery documents as Sanofi's New Drug Application that Sanofi filed with the U.S. FDA for the drug at issue in this case. Apotex also seeks Sanofi's laboratory notebooks, data and other development documents for the drug at

issue in this case. Apotex is entitled to this core discovery now. Although Sanofi is a French company, it chose to sue Apotex in the United States ostensibly to preserve its U.S. interests. It can hardly be heard to complain that it now has to participate in discovery in this case. Further, underlying the dubious nature of the concerns raised in Sanofi's brief is the fact that when Apotex requested Sanofi provide appropriate language to protect these alleged third party "interests" Sanofi was silent.

Sanofi's protestations notwithstanding, Apotex's proposed protective order is fully adequate to protect the interests of the parties to this litigation. This protective order is substantively identical to one that was entered by Judge Robinson in the District of Delaware (the same venue where Sanofi seeks to have this case transferred) in *Medpointe Healthcare, Inc. v. Apotex, Inc. et al.*, Civil Action No. 06-164-SLR (D. Del.). *Medpointe* is represented by many of the same Kirkland and Ellis lawyers that have appeared in this case. In that case, there have been several discovery depositions taken in Germany and the case has involved thousands of European documents. No EU privacy directive issues have arisen.

II. Apotex's Proposed Protective Order Will Be Useful And Effective to Protect the Parties' Interests Even If This Case Were To Be Transferred.

Sanofi's further suggestion that in the event that this case is transferred elsewhere, that the transferee court might have to modify or vacate the protective order entered by this Court is not a reason to delay entry of a protective order here. With discovery open and proceeding, a protective order is necessary here and now. If circumstances change, any protective order issues can be dealt with at that time. However, the reality is that any document that Sanofi has designated as "confidential" or "confidential outside counsel only" in this case will undoubtedly bear the same designation in any related case, so there is no burden to Sanofi through entry of a protective order in this case.

There also is no basis for presuming, as Sanofi does, that a transferee court would vacate a Protective Order entered by this Court. Furthermore, Apotex's proposed Protective Order could be readily modified and applied to accommodate the interests of other parties in the event that this case is consolidated. But at least the basic structure of the protective order will be in place. In short, the Court will preserve, rather than waste, judicial resources by entering Apotex's proposed protective order.

CONCLUSION

For the foregoing reasons, the Court should grant Apotex's Motion for entry of its proposed Protective Order together with such other relief as is appropriate under the circumstances.

Dated: February 15, 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 February 15, 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

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

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

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER DENYING PLAINTIFFS' EMERGENCY MOTION TO STAY PENDING JPML DECISION AND MOTION FOR HEARING

THIS CAUSE came before the Court upon Plaintiffs' Emergency Motion to Stay Pending JPML Decision **(D.E. No. 32)**, filed on **February 7, 2008** and Plaintiff's Motion for Hearing on the Emergency Motion **(D.E. No. 33)**, filed on **February 7, 2008**.

THE COURT has considered the motions and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motions are DENIED.

DONE AND ORDERED in Chambers at Miami, Florida, this 14th day of February, 2008.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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.,

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_____/

RULE 7.1. DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1(a), Defendants disclose that Aposherm, Inc. is the parent of Apotex Corp. No publicly held corporation owns 10% or more of the stock of Aposherm, Inc. or Apotex Corp. Apotex Pharmaceutical Holdings Inc. is the parent of Apotex Inc. No publicly held corporation owns 10% or more of the stock of Apotex Pharmaceutical Holdings Inc. or Apotex Inc.

Dated: February 19, 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 February 19, 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

Dated: January 21, 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.

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SOUTHERN DISTRICT OF FLORIDA
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SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

NOTICE OF APPEARANCE

An Appearance is hereby filed by the undersigned as attorney for Defendants, Apotex Inc. and Apotex Corp.

Dated: February 20, 2008

s/. Robert B. Breisblatt
Robert B. Breisblatt
rbbreisblatt@welshkatz.com
Fla. Bar No. 145928
Welsh & Katz, Ltd.
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606
Tel: 312-655-1500
Fax: 312-655-1501

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 07-61800-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. L.L.C.,,

Plaintiffs,

v.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

ORDER GRANTING DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER

Presently pending before the Court is the Motion for Entry of a Protective Order (DE # 25), filed by Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"). Plaintiffs, sanofi-aventis and sanofi-aventis U.S., L.L.C. (collectively, "sanofi"), responded to the motion (DE # 39) and Apotex replied (DE # 47). This motion has been referred to the undersigned Magistrate Judge (DE # 28). Based upon a thorough review of the record and for the reasons stated herein, Apotex's motion is hereby GRANTED.

I. BACKGROUND

This is a patent infringement action, in which the parties agree that discovery must be conducted under a Protective Order (DE # 39 at 1). However, the parties dispute whether this Court should enter a Protective Order immediately, as Apotex suggests, or delay the entry of a Protective Order until sanofi's motion to transfer and stay this litigation are resolved, as sanofi suggests. As explained below, it is appropriate to enter a Protective Order in this case without further delay.

II. THE PARTIES' POSITIONS

Sanofi argues that the entry of a Protective Order would be premature and create an undue burden on the parties and this Court, in light of its pending motion to stay and transfer these proceedings (DE # 5).[1] According to sanofi, it was forced to file suit in this District because Apotex would not consent to jurisdiction in Delaware, where other, similar actions had already been filed in federal court. Now that Apotex has agreed not to contest jurisdiction in Delaware, sanofi asserts that this case should be transferred to Delaware and consolidated with the related actions in that District (DE # 39 at 2-3 & n.2). Sanofi claims that Apotex's motion and proposed Protective Order, if granted, will harm the interests of this Court and the parties.

Sanofi contends that it would be an inefficient use of judicial resources to enter a Protective Order that may be reconsidered or vacated by the Delaware Court. In addition, sanofi predicts that the parties will be prejudiced by preparing and producing discovery under a Protective Order issued by this Court, given the likelihood that they will be forced to repeat the process under a Protective Order issued by the Delaware Court that contains different or conflicting standards (DE # 39 at 2 & 5-6).

Finally, sanofi identifies substantive aspects of Apotex's proposed Protective Order, which sanofi claims "will not adequately safeguard the confidential information" likely to be produced because, among other things, (1) it does not address the production of financial data, third-party agreements and research and development of

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[1] The undersigned notes that the Honorable Federico A. Moreno, Chief United States District Judge, recently denied sanofi's emergency motion to stay the instant proceedings until the Judicial Panel on Multidistrict Litigation rules on its motion to transfer this case to Delaware pursuant to 28 U.S.C. § 1407 (DE # 48). However, sanofi's motion to transfer this case to Delaware pursuant to 28 U.S.C. § 1404 is still pending (DE # 5).

future products; (2) it does not attempt to limit the presence of third parties at depositions that may cover confidential information; (3) it does not provide for the return of materials subject to the European Union ("EU") Privacy Directive or similar regulations; (4) it does not regulate the production of confidential materials to third parties for reproduction, copying, translation, etc.; (4) it requires the party seeking to disclose confidential information to an expert, rather than the party resisting disclosure, to petition the Court for redress of disputes concerning such disclosure; (5) it limits disclosure of confidential information to one in-house attorney or businessperson without providing a framework for objecting to the selection of an individual or making substitutions; and (6) it does not clearly delineate whether references to "CONFIDENTIAL INFORMATION" refer only to materials defined as "CONFIDENTIAL INFORMATION," or materials defined as "OUTSIDE COUNSELS EYES ONLY" information as well (DE # 39 at 6-7 & n.3).

Apotex replies that a Protective Order is necessary because the parties have already exchanged their initial disclosures, sanofi's responses to Apotex's discovery requests are past due, the final discovery cut-off date is August 6, 2008 and the trial is set to commence on October 6, 2008. Until sanofi's pending motions to stay and transfer this case are resolved, Apotex asserts that the parties must assume that this case will proceed to trial and that its proposed Protective Order, which is typical for this kind of litigation and which sanofi's counsel have themselves proposed in similar cases, should be entered in order to allow discovery to move forward (DE # 47 at 1-2).

In addition, Apotex claims that sanofi's argument that a transferee court would vacate this Court's Protective Order is speculative and irrelevant, since it is unknown whether sanofi's motions to stay and transfer will be granted. In addition, Apotex argues

that its proposed Protective Order is "typical" and the basic framework of its order is therefore unlikely to be disturbed by a transferee court, even if minor alterations are necessary to accommodate additional parties in the event this case is eventually consolidated with the action pending in the Delaware Court (DE # 47 at 3-4). Finally, Apotex contends that sanofi's substantive objections to its proposed Protective Order are merely hypothetical, and that sanofi has waived any objections by failing to substantiate them or to participate in drafting an order that addressed their concerns (DE # 47 at 2-3).

III. ANALYSIS AND ORDER

This Court agrees with Apotex that the absence of a Protective Order is delaying the progress of this case, notwithstanding sanofi's pending motion to stay and transfer this litigation. In fact, the District Judge presiding over this case recently denied one of sanofi's pending motions to stay these proceedings (DE # 48). Sanofi is correct that it may prove to be slightly inefficient to issue a Protective Order that may ultimately be modified by a transferee court. However, it would be significantly inefficient to refrain from issuing a Protective Order and further delay discovery on the assumption that this case might be transferred to another District.

The undersigned notes that sanofi has expressed a willingness to "promptly negotiate with Apotex on the terms of a fair and comprehensive Protective Order that adequately safeguards the parties' confidentiality interests" if the Court were to so order (DE # 39 at 8 n.4). Sanofi was scheduled to begin producing documents on February 18, 2008, and the discovery deadlines and trial dates are approaching rapidly. It is therefore apparent that a Protective Order must be in place to govern these proceedings. Even if this case is eventually transferred, this Court finds little cause for concern that the

parties will be subject to unnecessary production under two divergent Protective Orders, provided that the parties work together to produce a stipulated Protective Order that takes into account their interests and, to the extent practicable, the interests of defendants in related actions.[2] In fact, if this case is transferred, the transferee court may likely utilize all or substantial portions of the Protective Order entered in these proceedings.

Therefore, on or before March 3, 2008, the parties shall confer and submit a joint proposed Protective Order. If the parties are unable to agree, they shall submit a redlined version which contains the positions of both parties. It is accordingly

ORDERED AND ADJUDGED that Defendants' Motion for Entry of a Protective Order (DE # 25) is **GRANTED**.

DONE AND ORDERED in Chambers in Miami, Florida on February 20, 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

[2] The undersigned notes that neither party has 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.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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SANOFI-AVENTIS and
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Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

PLAINTIFFS' CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 7.1(a) of the Federal Rules of Civil Procedure, sanofi-aventis and sanofi-aventis U.S. LLC submit the following disclosure statement:

I. PARENT CORPORATION

Sanofi-aventis states that it has no parent corporation. Sanofi-aventis U.S. LLC states that it is wholly-owned indirectly by sanofi-aventis.

II. PUBLICLY HELD COMPANIES OWNING 10% OR MORE OF ITS STOCK

Sanofi-aventis states that no publicly held corporation owns 10% or more of its stock.

Dated: February 20, 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

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

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 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.

Dated: February 20, 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

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

SERVICE LIST

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

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

United States District Court
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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

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

SANOFI-AVENTIS and
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Plaintiffs,

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APOTEX CORP.,

Defendants. /

PLAINTIFFS' AMENDED CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 7.1(a) of the Federal Rules of Civil Procedure, sanofi-aventis and sanofi-aventis U.S. LLC submit the following amended disclosure statement:

I. PARENT CORPORATION

Sanofi-aventis states that it has no parent corporation. Sanofi-aventis U.S. LLC states that it is wholly-owned indirectly by sanofi-aventis.

II. PUBLICLY HELD COMPANIES OWNING 10% OR MORE OF ITS STOCK

Total SA (a French corporation whose shares are traded on the Eurolist of Euronext Paris and whose American Depository Receipts are publicly traded on the New York Stock Exchange) and L'Oreal (a French corporation whose shares are traded on the Eurolist of Euronext Paris and whose American Depository Receipts are traded Over The Counter) each own 10% or more of sanofi-aventis stock

Dated: February 21, 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

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

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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

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
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Attorneys for Plaintiffs

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ZUCKERMAN SPAEDER, LLP
Attorneys for Apotex Corp. and Apotex, Inc.
201 South Biscayne Blvd., Suite 900
Miami, FL 33131

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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
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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

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

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.

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.
_____/

DECLARATION OF WILLIAM T. VUK IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL DEFENDANTS TO COMPLY WITH THE COURT'S FEBRUARY 20, 2008 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' Motion to Compel Defendants to Comply With The Court's February 20, 2008 Order, and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 is a true and accurate copy of a letter dated February 21, 2008 from William T. Vuk to Sherry R. Rollo, sent by electronic mail on February 21, 2008.

2. Attached hereto as Exhibit 2 is a true and accurate copy of a letter dated February 21, 2008 from Sherry R. Rollo to Alexis Gorton, received by electronic mail on February 21, 2008.

3. Attached hereto as Exhibit 3 is a true and accurate copy of a letter dated February 22, 2008 from William T. Vuk to Sherry R. Rollo, sent by electronic mail on February 22, 2008.

4. Attached hereto as Exhibit 4 is a true and accurate copy of a letter dated February 22, 2008 from Sherry R. Rollo to William T. Vuk, received by electronic mail on February 22, 2008.

5. Attached hereto as Exhibit 5 is a true and accurate copy of a letter dated February 25, 2008 from Alexis Gorton to Sherry R. Rollo, sent by electronic mail on February 25, 2008.

6. Attached hereto as Exhibit 6 is a true and accurate copy of an electronic mail from James W. Parrett, Jr. to Andre G. Bouchard et al. dated February 25, 2008.

I declare under penalty of perjury that the foregoing is true and accurate.

/s/ William T. Vuk

William T. Vuk

February 26, 2008
New York, New York

Exhibit 1

William T Vuk/New York/Kirkland-Ellis
02/21/2008 08:08 PM

To "Rollo, Sherry" <srollo@welshkatz.com>
cc agorton@kirkland.com, asaikali@shb.com, "Coberly, Jennifer R." <jcoberly@zuckerman.com>, "Breisblatt, Robert" <rbbreisblatt@welshkatz.com>, "Feldman, Steve"
bcc
Subject Sanofi-aventis v. Apotex

Dear Sherry:

Please see the attached correspondence.

Regards,

Bill

William T. Vuk
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611
Telephone: (212) 446-4757
Facsimile: (212) 446-6460

2-21-08 ltr to rollo.PDF

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.

Exhibit 2

"Rollo, Sherry"
<srollo@welshkatz.com>
02/21/2008 09:32 PM

To <agorton@kirkland.com>
cc <wvuk@kirkland.com>, "Feldman, Steve" <sefeldman@welshkatz.com>, <asaikali@shb.com>, "Breisblatt, Robert" <rbbreisblatt@welshkatz.com>, "Coberly,
bcc
Subject FW: Sanofi v. Apotex

Re: Sanofi-Aventis et al. v. Apotex Inc. et al.
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Attached please find correspondence relating to the above-captioned case.

Regards,

Sherry

Sherry L. Rollo
Welsh & Katz, LTD
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
(312) 526-1547 (direct)
(312) 655-1501 (facsimile)

The information contained in this communication may be confidential, is intended only for the use of the recipient named above, and may be legally privileged. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication, or any of its contents, is strictly prohibited. If you have received this communication in error, please re-send this communication to the sender and delete the original message and any copy of it from your computer system.


gorton ltr 2-21-08.pdf

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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)

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 17, 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 Bill:

We acknowledge receipt of your January 16, 2008 letter. Once again we do not agree with your self-serving attempt to recount our discussion of the 14th. We also are disappointed that you went ahead and filed a motion to move this case to Complex Track without first providing us with your proposed schedule as we had requested and as you had agreed to do. It also is unacceptable that you had no authority to agree to various discovery issues or to a timetable for producing documents or agreeing to a Protective Order. This is unacceptable for a Rule 26(f) conference and for meet and confer in general under the Local Rules. In the future we expect that someone with actual authority to bind your client and to have meaningful discussions on discovery and related issues, such as Mr. Desmarais or Mr. Flattmann, will be present in any such discussions. We will raise this with the Court if your side fails to comply.

With respect to the Protective Order, your position that it is premature to enter into a Protective Order and that you are concerned about the rights of other defendants in separate actions in Delaware is frivolous and a bad faith effort to avoid discovery and delay this matter. As you know, under the *Hatch-Waxman Act*, 21 USC §355(j)(5)(B)(iii), parties to an ANDA action are required to "reasonably cooperate in expediting the action." As I mentioned previously, our respective firms including lawyers listed on the pleadings in this case already negotiated a Protective Order in the *Medpointe v. Apotex* case. We propose adopting that with appropriate modifications, and have attached our proposed Protective Order hereto. You also raise the "EU Data Privacy Directive" as a basis for delaying entry

of a Protective Order in this case. We disagree and do not believe this is legitimate basis for withholding discovery in this case. The *Medpointe v. Apotex* case involved thousands of documents from Germany and other European countries that would be subject to the EU Data Privacy Directive, and no issues have arisen. We also have reviewed the Protective Order from the earlier *Sanofi v. Apotex* litigation involving the drug Plavix® (Case No. 02-CV-2255 (RWS), S.D.N.Y.). It makes no mention of the EU Data Privacy Directive. To the extent that you have concerns about the "EU Data Privacy Directive," then please propose language dealing with the particular issues that are of concern to your client. We do not believe that this is a reason to delay entry of a Protective Order, however. Your client will be subject to discovery in this case, be it in Florida or Delaware, so there is no basis for further delay on your part.

You also continue to fail to provide a date certain when your side will produce documents of core significance to this case, such as Sanofi's INDA, NDA, lab notebooks, research notes, data and memoranda underlying the development of the alfuzosin product that Sanofi listed in the Orange book and the method of treatment claimed in the '491 patent. It is inconceivable that your client would have sued 13 other companies, some as early as last September, and yet not have these documents ready to produce. Until a Protective Order is entered, we are willing to receive these documents on an attorney's eyes only basis. Your refusal to produce these documents even on an attorney's eyes only basis or to commit to a date certain on which they will be produced is in bad faith and in violation of both the Court's January 3, 2008 Scheduling Order and 21 USC §355(j)(5)(B)(iii).

With respect to settlement, given that you had no actual authority to discuss settlement, which you acknowledged, we disagree that there have been any settlement discussions or that you have complied with the Court's Order requiring these to take place. We are ready and willing to discuss settlement of this matter with your side.

With respect to the mediator, please let us know immediately if any of the three names proposed by us are acceptable.

We believe that because our meet and confer took place on January 15, that the joint status report is actually due January 29.

Very truly yours,

WELSH & KATZ, Ltd.

By: Steven E. Feldman

SEF/mh
Encl.
cc: Alfred J. Saikali, Esq. (asaikali@shb.com)
Jennifer R. Coberly, Esq. (jcoberly@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Sherry L. Rollo, Esq. (srollo@welshkatz.com)

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.	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, the parties to the above-captioned action (the "Action") may seek discovery of documents, information or other materials that may contain trade secrets or other confidential research, development or commercial information of other parties or third parties;

NOW THEREFORE, pursuant to Federal Rule of Civil Procedure 26(c), upon the stipulation and consent of the parties and for good cause shown, the Court hereby **ORDERS** that:

1. This Protective Order (the "Order") shall govern the disclosure and/or production of information, documents and tangible things in connection with this Action.

2. Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the producing party and a unique identifying number. Likewise, each discrete unit of each tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the producing party and a unique identifying number.

3. Any producing person, entity or third party ("producing party") may designate any information, document or tangible item to be disclosed and/or produced as CONFIDENTIAL INFORMATION if: (a) the producing party claims in good faith that such information, document or tangible item comprises or contains trade secrets or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c); and (b) the producing party gives notice, as provided in this Order, that such information, document or tangible item comprises or contains CONFIDENTIAL INFORMATION.

a. All information, documents or tangible items to be produced in tangible form that the producing party wishes to designate as CONFIDENTIAL INFORMATION must, prior to production to the receiving party, be labeled by the producing party with the legend: **CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**, or a suitable equivalent. The parties shall agree on how electronic data will be marked.

b. All information to be disclosed initially for inspection (such as for selection of materials for copying and production) that the producing party wishes to designate as CONFIDENTIAL INFORMATION must, prior to such disclosure, be specified in a writing provided to the receiving party (or orally, if followed by the necessary writing) that identifies the specified information as CONFIDENTIAL INFORMATION. All information to be disclosed orally (such as a deposition) shall be automatically designated as CONFIDENTIAL INFORMATION for a period of thirty (30) days from the date the deposition transcript becomes available. Thereafter, the information contained in the deposition transcript will no longer be deemed

CONFIDENTIAL INFORMATION unless: (1) in a writing sent to counsel for the receiving party before the expiration of the thirty-day period, counsel for the producing party claims in good faith that the deposition transcript (or a specified portion of it) contains CONFIDENTIAL INFORMATION; or (2) at the deposition, counsel for the producing party stated on the record that certain portions of the deposition transcript contain CONFIDENTIAL INFORMATION.

4. In the event that a producing party believes access to particular information, document(s) or tangible item(s) requested by the receiving party should be more limited than is provided in Paragraph 6 below, the producing party may additionally designate the information **OUTSIDE COUNSEL EYES ONLY**. Information appropriate for designation as OUTSIDE COUNSEL EYES ONLY shall presumptively include Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration ("FDA"), and pending patent applications. Disclosure of information designated OUTSIDE COUNSEL EYES ONLY shall be limited to persons identified in Subparagraphs 6a, 6d, 6e, 6f, and 6g below.

5. Any information, document or tangible item designated CONFIDENTIAL INFORMATION that is disclosed and/or produced in connection with this Action shall be maintained in strict confidence by the receiving party; shall be used solely in connection with this Action, subject to any further order of this Court regarding confidentiality; and shall not be disclosed to, or used by, any individual or entity except as permitted by this Order.

6. Access to CONFIDENTIAL INFORMATION shall be strictly limited to the following persons:

a. Outside counsel for the receiving party, and the secretarial, clerical, paralegal and other supporting personnel of said outside counsel.

b. When Sanofi-Aventis and Sanofi-Aventis US LLC are the receiving parties, one (1) in-house legal or business person employed by Sanofi-Aventis and/or Sanofi-Aventis US LLC upon receipt by counsel for the producing party of a copy of the in-house legal or business person's completed and signed undertaking, and their secretarial, clerical, paralegal and other supporting personnel. Such person may not be directly involved in the prosecution of patent applications relating to pharmaceutical products. The in-house legal or business person shall be_____.

c. When Apotex Inc. and Apotex Corp. are the receiving parties, one (1) in-house legal or business person employed by Apotex Inc. and/or Apotex Corp. upon receipt by counsel for the producing party of a copy of the in-house legal or business person's completed and signed undertaking, and their secretarial, clerical, paralegal and other supporting personnel. Such person may not be directly involved in the prosecution of patent applications relating to pharmaceutical products. The in-house legal or business person shall be Shashank Upadhye, Esq., Vice President – Global Intellectual Property of Apotex Inc.

d. Outside experts or consultants for the receiving party who are not (and shall not become) employees of a receiving party and who are retained in connection with the disputes between or among the parties to this Action, and their supporting personnel;

provided that the disclosure of CONFIDENTIAL INFORMATION to any such expert or consultant shall be made only after:

i. Counsel desiring to disclose CONFIDENTIAL INFORMATION to such an expert or consultant obtains a competed and signed undertaking in the form of Exhibit A attached hereto from the expert or consultant and forwards a copy of said completed and signed undertaking and the expert's or consultant's current curriculum vitae to counsel for the producing party; and

ii. Expiration of ten (10) business days, commencing with the receipt by counsel for the producing party of a copy of the expert's or consultant's completed and signed undertaking and current curriculum vitae. During this period, counsel for the producing party may object in good faith to the disclosure of CONFIDENTIAL INFORMATION to this expert or consultant for cause, *e.g.,* an identified conflict of interest. If counsel for the producing party fails to object to such disclosure within the prescribed period, any objection to such disclosure shall be deemed waived, except as to a basis for objection that was not known and could not reasonably have been discovered within said ten-day period. In the event that a good-faith objection is made within the prescribed period, there shall be no disclosure of CONFIDENTIAL INFORMATION to the expert or consultant until there is an express written agreement of the parties or order of this Court removing the objection. The party seeking disclosure to an objected-to expert shall have the obligation to seek an order of the Court removing the objection;

e. Non-technical trial consultants and graphics or design firms retained by outside counsel for the receiving party for the purpose of preparing demonstrative or other exhibits, including their supporting personnel;

f. Licensed court reporters and videographers employed in connection with this Action; and

g. This Court and its authorized personnel.

7. Subject to Paragraph 4, the designated in-house legal or business person of the receiving party shall be permitted to inspect and have access to all CONFIDENTIAL INFORMATION and to discuss such CONFIDENTIAL INFORMATION with any other person identified in Paragraph 6. However, the in-house legal or business person may retain copies of documents designated or containing CONFIDENTIAL INFORMATION of a producing party only in a location exclusively within their control (*e.g.,* in a secure office or in a locked file cabinet) or in a location that is controlled by outside counsel.

8. CONFIDENTIAL INFORMATION may be used, relied upon and referred to in any testimony or other evidence presented at any trial, hearing or deposition conducted in connection with this Action, so long as the person presenting such testimony or evidence is authorized to have access to such CONFIDENTIAL INFORMATION under the terms of this Order, and subject to any further order of this Court regarding confidentiality.

9. If the CONFIDENTIAL INFORMATION of a producing party is to be filed with this Court in connection with any proceeding in this Action, it shall be filed in a sealed envelope marked with the caption of the case and the following legend, or its equivalent:

CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER TO BE OPENED ONLY BY OR AS DIRECTED BY THE COURT

10. This Order shall not limit a party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive CONFIDENTIAL INFORMATION under the terms of this Order, so long as such examination concerns CONFIDENTIAL INFORMATION that the witness authored or previously had access to or knowledge of, as demonstrated by the CONFIDENTIAL INFORMATION itself, or by foundation testimony during a deposition, hearing or trial. This Order shall not prevent counsel from examining a witness who was employed by the producing party during the relevant time and is reasonably believed to have had access to the CONFIDENTIAL INFORMATION to determine whether he or she authored or previously had access to or knowledge of CONFIDENTIAL INFORMATION.

11. Nothing in this Order shall bar or otherwise restrict any attorney from rendering advice to a party-client or, in the course thereof, relying upon his or her knowledge of CONFIDENTIAL INFORMATION; provided, however, that in rendering such advice the attorney shall not disclose any CONFIDENTIAL INFORMATION received from another party or third party to unauthorized persons.

12. A receiving party's acceptance of materials designated CONFIDENTIAL INFORMATION by a producing party shall not constitute an admission, or create an inference, that the material is in fact confidential within the meaning of Federal Rules of Civil Procedure 26(c). This Order shall not foreclose any party from moving for an order that materials designed CONFIDENTIAL INFORMATION are not confidential within the meaning of Federal Rule of Civil Procedure 26(c). Prior to bringing such a motion, however, the receiving party shall first request in writing that the producing party change

or remove its confidentiality designation. If the producing party refuses to change its confidentiality designation within ten (10) business days from the request, the receiving party may move for an order changing or removing the designation. On such a motion, the producing party shall have the burden of proof that the material it designated CONFIDENTIAL INFORMATION embodies its trade secrets or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c).

13. The disclosure and/or production of any information, document or tangible item without one of the designations provided by Paragraphs 3 or 4 of this 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 inadvertent 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 CONFIDENTIAL INFORMATION.

14. Should any CONFIDENTIAL INFORMATION be disclosed by a receiving party to any person not authorized to have access to such information under this Order, the receiving party shall: (a) use its best efforts to obtain the prompt return of any such CONFIDENTIAL INFORMATION and to bind such person to the terms of this

Order; (b) within three (3) business days of the discovery of such disclosure, inform such person of the provisions of this Order and identify such person to the producing party; and (c) request such person to sign an undertaking in the form of Exhibit A attached hereto. If executed, the undertaking shall be served upon counsel of record for the producing party within three (3) business days of its receipt by the receiving party. The requirements set forth in this Paragraph shall not prevent the producing party from applying to the Court for further or additional relief.

15. Nothing in this Order shall be construed to require disclosure of information, documents or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work-product immunity or any other applicable privilege or immunity. A producing party may produce a redacted version of information, documents or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work-product immunity or any other identified applicable privilege or immunity, identifying where the privileged or immune material was redacted with the designation **RP** (Redacted-Privileged).

16. If a producing party inadvertently or mistakenly produces information, documents or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information, provided that the producing party promptly makes a good-faith representation that such production was inadvertent or mistaken and takes prompt remedial action to withdraw the disclosure upon its discovery. 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 on a basis other than a waiver because of its inadvertent production as part of a discovery production under this protective order. The producing party shall retain copies of all returned documents and tangible items for further disposition.

17. If the discovery process calls for the production of information, documents or tangible items that a party cannot produce because its disclosure would breach an agreement with a third party to maintain such information in confidence, the producing party shall, no less than ten (10) business days before the date for production, give written notice to the third party that its information is subject to discovery in this Action and provide the third party with a copy of this Order. At the same time such written notice is given to the third party, the producing party shall advise the putative receiving party 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 requested information shall not be produced unless the third party so agrees or the requesting party secures a Court order compelling production.

18. The restrictions and obligations set forth in this Order relating to CONFIDENTIAL INFORMATION shall not apply to any information that: (a) the

parties agree, or the Court rules, is already public knowledge; (b) the parties agree, or the Court rules, has become public knowledge other than by a disclosure by the receiving party; or (c) has come or hereafter comes into the receiving party's legitimate possession without any confidentiality restrictions and independently of the producing party. The restrictions and obligations set forth in this Order shall not prohibit discussions with any person or entity regarding any CONFIDENTIAL INFORMATION if said person or entity already has legitimate possession thereof.

19. In the event that a receiving party desires to provide access to CONFIDENTIAL INFORMATION to any person not entitled to such access under this 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 CONFIDENTIAL 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 this Action may agree or this Court may order.

20. This Order shall not prevent any party from applying to the Court for further or additional protective orders.

21. This Order shall survive the termination of this Action.

22. After final termination of this Action including appeals, outside counsel identified in Subparagraph 6a for a receiving party may retain one archival copy of deposition transcripts, deposition exhibits, Court transcripts, Court exhibits, and other

submissions to the Court, including CONFIDENTIAL INFORMATION contained therein. Within thirty (30) days after final termination of this Action, including any appeals, all additional CONFIDENTIAL INFORMATION of a producing party in the possession, custody or control of a receiving party – or in the possession, custody or control of any person allowed access to such information under Paragraph 6 of this Order – must be either: (a) returned to outside counsel for the producing party; or (b) destroyed and such destruction certified in writing to outside counsel for the producing party.

SHOOK, HARDY & BACON L.L.P.

Alfred J. Saikali
201 South Biscayne Boulevard
Suite 2400
Miami, FL 33131

ZUCKERMAN SPAEDER LLP

Stephen J. Bronis
201 South Biscayne Boulevard, Suite 900
Miami, FL 33131

Robert B. Breisblatt (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.

SO ORDERED:

This _____day of _____, 2008

THE HONORABLE MORENO
United States District Judge

Southern District of Florida

EXHIBIT A

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.	)	

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I, _____, state that:

a. My home address is_____

and my current work address is _____

b. My present employer is _____

_____

c. My present title, occupation or job description is

d. A copy of my curriculum vitae is attached hereto (if an expert or consultant)

e. I have read and understand the provisions of the Stipulated Protective Order entered in this action and I will comply with the provisions of that Stipulated Protective Order. I consent to be subject to the jurisdiction of this Court for enforcement of this Stipulated Protective Order.

f. I will hold in confidence and not disclose to anyone not qualified under the Stipulated Protective Order any CONFIDENTIAL INFORMATION, or any summaries, abstracts or indices of any CONFIDENTIAL INFORMATION, that is disclosed to me or that I prepare.

g. Upon conclusion of the above-captioned litigation, including appeal, I will return all CONFIDENTIAL INFORMATION – and any summaries, abstracts and indices thereof, and documents or materials I received or prepared relating thereto – in my possession to outside counsel for the party for whom I was employed, retained or acted as a witness.

I declare under perjury of the laws of the United States of America that the foregoing is true and correct.

Dated:_____ _____

Exhibit 3

William T Vuk/New York/Kirkland-Ellis
02/22/2008 08:25 AM

To "Rollo, Sherry" <srollo@welshkatz.com>
cc agorton@kirkland.com, asaikali@shb.com, emoss@shb.com, JBlumenfeld@MNAT.com, "Coberly, Jennifer R." <jcoberly@zuckerman.com>, "Breisblatt, Robert"
bcc
Subject Sanofi-aventis v. Apotex

Dear Sherry:

Please see the attached correspondence.

Regards,

Bill

2-22 ltr to rollo.pdf

William T. Vuk
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611
Telephone: (212) 446-4757
Facsimile: (212) 446-6460

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.

Exhibit 4

"Rollo, Sherry"
<srollo@welshkatz.com>
02/22/2008 06:38 PM

To <wvuk@kirkland.com>
cc "Feldman, Steve" <sefeldman@welshkatz.com>, "Breisblatt, Robert" <rbbreisblatt@welshkatz.com>, <agorton@kirkland.com>, <asaikali@shb.com>
bcc
Subject Sanofi v. Apotex

Re: Sanofi-Aventis et al. v. Apotex Inc. et al.
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Attached please find correspondence relating to the above-captioned case.

Regards,

Sherry

Sherry L. Rollo
Welsh & Katz, LTD
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
(312) 526-1547 (direct)
(312) 655-1501 (facsimile)

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feb 22 ltr to vuk.pdf

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)

Exhibit 5

Alexis Gorton/New York/Kirkland-Ellis
02/25/2008 11:30 AM

To srollo@welshkatz.com
cc asaikali@shb.com, emoss@shb.com, JBlumenfeld@MNAT.com, "Coberly, Jennifer R." <jcoberly@zuckerman.com>, "Breisblatt, Robert"
bcc Sonja Manly/New York/Kirkland-Ellis@K&E
Subject Sanofi-aventis v. Apotex

Dear Sherry,

Please see the attached letter.

Thank you,
Alexis

- 2-25-08 Gorton to Rollo.pdf

Alexis Gorton
Kirkland & Ellis LLP
153 E. 53rd Street
New York, New York 10022
Phone: (212) 446-4887
Fax: (212) 446-4900

IRS Circular 230 Disclosure: To ensure compliance with requirements imposed by the U.S. Internal Revenue Service, we inform you that any tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, by any taxpayer for the purpose of (1) avoiding tax-related penalties under the U.S. Internal Revenue Code or (2) promoting, marketing or recommending to another party any tax-related matters addressed herein.

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.

Exhibit 6



"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>

bcc

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

DRAFT FOR DISCUSSIONS PURPOSES ONLY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS AND SANOFI-AVENTIS U.S. LLC, Plaintiffs, **v.** ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA 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 LIMITED, Defendants.	)	C.A. No. 07-572 (GMS)
SANOFI-AVENTIS AND SANOFI-AVENTIS U.S. LLC, Plaintiffs, **v.** BARR LABORATORIES, INC., Defendant.	)	C.A. No. 07-574 (GMS)
SANOFI-AVENTIS AND SANOFI-AVENTIS U.S. LLC, Plaintiffs, **v.** APOTEX INC. AND APOTEX CORP., Defendants.	)	C.A. No. 07-792 (GMS)

DRAFT FOR DISCUSSIONS PURPOSES ONLY

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]

[1] Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC and defendants Apotex Inc. and Apotex Corp. further agree that the terms of this Stipulated Protective Order will govern *Sanofi-aventis et al. v. Apotex Inc. et al.,* Case No. 07-61800-CIV-MORENO/SIMONTON, United States District Court for the Southern District of Florida, Miami Division, and will submit a parallel order for filing in that court.

DRAFT FOR DISCUSSIONS PURPOSES ONLY

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.

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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 **"<u>Outside-Counsel-Only Confidential Information</u>"**: 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:

i. Information relating to customer, supplier, distributor, licensee, licensor or partner identities; agreements with customers, suppliers, distributors, licensees, licensors or partners;

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ii. Financial projections, sales volumes, pricing, costs, profit margins 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, testing or studies on proposed potential, un-marketed, or future products or new indications;

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.

b. Information not described under Subsection 2.2a shall be rebuttably presumed not to be appropriate for "Outside-Counsel-Only Confidential Information" designation.

c. 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.

d. Protected Information designated Outside-Counsel-Only Confidential Information may only be disclosed in accordance with the provisions guiding disclosures under Section 3 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.

a. Protected Information designated Confidential Information may only be disclosed in accordance with the provisions guiding disclosures under Section 3 of this Protective Order.

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;

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, including the officers, directors, or managing agents (including In-House Counsel) of the Producing Party;

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 three (3) additional employee technical representatives 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 directly involved in the prosecution of pharmaceutical patents.

i. Each such person designated under Subparagraph (f) shall be identified by both name and title, and shall acknowledge receipt and

understanding of this Protective Order and execute a declaration in the form attached hereto as Exhibit A, a copy of which will be forwarded to counsel for the Producing Party. The Producing Party may object to the designation of persons under Subsection (f) for good cause within (7) business of receiving any such designation. Such written objection shall set forth in sufficient detail the grounds on which the objection is based. No disclosure of the Producing Party's Protected Information shall be made to the designated person while the objection is pending. If the Producing Party objects to the disclosure, the Producing Party and the Receiving Party wishing to make the disclosure must meet and confer to resolve any such objections. 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 business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen days after the written objection to disclosure is received by the Receiving Party, whichever is longer. 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.

ii. A Party may substitute a person designated under Subparagraph (f) by giving a five (5) business day notice to all other Parties, if such a person terminates his or her employment, so long as no more than six (6) such persons at any time are in possession of or receive Protected Information from the Producing

Party. The provisions for objecting under Subsection (f)(i) shall apply to such substitutions.

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:

a. 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 Third Party, such as a person designated as an Independent Expert, Technical Consultant, or Non-Technical Consultant, 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.

c. No disclosure of Protected Information shall be made to the Third Party or Independent Expert or Technical Consultant until at least seven (7) business days after all of the requirements set forth under (a) and (b) of this Subsection have been met. If the Producing Party objects in writing within said seven 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.

d. If the Producing Party objects to the disclosure, 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 business days after the parties have met and conferred as contemplated under this subsection and failed to reach an agreement, or fourteen days after the written objection to disclosure is received by the Receiving Party, whichever is longer. 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.

3.4 Notification Required Prior to Disclosure to Independent Experts or Technical Consultants: Prior to disclosure of any Protected Information to any person intended to serve as an Independent Expert or Technical Consultant in the Actions, the following conditions must first be met:

a. Outside Counsel for the Receiving Party wishing to disclose Protected Information to such Independent Expert or Technical Consultant shall, at least seven (7) 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. a true and accurate copy of the Independent Expert or Technical Consultant's current curriculum vitae or resume;

iii. a statement indicating whether or not the Independent Expert or Technical Consultant was an employee or is a current shareholder of a Party or any subsidiaries or affiliates of a Party;

iv. in the event that the proposed Independent Expert or Technical Consultant 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, 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.

4. MARKING PROTECTED MATERIAL

4.1 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 INFORMATION SUBJECT TO PROTECTIVE ORDER" and "OUTSIDE-COUNSEL-ONLY

CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER" 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 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 enclosed in a sealed envelope or other appropriate container. The sealed envelope or other appropriate container shall:

(a) show the caption of the Action or Actions as applicable;

(b) identify its contents; and

(c) include the following legend:

PROTECTED INFORMATION FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER

This envelope [or container] is sealed pursuant to court order and contains proprietary information. This envelope [or container] was filed by [name of party] and may not be opened, nor may its contents be displayed or revealed, except by court order or by written stipulation of the

parties.

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 fifteen (15) 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 twenty (20) 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 shall segregate any portion of the deposition transcript that has been stated to contain Protected Information designated "Outside-Counsel-Only Confidential Information" and may furnish copies of the segregated portions, in a sealed envelope, only to: the deponent as required by law, the Court, and the Outside Counsel for the Party to the deposition. Designations made within the fifteen 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 provisions of this Protective Order shall apply to all properly designated items of information, documents and things subject to discovery; submitted to the Court in the Actions; possessed or controlled by a Party or Third Party; which item of information, document or thing contains the designating Party's trade secret or other confidential research, development, or commercial information.

5.3 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.

5.4 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, commercial or business purpose, including the pursuit of intellectual property rights.

5.5 Nothing in this Protective Order shall restrict a Producing Party from using its own Protected Information for any purpose.

5.6 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.

5.7 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.

5.8 A document that contains or reveals Protected Information may be shown to any person indicated in such document to be its originator, author or recipient of a copy.

5.9 A document that contains or reveals Protected Information may be translated by an independent translation service and may be copied by an independent commercial copying or other litigation support service provider, and an exhibit based upon such a document may be prepared by an independent printer, illustrator or the like.

5.10 Protected Information may be disclosed to licensed stenographic reporters, official court reporters, videographers and their assistants who are engaged in proceedings necessary for the preparation and trial of the Actions.

5.11 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.

5.12 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.

5.13 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.

5.14 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.

5.15 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.

5.16 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 a 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.

5.17 No Party shall be responsible to another Party for any use made of information that was produced and not designated as Protected Information.

5.18 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.

5.19 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.

5.20 This Protective Order may be amended as need may arise by written agreement of the Parties without leave of the Court.

5.21 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 solely to those drafts. 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

6.1 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.

6.2 Only persons specifically authorized under the provisions of this Protective Order, the deponent, the court reporter and, if required, the videographer, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

7. CORRECTION OF INADVERTENT FAILURE TO DESIGNATE

7.1 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

8.1 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 research, development or commercial 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 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 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 Receiving Party may move the Court for an order that the disclosure be made, provided that any subsequent authorized disclosure be made after obtaining an agreement in the form of Exhibit A from all persons to whom disclosure is intended, or under such other conditions to which the parties 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.

12. DISCOVERY OF INFORMATION PROTECTED BY EUROPEAN UNION PRIVACY DIRECTIVE OR MEMBER STATE

One or more Parties or Third Parties may be asked to produce documents in the Actions subject to 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) or other member-state privacy

directives, laws or regulations. 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 or other member-state privacy directives, laws or regulations, 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, provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information.

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, work product immunity or any other applicable privilege or 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.

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.

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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:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

_____

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

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

OF COUNSEL:

John M. Desmarais
Geralad J. Flattmann, Jr.
William T. Vuk
Alexis Gorton
KIRKLAND & ELLIS LLP
Citigroup Center
153 E. 53rd Street
New York, NY 10022
(212) 446-4800

Dated: February __, 2008

DEFENDANTS TO INSERT SIG BLOCKS

DRAFT FOR DISCUSSIONS PURPOSES ONLY

ORDER

PURSUANT TO STIPULATION, IT IS SO ORDERED.

Dated:_____ , 2008.

_____
HONORABLE
JUDGE OF THE U.S. DISTRICT COURT

DRAFT FOR DISCUSSIONS PURPOSES ONLY

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
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 FOR STATUS CONFERENCE
AND INCORPORATED MEMORANDUM OF LAW

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully request a brief status conference with the Court to discuss the present state of the litigation. Specifically, sanofi-aventis seeks to address (1) the status of the related Delaware actions, in which the Delaware court has scheduled its Rule 16 conference with all parties for March 17, 2008; (2) the transfer motions currently pending before the Court, the Delaware court, and the Judicial Panel on Multidistrict Litigation ("the Panel"), and the impact of these motions on the present litigation; (3) the necessity and timing of a Markman hearing and dispositive motions; and (4) discovery limitations and scheduling. A status conference to address these outstanding issues concerning venue, discovery and scheduling is necessary at this time because their resolution will directly and immediately effect the parties' conduct in, and the Court's management of, the litigation.

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 Plaintiffs' Motion for Status Conference.

MEMORANDUM OF LAW

This case is a second-filed action based on Apotex Corp. and Apotex Inc.'s (collectively "Apotex") infringement of United States Patent No. 4,661,491 ("the '491 patent") by filing an Abbreviated New Drug Application ("ANDA") seeking FDA approval to manufacture, sell and use a generic version of sanofi-aventis's drug Uroxatral®. A parallel first-filed action, involving the same claims, defenses and counterclaims, is pending against Apotex in the district of Delaware. Two related actions are also pending in Delaware against 13 other defendants for infringement the '491 patent and/or United States Patent No. 6,149,940, both listed in the FDA Orange Book for sanofi-aventis U.S. LLC's drug Uroxatral® and to which sanofi-aventis is an assignee. The Delaware court has scheduled a Rule 16 status and scheduling conference for all three actions on March 17, 2008. Ex. 1, February 26, 2008 Rule 16 Orders in *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).[1]

The pleading stage of this action is complete, and the Court issued scheduling orders on January 3 and 22, 2008 setting various dates including mediation (April 28, 2008), final discovery cut-off (August 6, 2008) and trial (two weeks starting October 6, 2008). D.I. 4; D.I.

[1] A true and accurate copy of Exhibit 1 is attached to the accompanying Declaration of Alexis Gorton In Support of Plaintiffs' Motion for Status Conference.

23. The Court has not, however, scheduled other pretrial activities, such as a Markman hearing for claim construction, or set limitations on discovery, such as on the number of depositions each party may take and the number of document requests, interrogatories, and requests for admission that each party may serve. Additionally, the following motions are currently pending before the Court: Plaintiffs' Motion to Stay or Transfer (D.I. 5), Plaintiff's Motion for a Protective Order (D.I. 44), Plaintiff's Motion to Compel Defendants to Comply With The Court's February 20, 2008 Order (D.I. 54). Also currently pending in the Delaware court is Apotex's Motion to Transfer, or in The Alternative, to Stay, and at the Panel is sanofi-aventis's Motion to Transfer and Consolidate for Pretrial Proceedings. To date, the Court has not held an initial case management conference in this action.

Sanofi-aventis respectfully requests that the Court schedule a brief status conference to address the issues outlined above as they will directly and immediately impact the parties' conduct in, and the Court's management of, the litigation. As an initial matter, it is within the Court's discretion to schedule a status conference and parties may move the court to schedule such a conference. *See* 3-16 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE § 16.60 (Matthew Bender 3d ed.). Here, a status conference at this stage of the litigation would benefit both the parties and the Court. First, a conference would provide the parties with an opportunity to update the Court on the status of the three related actions currently pending in Delaware, including the identical, first-filed action against Apotex. Second, the parties and the Court can use the conference to address the various venue issues raised in the motions to transfer, stay, and/or consolidate pending before the Court, the Delaware court, and the Panel, and to address the impact of the venue issues on the parties' pretrial activities in this action. Third, at the conference, the parties can address the need for and timing of other pretrial activities such as

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. Finally, a conference will allow the parties and the Court to outline a roadmap for the most efficient conduct of discovery in this matter, which sanofi-aventis expects to be wide-ranging based on its investigation and the discovery requests served by Apotex to date, by setting additional discovery deadlines as well as limitations on depositions, document requests, interrogatories, and requests for admission.

For the foregoing reasons, the Court should enter an Order granting Plaintiffs' Motion for Status Conference.

Dated: February 27, 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)
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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 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 (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.
/

[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION FOR STATUS CONFERENCE

THIS CAUSE is before the Court on Plaintiffs' Motion for Status Conference, filed on February 27, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiffs' Motion for Status Conference is GRANTED.

A status conference will be held on _____, 2008, at _____.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of February, 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.
_____/

DECLARATION OF ALEXIS GORTON 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 Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC in this action. I submit this declaration in support of Plaintiffs' Motion for Status Conference, and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 are true and accurate copies of the Rule 16 Orders issued on February 26, 2008 in *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.

I declare under penalty of perjury that the foregoing is true and accurate.

/s/ Alexis Gorton

Alexis Gorton

February 27, 2008
New York, New York

EXHIBIT 1

Civil Action Nos.: 07-572 &
07-574 (GMS)

ORDER

IT IS HEREBY ORDERED that, pursuant to Rule 16, Federal Rules of Civil Procedure, and Local Rule 16.2(b), a status and scheduling conference in these matters has been scheduled with the Honorable Gregory M. Sleet for **Monday, March 17, 2008, at 9:30 a.m.** Counsel with primary responsibility for these cases shall appear at the United States District Court, 844 King Street, Room 4324, Wilmington, Delaware and be prepared to address any pending motions. Unless otherwise excused, local counsel shall appear as well. In preparation for this scheduling conference, the parties are directed to confer with respect to all agenda items listed below. **On or before the close of business on Monday, March 10, 2008, counsel shall file a JOINT STATUS REPORT addressing each agenda item.** Matters which the court will take up at the conference will include the following:

1. **Jurisdiction and Service.** Does the court have subject matter jurisdiction? Are all parties subject to the court's jurisdiction? Do any remain to be served?

2. **Substance of the Action.** What are the factual and legal bases for plaintiff's claims and defendants' defenses?

3. **Identification of Issues.** What factual and legal issues are genuinely in dispute?

4. **Narrowing of Issues.** Can the issues in litigation be narrowed by agreement or by motions? Are there dispositive or partially dispositive issues appropriate for decision on motion?

5. **Relief.** What specific relief does plaintiff seek? What is the amount of damages sought and generally how is it computed?
6. **Amendment of Pleadings?**

7. **Joinder of Parties?**

8. **Discovery.** Discovery contemplated by each party and the amount of time it may take to complete discovery? Can discovery be limited? Are less costly and time-consuming methods available to obtain necessary information?

9. **Estimated trial length.** Is it feasible or desirable to bifurcate issues for trial? Is it possible to reduce the length of the trial by stipulations, use of summaries or statements, or other expedited means of presenting evidence?

10. **Jury trial?**

11. **Settlement.** Have there been settlement discussions? What are the prospects for settlement? Is referral to the Magistrate for mediation or other ADR mechanism appropriate?

12. Such other matters as counsel considers conducive to the just, speedy and inexpensive determination of this action.

13. A statement that counsel for the parties have conferred about each of the above matters.

No continuance of the conference will be granted except by order of the court upon application of counsel made seven (7) days before the date of the conference supported by a declaration stating the reasons for the request.

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE

Civil Action No.: 07-792 (GMS)

ORDER

IT IS HEREBY ORDERED that, pursuant to Rule 16, Federal Rules of Civil Procedure, and Local Rule 16.2(b), a status and scheduling conference in this matter has been scheduled with the Honorable Gregory M. Sleet for **Monday, March 17, 2008, at 9:30 a.m.** Counsel with primary responsibility for this case shall appear at the United States District Court, 844 King Street, Room 4324, Wilmington, Delaware and be prepared to address any pending motions. Unless otherwise excused, local counsel shall appear as well. In preparation for this scheduling conference, the parties are directed to confer with respect to all agenda items listed below. **On or before the close of business on Monday, March 10, 2008, counsel shall file a JOINT STATUS REPORT addressing each agenda item.** Matters which the court will take up at the conference will include the following:

1. **Jurisdiction and Service.** Does the court have subject matter jurisdiction? Are all parties subject to the court's jurisdiction? Do any remain to be served?

2. **Substance of the Action.** What are the factual and legal bases for plaintiff's claims and defendants' defenses?

3. **Identification of Issues.** What factual and legal issues are genuinely in dispute?

4. **Narrowing of Issues.** Can the issues in litigation be narrowed by agreement or by motions? Are there dispositive or partially dispositive issues appropriate for decision on motion?

5. **Relief.** What specific relief does plaintiff seek? What is the amount of damages sought and generally how is it computed?

6. **Amendment of Pleadings?**

7. **Joinder of Parties?**

8. **Discovery.** Discovery contemplated by each party and the amount of time it may take to complete discovery? Can discovery be limited? Are less costly and time-consuming methods available to obtain necessary information?

9. **Estimated trial length.** Is it feasible or desirable to bifurcate issues for trial? Is it possible to reduce the length of the trial by stipulations, use of summaries or statements, or other expedited means of presenting evidence?

10. **Jury trial?**

11. **Settlement.** Have there been settlement discussions? What are the prospects for settlement? Is referral to the Magistrate for mediation or other ADR mechanism appropriate?

12. Such other matters as counsel considers conducive to the just, speedy and inexpensive determination of this action.

13. A statement that counsel for the parties have conferred about each of the above matters.

No continuance of the conference will be granted except by order of the court upon application of counsel made seven (7) days before the date of the conference supported by a declaration stating the reasons for the request.

/s/ Gregory M. Sleet
UNITED STATES DISTRICT 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' MOTION TO WITHDRAW IN PART
PLAINTIFFS' MOTION TO COMPEL DEFENDANTS TO COMPLY
WITH THE COURT'S FEBRUARY 20, 2008 ORDER

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-aventis") respectfully move to withdraw in part Plaintiffs' Motion To Compel Defendants To Comply With the Court's February 20, 2008 Order (D.I. 54) as moot. After sanofi-aventis filed its motion, Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") agreed to discuss the terms of the Protective Order. Sanofi-aventis continues to request, however, that the Court extend the parties' time to submit a joint proposed Protective Order to the Court by seven (7) days until March 10, 2008 so that sanofi-aventis, Apotex, and the other defendants in the related Delaware actions may continue their discussions on the terms of a global Protective Order to govern the disclosure, use and maintenance of confidential information in both the Florida and Delaware actions. Sanofi-aventis and the defendants in all four actions are scheduling a meet and confer on March 6, with defendants providing their proposed revisions to sanofi-aventis's

proposed order in advance of the call. Should Apotex fail to participate in these discussions in a meaningful way, sanofi-aventis reserves its rights to further move the Court to compel Apotex to comply with the February 20th Order.

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)
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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,

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201 South Biscayne Boulevard - Suite 2400
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Co-Counsel for Defendants
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SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO WITHDRAW IN PART 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 Withdraw In Part Plaintiffs' Motion To Compel Defendants To Comply With The Court's February 20, 2008 Order filed on February 28, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is:

ORDERED AND ADJUDGED that Plaintiffs' Motion To Withdraw In Part Plaintiffs' Motion To Compel Defendants To Comply With The Court's February 20, 2008 Order is GRANTED.

The parties shall propose a joint stipulated Protective Order in accordance 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.

Honorable Federico A. Moreno

United States District Court Judge