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**
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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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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 07-61800

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

CIV-MORENO

MAGISTRATE JUDGE
SIMONTON

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 company, Plaintiff sanofi-aventis U.S., which manufactures 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.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida 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.

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

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.

Dated this 10th day of December, 2007.
Miami, Florida

Respectfully submitted,

Alfred J. Saikali (Fla. Bar No. 178195)
asaikali@shb.com
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Miami Center, Suite 2400
Miami, FL 33131-4332
Telephone: (305)358-5171
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Attorney for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC

EXHIBIT A

United States Patent [19]

Regnier

[11] **Patent Number: 4,661,491**

[45] **Date of Patent: Apr. 28, 1987**

[54] **ALFUZOSINE COMPOSITIONS AND USE**

[75] Inventor: **François Regnier**, Nancy, France

[73] Assignee: **Synthelabo**, Paris, France

[21] Appl. No.: **867,031**

[22] Filed: **May 27, 1986**

[30] **Foreign Application Priority Data**

May 28, 1985 [FR] France 85 07950

[51] **Int. Cl.**[4] **A61K 31/505**

[52] **U.S. Cl.** **514/260**

[58] **Field of Search** 514/260

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,315,007 2/1982 Manoury 514/259

Primary Examiner—Allen J. Robinson

Attorney, Agent, or Firm—Wegner & Bretschneider

[57] **ABSTRACT**

A method for treating humans or non-human animals for dysuria comprising administering an effective non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

5 Claims, No Drawings

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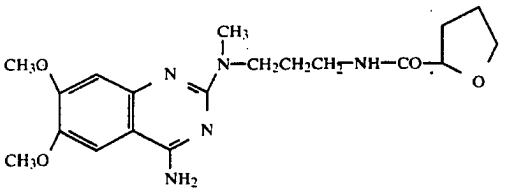
ALFUZOSINE COMPOSITIONS AND USE

The present invention relates to pharmaceutical compositions containing alfuzosine and the use of alfuzosine in the treatment of dysuria.

Alfuzosine, the compound of formula



is known for its antihypertensive activity. It is an antagonist of vascular α_1-adrenergic receptors which possesses direct muscle-relaxant properties.

In many patients manifesting dysuria, an exceptionally high cervico-urethral pressure is observed, which is related to a relative hyperactivity of the α-adrenergic receptors.

It has now been found that alfuzosine has activitity in altering the phenylephrine-induced contractions on preparations of smooth muscle originating from the base of the bladder (trigone muscle) and the urethra of rabbits and that alfuzosine can be used for the treatment of conditions of the lower urinary apparatus, in which hyperactivity of the alpha-adrenergic receptors of the vesicosphincter system disturbs the continence/micturition cycle.

Accordingly the present invention provides a method for treating dysuria in humans or non-human animals comprising administering a therapeutic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or animal suffering dysuria.

Patients who may be treated are, for example, men and women who have bladder neck disease, or men who have benign hypertrophy of the prostrate with dysuria of alpha-adrenergic origin.

Other patients who may be treated include those suffering from neurological disorders such as paraplegia or multiple sclerosis, for whom the disturbance of micturition also responds to alfuzosine.

The daily dosage can range from 0.5 to 10 mg for adult humans.

The present invention also provides a pharamceutical composition for treating dysuria comprising an effective amount of alfuzosine or a pharmaceutically acceptable salt thereof and a pharmaceutical diluent or carrier therefor.

The pharmaceutical compositions of the invention containing alfuzosine or a pharmaceutically acceptable salt thereof in combination with any suitable excipient can be administered orally, parenterally or transdermally. They are presented in any suitable form such as gelatine capsules, tablets, solutions, and the like. The pharmaceutical compositions can also be presented in the form of delayed-release tablets or gelatine capsules.

The pharmaceutically acceptable salts include acid addition salts of a pharamceutically acceptable organic or inorganic acid such as mineral acids and mono-, di- or tri- carboxylic acids, especially the hydrochloride salt.

The invention will now be illustrated by the following Pharmacological Data and Formulation Examples.

PHARMACOLOGICAL DATA

Male rabbits (CEGAN) weighing 3 to 4 kg are sacrificed by exsanguination and cervical dislocation.

The bladder and urethra are rapidly removed and placed in lukewarm Krebs solution containing bicarbonate.

The composition of this Krebs medium is as follows, in mM: NaCl 114; KCl 4.7; $CaCl_2$ 2.5; KH_2PO_4 1.2; $MgSO_4$ 1.2; $NaHCO_3$ 25.0; glucose 11.7; ascorbic acid 1.1. Propranolol (1.0 μM) is added into the Krebs medium to block the β-adrenergic receptors.

The bladder is opened transversely and the "trigone" region of the muscle, located on the dorsal surface of the bladder and between the two ureters, is dissected out.

A 5 mm ring of urethra, from the region situated between the base of the bladder and the prostate, is also prepared.

The portions of trigone muscle and urethra are washed under a tension of 1 g in Krebs medium.

The contraction-response curve to cumulated concentrations of phenylephrine is determined.

Additions of the agonist are performed every 5 min. The tissues are washed until the original tension is reestablished, and are then incubated for 30 min with alfuzosine. A second response curve to phenylephrine is determined in the presence of alfuzosine.

The response curves to concentrations of phenylephrine in the presence or absence of alfuzosine are expressed as a percentage of the maximum response obtained relative to the control curve.

The power of alfuzosine is calculated in the form of pA_2 by Schild's method, where pA_2=negative logarithm of the molar concentration of alfuzosine which causes a rightward shift of the response curve to the agonist.

Alfuzosine (at a dose of 3.0 μM) causes a significant rightward parallel shift of the response curve to phenylephrine both in the trigone muscle and in the urethra. Alfuzosine causes a 20 to 30% reduction in the maximum contractile effects of phenylephrine.

By Schild analysis, the pA_2 can be determined, this being 7.05–0.17.

By means of clinical studies, it has also been possible to show the efficacy of alfuzosine in patients suffering from dysuria of neurological origin with urethral hypertonia.

5 mg of alfuzosine are injected intravenously continuously for a period of 20 min. Sphincterometric measurements were made using an electronic micro-sensor, before and after the injection of the drug, at the bladder neck and at the striated sphincter of the posterior urethra.

The results of these measurements enabled a 44% pressure decrease ($p<0.001$) to be noted at the bladder neck, and a 39% decrease ($p<0.001$) at the striated sphincter.

A clinical study was also performed in paraplegics.

The paraplegic, or spinal man, gives rise to an experimental model of the peripheral receptors, since he embodies a disconnection from the influence of the higher, diencephalic and cortical nerve centres.

Given the localization of the alpha-adrenergic receptors in the posterior urethra and the vesico-urethral segment or neck, alpha-adrenergic hypertonia is the

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source of dysuria and disturbances of micturition. The opening of the neck and the fall in the pressure gradient in the posterior urethra are the two conditions required for the production of effective micturition.

Alfuzosine was administered intravenously, and then orally if the first test is positive. 5 mg of alfuzosine are injected intravenously in the course of 20 min.

After injection of alfuzosine, the intra-urethral pressures decrease significantly. The test is considered to be positive if an initiation of micturition, that is to say, necessarily, opening of the neck, takes place.

For patients for whom the test is positive, the administration of alfuzosine was then performed orally at the rate of 9 mg/24 h/28 d.

In most cases, the treatment per os enabled micturition to be rendered easier to initiate.

FORMULATION EXAMPLES

Examples of pharmaceutical formulations are given below:

	mg
Tablet:	
Alfuzosine (as the hydrochloride salt)	5
Microcrystalline cellulose	36
Lactose	122
Sodium carboxymethylamide	7
Polyvidone excipient	9
Magnesium stearate	1
	180
Coating env.	8
Injectable Solution	
Alfuzosine (as the hydrochloride salt)	1
Sodium chloride	44.9
Water for injection qs	5 ml

I claim:

1. 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 animal suffering dysuria.

2. A method according to claim **1** comprising administering alfuzosine hydrochloride.

3. A method according to claim **1** comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof.

4. A method according to claim **1** for treating dysuria in patients having bladder neck disease or a neurological disorder.

5. A method according to claim **1** for treating dysuria in male patients having benign hypertrophy of the prostrate of alpha-adrenergic origin.

* * * * *

JS 44 (Rev. 11/05)

CIVIL COVER SHEET

07-61800

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS

sanofi-aventi and

sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff France
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

DEFENDANTS

Apotex Inc. and

Apotex Corp.

County of Residence of First Listed Defendant Broward
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED.

Attorneys (If Known) CIV-MORENO

(d) Check County Where Action Arose: ☐ MIAMI- DADE ☐ MONROE ☒ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

FIL- 07 CV 61800 FAM/Simonton

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
[illegible]	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

MAGISTRATE JUDGE SIMONTON

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	LABOR	☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability		☐ 710 Fair Labor Standards Act	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury			☐ 720 Labor/Mgmt. Relations	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability				☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise				☐ 740 Railway Labor Act	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		☐ 790 Other Labor Litigation	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence		☐ 791 Empl. Ret. Inc. Security Act	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:		SOCIAL SECURITY	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 861 HIA (1395ff)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 862 Black Lung (923)	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other		☐ 863 DIWC/DIWW (405(g))	☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights		☐ 864 SSID Title XVI	☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition		☐ 865 RSI (405(g))	
				FEDERAL TAX SUITS	
				☐ 870 Taxes (U.S. Plaintiff or Defendant)	
				☐ 871 IRS—Third Party 26 USC 7609	

FILED by INTAKE D.C. DEC 10 2007 CLARENCE MADDOX CLERK U.S. DIST. CT. S.D. OF FLA. - MIAMI

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed- (see VI below) ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. RELATED/RE-FILED CASE(S).

(See instructions second page):

a) Re-filed Case ☐ YES ☐ NO b) Related Cases ☒ YES ☐ NO

JUDGE Sleet Manning

DOCKET NUMBER 1:07-cv-00572-GMS (D. Del.) 1:07-cv-00574-GMS (D. Del.) 1:07-cv-00792 (D. Del.) 1:07-cv-5807 (N.D. Ill.)

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause **(Do not cite jurisdictional statutes unless diversity):**

35 U.S.C. Section 271

Patent Infringement

LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

SIGNATURE OF ATTORNEY OF RECORD

DATE Dec. 10, 2007

FOR OFFICE USE ONLY

AMOUNT 350- RECEIPT # 971492 IFP

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.
_____/

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*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, 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 Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

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. admit that venue is proper in this judicial district.

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. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

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.

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

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.

AFFIRMATIVE 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 affirmative defenses to the Complaint:

FIRST AFFIRMATIVE 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 AFFIRMATIVE 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 AFFIRMATIVE 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. conducts substantial business in and has regular systematic contacts with 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 "AFLUZOSINE 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 AFLUZOSINE 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. 70-013 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 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 70-013 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.

DATED: December 28, 2007
Miami, FL

Respectfully submitted,

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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on December 28, 2007 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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

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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.
_____/

ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE DEFENSES AND AMENDED COUNTERCLAIMS[1]

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.

[1] This pleading is identical to the pleading filed December 28, 2007, except that certain inadvertent typographical errors in paragraphs 9, 11, 15 and 16 of the Counterclaims have been corrected.

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*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, 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 Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

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. admit that venue is proper in this judicial district.

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. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

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.

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

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.

AFFIRMATIVE 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 affirmative defenses to the Complaint:

FIRST AFFIRMATIVE 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 AFFIRMATIVE 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 AFFIRMATIVE 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.

AMENDED 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. conducts substantial business in and has regular systematic contacts with 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.

DATED: January 2, 2008
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis
Stephen J. Bronis
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and

s/. Robert B. Breisblatt
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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on January 2, 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
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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.
_____/

SCHEDULING ORDER

THIS COURT issues this Order in accordance with S.D. Fla. L. R. 16.1. The parties shall comply with the following deadlines.

Conference and selection of a mediator to be completed no later than:	**January 17, 2008**
Deadline to join additional parties or to amend pleadings:	**January 31, 2008**
Deadline to complete all discovery:	**March 27, 2008**
Deadline for the filing of all motions for summary judgment:	**April 10, 2008**
Deadline for the filing of pretrial motions, including motions *in limine* and *Daubert* motions:	**April 28, 2008**
Mediation to be completed no later than:	**April 28, 2008**
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	**May 7, 2008**
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	**May 9, 2008**
Pretrial stipulation to be filed by:	**May 13, 2008**
Calendar Call at 2:00 P.M. on:	**May 20, 2008**
Trial set for the two-week period commencing:	**May 27, 2008**

To the extent that the parties request modification of any date in this Court's Scheduling Order, the parties shall file either a *Motion to Continue Trial* or a *Motion to Continue Pretrial Deadlines*.

DONE AND ORDERED in Chambers at Miami, Florida, this 3rd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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.
_____/

SCHEDULING ORDER SETTING TRIAL

Pursuant to Fed. R. Civ. P. 40 and S.D. Fla. L. R. 40.1, this action is at issue. It is therefore **ADJUDGED** that:

(1) TRIAL DATE - This case is set for trial during the two-week period commencing **May 27, 2008**, in Miami, Florida

(2) CALENDAR CALL - Counsel must appear at Calendar Call which shall take place before the undersigned at the United States Courthouse, Federal Justice Building, Courtroom IV, Tenth Floor, 99 Northeast 4th Street, Miami, Florida 33132, on **Tuesday, May 20, 2008, at 2:00 P.M.** The parties need not appear at Calendar Call. At Calendar Call counsel may bring all matters relating to the scheduled trial date to the attention of the Court. Counsel also shall be prepared to address all pending motions.

(3) PRETRIAL CONFERENCE - The Pretrial Conference allowed for under Fed. R. Civ. P. 16(a) and required by S.D. Fla. L.R. 16.1.C., shall take place immediately following Calendar Call only if requested by the parties in advance. If the parties do not request a pretrial conference

in advance of Calendar Call then no pretrial conference will be held.

(4) PLAINTIFFS' WITNESS AND EXHIBIT LISTS - Plaintiffs shall provide Defendants, by either fax or hand delivery, a copy of Plaintiffs' Witness List and a copy of Plaintiffs' Exhibit List no later than **Wednesday, May 7, 2008, at 5:00 P.M.**

(a) PLAINTIFFS' WITNESS LIST - Plaintiffs' Witness List shall include all the witnesses, both lay and expert, that Plaintiffs intend to call at trial. Plaintiffs' Witness List shall briefly describe the nature of each witness's testimony and whether such witness will be testifying live or by deposition. Witnesses omitted from the list will not be allowed at trial.

(b) PLAINTIFFS' EXHIBIT LIST - Plaintiffs' Exhibit List shall include all the exhibits that Plaintiffs intend to use at trial. Plaintiffs' Exhibit List shall in consecutively numbered paragraphs adequately describe the nature of each document listed. The actual exhibits shall be pre-marked with corresponding numbers (*e.g.* Plaintiffs' Exhibit #1, P.E. #2, P.E. #3...) which numbers they will retain through the end of trial. The exhibit list shall refer to specific items and shall not include blanket statements such as *all exhibits produced during depositions* or *Plaintiffs reserve the use of any other relevant evidence*. Exhibits omitted from the list will not be allowed at trial.

(5) DEFENDANTS' WITNESS AND EXHIBIT LISTS - Defendants shall provide Plaintiffs, by either fax or hand delivery, a copy of Defendants' Witness List and a copy of Defendants' Exhibit List no later than **Friday, May 9, 2008, at 5:00 P.M.**

(a) DEFENDANTS' WITNESS LIST - Defendants' Witness List shall include only those additional lay and expert witnesses not included on Plaintiffs' Witness

List. Witnesses listed by Plaintiffs will be available for both parties and should not be re-listed on Defendants' Witness List. Defendants' Witness List shall briefly describe the nature of each additional witness's testimony and whether such witnesses will be testifying live or by deposition. Witnesses omitted from Defendants' Witness List and not listed on Plaintiffs' Witness List will not be allowed at trial.

(b) DEFENDANTS' EXHIBIT LIST - Defendants' Exhibit List shall include only those additional exhibits that Defendants wish to introduce at trial which are not on Plaintiffs' Exhibit List. Defendants' Exhibit List shall in consecutively numbered paragraphs adequately describe the nature of each document listed. The actual exhibits shall be pre-marked with corresponding numbers (*e.g.* Defendants' Exhibit #1, D.E. #2, D.E. #3...) which numbers they will retain through the end of trial. The exhibit list shall refer to specific items and shall not include blanket statements such as *all exhibits produced during depositions* or *Defendants reserve the use of any other relevant evidence*. Exhibits omitted from Defendants' Exhibit List and not listed on Plaintiffs' Exhibit List will not be allowed at trial.

(6) PRETRIAL STIPULATION - Pursuant to S.D. Fla. L.R. 16.1.E., the parties shall file a Pretrial Stipulation no later than **Tuesday, May 13, 2008**. The Pretrial Stipulation shall conform to the requirements of S.D. Fla. L.R. 16.1.E. The parties shall attach to the Pretrial Stipulation copies of the witness and exhibit lists along with any objections as allowed for under S.D. Fla. L.R. 16.1.E.9. A pending motion for continuance shall not stay the requirement for the filing of a Joint Pretrial Stipulation.

(7) SERVICE LIST - Plaintiffs' counsel shall notify any party or attorney not listed below of this Order, and shall advise the Court, through a written notice filed with the Clerk of

Court, of any party or attorney not copied with the Order.

(8) CONTINUANCE / SETTLEMENT - A motion for continuance or a stipulation of settlement must be in writing and accompanied by self-addressed stamped envelopes. S.D. Fla. L.R. 7.1.4. Unless the Court grants the motion in writing, counsel must appear at the Calendar Call.

(9) MOTIONS - When submitting motions, the parties shall: (a) submit a proposed order only for those motions listed in S.D. Fla. L.R. 7.1.A.1; and (b) submit only one original proposed order attached to the Judge's copy. All filings that include a memorandum of law required by S.D. Fla. L.R. 7.1.A.1 also must be submitted on an IBM-compatible 3.5 floppy diskette in WordPerfect format unless filed as part of the Court's electronic filing program.

(10) DEPOSITIONS - Depositions are limited to seven hours during one day absent court order or agreement of the parties and any affected non-party witnesses.

(11) MOTIONS TO DISMISS - Motions to dismiss shall not stay discovery.

(12) SUMMARY JUDGMENT - The practice of filing multiple motions for partial summary judgment which are collectively intended to dispose of the case (as opposed to one comprehensive motion for summary judgment) in order to evade memorandum page limitations is specifically prohibited. *See Administrative Order 97-06* (S.D. Fla. January 31, 1997)(amending S.D. Fla. L.R. 7.1.C.2.).

DONE AND ORDERED in Chambers at Miami, Florida, this 3rd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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.
_____/

PRETRIAL ORDER SETTING CONFERENCE

THIS CAUSE came before the Court upon a *sua sponte* examination of the record. It is

ADJUDGED that S.D. Fla. L.R. 16.1 shall apply to this case and the parties shall hold a conference no later than **January 17, 2008**. The conference may be held via telephone. At the conference, the parties shall comply with the following agenda that the Court adopts from S.D. Fla. L.R. 16.1.

(1) Documents (S.D. Fla. L.R. 16.1.B.1 and 2) - The parties shall determine the procedure for exchanging a copy of or a description by category and location of all documents and other evidence that is reasonably available and that a party expects to offer or may offer if the need arises. Fed. R. Civ. P. 26(a)(1)(B).

(a) Documents include computations of the nature and extent of any category of damages claimed by the disclosing party unless the computations are privileged or otherwise protected from disclosure. Fed. R. Civ. P. 26(a)(1)(C).

(b) Documents include insurance agreements which may be at issue with the satisfaction of the judgment. Fed. R. Civ. P. 26(a)(1)(D).

(2) List of Witnesses - The parties shall exchange the name, address and telephone

number of each individual known to have knowledge of the facts supporting the material allegations of the pleading filed by the party. Fed. R. Civ. P. 26(a)(1)(A). The parties have a continuing obligation to disclose this information.

(3) Settlement Discussions (S.D. Fla. L.R. 16.1.B.2) - The parties shall discuss the nature and basis of their claims and defenses and the possibilities for a prompt settlement or resolution of the case.

To the extent that the parties request modification of the Court's Scheduling Order, the parties shall also file either a *Motion to Continue Trial* or a *Motion to Continue Pretrial Deadlines*.

Failure to comply with this Order or to exchange the information listed above may result in sanctions and/or the exclusion of documents or witnesses at the time of trial. S.D. Fla. L.R. 16.1.M.

DONE AND ORDERED in Chambers at Miami, Florida, this 3rd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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 REFERRING CASE TO MEDIATION

Trial having been set in this matter for **the two-week period commencing May 27, 2008** pursuant to Fed. R. Civ. P. 16 and S.D. Fla. L.R. 16.2, it is

ADJUDGED as follows:

(1) MEDIATION - All parties must participate in mediation. The parties shall complete mediation no later than **April 28, 2008**.

(2) SELECTION OF MEDIATOR - Plaintiffs' counsel, or another attorney agreed upon by all counsel of record and any unrepresented parties, shall be the "lead counsel" and responsible for scheduling the mediation conference. The parties are encouraged to avail themselves of the services of any mediator on the List of Certified Mediators, maintained in the office of the Clerk of this Court, but may select any other mediator. The parties shall agree upon a mediator no later than **January 17, 2008**. If there is no agreement, lead counsel shall promptly notify the Clerk in writing and the Clerk shall designate a mediator from the List of Certified Mediators, which designation shall be made on a blind rotation basis.

(3) ORDER SCHEDULING MEDIATION - A place, date, and time for mediation convenient to the mediator, counsel of record, and unrepresented parties shall be established. Lead

counsel shall complete the form order attached and submit it to the Court. After the Court enters the completed form order, the mediator may, with consent of the parties, reschedule mediation at the mediator's discretion without further order of the Court.

(4) ATTENDANCE - The appearance of counsel and each party or representatives of each party with full authority to enter into a full and complete compromise and settlement is mandatory. If an insurer is involved, an adjuster with authority up to the policy limits or the most recent demand, whichever is lower, shall attend.

(5) CONFIDENTIALITY - All discussions, representations and statements made at the mediation conference shall be confidential and privileged.

(6) MEDIATOR SUMMARY - At least **ten** days prior to the mediation date, all parties shall present to the mediator a brief written summary of the case identifying issues to be resolved. Copies of these summaries shall be served on all other parties.

(7) NON-COMPLIANCE - The Court may impose sanctions against parties and/or counsel who do not comply with the attendance or settlement authority requirements or who otherwise violate the terms of this Order. The mediator shall report non-attendance and may recommend imposition of sanctions by the Court for non-attendance.

(8) MEDIATOR COMPENSATION - The mediator shall be compensated in accordance with the standing order of the Court entered pursuant to S.D. Fla. L.R. 16.2.B.6, or on such basis as may be agreed to in writing by the parties and mediator selected by the parties. The parties shall share equally the cost of mediation unless otherwise ordered by the Court. All payments shall be remitted to the mediator within thirty days of the date of the bill. Notice to the mediator of cancellation or settlement prior to the scheduled mediation conference must be given at least two full business days in advance. Failure to do so will result in imposition of a fee for one hour.

(9) SETTLEMENT - If a full or partial settlement is reached in this case, counsel shall promptly notify the Court of the settlement in accordance with S.D. Fla. L.R. 16.2.F, by the filing

of a notice of settlement signed by counsel of record within **ten** days of the mediation conference. Thereafter the parties shall submit an appropriate pleading concluding the case.

(10) MEDIATION REPORT - Within **five** days following the mediation conference, the mediator shall file a Mediation Report indicating whether all required parties were present. The report shall also indicate whether the case settled (in full or in part), was continued with the consent of the parties or whether the mediator declared an impasse.

(11) SANCTIONS - If mediation is not timely conducted, the case may be stricken from the trial calendar, and other sanctions including dismissal or default may be imposed.

DONE AND ORDERED in Chambers at Miami, Florida, this 3rd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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 SCHEDULING MEDIATION

The mediation conference in this matter shall be held with _____ on _____, 200__, at _____AM / PM at _____ _____.

DONE AND ORDERED in Chambers at Miami, Florida, this ___ day of _____, 200__.

_____
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.
/

PLAINTIFFS' MOTION TO TRANSFER OR STAY
AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action is currently pending. Defendants Apotex Corp. and Apotex Inc. do not contest personal jurisdiction in Delaware and admit that venue in that forum is proper. Plaintiffs' choice of forum, the first-filed rule, and the interests of justice and convenience to the parties and witnesses favor transfer of this action to Delaware where it will proceed before the same Judge and Magistrate Judge as two related actions involving 13 other defendants and the parallel action against Apotex Corp. and Apotex Inc. Alternatively, Plaintiffs respectfully move this Court to stay the present action pending the disposition of any transfer issues raised by Defendants in the first-filed forum.

Counsel for Plaintiffs certify that pursuant to Local Rule 7.1.A.3(a) it has met and conferred with counsel for Defendants in an effort to resolve the issues raised by Plaintiffs' Motion to Transfer or Stay. The parties were unable to resolve those issues.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully requests that the Court enter an Order granting Plaintiffs' Motion to Transfer or Stay.

MEMORANDUM OF LAW

This is an action brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this memorandum in support of their motion to transfer this action to the District of Delaware where an identical, parallel, first-filed action and two related cases against 13 other defendants are currently pending. Alternatively, Plaintiffs request that the Court stay this action pending the resolution of any venue issues raised in the Delaware action by Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex").

The District of Delaware is Plaintiffs' forum of choice and the first-filed forum. This is true not only for the parallel proceeding against Apotex, but also for sanofi-aventis's claims against 13 other defendants. Plaintiffs would not have even filed this action if Apotex had timely confirmed what it has now admitted in its pleadings and in its representations to Plaintiffs — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in that forum.

But rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions as the majority of Apotex's documents and witnesses are likely located in Canada where it develops its generic products, and the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum

in which they proceed. If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of time and resources on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts. Apotex's tactics will not only impact the parties in this case, but also the 13 additional defendants in Delaware where sanofi-aventis's other patent infringement actions will proceed regardless of what happens in this jurisdiction. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and transfer this case to Delaware so that all claims for patent infringement may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

Alternatively, if the Court does not transfer at this time, Plaintiffs respectfully request that it stay the present action and defer to the first-filed District of Delaware on the issue of venue while the parties continue to litigate their claims and defenses in that forum.

BACKGROUND

I. The Parties

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

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. Apotex Inc. and Apotex Corp.

sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. 1, The Apotex Group Corporate Info.[1]

II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 (issued April 28, 1987) ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000) ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287.

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

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation and/or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale

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[1] True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Motion to Transfer or Stay.

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

of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. 2, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. 3, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

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

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

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

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try each of sanofi-aventis's claims against all defendants, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications. [3]

[3] In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940

See Ex. 4, Delaware Complaint No. 07-572; Ex. 5, Delaware Complaint No. 07-574.

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

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. 6, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent. Ex. 7, Apotex Delaware Complaint. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

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

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. 9, 12/06/07 W. Vuk ltr to B. Sherman. It was only after that period ran that Apotex represented

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patent alone against four additional defendants.

[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. 8, Answer in *Allergan, Inc. v. Apotex Inc.et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3**;** Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. 8, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4**.**

that it would not contest jurisdiction in Delaware. Ex. 10, 12/11/07 M. Noreika email to S. Rollo; Ex. 11, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the complaint in Delaware and conceded that jurisdiction and venue were proper in Delaware:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." *See* Ex. 12, Apotex Delaware Answer And Counterclaims ¶ 7.
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Despite these clear admissions to the Delaware court as to the appropriateness of jurisdiction and venue, Apotex has indicated that it will move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* Ex. 12 ¶ 10; Ex. 13, 01/07/08 S. Feldman ltr to W. Vuk; Ex. 14, 01/07/08 W. Vuk ltr to S. Feldman.

All three first-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and the same Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. *See* Ex. 15, Delaware Docket Sheets. [5]

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

Apotex's refusal to consent to jurisdiction in Delaware within the 45-day window to bring

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5 One additional protective suit is currently pending against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. Plaintiffs have not served the complaint in that action and expect that their claims against the Aurobindo defendants will proceed in the District of Delaware where jurisdiction and venue are proper with respect to both parties.

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

Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over Apotex, this is the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring this second-filed action within the 45-day window on December 10, 2007.[6] Ex. 16, Florida

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

Complaint. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing so that sanofi-aventis could voluntarily dismiss the Florida complaint.

It is now clear that this tactic was an attempt to make an end rule around Plaintiffs' choice of forum. Apotex filed its Answer and Counterclaims in this action on December 28, 2007, one business day before answering the first-filed Delaware action, in a thinly-veiled attempt to manufacture an argument that this action is at a more advanced state than the first-filed Delaware actions.[7] *See* Ex. 17, Florida Answer And Counterclaims; Ex. 18, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that this forum is "more convenient" with the "fact" that this action has progressed farther than the Delaware actions because it filed its answer in Florida one business day before answering in Delaware. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have failed.

ARGUMENT

I. All Relevant Factors Favor Transfer To Delaware Where Identical Claims And Counterclaims Are Pending With Related Claims Against 13 Other Defendants

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been

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[7] In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. 17 ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest the Delaware court's personal jurisdiction over Apotex Inc. Ex. 12 ¶ 8; *see also* Ex. 10; Ex. 11.

brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Manuel v. Convergys Corp.*, 430 F.3d 1132, 1135 n.1 (11th Cir. 2005).

There is no dispute that this Court has the power to transfer this action to the District of Delaware as, unlike the circumstances of many motions to transfer, sanofi-aventis and Apotex agree that jurisdiction and venue are proper in Delaware. The Court should exercise its power and transfer this action to the first-filed forum for adjudication with the parties' identical claims pending in that court along with two related patent infringement litigations involving the same patents-in-suit and reference drug—actions that will proceed regardless of what happens in this forum. First, Delaware is both Plaintiffs' forum of choice and the first-filed forum, two factors that weigh heavily in favor of transfer. Second, transfer would avoid the duplicative efforts and costs of two separate courts conducting extensive pretrial activities and prevent potentially inconsistent rulings on critical issues such as claim construction and summary judgment. Finally, although Apotex claims that it would be more convenient for it to proceed in this forum, that convenience is minimal as most of its relevant witnesses and documents are likely located in Canada where it develops generic products. Additionally, it is likely that this action will take a significant amount of time to adjudicate regardless of where it proceeds in light of the complex nature of the case and the expected scope of discovery. Any minimal added burden of litigating in Delaware, where Apotex has recently litigated several other ANDA actions without moving to transfer, is heavily outweighed by the interests of judicial economy and certainty of patent rights as well as the inconvenience the parties would experience by litigating the same issues in two separate judicial districts. *See Abbott,* 2006 WL 850916, at *8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint).

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

Plaintiff's choice of forum weighs in favor of a request to transfer and should not be disturbed unless clearly outweighed by other considerations. *Cf. Robinson v. Giarmarco & Bill, P.C.*, 74 F.3d 253, 260 (11th Cir. 1996) (refusing to transfer outside of plaintiffs' forum where such a transfer would merely shift the burdens on the parties). Here, sanofi-aventis chose the District of Delaware because it was the district where Plaintiffs could bring each of the ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. Plaintiffs were only forced to bring this second-filed action because Apotex refused to confirm that it would not contest jurisdiction in Delaware within the 45-day window Plaintiffs had to bring suit under the Hatch-Waxman Act. *See, e.g.,* Ex. 9. As discussed above, the law remains unclear as to whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act, namely the 30-month stay of approval of the proposed generic product, if its action, properly brought within the 45-day window, is later dismissed for lack of personal jurisdiction. *See Abbott*, 2006 WL 850916, at *8; *PDL,* 2007 WL 2261386, at *2. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should transfer this action to Plaintiffs' forum of choice. *See* Ex. 10; Ex. 11; Ex. 12 ¶¶ 7-10.

Transfer under this set of facts would also comport with the 11th Circuit's "first-filed" rule. Under that standard, if two actions involving the same parties and identical issues are pending in different districts, the first-filed action should typically be given priority and be allowed to proceed in favor of the later action. *See Manuel*, 430 F.3d at 1135-38 ("[W]here two actions involving overlapping issues and parties are pending in two federal courts, there is a strong presumption across the federal circuits that favors the forum of the first-filed suit under the first-filed rule."); *Philibert v. Ethicon, Inc.*, No. 04-81101-CIV, 2005 WL 525330, at *1 (S.D.

Fla. Jan. 14, 2005). Contrary to Apotex's unsupported assertions, this rule applies even where plaintiff files both actions, a measure that courts have recognized as necessary under the Hatch-Waxman Act. Ex. 14; *PDL*, 2007 WL 2261386, at *2; *see also Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202-03 (S.D. Fla. 1987) (rejecting defendants' assertion that a plaintiff must show a change of circumstances when moving under § 1404 and ordering transfer to the first filed forum where four related litigations involving these and other defendants were already pending).[8]

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Consequently, the Court should transfer this action under the first-filed rule. *Philibert*, 2005 WL 525330 at *2 (transferring to the first-filed forum where identical claims were pending to serve the interests of justice); *Tiber Labs., LLC v. Cypress Pharm., Inc.*, No. 2:07-CV-0014-RWS, 2007 WL 3216625, at *2-3 (N.D. Ga. May 11, 2007).

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[8] The first-filed rule is measured by which action was filed first, not by when counterclaims are first filed. Consequently, Delaware is the first-filed forum in this case, even though Apotex's counterclaims with respect to the '940 patent were filed in this District one business day before filing them in Delaware. *See Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d 738, 740-41 (E.D. Wis. 2003) (rejecting a similar argument concerning declaratory judgment counterclaims asserted in the second-filed action concerning patents not initially at issue in the first-filed action because "[t]he issue, however, is not which of the claims was filed first, but rather which action was filed first."); *Versus Tech., Inc. v. Hillenbrand Indus., Inc.,* No. 1:04-CV-168, 2004 WL 3457629, at *6-7 (W.D. Mich. Nov. 23, 2004); *cf. Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.,* 535 U.S. 826, 831-32 (2002) (holding that counterclaims cannot serve as the basis for "arising under" jurisdiction under the well-pleaded complaint rule).

B. The Interests of Justice Can Only Be Served By Transfer To The Forum Where All Others Claims Concerning The Patents Are Pending

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997).

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.,* a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at *1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a separate declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at *2; *Cordis Corp.*, 682 F. Supp. at 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel

between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the Court held that all the parties would benefit because:

> The two actions should be consolidated before one judge thereby promoting judicial efficiency, pretrial discovery could be conducted in a more orderly manner, witnesses could be saved the time and expense of appearing at trial in more than one court, duplicative litigation involving the filing of records in both courts could be avoided eliminating unnecessary expense and the possibility of inconsistent results could be avoided."

Id. at 888 (internal quotations omitted).

The facts supporting transfer are even more compelling here where sanofi-aventis has multiple suits pending in the District of Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to the parallel action against Apotex, there are two other cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of what happens in this forum. Each of these actions has been assigned to the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order from the court. Plaintiffs expect that the Delaware court will coordinate pretrial activities in all three pending cases, and may consolidate all three actions for pretrial proceedings, in order to avoid duplicative discovery efforts and improve the efficiency of its docket.

By transferring this action for coordination with the Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. For example, as the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer will avoid multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the ANDA filers may seek discovery.

Likewise, transfer will avoid duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Delaware will obviate the need for multiple courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, transfer will prevent potentially inconsistent rulings on critical issues such as the validity and enforceability of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to the specialized *Markman* hearing courts must hold to construe the meaning of asserted claim terms as a matter of law, where inconsistent rulings could result in identical claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MRL, LLC v. U.S. Robotics Corp.,* No. 02 C 2898, 2003 WL 685504, at *1-2 (N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

C. Apotex's Unsupported Convenience And Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors

Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in this District. Ex. 12 ¶ 10; Ex. 18 ¶ 19. As discussed above, Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations without moving to transfer. In this case, as in the *Alere* and *Tingley* cases discussed above, any marginal convenience to Apotex of proceeding in Florida is vastly outweighed by the courts' and the

parties' interests in avoiding duplicative pretrial activities, in preventing potentially inconsistent rulings, and the inconvenience to the parties of having to proceed in two separate jurisdictions.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to this forum even though there were no related actions pending in Indiana, let alone claims against 13 other defendants as in the case at bar. *See Alcon Mfg., Ltd. v. Apotex Inc.,* No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007). In *Alcon*, Apotex argued that (1) this forum was more convenient to Apotex and its witnesses and no less convenient for the plaintiff and (2) the interests of justice favored this forum because it had an interest in deciding local controversies and could conduct a more speedy trial.

The *Alcon* court rejected both of Apotex's arguments. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally; thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon,* 2007 WL 854026, at *2-3. Second, Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.; see also Abbott*, 2006 WL 850916, at *7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). Finally, the court rejected Apotex's interest of justice arguments as the suit was likely to affect consumers nationwide, not just in Florida, and because the case involved complex issues concerning patent infringement, it would likely take several years to

adjudicate, regardless of the venue. *Alcon,* 2007 WL 854026, at *4.

This case falls squarely within the *Alcon* court's rationale. Sanofi-aventis's witnesses and documents are likely to be found in Europe, New Jersey, and Pennsylvania, not Florida. As in *Alcon*, Apotex Inc., the Canadian corporation, is the holder of the ANDA, and it is likely that Canada is the situs of events such as preparation of that ANDA and its underlying research and development as well as the documents concerning and the witnesses with knowledge of those issues. Likewise, Apotex can make no showing this is a local dispute over which Florida has any specialized interest because Uroxatral® is sold throughout the country and Plaintiffs expect that Apotex will seek to market its products well beyond the borders of this forum as it has with its other generic products developed and manufactured abroad.

Apotex has indicated that the interest of a speedy trial necessitates proceeding in this Court. Ex. 13, Ex. 14. That argument failed in *Alcon* and should fail here as well. This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art, and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, sanofi-aventis will ask Apotex to consent, or otherwise move the Court, to place this action on a Complex Track under Local Rule 16.1.A to ensure that the parties conduct

discovery in a fair and efficacious manner and fully develop their claims and defenses prior to trial.

And here of course, there is the additional factor that was not present in *Alcon*: that there are actions pending against 13 other defendants in the first-filed forum that must proceed regardless of where the present case is adjudicated.[9]

II. Alternatively, This Court Should Exercise Its Discretion To Stay This Action Pending The District Of Delaware's Adjudication Of Any Transfer Issues

If the Court does not transfer, sanofi-aventis respectfully requests that it stay the present action pending resolution of any transfer issues raised by Apotex in the first-filed Delaware action. It is well-settled that district courts have discretion to stay an action to give priority to first-filed parallel proceedings in another district. *See, e.g., Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183-4 (1952); *Landis v. N. Am. Co.*, 299 U.S. 248 (1936); *Perkins v. Am. Nat. Ins. Co.*, 446 F. Supp. 2d 1350, 1353-54 (M.D. Ga. 2006). This power to stay actions is in the interest of "[w]ise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation . . . ." *Kerotest*, 342 U.S. at 183; *Landis*, 299 U.S. at 254; *Lisa v. Mayorga*, 232 F. Supp. 2d 1325, 1326 (S.D. Fla. 2002). In deciding whether to order a stay, a district court should weigh the factors of judicial economy and balance the interests of the parties and the Court. *Id.*

The court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay a second-filed so-called "protective action" based on the "first-filed" rule. ANDA filer and defendant Sun opposed

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9 For the forgoing reasons, Plaintiffs expect that Apotex will likely fail in any motion to transfer the Delaware action to this forum. *See, e.g., Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at *2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where, *inter alia*, plaintiff had a rational and legitimate reason to sue defendants in the forum and noting that "a flight to Delaware is not an onerous task warranting transfer.").

the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *PDL*, 2007 WL 2261386, at *2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

> Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the 'extraordinary circumstances' of the case weighs in favor of the stay.

Id. "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay." *Id.; see* Ex. 19, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (staying second-filed action while jurisdictional issues were pending before the first-filed court).

The facts in the present case are identical in all relevant respects to those in *PDL*. Sanofi-aventis was forced by Apotex's temporary refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in this District. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge

jurisdiction. *See* Ex. 12. Apotex can hardly argue that sanofi-aventis's filing of parallel actions, or this motion, are motivated by bad faith or forum shopping. *See PDL*, 2007 WL 2261386, at *2; *see also Abbott*, 2006 WL 850916, at *8.

As in *PDL*, balancing the interests of the parties favors a stay of this action. Requiring the parties to litigate the same issues in this action in parallel to the first-filed Delaware actions is likely to lead to significant duplication of effort and expense, as discussed above with respect to transfer. There is no prejudice to weigh against these interests as the parties will continue to litigate their claims and defenses in the District of Delaware. Moreover, in the unlikely event that Apotex successfully moves the Delaware court to transfer the first-filed action here, the Court can immediately lift the stay and proceed in this case.

CONCLUSION

For all the foregoing reasons sanofi-aventis requests that the Court transfer this action to the District of Delaware. In the alternative, sanofi-aventis requests that the Courts stay this action until the District of Delaware adjudicates any motion to transfer brought by Apotex.

Dated: January 8, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

s/ Alfred J. Saikali_____
Alfred J. Saikali
Fla. Bar No.: 178195
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470
asaikali@shb.com
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470

Attorneys for Plaintiffs

SERVICE LIST

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

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

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

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

VIA CM/ECF

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.

[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION TO TRANSFER OR STAY

THIS CAUSE is before the Court on Plaintiffs' Motion to Transfer or Stay, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that:

1. [ ] The above-captioned proceeding is hereby transferred to the United States District Court for the District of Delaware.

   [ ] The above-caption proceeding is hereby stayed until the District of Delaware adjudicates any motion to transfer brought by Defendants.

2. The Parties are hereby authorized to take action consistent with this Court's ruling.

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

Honorable Federico A. Moreno
United States District Court Judge

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 TRANSFER OR STAY

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 with respect to *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (GMS) (MJT) and *sanofi-aventis and sanofi-aventis U.S. LLC, v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT) currently pending in the District Court for the District of Delaware. I submit this declaration in support of Plaintiffs' Motion to Transfer or Stay and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit 1 is a true and accurate copy of Apotex Inc. - Corporate Info, http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes (last visited January 7, 2008).

2. Attached hereto as Exhibit 2 is a true and accurate copy of a letter dated August 14, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.

3. Attached hereto as Exhibit 3 is a true and accurate copy of a letter dated October 25, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.

4. Attached hereto as Exhibit 4 is a true and accurate copy of the Complaint 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.

5. Attached hereto as Exhibit 5 is a true and accurate copy of the Complaint 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.

6. Attached hereto as Exhibit 6 is a true and accurate copy of a letter dated October 1, 2007 from William T. Vuk to Bernice Tao.

7. Attached hereto as Exhibit 7 is a true and accurate copy of the Complaint 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.

8. Attached hereto as Exhibit 8 are true and correct copies of:

- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated June 11, 2007 filed in *Allergan, Inc. v. Apotex, Inc. and Apotex Corp.*, Civil Action No. 07-278-GMS, in the District Court for the District of Delaware;

- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated May 30, 2007 filed in *Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-204-SLR, in the District Court for the District of Delaware;

- excerpts from Answer of Apotex Inc. and Apotex Corp. to Plaintiff's Amended Complaint, Affirmative Defenses and Counterclaims dated April 14, 2006 filed in

Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp., Civil Action No. 06-164 (SLR), in the District Court for the District of Delaware;

- excerpts from Defendant Apotex, Inc.'s Answer, Affirmative Defenses and Counterclaims dated May 9, 2006 filed in *Merck & Co., Inc. v. Apotex, Inc.*, Civil Action No. 06-230-GMS, in the District Court for the District of Delaware; and

- Complaint for Declaratory Judgment and Demand for Jury Trial dated October 29, 2003 filed in *Torpharm Inc., Apotex Corp., and Apotex , Inc., v. Pfizer Inc. and Warner-Lambert Company*, Civil Action No. 03-990, in the District Court for the District of Delaware.

9. Attached hereto as Exhibit 9 is a true and accurate copy of a letter dated December 6, 2007 from William T. Vuk to Dr. Bernard Sherman and Tammy McIntyre.

10. Attached hereto as Exhibit 10 is a true and accurate copy of an email dated December 11, 2007 from Maryellen Noreika to Sherry L. Rollo.

11. Attached hereto as Exhibit 11 is a true and accurate copy of a letter dated December 31, 2007 from Maryellen Noreika to Sherry L. Rollo.

12. Attached hereto as Exhibit 12 is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Counterclaims dated January 2, 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.

13. Attached hereto as Exhibit 13 is a true and accurate copy of a letter dated January 7, 2008 from Steven E. Feldman to William T. Vuk.

14. Attached hereto as Exhibit 14 is a true and accurate copy of a letter dated January 7, 2008 from William T. Vuk to Steven E. Feldman.

15. Attached hereto as Exhibit 15 are accurate and correct copies of the docket sheets for Civil Action Nos. 07-572 (GMS) (MJT); 07-574 (GMS) (MJT); and 07-792 (GMS) (MJT), in the District Court for the District of Delaware, printed from the PACER website on January 8, 2008.

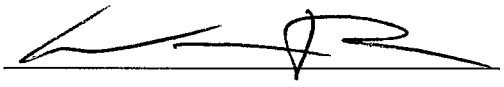
16. Attached hereto as Exhibit 16 is a true and accurate copy of the Complaint dated December 10, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

17. Attached hereto as Exhibit 17 is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Counterclaims dated December 28, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

18. Attached hereto as Exhibit 18 is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Amended Counterclaims dated January 2, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court of the Southern District of Florida.

19. Attached hereto as Exhibit 19 is a true and accurate copy of the Transcript of Scheduling Conference Before The Honorable Shelby Highsmith, United States District Judge, dated July 10, 2000, from *Abbott Laboratories v. Andrx Corporation, et al.*, Civil Action No. 00-6520-CV-SH, in the District Court of the Southern District of Florida.

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



William T. Vuk

January 8, 2008
New York, New York

EXHIBIT 1

THE APOTEX GROUP
CANADA'S PHARMACEUTICAL COMPANIES

Select a Country

- Home
- Sales
- Products
- Corporate Info
- Bioequivalence
- Career Opportunities
- Healthcare Professionals
- Corporate Purchasing
- Press Releases
- Contact Us
- Apo-TriAvir
- Printer Friendly Version



Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. From its 2 employees, 5,000 square foot beginning, the company has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide. The Canadian operations of the Apotex Group of Companies with approximately 5,500 employees now occupy over 3.4 million square feet in Montreal, Richmond Hill, Toronto, Etobicoke, Mississauga, Brantford, Windsor, Winnipeg, Calgary and Vancouver.

In the last few years, Apotex has hired over 1200 new employees in Production, Engineering, Operations, Quality and Research. Out of the total employee base, there are over 2,100 scientific staff including over 110 PhD's. To meet the growing world demand for Apotex medicines, hundreds of new qualified technical professionals need to be hired. Apotex produces more than 300 generic pharmaceuticals in over 4000 dosages and formats which, in Canada, are used to fill over 70 million prescriptions a year - the largest amount of any pharmaceutical company in this country.

→Chairman's Message →President's Message



"**Apotex** believes that every man, woman and child is entitled to affordable healthcare and freedom from unnecessary pain and suffering."

View Our Corporate Video

Today, Apotex is a necessary and trusted member of Canada's healthcare community. The company's pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe. Export markets represent an ever growing portion of the total sales. Apotex has also established a presence through subsidiaries, joint ventures or licensing agreements in the Czech Republic, Mexico, China, Poland, New Zealand, France, and Italy, to name just a few. Healthcare professionals around the world rely on Apotex for quality and value.

Although the company's own business is developing and manufacturing generic pharmaceuticals, the success of Apotex has enabled it to diversify into a number of other health-related areas. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use.

The worldwide sales of the Apotex Group of companies exceed $1 billion

(Canadian $) per year.

→Leading the Way With Research and Development

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Last Modified: August 10, 2007 8:18:14 AM

EXHIBIT 2

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

RECEIVED
AUG 17 2007
Joseph F. Haggerty

August 14, 2007

Sanofi-Aventis US
55 corporate Drive
Bridgewater, NJ 08807

and

Sanofi-Aventis and Jagotec AG
c/o Jacobson Holman PLLC
400 Seventh St. NW
Washington, DC 20004

Attention: Harvey B. Jacobson Jr.

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Dear Sir or Madam:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, we advise you, as the New Drug Application ("NDA") holder for the reference drug and the patent owner of the listed patent, that the United States Food and Drug Administration ("FDA") has received an Abbreviated New Drug Application ("ANDA") from Apotex Inc. (hereinafter "Apotex") for alfuzosin hydrochloride extended release tablets of 10 mg strength. Apotex's ANDA was submitted under 21 U.S.C. § 355(j)(1) and 2(A) with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of U.S. Patent No. 6149940 ("the '940 patent).

Required Disclosures under 21 C.F.R. § 314.95(c)

Pursuant to 21 C.F.R. § 314.95(c)(1), we advise you that FDA has received an ANDA from Apotex containing any required bioavailability or bioequivalence data or information from studies on alfuzosin hydrochloride extended release tablets.

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned ANDA No. 79-013 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Apotex's ANDA is "Alfuzosin Hydrochloride Extended Release Tablets".

MEMBER CGPA

Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active pharmaceutical ingredient of Apotex's proposed drug product is alfuzosin hydrochloride. The proposed method of administration is oral.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patent in the paragraph IV certification, alleged to be not infringed is the '940 patent.

Detailed Statement

Apotex alleges, and has certified to the FDA, that in its opinion and to the best of its knowledge, each claim of the '940 patent will not be infringed by the commercial manufacture, use or sale of the drug product described by Apotex's ANDA No. 79-013. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6), Apotex's detailed statement of the legal and factual basis for the certification set forth in Apotex's ANDA is as follows:

The claims of the '940 patent are limited to a tablet comprising at least two layers, one of which contains alfuzosin hydrochloride. Our tablets will not infringe because they do not comprise two or more layers but are comprised of a single homogenous matrix.

Apotex certifies pursuant to 21 C.F.R. § 314.95(c)(7) that:

Tammy McIntire
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

Is hereby authorized to accept service of process on behalf of Apotex in connection with its ANDA No. 79-013 relating to alfuzosin hydrochloride extended release tablets.

Offer of Confidential Access to Application Pursuant to 21 U.S.C. § 355(j)(5)(c)

Apotex offers to provide confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(c)(i)(III) can be brought.

21 U.S.C. § 355(j)(5)(C)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also

grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential access:

1. Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution for you or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, "Confidential Apotex Information") shall be marked "CONFIDENTIAL".

2. The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without one prior written consent.

3. As provided by § 355(j)(5)(c)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. Your outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Information, and that all Confidential Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.

4. The Confidential Information disclosed is, and remains, the property of Apotex.

5. By providing the Confidential Information, Apotex does not grant your outside law firm any interest in or license for the Confidential Information. Your outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Information, return to Apotex, all Confidential Information and any copies thereof. Your outside law firm shall return all Confidential Information to Apotex before any infringement suit is filed by you. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Information that Apotex provides shall be included in any publicly-available complaint or other pleading.

6. Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or

infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance, or materiality of any such Confidential Information, document, or thing. The fact that Apotex provides Confidential Information upon your request shall not be construed as an admission by Apotex that such Confidential Information is relevant to the disposition of any issue relating to any alleged infringement of any patent, or to the validity or enforceability of any patent.

7. The attorneys from your outside law firm shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Information.

Section 355(j)(5)(C)(i)(III) further provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access", and that the "restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract". Thus, to the extent that you request access to Confidential Apotex Information, you mandatorily accept the terms and restrictions attached hereto. Written notice requesting access under this Offer of Confidential Access should be made to:

Bernice Tao
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Reservation of Legal Rights

Apotex reserves the right to allege the same, similar, different or new theories of non-infringement, invalidity, and/or unenforceability, and nothing in the Notice Letter or Detailed Statement shall be construed as to limit Apotex's rights to make any allegation in any subsequent litigation regarding any issue.

Yours very truly,

APOTEX INC.



Bernard C. Sherman,Ph.D.,P.Eng.
Chairman and C.E.O.

EXHIBIT 3

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

OCT 2007

October 25, 2007

VIA REGISTERED MAIL -
RETURN RECEIPT REQUESTED

Sanofi-Aventis US
55 Corporate Drive
Bridgewater, NJ 08807

and

Sanofi-Aventis and Jagotec AG
c/o Jacobson Holman PLLC
400 Seventh St., NW
Washington, DC 20004

Attention: Harvey B. Jacobson Jr.

Re: Notice of Amended Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Para. IV Notice Letter for Alfuzosin ER; US Patent No. 4,661,491

Dear Sir:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, we advise you, as the New Drug Application ("NDA") holder for the reference drug and the patent owner of the listed patent, that the United States Food and Drug Administration ("FDA") has received Abbreviated New Drug Application No. 79-013 ("ANDA") from Apotex Inc. (hereafter "Apotex") for alfuzosin hydrochloride extended release tablets of 10 mg strength, and that Apotex has amended this ANDA under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of U.S. Patent No 4,661,491 ("the '491 patent") on January 18, 2011.

Required Disclosures under 21 C.F.R. § 314.95(c)

Pursuant to 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an ANDA from Apotex containing any required bioavailability or bioequivalence data or information from studies on alfuzosin hydrochloride extended release tablets.

MEMBER CGPA

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned ANDA No. 79-013 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Apotex's ANDA is "Alfuzosin Hydrochloride Extended Release Tablets."

Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active pharmaceutical ingredient of Apotex's proposed drug product is alfuzosin hydrochloride. The proposed method of administration is oral.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patent in the paragraph IV certification alleged to be invalid is the '491 patent.

Detailed Statement

Apotex Inc. ("Apotex") has requested approval for alfuzosin hydrochloride extended release tablets of 10 mg strength ("the Apotex Products") in ANDA No. 79-013. Apotex now seeks approval for the commercial manufacture, use, sale, offer for sale, and importation of the Apotex Products prior to the expiration of the '491 Patent.

Accordingly, Apotex sets forth this Detailed Statement, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), to provide the factual and legal basis for its opinion that the '491 Patent is invalid. Because additional defenses to patent infringement may occur, be developed, be uncovered and/or be discovered in the future, Apotex expressly reserves the right to assert additional related and unrelated defenses to patent infringement, in addition to those set forth below, in the event Apotex is sued for patent infringement in the future.

Applicable Law

The United States Patent Statute, 35 U.S.C. § 103(a) provides:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Accordingly, an invention is unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a).

The U.S. Supreme Court recently reaffirmed that the "*Graham* factors" control an obviousness inquiry. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). These factors are (1) "the scope and content of the prior art"; (2) the "differences between the prior art and the claims"; (3) "the level of ordinary skill in the pertinent art"; and (4) objective evidence of nonobviousness. *Id.*, 127 S. Ct. at 1734 (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 at 17-18 (1966)).

The prior art includes printed publications that had "been disseminated or otherwise made available" to those persons interested and of ordinary skill in the art. *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985). Such printed publications include articles that appeared in scientific journals published prior to the filing date of the relevant patent. *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 266 F.3d 1358, 1360-61 (Fed. Cir. 2001). When a journal article was published more than one year before the earliest effective filing date of the relevant patent, the article presents a statutory bar to patentability. *In re Schoenwald*, 964 F.2d 1122, 1122-23 (Fed. Cir. 1992). This statutory bar applies even when the article is one of a combination of references that collectively render the claimed invention obvious, where each of those references has a publication date more than a year before the filing date of the relevant patent. *In re Foster*, 343 F.2d 980, 988-89 (C.C.P.A. 1965). In this case, even though the US patent claims priority to the French priority document, the Section 102 prior art date is still one year before the US filing date; not one year before the French filing date. See, 35 U.S.C. 119.

U.S. Patent No. 4,661,491

The '491 patent is entitled "Alfuzosine Compositions and Use." The '491 patent, which claims priority to French patent application 85 07950, filed May 28, 1985, has an earliest effective U.S. filing date of May 27, 1986. Therefore, the "critical date" of the '491 patent is May 27, 1985.

The '491 patent contains five claims. Claim 1, the only independent claim, reads as follows:

1. 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 animal suffering dysuria.

The '491 patent also includes four dependent claims, which read as follows:

2. A method according to claim 1 comprising administering alfuzosine hydrochloride.

3. A method according to claim 1 comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof.

4. A method according to claim 1 for treating dysuria in patients having bladder neck disease or a neurological disorder.

5. A method according to claim 1 for treating dysuria in male patients having benign hypertrophy of the prostate of alpha-adrenergic origin.

Analysis

Claim 1

As noted above, independent claim 1 recites administering alfuzosin (or a pharmaceutically acceptable salt thereof) in an amount effective to control dysuria (i.e., painful urination).

Several publications prior to the '491 patent's critical date of May 27, 1985 disclose the use of alfuzosin as an α-adrenergic receptors antagonist. For example, an article published in the *British Journal of Pharmacology* in 1984 explicitly describes using alfuzosin to block vascular α-adrenoceptors. *See* 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," page 4 (1984) ("Cavero"). Similarly, in an abstract published in *Federation Proceedings* in 1984, alfuzosin is described as antihypertensive agent with α-adrenoceptor antagonist properties. *See* Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, "Alfuzosin, Antihypertensive Agent With α-Adrenoceptor Antagonist Properties," abstract 2627 (1984). Therefore, the use of alfuzosin to block α-adrenergic receptors was known in the art at least as early as 1984.

Additionally, several articles published prior to the '491 patent's critical date of May 27, 1985 teach using α-adrenergic receptor antagonists to treat conditions of the bladder neck or prostate, including treatment for dysuria.

Specifically, an article published in the Journal of Urology in 1983 describes using α-adrenergic blockers to treat benign prostatic obstruction. Hedlund et al., The Journal of Urology, Vol. 133, "Effects of Prazosin In Patients With Benign Prostatic Obstruction," pages 275-278 (1983) ("Hedlund"). In particular, the article describes using the α-adrenergic blocker prazosin. It is noteworthy that "Cavero," which discloses the use of alfuzosin as an α-adrenergic antagonist, teaches that alfuzosin has similar α-adrenergic blocking properties to prazosin. In light of the prior art teachings to use alfuzosin as an α-adrenergic antagonist, it would clearly have been obvious to one skilled in the art to use alfuzosin as an α-adrenergic blocker for treating prostatic obstruction, as described in Hedlund. This is particularly true in light of the fact the α-adrenergic antagonist used in

Hedlund is prazosin, and Cavero explicitly describes the similar α-adrenergic blocking properties of alfuzosin and prazosin.

Similarly, an article published in *Urological Research* in 1982 describes using α-adrenergic blockers to treat benign prostatic obstruction, and specifically, dysuria. 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," pages 131-134 (1982) (Ronchi). Therefore, because it was known that alfuzosin could be used as an α-adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α-adrenergic blocker to treat patients suffering from dysuria.

Claim 2

As noted above, claim 2 further recites administering alfuzosin hydrochloride. It is well known that converting organic bases into their hydrochlorides is a common way of making them soluble in water. Therefore, it is also well known to prepare pharmaceuticals as hydrochlorides so that they may be quickly absorbed from the gastrointestinal tract. Accordingly, it would have been obvious for one skilled in the art that, when administering alfuzosin for the treatment of prostate conditions, it would be advantageous to administer alfuzosin as the hydrochloride salt.

Claim 3

As noted above, claim 3 recites administering alfuzosin (or a pharmaceutically acceptable salt thereof) in the amount of 0.5 to 10 mg. As discussed above, Cavero explains that alfuzosin has similar α-adrenergic blocking properties to prazosin, and Hedlund teaches to use α-adrenergic blockers to treat prostatic obstruction. Hedlund explicitly describes administering prazosin to treat prostatic obstruction in doses between 0.5 and 10 mg, including 1 mg, 2 mg, and 4 mg doses. Therefore, for same reason the combined disclosures of Cavero and Hedlund rendered obvious the administration of alfuzosin for treating conditions of the prostate (including dysuria), it would have been obvious for one skilled in the art to administer between 0.5 to 10 mg of alfuzosin.

Claim 4

As noted above, claim 4 further recites administering the alfuzosin (or a pharmaceutically acceptable salt thereof) to patients having bladder neck disease or a neurological disorder, which can impede the flow of urine. As discussed above, multiple publications prior to the '491 patent's critical date of May 27, 1985 disclose using alfuzosin as an α-adrenergic blocker, and various references teach using α-adrenergic receptor antagonists to treat conditions of the bladder neck or prostate. More specifically, an article published in the *British Journal of Pharmacology* in 1976 describes using α-adrenergic

blockers to treat urine outflow resistance caused by the bladder neck. *See* Whitfield et al., *Br. J. Pharmacol.*, Vol. 47, "The Effect of Adrenergic Blocking Drugs On Outflow Resistance," pages 823-827 (1976). Therefore, because it was known that alfuzosin could be used as an α-adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α-adrenergic blocker to treat patients with bladder neck disease.

Claim 5

As noted above, claim 5 further recites administering the alfuzosin (or a pharmaceutically acceptable salt thereof) to patients having benign hypertrophy of the prostate of alpha-adrenergic origin (also referred to as benign prostatic obstruction), in which the prostate becomes enlarged and obstructs the flow of urine. As discussed above, multiple publications prior to the '491 patent's critical date of May 27, 1985 disclose using alfuzosin as an α-adrenergic blocker, and various references teach using α-adrenergic receptor antagonists to treat conditions of the bladder neck or prostate. Both Hedlund and Ronchi explicitly teach using α-adrenergic receptor antagonists to treat benign prostatic obstruction. Therefore, because it was known that alfuzosin could be used as an α-adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α-adrenergic blocker to treat patients with benign prostatic obstruction.

Apotex certifies pursuant to 21 C.F.R. § 314.95(c)(7) that:

Tammy McIntire
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

Is hereby authorized to accept service of process on behalf of Apotex in connection with its ANDA No. 79-013 relating to alfuzosin hydrochloride extended release tablets.

Offer of Confidential Access to Application Pursuant to 21 U.S.C § 355(j)(5)(c)

As this Para. IV Notice Letter discusses invalidity only, the provisions for the Offer of Confidential Access do not necessarily apply as the contents of the ANDA have zero bearing on the question of patent invalidity. However, Apotex offers to provide confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(c)(i)(III) can be brought.

21 U.S.C. § 355(j)(5)(c)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a

protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential access:

1. Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution for you or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, "Confidential Apotex Information") shall be marked "CONFIDENTIAL".

2. The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without our prior written consent.

3. As provided by § 355(j)(5)(c)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. Your outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Information, and that all Confidential Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.

4. The Confidential Information disclosed is, and remains, the property of Apotex.

5. By providing the Confidential Information, Apotex does not grant your outside law firm any interest in or license for the Confidential Information. Your outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Information, return to Apotex, all Confidential Information and any copies thereof. Your outside law firm shall return all Confidential Information to Apotex before any infringement suit is filed by you. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Information that Apotex provides shall be included in any publicly-available complaint or other pleading.

6. Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance or materiality of

any such Confidential Information, document, or thing. The fact that Apotex provides Confidential Information upon your request shall not be construed as an admission by Apotex that such Confidential Information is relevant to the disposition or any issue relating to any alleged infringement of any patent, or to the validity or enforceability of any patent.

7. The attorneys from your outside law firm shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Information.

Section 355(j)(5)(C)(i)(III) further provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access," and that the "restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that you request access to Confidential Apotex Information, you mandatorily accept the terms and restrictions attached hereto. Written notice requesting access under this Offer of Confidential Access should be made to:

Bernice Tao
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Reservation of Legal Rights

Apotex reserves the right to allege the same, similar, different or new theories of non-infringement, invalidity, and/or unenforceability, and nothing in the Notice Letter or Detailed Statement shall be construed as to limit Apotex's rights to make any allegation in any subsequent litigation regarding any issue.

Further, please be advised that Apotex considers this information to be confidential, is disclosing this information solely in order to comply with 21 U.S.C. § 355(j)(2)(B), and requests that the recipients of this information protect it from disclosure to third parties by means consistent with their own standards for protecting their own confidential information.

THIS CONFIDENTIALITY APPLIES TO THIS LETTER, WHICH MAY NOT, AND SHOULD NOT, BE ATTACHED TO ANY COMPLAINT OR OTHER PUBLICLY AVAILABLE DOCUMENT. SIMILARLY, THE INFORMATION CONTAINED IN THIS DOCUMENT MAY NOT, AND SHOULD NOT, BE INCLUDED IN ANY COMPLAINT OR OTHER PUBLICLY AVAILBLE DOCUMENT.

* * *

Whereas service of process for Apotex Corp. is based on the Weston, Florida address indicated above, as a professional courtesy, please also copy any service of process to:

Shashank Upadhye, Esq.
Vice President – Global Intellectual Property
150 Signet Drive
Toronto, ON, CANADA
M9L 1T9

Yours very truly,
APOTEX INC.



Bernard C. Sherman, PhD.,P.Eng.
Chairman and C.E.O.

EXHIBIT 4

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
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

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Dated: September 21, 2007

EXHIBIT 5

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 4:0
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

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Dated: September 21, 2007

EXHIBIT 6

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

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October 1, 2007

By Email
Bernice Tao
Director, Regulatory Affairs US
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Re: Notification of Paragraph IV Certification
for Apotex Inc.'s Alfuzosin Hydrochloride Tablets, 10 mg

Dear Ms. Tao:

By letter dated August 14, 2007, Apotex Inc. ("Apotex") indicated that it submitted Abbreviated New Drug Application ("ANDA") 79-013 for alfuzosin hydrochloride extended release tablets, 10 mg, including a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") against U.S. Patent No. 6,149,940 ("the '940 patent"). Apotex further indicated that it intends to engage in the commercial manufacture, use, import, sale and/or offer for sale of the generic 10 mg alfuzosin hydrochloride extended release product defined by ANDA 79-013 before the expiration of the '940 patent.

In compliance with the procedures provided by the Hatch-Waxman Act, we have reviewed Apotex's letter and the portions of ANDA 79-013 provided by Apotex, as well as discussed Apotex's documents and method of manufacturing with you. In connection with this review, we carefully considered, *inter alia*:

(1) Apotex's representation at page 2 of the August 14th letter that Apotex's proposed alfuzosin hydrochloride tablets "do not comprise two or more layers;" and

(2) Apotex's representations in the portions of ANDA 79-013 provided regarding the composition of its proposed generic alfuzosin hydrochloride extended release product and the method of manufacturing for that product.

In reliance on Apotex's representations in its letter, the portions of ANDA 79-013 provided and the conversation with you, including the specific representations recited above,

sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") will not file an action for infringement of the '940 patent against Apotex at this time. Sanofi-aventis, however, reserve the right to file such an action if they learn that Apotex's representations were incorrect or if Apotex or any other party amends ANDA 79-013.

In this regard, we remind Apotex that it is required to submit to the U.S. Food and Drug Administration an additional certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '940 patent if it amends ANDA 79-013 to change the composition or the method of manufacturing f the generic alfuzosin hydrochloride product defined therein. To the extent that Apotex makes any such certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it must also provide sanofi-aventis with the notice required by 21 U.S.C. § 355(j)(2)(B).

Sincerely,



William T. Vuk

cc: Dr. Bernard C. Sherman (via Federal Express)

EXHIBIT 7

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;

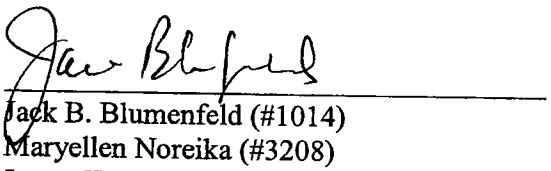
C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® 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



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December 6, 2007

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-278-GMS
	)	
APOTEX, INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S ANSWER, DEFENSES, AND COUNTERCLAIMS.

Defendants Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the Complaint of Allergan, Inc. ("Allergan" or "Plaintiff"), state and allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2).

ANSWER: Apotex Inc. and Apotex Corp. admit that the Complaint alleges infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2); otherwise denied.

THE PARTIES

2. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

3. On information and belief, defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Admitted that Apotex Inc. is a Canadian corporation with a place of business in Ontario Canada, all other allegations are denied.

4. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER: Admitted.

5. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

ANSWER: Admitted.

6. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States, including this judicial district; otherwise denied.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq. This Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338.

ANSWER: Apotex Inc. and Apotex Corp. admit that Allergan purports to bring this action under the patent laws of the United States, Title 35, Section 1, et seq. Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338(a). Except where specifically admitted, the allegations in this paragraph are otherwise denied.

8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

ANSWER: Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

9. Venue is proper in this Court under 28 U.S.C. §1391 and 1400(b).

ANSWER: Admitted.

BACKGROUND

10. The '078 patent, entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same," issued to Anthony Dziabo and Paul Ripley on June 13, 1995. A copy of the '078 patent is attached to this complaint as Exhibit A.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '078 patent includes a title of "Aqueous Ophthalmic Formulations and Methods for Preserving Same," lists the inventors as Anthony Dziabo and Paul Ripley, and lists an issue date of June 13, 1995. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

11. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '078 patent.

ANSWER: Admitted that in conjunction with NDA No. 21-262 and 21-770, Allergan listed the '078, '873, '210, '337 and '834 patents. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

22. ALPHAGAN® P 0.15% and 0.10% are covered by at least one claim of each of the Listed Patents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

23. On April 30,2007, Allergan received a letter, dated April 26,2007, signed on behalf of Apotex, Inc. The letter stated that Apotex had filed Abbreviated New Drug Application Nos. 78-479 and 78-480 ("ANDAs") with the United States Food and Drug Administration ("FDA") under section 505('j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market generic versions of Allergan's ALPHAGAN® P products, both the 0.15% and 0.10% formulations, before the expiration of the Listed Patents.

ANSWER: Admitted that Apotex Inc. sent a letter to Allegan on April 26, 2007; that the letter stated that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, before the expiration of the listed patents; otherwise denied.

24. The purpose of the April 26, 2007 letter was to notify Allergan that Apotex had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(l)(i)(A)(4) ("Paragraph IV

certification") in conjunction with its ANDAs. The letter alleged: (1) that the Listed Patents were invalid or unenforceable and (2) that, even if valid and enforceable, some claims of the Listed Patents would not be infringed by Apotex's generic versions of Allergan's ALPHAGAN® P products.

ANSWER: Admitted that the April 26, 2007 letter provided Allergan with notice that Apotex Inc. had filed a Paragraph IV certification with the FDA in conjunction with ANDA application nos. 78-479 and 78-480, admitted that the April 26, 2007 letter stated that the listed patents are invalid, unenforceable, and/or will not be infringed by Apotex's manufacture, use, or sale of the Apotex Brimonidine Products, otherwise denied.

25. In filing its ANDAs, Apotex has requested the FDA's approval to market generic versions of Allergan's ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, throughout the United States, including Delaware; otherwise denied.

26. On information and belief, following FDA approval of its ANDAs, Apotex, Inc., through Apotex Corp., will sell the approved generic versions of Allergan's ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that if the FDA approves Apotex Inc.'s ANDA applications, it will seek to sell its approved Brimonidine Tartrate products throughout

the United States, and that it would be expected that such approved products would be sold by Apotex Inc., otherwise denied.

COUNT I

(Infringement of the '078 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

28. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

ANSWER: Denied.

COUNT II

(Infringement of the '873 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

products for which approval is sought under ANDA applications 78-479 and 78-480 do not directly or indirectly infringe any valid claim of the '078, '873, '210, '337 and '834 patents.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '078, '873, '210, '377 and '834 patents are invalid and unenforceable;

b. Finding that the '078, '873, '210, '377 and '834 patents are not infringed in any manner by either Apotex Inc. or Apotex Corp.;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand a trial by jury on all issues appropriately tried to a jury.

POTTER ANDERSON & CORROON LLP

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Dated: June 11, 2007
800700 / 31920

Attorneys for Defendants
Apotex Inc. and Apotex Corp.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-204-SLR
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the complaint of MedPointe Healthcare Inc. ("Plaintiff" or "MedPointe"), state and allege as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 1 of the Complaint, and therefore deny same.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admitted.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Admitted.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

ANSWER: Apotex Inc. and Apotex Corp. admit that MedPointe purports to bring an action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, for the alleged infringement of United States Patent No. 5,164,194; otherwise denied.

JURISDICTION AND VENUE

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

ANSWER: Admitted.

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

ANSWER: Admitted that this Court has personal jurisdiction over Apotex Corp. for this action.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego; (4) its consent to personal jurisdiction in this Court in connection with another action for infringement of the '194 patent, Civil Action No. 06-164-SLR.

ANSWER: Denied, except to admit that this Court has personal jurisdiction over Apotex Inc. for this action.

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

ANSWER: Admitted.

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Apotex Inc. and Apotex Corp. admit that the '194 patent, entitled "Azelastine Containing Medicaments," was issued by the United States Patent and Trademark Office on November 17, 1992, that Asta Pharma AG is listed as the assignee, and that a document purporting to be a copy of the '194 patent is attached to the Complaint. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of paragraph 14, and therefore deny same. Defendants deny all other allegations in paragraph 14.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about December 13, 2006, Apotex submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on or about December 13, 2006.

16. ANDA 78-621 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 78-621 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Denied, except to admit that ANDA 78-621 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a proposed drug

product as defined in ANDA 78-621 and that ANDA 78-621 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent.

17. ANDA 78-621 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation on March 14, 2007.

ANSWER: The first sentence of paragraph 17 of the Complaint is admitted. With regard to the second sentence in paragraph 17, Apotex Inc. and Apotex Corp. admit that Apotex Inc. sent written notification of ANDA 78-621 to MedPointe on or about March 12, 2007.

18. Upon information and belief, consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the United States for purposes of filing ANDA 78-621 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States following FDA approval. Apotex Inc. and Apotex Corp. further admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

19. Apotex's submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Denied.

20. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '194 patent is invalid and unenforceable;

b. Finding that the '194 patent is not infringed in any manner by either Apotex Inc. or Apotex Corp.;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury. This demand is contingent upon MedPointe seeking monetary damages as set forth in paragraph D of its prayer for relief in its complaint.

POTTER ANDERSON & CORROON LLP

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Dated: May 30, 2007
798352 / 30136-001

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-164 (SLR)
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

ANSWER OF APOTEX INC. AND APOTEX CORP. TO PLAINTIFF'S AMENDED COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., Answer the Amended Complaint of Plaintiff, MedPointe Healthcare Inc., as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments in this paragraph.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admit that Apotex, Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for purposes of this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. are related companies and that Plaintiff may refer to them collectively as Apotex even though they are separate entities.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*

ANSWER: This paragraph contains MedPointe's characterization of its action and to which no answer is required, but insofar as an answer is required, deny.

JURISDICTION AND VENUE

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

ANSWER: Admit.

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

ANSWER: Admit.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; and (3) its performance of acts, either directly or through an agent, that have caused tortuous injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego.

ANSWER: Deny, except to admit that this Court has personal jurisdiction over Apotex, Inc. for this matter.

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

ANSWER: Apotex admits that venue in this district is proper for this action

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Deny that the '194 patent was duly and legally issued on November 17, 1992. Admit that a document purporting to be U.S. Patent Number 5,164,194 was attached to the Complaint, and that Asta Pharma AG is listed thereon as assignee. With regard to the remaining allegations, Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments, which has the effect of denial reasonably based on lack of information and belief.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about November 14, 2005, Apotex submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Deny, expect to admit that Apotex Inc. submitted ANDA 077954 to the FDA under §505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335) on or about November 14, 2005.

16. ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal rhinitis ("the Generic Product"). ANDA 77-954 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Admit that ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution having the name Azelastine Hydrochloride Nasal Spray (the "proposed product") for use in treating, *inter alia*, seasonal rhinitis, and that ANDA 77-954 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent. The remaining allegations are denied.

17. ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written Notification of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation on January 27, 2005.

ANSWER: Admit that ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the proposed drug product. Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining averments, which has the effect of denial reasonably based on lack of information and belief.

18. In the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its "agent in the United States authorized to accept service of process for Apotex."

ANSWER: Admit that in the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its "agent in the United States authorized to accept service of process for Apotex."

19. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the

United States for purposes of filing ANDA 77-954 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. has designated Apotex Corp. as its agent in the United States in ANDA 77-954 to the extent required by FDA regulations and for service of legal process.

20. Apotex's submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

21. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

ANSWER: Deny.

22. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny that Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. Admit that Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and intends to, *inter alia*, manufacture the proposed drug product upon receipt of FDA approval of ANDA 77-954.

23. Apotex Inc.'s submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35

U.S.C. §271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the §505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

24. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 77-954 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny, except to admit that if ANDA 77-954 is approved, it is expected that Apotex Corp. would offer to sell and sell the proposed drug product in the United States.

25. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271 (e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Deny.

26. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. had access to the FDA Orange Book which listed the '194 patent.

27. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law.

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Dated: April 14, 2006
728036 / 30136

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

DEFENDANT APOTEX, INC.'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

ANSWER: Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

ANSWER: Admitted.

BACKGROUND

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the "'941 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '941 patent is currently set to expire on December 2, 2012. The '941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '941 patent is attached to this Complaint as Exhibit 1.

ANSWER: Apotex admits that United States Patent No. 5,358,941, entitled "Dry Mix Formulation For Bisphosphonic Acids With Lactose" was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the "'590 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '590 patent is currently set to expire on December 2, 2012. The '590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX® tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX® tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

ANSWER: Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

ANSWER: Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX® pharmaceutical products have created due to their benefits and advantages.

ANSWER: Denied, accept to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax®.

COUNT I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

I hereby certify that on May 9, 2006, I have Federal Expressed the attached document to the following non-registered participants:

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Gerard M. Devlin
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/s/ Richard L. Horwitz
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728942

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TORPHARM, INC., APOTEX CORP., and APOTEX, INC. Plaintiffs, v. PFIZER INC., and WARNER-LAMBERT COMPANY (n/k/a WARNER-LAMBERT LLC) Defendants.	)	Civil Action No. 03 - 990

COMPLAINT FOR DECLARATORY JUDGMENT
AND DEMAND FOR JURY TRIAL

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc. (collectively "TorPharm"), for their Complaint against Defendants Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) (collectively "Pfizer"), allege as follows:

Nature Of The Action

1. This action for declaratory judgment of patent noninfringement arises, *inter alia*, out of TorPharm's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's blockbuster drug Accupril® (quinapril hydrochloride). FDA approval of TorPharm's ANDA is imminent.

2. Pfizer owns U.S. Patent No. 4,743,450 ("the '450 patent"), which discloses and claims, *inter alia*, a quinapril pharmaceutical composition. Pfizer has listed the '450 patent in the FDA's "Orange Book" and, as a consequence, maintains that the '450 patent claims the approved drug, Accupril® (quinapril hydrochloride), and that a claim for patent infringement

could reasonably be asserted against any ANDA applicant attempting to market a generic quinapril product. Pfizer, moreover, has enforced and continues to vigorously enforce its intellectual property rights on blockbuster drugs against TorPharm and others, and has already sued and obtained a judgment of infringement on the '450 patent against another generic quinapril applicant.

3. TorPharm has designed around the '450 patent with its proposed quinapril product and so, as required by statute, has certified to the FDA that its product will not infringe the '450 patent and further notified Pfizer of the legal and factual bases for that certification. TorPharm's certification to the '450 patent constitutes a technical or artificial act of infringement under the Hatch-Waxman Act putting TorPharm at considerable risk of being sued by Pfizer both before and after market entry. Pfizer has not yet responded to the submission of TorPharm's ANDA and certification that TorPharm does not infringe. Moreover, Pfizer has not informed TorPharm that TorPharm does not infringe the '450 patent and has not covenanted not to sue TorPharm for infringement of the '450 patent.

4. On information and belief, Pfizer believes that a claim for infringement could be reasonably asserted against TorPharm and Pfizer intends to sue TorPharm for infringement of the '450 patent. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent, for which this Court can declare the rights of the parties. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril product does not and will not infringe the '450 patent.

The Parties

5. Plaintiff TorPharm, Inc. is a corporation duly organized and existing under the laws of Canada and having its principal place of business in Etobicoke, Ontario, Canada. TorPharm develops, manufactures and markets generic drugs, and in particular solid oral dosage forms such as capsules and tablets, for sale and use in the United States following FDA approval.

6. Plaintiff Apotex Corp. is a corporation incorporated and existing under the laws of the State of Delaware, having a place of business at 616 Heathrow Drive, Lincolnshire, Illinois 60069. Apotex Corp. is the United States marketing and sales affiliate for TorPharm. Following FDA approval of an ANDA, TorPharm manufactures and supplies generic drug products to Apotex Corp., which then markets and sells those products to large wholesalers, warehousing chains, mail order organizations, and distributors in the United States. Apotex Corp. also acts as TorPharm's U.S. agent for purposes of making regulatory submissions, including ANDAs, to the FDA.

7. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having its principal place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

8. Plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. are collectively referred to in this Complaint as "TorPharm."

9. On information and belief, Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017-5575.

10. On information and belief, Defendant Warner-Lambert Company was or is a Delaware corporation with a place of business at 201 Tabor Road, Morris Plains, New Jersey 07950. On information and belief, Warner-Lambert Company became a wholly-owned

subsidiary of Pfizer Inc. as of June 19, 2000. On information and belief, Warner-Lambert Company subsequently became Warner-Lambert LLC, a limited liability company incorporated under the laws of the State of Delaware, having its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950.

11. Defendants Pfizer Inc. and Warner-Lambert Company are collectively referred to in this Complaint as "Pfizer."

Jurisdiction And Venue

12. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

14. There exists a substantial and continuing actual, justiciable case or controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

15. This Court may declare the rights and legal relations of the parties regarding noninfringement of the '450 patent pursuant to, *inter alia*, 28 U.S.C. §§ 2201, 2202.

16. This Court has personal jurisdiction over Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) because they both reside and are located in this District and because they both conduct substantial business in, and have regular and systematic contact with, this District.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Statutory Scheme For Approval Of New And Generic Drugs

18. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 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 in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman").

New drugs and patent listing requirements

19. Before marketing an original new drug (*i.e.*, not a generic drug) in the United States, Hatch-Waxman requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

20. An NDA applicant is required, within its NDA, to submit information (*i.e.*, *inter alia*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1).

21. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

22. By filing an NDA and listing a patent in the Orange Book, the NDA-holder and/or patentee, by law, necessarily maintains that the listed patent claims the approved NDA drug and

that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, sale or use of the drug.

23. In other words, the NDA-holder and/or patentee necessarily puts all prospective generic ANDA-filers on notice that a suit for infringement can and will be asserted against any ANDA-filer that attempts to seek approval for and market a generic version of the NDA drug.

24. Such conduct by the NDA-holder and/or patentee gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

Generic drugs and patent certification requirements

25. Hatch-Waxman provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-cost generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

26. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

27. Instead of repeating the comprehensive, extensive human studies conducted for the previously approved NDA drug, a generic applicant submitting an ANDA is only required to establish, among other details, that its proposed generic product is bioequivalent to the already approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that

it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

28. An ANDA applicant is also required to address each patent listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder has not submitted any patent information to FDA; (II) that the listed patent(s) has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent.

29. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder and the patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal basis for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(ii).

30. The submission of a paragraph IV certification for a listed patent constitutes an artificial or technical act of infringement that creates the necessary subject matter jurisdiction to enable a patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

31. Upon receipt of the notice of the paragraph IV certification for the listed patent submitted by the ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within forty-five (45) days of receiving such notification.

32. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of generic drug products.

33. Congress intended that the generic manufacture and marketing of a drug should be allowed as soon as it is determined that the particular drug does not violate patent rights, and should not be delayed just because the patentee has not sued the generic applicant first, but rather has merely held its patents over the generic applicant like a modern-day "Sword of Damocles."

34. Congress therefore contemplated that ANDA-filers must obtain a favorable court decision on the patent in order to market the generic drug. This can be accomplished by either being sued by the NDA-holder/patentee within the 45-day period or by the generic ANDA-filer seeking a declaratory judgment of patent infringement and/or invalidity.

35. An ANDA-filer is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder may bring suit after receiving notification of the ANDA and paragraph IV certification. Congress, however, clearly intended that a

declaratory judgment action be available for ANDA-filers who are not sued by the NDA patentee within the 45-day period.

36. The acts of an NDA-holder/patentee listing a patent in the Orange Book through the filing of an NDA and a generic manufacturer filing an ANDA together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement and/or invalidity.

Pfizer's Accupril® (Quinapril Hydrochloride)

37. On information and belief, Pfizer Inc. is the holder of approved NDA No. 19-885 for quinapril hydrochloride tablets, which are sold under the brand-name Accupril®.

38. Accupril® (quinapril hydrochloride) is indicated for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

39. On information and belief, Warner-Lambert Company purports and claims to be the owner of U.S. Patent No. 4,743,450 ("the '450 patent"), the term of which expires on or about August 24, 2007. The '450 patent recites a quinapril pharmaceutical formulation containing a metal-containing stabilizer and a saccharide which minimize the cyclization, hydrolysis and coloration of certain ACE inhibitors, including quinapril. A true and correct copy of the '450 patent is attached to this Complaint as Exhibit A.

40. On information and belief, Pfizer purports and claims to have the right to enforce the '450 patent.

41. Pfizer submitted information on the '450 patent to FDA for placement in the Orange Book. By virtue of that submission, the FDA listed the '450 patent in the Orange Book in connection with Pfizer's approved NDA for Accupril® (quinapril hydrochloride) tablets.

42. By listing the '450 patent in the Orange Book, Pfizer maintains that the '450 patent claims Accupril® (quinapril hydrochloride) tablets and that an infringement suit could reasonably be asserted against any generic ANDA-filer that attempts to seek approval for and market a generic version of quinapril.

TorPharm's ANDA For Quinapril Hydrochloride Tablets

43. On September 13, 2001, TorPharm submitted an ANDA to the FDA seeking approval to market a generic version of Accupril® (quinapril hydrochloride) tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths. That ANDA was received by the FDA on September 20, 2001 and was assigned ANDA number 76-240 by the FDA ("ANDA No. 76-240").

44. TorPharm's ANDA sought permission to market quinapril hydrochloride tablets for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

45. As part of its ANDA No. 76-240, TorPharm submitted a paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying to FDA that the '450 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

46. On information and belief, the FDA's review of TorPharm's ANDA No. 76-240 will be completed in the near future and approval is imminent.

47. TorPharm intends and is prepared to market its generic quinapril product before expiration of the '450 patent.

48. On or about November 15, 2001, in accordance with 21 U.S.C. §§ 355(j)(2)(B)(i),(ii), TorPharm provided Pfizer with notice that it submitted a quinapril ANDA and a paragraph IV certification to the '450 patent. This notice included a detailed statement setting forth the factual and legal bases why the '450 patent will not be infringed by the

manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

Pfizer's Litigious Conduct And Vigorous Enforcement Of Its Intellectual Property Rights

49. Pfizer has a long history and program of vigorously enforcing its patents against generic drug applicants, including TorPharm.

50. For example, Pfizer (and its predecessors) have sued numerous ANDA-filers for alleged infringement of patents covering its blockbuster drug Zoloft®. (*Pfizer v. Zenith Goldline Pharms., Inc.*, 00-CV-0408 (D.N.J.)).

51. Pfizer (and its predecessors) have also sued ANDA-filers for alleged infringement of patents covering its blockbuster drug Norvasc®. (*Pfizer v. Dr. Reddy's Labs.*, 02-CV-2829 (D.N.J.)).

52. Pfizer (and its predecessors) also filed suit against a generic competitor regarding Pfizer's drug Procardia XL® (nifedipine). (*Bayer AG, et al. v. Mylan Labs.*, 97-CV-1309 (W.D. Pa.)).

53. Similarly, Pfizer (and its predecessors) have sued ANDA-filers for alleged infringement of patents covering Pfizer's drug Glucotrol XL® (glipizide). (*Pfizer Inc. v. Andrx Corp.*, 01-CV-3260 (D.N.J.)).

54. Pfizer (and its predecessors) also sought to protect its drug Diflucan® (fluconazole) from generic competition by filing suit against ANDA-filers. (*Pfizer Inc. v. Novopharm Ltd.*, 00-CV-1475 (N.D. Ill.)).

55. Pfizer (and its predecessors) have further sued at least eight ANDA-filers, including TorPharm, in numerous Districts for alleged infringement of three patents purportedly covering Pfizer's drug Neurontin® (gabapentin). (*In re Gabapentin Patent Litig.*, MDL No. 1384

(D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 01-CV-611 (D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 00-CV-4398 (N.D. Ill.); *Warner-Lambert Co. v. Apotex Corp.*, 98-CV-4293 (N.D. Ill.); *Pfizer Inc. v. Pharm. Holdings Corp.*, 03-CV-740 (E.D. Pa.)); *Pfizer Inc. v. Geneva Pharms., Inc.*, 03-CV-1545 (D.N.J.); *Pfizer Inc. v. Ranbaxy Pharms., Inc.*, 03-CV-1824 (D.N.J.)).

56. Indeed, as recently as October 7, 2003, Pfizer stated that it intends to aggressively defend its intellectual property. *Found at* http://www.pfizer.com/are/news_releases.

Quinapril Hydrochloride Litigation

57. Pfizer has further demonstrated a willingness and intention to enforce the '450 patent against similarly-situated generic pharmaceutical companies that have filed an ANDA to market generic quinapril hydrochloride.

58. Pfizer has filed suit against one of TorPharm's competitors in *Warner-Lambert v. Teva Pharms. USA, Inc.*, 99-CV-0922 (D.N.J.), alleging infringement of the '450 patent. The district court in New Jersey recently granted Pfizer a summary judgment of infringement against Teva regarding the '450 patent.

59. Pfizer recently noted that the court decision on the '450 patent "affirms positions that [Pfizer] has taken with respect to the Accupril patent from the very beginning of the litigation." *Found at* http://www.pfizer.com/are/news_releases.

There Is A Substantial And Continuing Justiciable Controversy Between TorPharm And Pfizer Regarding Infringement Of The '450 Patent

60. By preparing and filing TorPharm's ANDA No. 76-240, TorPharm has substantially prepared to make, use, import, offer to sell, and sell quinapril hydrochloride tablets in the United States.

61. By submitting its ANDA No. 76-240 to engage in the commercial manufacture, use, offer for sale, sale, or importation of quinapril hydrochloride tablets before the expiration of

the '450 patent, as well as filing a paragraph IV certification to the '450 patent, TorPharm has committed an act that may be viewed as an artificial or technical act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2)(A).

62. By submitting the '450 patent to the FDA for listing in the Orange Book, Pfizer has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." *See* 21 U.S.C. § 355(b)(1). In other words, Pfizer necessarily maintains that an infringement claim on the '450 patent could be reasonably asserted against any generic quinapril applicant, including TorPharm.

63. Pfizer did not sue TorPharm for infringement of the '450 patent within forty-five (45) days of receipt of TorPharm's notice of paragraph IV certification. As such, a declaratory judgment action is available to TorPharm.

64. Pfizer has never communicated to TorPharm that TorPharm does not infringe or that Pfizer does not intend to bring a lawsuit against TorPharm for infringement of the '450 patent.

65. Pfizer has demonstrated a willingness and, further, an intention to enforce its '450 patent against similarly situated quinapril hydrochloride ANDA-filers. Also, just three weeks ago and after a favorable summary judgment award regarding the '450 patent, Pfizer made public representations that the decision is in line with Pfizer's beliefs regarding Accupril® (quinapril hydrochloride) and that Pfizer intends to continue aggressively defending its intellectual property.

66. Based upon, *inter alia*, Pfizer's listing of the '450 patent and implicit assertions that an infringement claim could be brought against any generic quinapril applicant; TorPharm's ANDA with a paragraph IV certification to the '450 patent and technical or artificial act of

infringement; TorPharm's intention to market its generic quinapril product before expiration of the '450 patent; Pfizer's failure to state that TorPharm does not infringe the '450 patent or covenant that it will not sue TorPharm for infringement of the '450 patent; Pfizer's suits against similarly situated third-parties concerning the '450 patent; Pfizer's public statements that it will continue to aggressively defend challenges to its intellectual property; Pfizer's (and its predecessors') pattern of aggressively enforcing its patents against TorPharm specifically and the generic pharmaceutical industry generally; and Pfizer's recent summary judgment of infringement regarding the '450 patent, TorPharm is under a reasonable apprehension that Pfizer will sue TorPharm alleging infringement of the '450 patent. Such a reasonable apprehension creates an actual controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

67. To avoid legal uncertainty, to protect its substantial investment, and to protect its anticipated future investments in its manufacturing process for TorPharm's quinapril hydrochloride tablets, TorPharm has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '450 patent.

Declaratory Judgment Of Noninfringement

68. TorPharm asserts and realleges paragraphs 1 through 67 above as if fully set forth herein.

69. TorPharm has already committed what may constitute a technical or artificial act of infringement by submitting its ANDA with an accompanying paragraph IV certification. TorPharm has also produced an allegedly infringing quinapril product and intends and is prepared to market that product before expiration of the '450 patent.

70. Pfizer has engaged, and continues to engage, in conduct giving rise to a reasonable and objective apprehension on TorPharm's part that TorPharm will face an infringement suit if it commences marketing of its generic quinapril product.

71. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

72. The manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

73. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

Prayer For Relief

WHEREFORE, TorPharm respectfully prays for judgment in its favor and against Pfizer:

(a) Declaring that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent; and

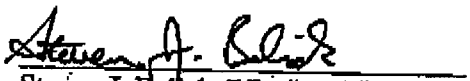
(b) Awarding TorPharm its reasonable attorneys' fees and costs of this action; and,

(c) Awarding TorPharm such other and further relief as the Court may deem just and proper.

Jury Demand

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc., hereby demand a trial by jury on all issues so triable.

ASHBY & GEDDES



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Dated: October 29, 2003
134500.1

EXHIBIT 9

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

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December 6, 2007

By Federal Express
and Electronic Mail

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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/sg

William T. Vuk

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

Jack Blumenfeld, Esq.
Morris Nichols Arsht & Tunnell

EXHIBIT 10

From: Noreika, Maryellen

Sent: Tuesday, December 11, 2007 4:30 PM

To: 'srollo@welshkatz.com'

Subject: sanofi v. Apotex

Dear Sherry --

This will confirm our earlier discussion that 1) the Apotex defendants will not contest jurisdiction in the District of Delaware in the litigation -- *sanofi-aventis, et al. v. Apotex Inc., et al.,* C.A. No. 07-792 (D. Del) -- and 2) plaintiffs will consent to Apotex's request for a 14 day extension to respond to the complaint. I will draft a stipulation regarding the extension for your review.

Maryellen Noreika

This message, including any accompanying documents or attachments, may contain information that is confidential or that is privileged. If you are not the intended recipient of this message, please note that the dissemination, distribution, use or copying of this message or any of the accompanying documents or attachments is strictly prohibited. If you believe that you may have received this message in error, please contact me at (302) 658-9200 or by return e-mail.

EXHIBIT 11

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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WILMINGTON, DELAWARE 19899-1347

302 658 9200
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MARYELLEN NOREIKA
302 351 9278
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December 31, 2007

Sherry L. Rollo, Esquire
WELSH & KATZ, LTD.
120 South Riverside Plaza
Chicago, IL 60606-3912

VIA ELECTRONIC MAIL

Re: *sanofi-aventis et al v. Apotex Inc. et al*,
C.A. No. 07-792-GMS

Dear Sherry:

On December 11, 2007, you agreed that the Apotex defendants would not contest jurisdiction in the District of Delaware. Despite your agreement, in the answer filed in Florida, Apotex now denies that the Delaware court has personal jurisdiction over Apotex Inc. Please let me know the basis on which Apotex has denied that there is personal jurisdiction over Apotex Inc. in Delaware after you agreed that defendants would not challenge jurisdiction in Delaware.

Sincerely,

Maryellen Noreika

cc: Richard L. Horwitz, Esquire
Gerald J. Flattmann, Esquire

EXHIBIT 12

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)
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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)

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840408 / 32533

EXHIBIT 13

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January 7, 2008

Via Electronic Mail (wvuk@kirland.com) &
Confirmation by U.S. Mail

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Re: ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Dear William:

We acknowledge receipt of your January 4, 2008 correspondence. We do not agree to transfer the above-captioned case to Delaware. Nor do we agree to a stay of the Florida action pending resolution of any motions to transfer. Sanofi is obligated under the Hatch-Waxman Act to "reasonably cooperate in expediting the action." *E.g.,* 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, we believe that Sanofi should dismiss its Delaware lawsuit against our clients in favor of the Florida action, which necessarily will proceed more quickly to resolution. Please let us know whether your client will agree to dismissal of the Delaware complaint.

I am available this afternoon (after 2pm (CST)) to discuss this and other issues related to the Court's scheduling order.

Very truly yours,

WELSH & KATZ, Ltd.

By: 
Steven E. Feldman

SEF/mh
cc: Alfred J. Saikali, Esq. (asikali@shb.com)
Stephen J. Bronis, Esq. (sbronis@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Sherry L. Rollo, Esq. (srollo@welshkatz.com)

EXHIBIT 14

KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

Citigroup Center
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William T. Vuk
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January 7, 2008

By Electronic Mail
Steven E. Feldman, Esq.
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sefeldman@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 Steven:

I write to memorialize our meet and confer discussion from earlier today related to the above matters.

In light of sanofi-aventis's first-filed Delaware action, sanofi-aventis requested that the parties meet and confer on the disposition of the second-filed Florida action in an attempt to avoid any unnecessary motion practice before the Court. Specifically, we asked that Apotex agree to the dismissal of the Florida action, transfer to Delaware, or stay pending the disposition of any venue issues in Delaware. Because Apotex has refused to agree that the identical claims and counterclaims of the Delaware and Florida actions should proceed in Delaware along with sanofi-aventis's claims against 13 other defendants, we are left with no choice but to seek relief from the Court.

The following summary confirms the results of the parties' meet and confer today. Please let me know if there is anything you disagree with.

Dismissal or Stay of Claims/Counterclaims Pending In Florida: You confirmed that Apotex would not consent to the dismissal of all claims and counterclaims pending in Florida. You also confirmed that Apotex would not stay any aspect of the second-filed Florida action pending the resolution of any motions that either party might bring.

sanof-aventis's Dismissal of Their Claims Pending In Delaware: I informed you that sanofi-aventis would not consent to your request to dismiss the claims pending against Apotex in Delaware.

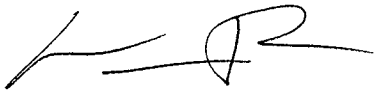
KIRKLAND & ELLIS LLP

Apotex's Motion to Transfer You confirmed that Apotex intends to file a motion to transfer the first-filed Delaware action to the Southern District of Florida because the Southern District of Florida is a more convenient forum. You explained that Florida is a more convenient venue because Apotex Corp. is headquartered in Florida and, while you could not identify any, you are certain there are potential witnesses/deponents who reside in Florida. You also explained that at this time you were unaware as to whether any Research and Development related to Apotex's generic alfuzosin hydrochloride tablets occurred in Florida. Additionally, you stated that Apotex believes that the second-filed Florida action will be adjudicated faster then the first-filed action in Delaware because Apotex would be on its own against sanofi-aventis as opposed to in one coordinated action in Delaware involving 13 other defendants. You further stated that the Florida Courts issuance of a scheduling order, which I noted was pro forma, setting trial for May 2008 supports the conclusion that the action in Florida would proceed faster then the first-filed Delaware action. At this time, you do not know when Apotex will bring this motion. You also noted that Apotex would not agree to stay the Florida action pending resolution of Apotex's Motion to Transfer. I confirmed that sanofi-aventis would oppose Apotex's motion.

sanofi-aventis's Motion to Transfer and Stay: You confirmed that Apotex would oppose any motion to transfer the second-filed Florida action to Delaware that sanofi-aventis might bring.

The '940 Patent: I notified you that sanofi-aventis does not believe the '940 patent is in dispute against Apotex. You stated that based upon the recent *Forest Labs.* decision you disagreed. However, I informed you that I was unaware of any such decision and you identified no such decision.

Sincerely,



William T. Vuk

cc (via email):
Jack Blumenfeld, Esq.
Stephen J. Bronis, Esq.
Richard L. Horwitz, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

EXHIBIT 15

Case 0:07-cv-00572-GMS Document 6-10 Filed 01/23/2008 Page 2 of 17

PATENT

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

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

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

Date Filed	#	Docket Text
09/21/2007	1	COMPLAINT filed against Par Pharmaceutical Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., Torrent Pharma Inc., Torrent Pharmaceuticals Limited, Actavis South Atlantic LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc., Mylan Pharmaceuticals Inc. - Magistrate Consent Notice to Pltf. (Filing fee $ 350, receipt number 148987.) - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibits A and B# 2 Civil Cover Sheet # 3 Acknowledgement of Consent Form)(ead) (Entered: 09/24/2007)
09/21/2007		Summons Issued as to Par Pharmaceutical Inc. on 9/21/2007; Ranbaxy Inc. on 9/21/2007; Ranbaxy Laboratories Limited on 9/21/2007; Sun Pharmaceutical Industries Inc. on 9/21/2007; Sun Pharmaceutical Industries Ltd. on 9/21/2007; Teva Pharmaceuticals USA Inc. on 9/21/2007; Torrent Pharma Inc. on 9/21/2007; Torrent Pharmaceuticals Limited on 9/21/2007; Actavis South Atlantic LLC on 9/21/2007; Aurobindo Pharma Ltd. on 9/21/2007; Aurobindo Pharma USA Inc. on 9/21/2007; Mylan Pharmaceuticals Inc. on 9/21/2007. (ead) (Entered: 09/24/2007)
09/21/2007	2	Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (ead) (Entered: 09/24/2007)
09/21/2007	3	Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (ead) (Entered: 09/24/2007)
09/24/2007	4	Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) 4,661,491; 6,149,940; (ead) (Entered: 09/24/2007)
09/25/2007	5	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Sun Pharmaceutical Industries Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	6	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US

		LLC. Sun Pharmaceutical Industries Ltd. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	7	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Torrent Pharmaceuticals Limited served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	8	SUMMONS Returned Executed by Sanofi-Aventis US LLC. Ranbaxy Laboratories Limited served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	9	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Aurobindo Pharma Ltd. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	10	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Actavis South Atlantic LLC served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	11	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Aurobindo Pharma USA Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	12	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Par Pharmaceutical Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	13	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Ranbaxy Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	14	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Torrent Pharma Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	15	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Teva Pharmaceuticals USA Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
09/25/2007	16	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Mylan Pharmaceuticals Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
10/03/2007	17	DECLARATION *of Mailing (regarding service on Mylan Pharmaceuticals Inc. pursuant to 10 Del. C. Section 3104)* by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibit A & B) (Parrett, James) (Entered: 10/03/2007)
10/03/2007		Case assigned to Judge Gregory M. Sleet and referred to Magistrate-Judge Mary Pat Thynge. Please include the initials of the Judge (GMS) after the case number on all documents filed. (rjb) (Entered: 10/03/2007)
10/05/2007	18	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Torrent Pharmaceuticals Limited served on 9/28/2007, answer due

		10/18/2007. (Parrett, James) (Entered: 10/05/2007)
10/08/2007	19	DECLARATION *of Mailing (regarding service on Sun Pharmaceutical Industries, Inc. pursuant to 10 Del. C. Section 3104)* by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibit A & B)(Parrett, James) (Entered: 10/08/2007)
10/10/2007	20	STIPULATION TO EXTEND TIME to respond to complaint to November 5, 2007 - filed by Sanofi-Aventis, Sanofi-Aventis US LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc.. (Matterer, Mary) (Entered: 10/10/2007)
10/11/2007		SO ORDERED, re 20 STIPULATION TO EXTEND TIME to respond to complaint to November 5, 2007 filed by Sanofi-Aventis, Sanofi-Aventis US LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. Reset Answer Deadlines: Aurobindo Pharma Ltd. answer due 11/5/2007; Aurobindo Pharma USA Inc. answer due 11/5/2007. Ordered by Judge Gregory M. Sleet on 10/11/2007. (asw) (Entered: 10/11/2007)
10/12/2007	21	REQUEST FOR WAIVER of Service sent to Ranbaxy Inc. on 10/10/2007 by Sanofi-Aventis, Sanofi-Aventis US LLC.Waiver of Service due by 11/9/2007. (Parrett, James) (Entered: 10/12/2007)
10/12/2007	22	WAIVER OF SERVICE returned executed by Sanofi-Aventis, Sanofi-Aventis US LLC: For Ranbaxy Inc. waiver sent on 10/10/2007, answer due 12/10/2007. (Parrett, James) (Entered: 10/12/2007)
10/12/2007	23	REQUEST FOR WAIVER of Service sent to Ranbaxy Laboratories Limited on 10/10/2007 by Sanofi-Aventis, Sanofi-Aventis US LLC.Waiver of Service due by 11/9/2007. (Parrett, James) (Entered: 10/12/2007)
10/12/2007	24	WAIVER OF SERVICE returned executed by Sanofi-Aventis, Sanofi-Aventis US LLC: For Ranbaxy Laboratories Limited waiver sent on 10/10/2007, answer due 12/10/2007. (Parrett, James) (Entered: 10/12/2007)
10/12/2007	25	NOTICE of Extension of Time (extending Teva's time to answer, move or otherwise respond to the complaint through and including October 22, 2007) by Sanofi-Aventis, Sanofi-Aventis US LLC (Blumenfeld, Jack) (Entered: 10/12/2007)
10/15/2007	26	ANSWER to Complaint (Notice of Removal), COUNTERCLAIM against all plaintiffs by Actavis South Atlantic LLC. (Attachments: # 1 Certificate of Service)(Gattuso, Dominick) (Entered: 10/15/2007)
10/15/2007	27	Disclosure Statement pursuant to Rule 7.1 filed by Actavis South Atlantic LLC. (Attachments: # 1 Certificate of Service)(Gattuso, Dominick) (Entered: 10/15/2007)
10/15/2007	28	ANSWER to Complaint, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Mylan Pharmaceuticals Inc..(Horwitz, Richard) (Entered: 10/15/2007)

10/15/2007	29	ANSWER to Complaint, COUNTERCLAIM *and Affirmative Defenses* against Sanofi-Aventis, Sanofi-Aventis US LLC by Torrent Pharma Inc., Torrent Pharmaceuticals Limited. (Attachments: # 1 Disclosure Statement for Torrent Pharma Inc. to answer to complaint# 2 Torrent Pharmaceuticals Ltd. Disclosure to answer to complaint)(Murphy, Francis) (Entered: 10/15/2007)
10/15/2007	30	NOTICE of Extension of Time by Sanofi-Aventis, Sanofi-Aventis US LLC re 1 Complaint,, (Noreika, Maryellen) (Entered: 10/15/2007)
10/15/2007	31	Disclosure Statement pursuant to Rule 7.1 filed by Mylan Pharmaceuticals Inc. identifying Mylan Inc. as Corporate Parent. (Moore, David) (Entered: 10/15/2007)
10/15/2007	32	MOTION for Extension of Time to File Answer re 1 Complaint,, *to October 29, 2007* - filed by Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., Sanofi-Aventis, Sanofi-Aventis US LLC. Motions referred to Mary Pat Thynge.(Parrett, James) (Entered: 10/15/2007)
10/16/2007		SO ORDERED, re 32 MOTION for Extension of Time to File Answer re 1 Complaint, *to October 29, 2007* MOTION for Extension of Time to File Answer re 1 Complaint, *to October 29, 2007* filed by Sanofi-Aventis, Sun Pharmaceutical Industries Inc., Sanofi-Aventis US LLC, Sun Pharmaceutical Industries Ltd. Reset Answer Deadlines: Sun Pharmaceutical Industries Inc. answer due 10/29/2007; Sun Pharmaceutical Industries Ltd. answer due 10/29/2007. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/16/2007		SO ORDERED re 30 Notice (Other) filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Reset Answer Deadlines: Par Pharmaceutical Inc. answer due 10/30/2007. PLEASE NOTE FOR FUTURE REFERENCE: THIS TYPE OF REQUEST SHALL BE FILED IN THE FORM OF A STIPULATION RATHER THAN A NOTICE TO EXTEND TIME. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/16/2007		SO ORDERED re 25 Notice (Other) filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Reset Answer Deadlines: Teva Pharmaceuticals USA Inc. answer due 10/22/2007. PLEASE NOTE FOR FUTURE REFERENCE: THIS TYPE OF REQUEST SHALL BE FILED IN THE FORM OF A STIPULATION RATHER THAN A NOTICE TO EXTEND TIME. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/16/2007	33	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Aurobindo Pharma Ltd. served on 9/28/2007, answer due 11/5/2007. (Parrett, James) (Entered: 10/16/2007)
10/17/2007	34	Disclosure Statement pursuant to Rule 7.1 filed by Torrent Pharma Inc., Torrent Pharmaceuticals Limited identifying Torrent Pharmaceuticals Ltd. as Corporate Parent. (Murphy, Francis) (Entered: 10/17/2007)

10/17/2007	35	NOTICE of Appearance by Frederick L. Cottrell, III on behalf of Ranbaxy Inc., Ranbaxy Laboratories Limited (Cottrell, Frederick) (Entered: 10/17/2007)
10/17/2007	36	NOTICE of Appearance by Jameson A.L. Tweedie on behalf of Ranbaxy Inc., Ranbaxy Laboratories Limited (Tweedie, Jameson) (Entered: 10/17/2007)
10/22/2007	37	ANSWER to Complaint, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Teva Pharmaceuticals USA Inc..(Shaw, John) (Entered: 10/22/2007)
10/22/2007	38	Disclosure Statement pursuant to Rule 7.1 filed by Teva Pharmaceuticals USA Inc. identifying Orvet UK Ltd., Teva Pharmaceuticals Europe B. V. (Holland) and Teva Pharmaceutical Industries Ltd. (Israel) as Corporate Parent. (Shaw, John) (Entered: 10/22/2007)
10/24/2007	39	ANSWER to Complaint, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Par Pharmaceutical Inc..(Gattuso, Dominick) (Entered: 10/24/2007)
10/24/2007	40	Disclosure Statement pursuant to Rule 7.1 filed by Par Pharmaceutical Inc.. (Gattuso, Dominick) (Entered: 10/24/2007)
10/24/2007	41	MOTION for Pro Hac Vice Appearance of Attorney Darrell L. Olson and William R. Zimmerman - filed by Ranbaxy Inc., Ranbaxy Laboratories Limited. Motions referred to Mary Pat Thynge.(Cottrell, Frederick) (Entered: 10/24/2007)
10/24/2007		SO ORDERED, re 41 MOTION for Pro Hac Vice Appearance of Attorney Darrell L. Olson and William R. Zimmerman filed by Ranbaxy Inc., Ranbaxy Laboratories Limited. Ordered by Judge Gregory M. Sleet on 10/24/2007. (asw) (Entered: 10/24/2007)
10/26/2007	42	DECLARATION *of Mailing (regarding service on Sun Pharmaceutical Industries, Ltd. pursuant to 10 Del. C. Section 3104)* by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibit A & B)(Parrett, James) (Entered: 10/26/2007)
10/29/2007	43	ANSWER to Complaint by Sun Pharmaceutical Industries Inc..(Rovner, Philip) (Entered: 10/29/2007)
10/29/2007	44	Disclosure Statement pursuant to Rule 7.1 filed by Sun Pharmaceutical Industries Inc. identifying Sun Pharmaceutical Industries Ltd. as Corporate Parent. (Rovner, Philip) (Entered: 10/29/2007)
10/29/2007	45	ANSWER to Complaint by Sun Pharmaceutical Industries Ltd..(Rovner, Philip) (Entered: 10/29/2007)
10/29/2007	46	Disclosure Statement pursuant to Rule 7.1 filed by Sun Pharmaceutical Industries Ltd. identifying None as Corporate Parent. (Rovner, Philip) (Entered: 10/29/2007)
10/30/2007	47	MOTION for Pro Hac Vice Appearance of Attorney William A.

		Rakoczy, Attorney Paul J. Molino, Attorney Deanne M. Mazzochi, Attorney Christine J. Siwik, Attorney Theodore J. Chiacchio and Attorney Tara M. Raghavan - filed by Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc.. Motions referred to Mary Pat Thynge. (Matterer, Mary) (Entered: 10/30/2007)
10/30/2007		SO ORDERED, re 47 MOTION for Pro Hac Vice Appearance of Attorney William A. Rakoczy, Attorney Paul J. Molino, Attorney Deanne M. Mazzochi, Attorney Christine J. Siwik, Attorney Theodore J. Chiacchio and Attorney Tara M. Raghavan filed by Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. Ordered by Judge Gregory M. Sleet on 10/30/2007. (asw) (Entered: 10/30/2007)
10/30/2007	48	MOTION for Pro Hac Vice Appearance of Attorney Christopher J. Sorenson, Esquire, Attorney Samuel T. Lockner, Esquire, and Attorney Aaron M. Johnson, Esquire - filed by Teva Pharmaceuticals USA Inc.. Motions referred to Mary Pat Thynge.(Shaw, John) (Entered: 10/30/2007)
10/31/2007		SO ORDERED, re 48 MOTION for Pro Hac Vice Appearance of Attorney Christopher J. Sorenson, Esquire, Attorney Samuel T. Lockner, Esquire, and Attorney Aaron M. Johnson, Esquire filed by Teva Pharmaceuticals USA Inc. Ordered by Judge Gregory M. Sleet on 10/31/2007. (asw) (Entered: 10/31/2007)
11/01/2007	49	MOTION for Pro Hac Vice Appearance of Attorney Sanjay B. Sitlani - filed by Actavis South Atlantic LLC. (Attachments: # 1 Certification of Counsel to be admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Gattuso, Dominick) (Entered: 11/01/2007)
11/01/2007	50	MOTION for Pro Hac Vice Appearance of Attorney Chad A. Landmon - filed by Actavis South Atlantic LLC. (Attachments: # 1 Certification of Counsel to be admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Gattuso, Dominick) (Entered: 11/01/2007)
11/01/2007	51	MOTION for Pro Hac Vice Appearance of Attorney John Will Ongman - filed by Actavis South Atlantic LLC. (Attachments: # 1 Certification of Counsel to be admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Gattuso, Dominick) (Entered: 11/01/2007)
11/01/2007		SO ORDERED, re 49 MOTION for Pro Hac Vice Appearance of Attorney Sanjay B. Sitlani filed by Actavis South Atlantic LLC. Ordered by Judge Gregory M. Sleet on 11/1/2007. (asw) (Entered: 11/01/2007)
11/01/2007		SO ORDERED, re 50 MOTION for Pro Hac Vice Appearance of Attorney Chad A. Landmon filed by Actavis South Atlantic LLC. Ordered by Judge Gregory M. Sleet on 11/1/2007. (asw) (Entered: 11/01/2007)
11/01/2007		SO ORDERED, re 51 MOTION for Pro Hac Vice Appearance of Attorney John Will Ongman filed by Actavis South Atlantic LLC. Ordered by Judge Gregory M. Sleet on 11/1/2007. (asw) (Entered: 11/01/2007)

11/02/2007	52	MOTION for Pro Hac Vice Appearance of Attorney Gerald J. Flattmann, Jr.; William Thomas Vuk and Alexis Gorton - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Motions referred to Mary Pat Thynge.(Noreika, Maryellen) (Entered: 11/02/2007)
11/02/2007		SO ORDERED, re 52 MOTION for Pro Hac Vice Appearance of Attorney Gerald J. Flattmann, Jr.; William Thomas Vuk and Alexis Gorton filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Ordered by Judge Gregory M. Sleet on 11/2/2007. (asw) (Entered: 11/02/2007)
11/05/2007	53	ANSWER to Complaint with Jury Demand, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Aurobindo Pharma USA Inc..(Matterer, Mary) (Entered: 11/05/2007)
11/05/2007	54	Disclosure Statement pursuant to Rule 7.1 filed by Aurobindo Pharma USA Inc. identifying Aurobindo Pharma Ltd. as Corporate Parent. (Matterer, Mary) (Entered: 11/05/2007)
11/05/2007	55	ANSWER to Complaint with Jury Demand, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Aurobindo Pharma Ltd.. (Matterer, Mary) (Entered: 11/05/2007)
11/05/2007	56	Disclosure Statement pursuant to Rule 7.1 filed by Aurobindo Pharma Ltd.. (Matterer, Mary) (Entered: 11/05/2007)
11/06/2007	57	MOTION for Pro Hac Vice Appearance of Attorney Mark D. Schuman, Esquire - filed by Teva Pharmaceuticals USA Inc.. Motions referred to Mary Pat Thynge.(Shaw, John) (Entered: 11/06/2007)
11/07/2007	58	MOTION for Pro Hac Vice Appearance of Attorney ERIC C. COHEN, ESQ. AND MANOTTI L. JENKINS, ESQ. OF KATTEN MUCHIN ROSENMAN LLP - filed by Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd.. Motions referred to Mary Pat Thynge. (Rovner, Philip) (Entered: 11/07/2007)
11/07/2007	59	MOTION for Pro Hac Vice Appearance of Attorney John M. Desmarais - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Motions referred to Mary Pat Thynge.(Blumenfeld, Jack) (Entered: 11/07/2007)
11/07/2007	60	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Actavis South Atlantic LLC's Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/07/2007)
11/07/2007	61	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Mylan Pharmaceuticals Inc.'s Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/07/2007)
11/07/2007	62	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendants Torrent Pharma Inc.'s and Torrent Pharmaceuticals, Ltd.'s Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/07/2007)
11/07/2007		SO ORDERED, re 59 MOTION for Pro Hac Vice Appearance of Attorney John M. Desmarais filed by Sanofi-Aventis, Sanofi-Aventis US

		LLC. Signed by Judge Gregory M. Sleet on 11/7/07. (mmm) (Entered: 11/07/2007)
11/08/2007	63	MOTION for Pro Hac Vice Appearance of Attorney Timothy H. Kratz, Robert J. Waddell Jr., Robert L. Florence, and Lynn E. Eccleston of McGuire Woods LLP - filed by Mylan Pharmaceuticals Inc.. Motions referred to Mary Pat Thynge.(Moore, David) (Entered: 11/08/2007)
11/14/2007	64	ANSWER to Counterclaim *Reply to Defendant Teva Pharmaceuticals USA. Inc.'s Counterclaims* by Sanofi-Aventis, Sanofi-Aventis US LLC. (Blumenfeld, Jack) (Entered: 11/14/2007)
11/15/2007	65	MOTION for Pro Hac Vice Appearance of Attorney Kathryn M. Liberatore of Kirkland & Ellis LLP - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Motions referred to Mary Pat Thynge.(Blumenfeld, Jack) (Entered: 11/15/2007)
11/16/2007	66	AMENDED ANSWER to 1 Complaint,, 26 Answer to Complaint (Notice of Removal), Counterclaim, COUNTERCLAIM *First Amended Answer and Counterclaims of Defendant Par Pharmaceutical, Inc. to Plaintiffs' Complaint* against Sanofi-Aventis US LLC by Par Pharmaceutical Inc.. (Gattuso, Dominick) (Entered: 11/16/2007)
11/16/2007	67	STIPULATION Allow Defendant Actavis South Atlantic LLC to file an amended answer and counterclaims re 26 Answer to Complaint (Notice of Removal), Counterclaim by Actavis South Atlantic LLC. (Attachments: # 1 Exhibit First Amended Answer and Counterclaims of Defendant Actavis South Atlantic LLC to Plaintiffs' Complaint# 2 Exhibit Tab 2 - Redline Version of Amended Answer and Counterclaim) (Gattuso, Dominick) (Entered: 11/16/2007)
11/16/2007	68	AMENDED ANSWER to 1 Complaint,, 26 Answer to Complaint (Notice of Removal), Counterclaim, COUNTERCLAIM *First Amended Answer and Counterclaims of Defendant Actavis South Atlantic LLC to Plaintiffs' Complaint* against all plaintiffs by Actavis South Atlantic LLC. (Gattuso, Dominick) (Entered: 11/16/2007)
11/20/2007	69	MOTION for Pro Hac Vice Appearance of Attorney David B. Abramowitz, Keith D. Parr, Kevin M. Nelson - filed by Torrent Pharma Inc., Torrent Pharmaceuticals Limited. Motions referred to Mary Pat Thynge.(Murphy, Francis) (Entered: 11/20/2007)
11/21/2007		SO ORDERED, re 57 MOTION for Pro Hac Vice Appearance of Attorney Mark D. Schuman, Esquire filed by Teva Pharmaceuticals USA Inc., 63 MOTION for Pro Hac Vice Appearance of Attorney Timothy H. Kratz, Robert J. Waddell Jr., Robert L. Florence, and Lynn E. Eccleston of McGuire Woods LLP filed by Mylan Pharmaceuticals Inc., 58 MOTION for Pro Hac Vice Appearance of Attorney ERIC C. COHEN, ESQ. AND MANOTTI L. JENKINS, ESQ. OF KATTEN MUCHIN ROSENMAN LLP filed by Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., 69 MOTION for Pro Hac Vice Appearance of Attorney David B. Abramowitz, Keith D. Parr, Kevin M. Nelson filed by Torrent Pharmaceuticals Limited, Torrent Pharma Inc.,

		65 MOTION for Pro Hac Vice Appearance of Attorney Kathryn M. Liberatore of Kirkland & Ellis LLP filed by Sanofi-Aventis, Sanofi-Aventis US LLC. Signed by Judge Gregory M. Sleet on 11/21/07. (mmm) (Entered: 11/21/2007)
11/28/2007	70	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Aurobindo Pharma Ltd.'s Counterclaim)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/28/2007)
11/28/2007	71	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Aurobindo Pharma USA Inc.'s Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/28/2007)
12/03/2007	72	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Par Pharmaceutical, Inc.'s Amended Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 12/03/2007)
12/03/2007	73	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Actavis South Atlantic LLC's Amended Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 12/03/2007)
12/10/2007	74	STIPULATION TO EXTEND TIME For Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. To File Their Answer To Plaintiffs' Complaint to January 7, 2008 - filed by Ranbaxy Inc., Ranbaxy Laboratories Limited. (Tweedie, Jameson) (Entered: 12/10/2007)
12/10/2007		SO ORDERED, re 74 STIPULATION TO EXTEND TIME For Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. To File Their Answer To Plaintiffs' Complaint to January 7, 2008 filed by Ranbaxy Inc., Ranbaxy Laboratories Limited. THE COURT WILL NOT ENTERTAIN ANY ADDITIONAL STIPULATIONS TO EXTEND TIME TO FILE AN ANSWER TO THE COMPLAINT. Ordered by Judge Gregory M. Sleet on 12/10/2007. (asw) (Entered: 12/10/2007)
12/10/2007		Set/Reset Answer Deadlines: Ranbaxy Inc. answer due 1/7/2008; Ranbaxy Laboratories Limited answer due 1/7/2008. (asw) (Entered: 12/10/2007)
12/19/2007	75	DECLARATION *of Mailing (for service upon Torrent Pharmaceuticals Limited pursuant to 10 Del. C. Section 3104)* by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibit A & B)(Parrett, James) (Entered: 12/19/2007)
12/21/2007	76	NOTICE of Withdrawal of Counsel Jameson A.L. Tweedie by Ranbaxy Inc., Ranbaxy Laboratories Limited (Tweedie, Jameson) (Entered: 12/21/2007)
12/27/2007	77	NOTICE OF SUBSTITUTION OF COUNSEL re Actavis South Atlantic LLC: Entry of appearance of attorney David J. Margules. Attorney Dominick T. Gattuso terminated. (Margules, David) (Entered: 12/27/2007)
12/27/2007	78	NOTICE OF SERVICE of (1) First Set of Interrogatories and (2) First Set of Document Requests by Aurobindo Pharma Ltd., Aurobindo

		Pharma USA Inc..(Matterer, Mary) (Entered: 12/27/2007)
01/07/2008	79	NOTICE OF SUBSTITUTION OF COUNSEL re Par Pharmaceutical Inc.: Entry of appearance of attorney David J. Margules. Attorney Dominick T. Gattuso terminated. (Margules, David) (Entered: 01/07/2008)
01/07/2008	80	Disclosure Statement pursuant to Rule 7.1 filed by Ranbaxy Inc., Ranbaxy Laboratories Limited identifying (No Corporate Parent as to Ranbaxy Laboratories Limited) and (Ranbaxy Holdings (UK) Limited as to Ranbaxy Inc.) as Corporate Parent. (Cottrell, Frederick) (Entered: 01/07/2008)
01/07/2008	81	ANSWER to Complaint, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis US LLC by Ranbaxy Inc., Ranbaxy Laboratories Limited.(Cottrell, Frederick) (Entered: 01/07/2008)
01/07/2008	82	ANSWER to Counterclaim *of Ranbaxy Laboratories Limited and Ranbaxy Inc.* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Parrett, James) (Entered: 01/07/2008)
01/08/2008	83	MOTION for Pro Hac Vice Appearance of Attorney Scott B. Feder - filed by Torrent Pharma Inc., Torrent Pharmaceuticals Limited. (Murphy, Francis) (Entered: 01/08/2008)

PATENT

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

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

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

Date Filed	#	Docket Text
09/21/2007	1	COMPLAINT filed against Barr Laboratories Inc. - Magistrate Consent Notice to Pltf. (Filing fee $ 350, receipt number 148988.) - filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (Attachments: # 1 Exhibits A and B# 2 Civil Cover Sheet # 3 Acknowledgement of Consent Form) (ead) (Entered: 09/24/2007)
09/21/2007		Summons Issued as to Barr Laboratories Inc. on 9/21/2007. (ead) (Entered: 09/24/2007)
09/21/2007	2	Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis US LLC. (ead) (Entered: 09/24/2007)
09/21/2007	3	Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (ead) (Entered: 09/24/2007)
09/24/2007	4	Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) 4,661,491; 6,149,940; (ead) (Entered: 09/24/2007)
09/25/2007	5	Return of Service Executed by Sanofi-Aventis, Sanofi-Aventis US LLC. Barr Laboratories Inc. served on 9/24/2007, answer due 10/15/2007. (Parrett, James) (Entered: 09/25/2007)
10/03/2007		Case assigned to Judge Gregory M. Sleet and referred to Magistrate-Judge Mary Pat Thynge. Please include the initials of the Judge (GMS) after the case number on all documents filed. (rjb) (Entered: 10/03/2007)
10/12/2007	6	STIPULATION TO EXTEND TIME to answer complaint to October 29, 2007 - filed by Sanofi-Aventis, Sanofi-Aventis US LLC, Barr Laboratories Inc.. (Phillips, John) (Entered: 10/12/2007)
10/16/2007	7	MOTION for Pro Hac Vice Appearance of Attorney Kurt A. Mathas, Esquire - filed by Barr Laboratories Inc.. (Attachments: # 1 Certification of Counsel to be Admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Phillips, John) (Entered: 10/16/2007)

10/16/2007	8	MOTION for Pro Hac Vice Appearance of Attorney Ivan M. Poullaos, Esquire - filed by Barr Laboratories Inc.. (Attachments: # 1 Certification by Counsel to be Admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Phillips, John) (Entered: 10/16/2007)
10/16/2007		SO ORDERED, re 7 MOTION for Pro Hac Vice Appearance of Attorney Kurt A. Mathas, Esquire filed by Barr Laboratories Inc. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/16/2007		SO ORDERED, re 8 MOTION for Pro Hac Vice Appearance of Attorney Ivan M. Poullaos, Esquire filed by Barr Laboratories Inc. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/16/2007		SO ORDERED, re 6 STIPULATION TO EXTEND TIME to answer complaint to October 29, 2007 filed by Sanofi-Aventis, Sanofi-Aventis US LLC, Barr Laboratories Inc. Reset Answer Deadlines: Barr Laboratories Inc. answer due 10/29/2007. Ordered by Judge Gregory M. Sleet on 10/16/2007. (asw) (Entered: 10/16/2007)
10/29/2007	9	ANSWER to Complaint with Jury Demand, COUNTERCLAIM against all plaintiffs by Barr Laboratories Inc..(Phillips, John) (Entered: 10/29/2007)
10/29/2007	10	Disclosure Statement pursuant to Rule 7.1 filed by Barr Laboratories Inc. identifying Barr Pharmaceuticals, Inc. as Corporate Parent. (Phillips, John) (Entered: 10/29/2007)
10/31/2007	11	MOTION for Pro Hac Vice Appearance of Attorney George C. Lombardi, Esquire - filed by Barr Laboratories Inc.. (Attachments: # 1 Certification by Counsel to be Admitted Pro Hac)Motions referred to Mary Pat Thynge.(Phillips, John) (Entered: 10/31/2007)
10/31/2007	12	MOTION for Pro Hac Vice Appearance of Attorney Taras A. Gracey, Esquire - filed by Barr Laboratories Inc.. (Attachments: # 1 Certification by Counsel to be Admitted Pro Hac Vice)Motions referred to Mary Pat Thynge.(Phillips, John) (Entered: 10/31/2007)
10/31/2007		SO ORDERED, re 11 MOTION for Pro Hac Vice Appearance of Attorney George C. Lombardi, Esquire filed by Barr Laboratories Inc. Ordered by Judge Gregory M. Sleet on 10/31/2007. (asw) (Entered: 10/31/2007)
10/31/2007		SO ORDERED, re 12 MOTION for Pro Hac Vice Appearance of Attorney Taras A. Gracey, Esquire filed by Barr Laboratories Inc. Ordered by Judge Gregory M. Sleet on 10/31/2007. (asw) (Entered: 10/31/2007)
11/21/2007	13	ANSWER to Counterclaim *(Plaintiffs' Reply to Defendant Barr Laboratories, Inc.'s Counterclaims)* by Sanofi-Aventis, Sanofi-Aventis US LLC.(Blumenfeld, Jack) (Entered: 11/21/2007)

PATENT

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

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

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

Date Filed	#	Docket Text
12/06/2007	1	COMPLAINT filed against Apotex Inc., Apotex Corp. - Magistrate Consent Notice to Pltf. (Filing fee $ 350, receipt number 149816.) - filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Exhibit A# 2 Civil Cover Sheet # 3 Acknowledgement of Consent Form)(lid) (Entered: 12/07/2007)
12/06/2007		Summons Issued as to Apotex Inc. and Apotex Inc. c/o Secretary of State on 12/6/2007; Apotex Corp. on 12/6/2007. (lid) (Entered: 12/07/2007)
12/06/2007	2	Disclosure Statement pursuant to Rule 7.1 filed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC identifying Sanofi-Aventis as Corporate Parent of Sanofi-Aventis U.S. LLC. (lid) (Entered: 12/07/2007)
12/06/2007	3	Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (lid) (Entered: 12/07/2007)
12/06/2007	4	Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) 4,661,491; (lid) (Entered: 12/07/2007)
12/10/2007	5	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. Apotex Corp. served on 12/10/2007, answer due 1/2/2008. (Blumenfeld, Jack) (Entered: 12/10/2007)
12/11/2007		Summons reissued as to Apotex Inc. on 12/11/2007. (rwc) (Entered: 12/11/2007)
12/12/2007		Case assigned to Judge Gregory M. Sleet and referred to Magistrate-Judge Mary Pat Thynge. Please include the initials of the Judge (GMS) after the case number on all documents filed. (rjb) (Entered: 12/12/2007)
12/28/2007	6	SUMMONS Returned Executed by Sanofi-Aventis, Sanofi-Aventis U.S. LLC. Apotex Inc. served on 12/12/2007, answer due 1/2/2008. (Parrett, James) (Entered: 12/28/2007)
01/02/2008	7	ANSWER to Complaint with Jury Demand, COUNTERCLAIM against Sanofi-Aventis, Sanofi-Aventis U.S. LLC by Apotex Inc., Apotex Corp..

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		(Horwitz, Richard) (Entered: 01/02/2008)
01/03/2008	8	ANSWER to Counterclaim *Plaintiffs' Reply To Defendants Apotex Inc. And Apotex Corp.'s Counterclaims* by Sanofi-Aventis, Sanofi-Aventis U.S. LLC.(Blumenfeld, Jack) (Entered: 01/03/2008)
01/04/2008	9	Disclosure Statement pursuant to Rule 7.1 filed by Apotex Inc., Apotex Corp. identifying Aposherm, Inc. as Corporate Parent. (Horwitz, Richard) (Entered: 01/04/2008)

EXHIBIT 16

FILED by _____ D.C.
INTAKE
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CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA. – MIAMI

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 07-61800

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

CIV-MORENO

MAGISTRATE JUDGE
SIMONTON

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 company, Plaintiff sanofi-aventis U.S., which manufactures 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.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida 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.

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

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.

Dated this 10th day of December, 2007.
Miami, Florida

Respectfully submitted,

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Attorney for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC

EXHIBIT 17

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.
_____/

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*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, 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 Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

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. admit that venue is proper in this judicial district.

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. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

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.

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

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.

AFFIRMATIVE 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 affirmative defenses to the Complaint:

FIRST AFFIRMATIVE 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 AFFIRMATIVE 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 AFFIRMATIVE 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. conducts substantial business in and has regular systematic contacts with 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 "AFLUZOSINE 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 AFLUZOSINE 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. 70-013 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 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 70-013 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.

DATED: December 28, 2007
Miami, FL

Respectfully submitted,

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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on December 28, 2007 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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

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EXHIBIT 18

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.
_____/

ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE DEFENSES AND AMENDED COUNTERCLAIMS[1]

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.

[1] This pleading is identical to the pleading filed December 28, 2007, except that certain inadvertent typographical errors in paragraphs 9, 11, 15 and 16 of the Counterclaims have been corrected.

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*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, 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 Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

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. admit that venue is proper in this judicial district.

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. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

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.

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

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.

AFFIRMATIVE 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 affirmative defenses to the Complaint:

FIRST AFFIRMATIVE 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 AFFIRMATIVE 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 AFFIRMATIVE 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.

AMENDED 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. conducts substantial business in and has regular systematic contacts with 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.

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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.

DATED: January 2, 2008
Miami, FL

Respectfully submitted,

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and

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Case 0:07-cv-61800-FAM Document 6-19 Entered on FLSD Docket 01/23/2008 Page 17 of 18

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on January 2, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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EXHIBIT 19

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

FILED by _____ D.C.
APPEAL
JUL 28 2000
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

ABBOTT LABORATORIES,

PLAINTIFF,

VS.

ANDRX CORPORATION, ET AL.,

DEFENDANTS.

CASE 00-6520-CV-SH

MIAMI, FLORIDA
JULY 10, 2000

TRANSCRIPT OF SCHEDULING CONFERENCE
BEFORE THE HONORABLE SHELBY HIGHSMITH,
UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFF:
JOHN F. O'SULLIVAN, ESQ.
JAMES R. DALY, ESQ.
DAVID C. GOODWIN, ESQ.
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REPORTED BY:
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MORNING SESSION

9:00 O'CLOCK A.M.

[CALL TO ORDER]

THE COURT: GOOD MORNING. PLEASE BE SEATED. ALL RIGHT.

THE CLERK: ABBOTT LABORATORIES VERSUS ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. AND ANDRX PHARMACEUTICALS L.L.C.

CIVIL CASE NUMBER 00-6520-CIVIL-HIGHSMITH. WOULD COUNSEL FOR THE RESPECTIVE PARTIES PLEASE ANNOUNCE THEMSELVES.

MR. GOODWIN: FOR PLAINTIFF ABBOTT LABORATORIES, DAVID C. GOODWIN.

THE COURT: MR. GOODWIN.

MR. DALY: GOOD MORNING, YOUR HONOR. JAMES R. DALY FOR JONES-DALY IN CHICAGO FOR THE PLAINTIFF ABBOTT LABORATORIES.

THE COURT: MR. DALY.

MR. O'SULLIVAN: YOUR HONOR, JOHN O'SULLIVAN FROM AKERMAN & SENTERFITT ALSO FOR ABBOTT LABORATORIES.

THE COURT: MR. O'SULLIVAN.

MR. ISICOFF: GOOD MORNING. ERIC ISICOFF FROM MIAMI FOR THE ANDRX DEFENDANTS.

THE COURT: ALL RIGHT. MR. ISICOFF.

MR. ISICOFF: PRESENT WITH ME ARE MARTIN ENDRES

AND THIS IS HERSCHEL SPARKS, IN-HOUSE COUNSEL FOR THE ANDRX.

THE COURT: WELL, WELCOME TO ALL OF YOU. MY GOODNESS. HOW LONG HAS IT BEEN SINCE YOU HAVE BEEN IN MY COURTROOM, DAVE GOODWIN?

MR. GOODWIN: JUDGE HIGHSMITH, PROBABLY NEVER IN THIS COURTROOM.

THE COURT: THAT'S WHAT I WAS TRYING TO REFLECT UPON. I KNOW I HAVE SEEN YOU ON OCCASION.

MR. GOODWIN: I THINK I HAVE SEEN YOU IN CHAMBERS, AND THAT'S BEEN IN --

THE COURT: WELL, IT IS A DELIGHT, AS IT IS ALL OF YOU. MR. GOODWIN AND I GO A LONG WAYS. WE WERE NEVER TOGETHER PRACTICING AND WHATNOT. MOST OFTEN, SOMETIMES OPPOSITE.

IN ANY EVENT, LET ME FIRST ADVISE YOU THAT I HOLD THESE STATUS CONFERENCES IN ALL OF MY CIVIL CASES IN AN EFFORT TO HOPEFULLY GET THEM STARTED ON THE RIGHT TRACK.

ORDINARILY, FOLLOWING A CONFERENCE OF THIS NATURE -- THE STATUS CONFERENCE, IF YOU WILL -- THERE WOULD BE A VERY COMPREHENSIVE ORDER THAT WOULD FOLLOW THAT WOULD SET FORTH THE MATTERS THAT YOU MUST ACCOMPLISH, YOU AND YOUR CLIENTS, IN THE INTERIM PRECEDING OF THE ULTIMATE TRIAL.

I DO NOT SET PRETRIAL CONFERENCES, EXCEPT IN VERY UNUSUAL CIRCUMSTANCES. I FOUND THAT RELIANCE UPON THE

PRETRIAL CONFERENCE CONCEPT OFTEN LEADS THE COURT -- AS WELL AS COUNSEL, ON OCCASION -- TO SORT OF IGNORE THE CASE UNTIL THE PRETRIAL CONFERENCE, AND THEN WE ARE SET ON THE TIME OF TRIAL OR ON THE EVE OF TRIAL.

IN ANY EVENT, ALL OF THE MATTERS THAT WOULD OTHERWISE BE COVERED ON A PRETRIAL CONFERENCE WOULD ORDINARILY BE COVERED NOT ONLY IN THIS CONFERENCE BUT IN THE ORDER THAT WILL FOLLOW.

THIS IS A RATHER PECULIAR SITUATION. IT IS OBVIOUSLY COMPLEX, WHAT WE WOULD PUT ON OUR COMPLEX TRACK, BUT I AM TALKING ABOUT THE TWO OTHER PENDING PREVIOUSLY FILED CASES IN OTHER JURISDICTIONS.

NOW, THERE HAS BEEN A MOTION TO STAY. WHAT IS THE FEELING OF COUNSEL IN THAT REGARD? LET'S START WITH YOU, MR. GOODWIN.

MR. GOODWIN: MAY I APPROACH THE LECTERN, YOUR HONOR?

THE COURT: YES, PLEASE.

MR. GOODWIN: JUDGE, THE MOTION TO STAY, IF WE COULD HOLD THAT BACK JUST FOR A HOUSEKEEPING MATTER FIRST, PRO HAC PAPERS HAVE BEEN FILED ON BEHALF OF MR. JAMES R. DALY. HE IS A MEMBER OF THE TRIAL BAR OF THE NORTHERN DISTRICT OF ILLINOIS. HE IS HERE WITH US THIS MORNING. OBVIOUSLY, WE WOULD WANT HIM APPROVED.

THE COURT: ALL RIGHT.

MR. ISICOFF: NO OBJECTION, YOUR HONOR.

THE COURT: VERY WELL. CERTAINLY. WELCOME.

MR. DALY: THANK YOU, YOUR HONOR.

MR. GOODWIN: ON THE MOTION TO STAY, YOUR HONOR, AND I WAS GOING TO BE TALKING MORE IN TERMS OF THE SCHEDULING CONFERENCE AND SOME OF THE DATES -- AND WE HAVE MET, WE HAVE DONE OUR RESPECTIVE HOMEWORKS, WE HAVE DONE ALL THAT, BUT ON THE FACTUAL MATTERS CONTAINED, AS YOUR HONOR KNOWS, AND THE MEMORANDUM IN SUPPORT THAT WAS FILED UNDER SEAL -- AND SO THAT I DON'T MISSTEP OR SAY SOMETHING BECAUSE I AM NEWLY ACTIVATED INTO THIS MATTER, WOULD IT BE ALL RIGHT IF MR. DALY CAME HERE AND ADDRESSED THESE MOTIONS TO STAY?

THE COURT: OF COURSE. MR. DALY?

MR. DALY: THANK YOU, YOUR HONOR. YOUR HONOR, THE -- BY WAY OF BACKGROUND TO THE MOTION TO STAY, THE REASON THAT WE HAVE THESE THREE PARALLEL LAWSUITS GOING ON AT THE SAME TIME IS AS FOLLOWS:

WHEN ABBOTT RECEIVED THE NOTICE, THE PARAGRAPH HAD CERTIFICATION FROM ANDRX. WE HAD 45 DAYS WITHIN WHICH TO BRING AN ACTION AGAINST THE DEFENDANTS.

WHEN WE GOT THE NOTICE, THE NOTICE THAT HAD BEEN FILED BY ANDRX L.L.C., AND WE TOOK A LOOK AT IT AND STARTED TO DO SOME RESEARCH ON WHO ANDRX L.L.C. WAS, WE FOUND OUT THAT THEY WERE A NEWLY FORMED LIMITED LIABILITY COMPANY IN

VIRGINIA. WE LOOKED AT THE PARENTS. WE FOUND OUT THAT THEY HAD JUST BEEN FORMED A COUPLE OF WEEKS EARLIER. AND WE BELIEVE THAT WE HAD A BASIS FOR JURISDICTION OVER ALL THREE DEFENDANTS IN CHICAGO.

SO WE FILED FIRST THERE AND WAITED TO SEE WHAT THE DEFENDANTS DID WITH RESPECT TO THE ISSUE OF PERSONAL JURISDICTION.

AS ANTICIPATED, ALL THREE DEFENDANTS CAME INTO CHICAGO AND CONTESTED THE ISSUE OF PERSONAL JURISDICTION. WE THEN MOVED THE COURT FOR EXPEDITED DISCOVERY, GOT IT, GOT ALL THE BRIEFING DONE, BUT WE WERE UNABLE TO GET A DECISION OUT OF THE NORTHERN DISTRICT OF ILLINOIS WITHIN THE INITIAL 45 DAYS.

AND THE IMPORTANCE OF THAT IS, IS THAT IF YOU DON'T HAVE AN ACTION PENDING AGAINST THE DEFENDANTS WITHIN THAT 45 DAYS, YOU LOSE THE THREE-MONTH STAY THAT IS STATUTORILY PROVIDED FOR PROHIBITING FINAL F.D.A. APPROVAL OF THE END.

SO UNDER THE THEORY THAT WITH THE IMPORTANCE OF THAT ISSUE, 99.9 PERCENT SURETY EVEN WOULD NOT BE ENOUGH, WE WENT AHEAD AND WE SUED ALL THREE DEFENDANTS HERE IN FLORIDA, WHICH IS WHERE THE ANDRX CORPORATION AND ANDRX PHARMACEUTICAL, INC. ARE LOCATED, AND WE ALSO SUED THE L.L.C. HERE ON THE BASIS THAT ALL OF THE ACTS THAT IT APPEARS TO HAVE DONE -- IN OTHER WORDS, THE SENDING OF THE

NOTICE, THE FILING WITH THE F.D.A. -- APPEARS TO HAVE EMANATED UNDER FLORIDA FOR ALL THREE DEFENDANTS.

AND THEN NOT KNOWING WHAT THE L.L.C. WOULD DO, WHETHER THEY WOULD EVEN CONSENT TO JURISDICTION HERE, WE ALSO SUED THE L.L.C. ALONE IN VIRGINIA JUST TO MAKE SURE THAT WE HAD A LAWSUIT ON FILE WITHIN THE 45 DAYS.

IN TERMS OF THIS COURT, THE L.L.C. HAS RAISED PERMANENT JURISDICTION AS AN AFFIRMATIVE DEFENSE HERE, SO WE ARE NOT 100 PERCENT SURE WHERE WE ARE GOING TO END UP. I CAN TELL THE COURT AND COUNSEL, WE TALKED OUTSIDE BEFORE COMING IN, WE HAVE BEEN INFORMED IN CHICAGO BY JUDGE HIBLER THAT HE IS READY TO RULE. WE BELIEVE THE OPINION HAS BEEN WRITTEN.

WHAT I DID LAST WEEK, YOUR HONOR, IS SEND OUT AN ORDER INDICATING THAT HE WAS READY TO RULE; BUT BECAUSE THE PARTIES HAD ENTERED INTO A PROTECTIVE ORDER AND FILED THE BRIEFS UNDER SEAL, HE WANTED PUBLIC BRIEFS TO BE FILED WITH THINGS REDACTED IF WE COULD NOT AGREE SO HE WOULD KNOW EXACTLY WHAT HE COULD AND COULD NOT SITE FACTUALLY IN HIS PAPER IN ACCORDANCE WITH THE PROTECTIVE ORDER.

THAT HAS BEEN ACCOMPLISHED BY THE PARTIES IN CHICAGO LAST WEEK AND WE ARE EXPECTING A RULING OUT OF THE COURT ANY DAY.

IN VIRGINIA, YOUR HONOR, WE MOVED FOR A STAY AND WE ARGUED THAT -- I THINK IT WAS ON JUNE 7, AND THE COURT

IN VIRGINIA HAS ISSUED A STAY PENDING RESOLUTION OF THE MOTION THAT STANDS BEFORE JUDGE HIBLER IN THE NORTHERN DISTRICT OF ILLINOIS.

THE ISSUE THAT THE COURT THERE IS FACING -- NOT TO GO INTO TOO MUCH DETAIL -- IS THAT THERE IS A BODY OF CASE LAW THAT TALKS ABOUT PIERCING THROUGH THE PARENTS TO GET TO THE SON TO BRING THE DEFENDANTS TO COURT IN A JURISDICTION WHERE THE PARENTS ARE SUBJECT TO SUIT.

AND WE, ANDRX PHARMACEUTICAL, INC., DOES BUSINESS IN ILLINOIS. THAT IS SOMETHING THAT WE WERE ABLE TO ESTABLISH UNDER OUR EXPEDITED DISCOVERY THERE.

AND WE BELIEVE THAT THE CREATION OF THE L.L.C. FOR THE SOLE PURPOSE OF ATTEMPTING TO FORCE PLAINTIFFS TO SUE THE DEFENDANTS ONLY IN THE NORTHERN -- OR IN THE DISTRICT OF VIRGINIA IS NOT GOING TO SUCCEED, WE BELIEVE, AND WE HAVE FOUND GOOD AUTHORITY TO THAT EFFECT, INCLUDING SOME CASES THAT SAY THAT TAKING PATENTS AND ASSIGNING THEM TO A SUB THAT NEVER GOES OUTSIDE A GIVEN JURISDICTION IS NOT GOING TO BE A BAR TO THE PLAINTIFFS BEING ABLE TO SUE THE REAL PARTIES IN INTEREST.

SO WE HAVE SIMPLY BROUGHT THAT MATTER IN OUR MOTION TO THE COURT'S ATTENTION HERE. I WANTED TO TAKE THE OPPORTUNITY TO EXPLAIN WHY WE HAVE THREE LAWSUITS PENDING. IT IS OUR HOPE THAT THE COURT IN ILLINOIS DENIES THE MOTION TO DISMISS, IN WHICH CASE WE WOULD BE ASKING THE COURT IN

VIRGINIA AND THIS COURT TO TRANSFER THESE ACTIONS TO THE DISTRICT OF ILLINOIS WHERE -- WHICH IS THE FIRST FILED ACTION.

AND IF THE COURT IN CHICAGO WERE TO DENY -- OR TO GRANT THE MOTION TO DISMISS, YOUR HONOR, WE WOULD THEN ASK THIS COURT AND THE COURT IN VIRGINIA TO TRANSFER THE ACTION TO THIS COURT, WHICH IS A COURT WHERE ALL THREE DEFENDANTS HAVE NOW APPEARED AND ANSWERED.

AND SO -- AND AGAIN, IN TERMS OF THE TIME THAT WE ARE LOOKING AT, JUDGE, ALL INDICATIONS APPEAR TO BE THAT IT SHOULD BE WITHIN A WEEK OR WITHIN A COUPLE OF WEEKS GIVEN THE ADVICE THAT WE HAVE RECEIVED FROM CHAMBERS IN CHICAGO.

THE COURT: MR. ISICOFF?

MR. ISICOFF: THANK YOU, YOUR HONOR. YOUR HONOR, OUR POSITION IS AS FOLLOWS: WE CERTAINLY UNDERSTAND THAT IF THE COURT IN ILLINOIS IS GOING TO RULE WITHIN THE NEXT FEW DAYS, A WEEK OR SO, IT MAY WELL MAKES SENSE TO WAIT FOR THAT PERIOD OF TIME.

HOWEVER, WE DO BELIEVE THAT VENUE JURISDICTION IS MOST APPROPRIATE HERE. WE HAVE ANSWERED -- WE ARE PREPARED TO GO FORWARD. THE 30 MONTH AUTOMATIC STAY THAT MR. DALY MENTIONED IS EXACTLY THE REASON WHY IT IS VERY IMPORTANT THAT WE DO NOT DELAY.

AS THIS COURT KNOWS, THE MERE FILING OF THIS ACTION THROWS INTO EFFECT A THREE MONTH STAY WHICH CAN BE

ONLY DENIED BY THE CONCLUSION OF THIS ACTION. SO IT IS VERY IMPORTANT FOR US TO MOVE QUICKLY AS FAR AS WE CAN AND THAT IS WHY WE HAVE COME INTO COURT.

WE ARE TRYING TO MOVE THIS CASE FORWARD. AS THE COURT HAS SEEN, THE DISCOVERY DATES AS SUGGESTED -- WE WOULD LIKE TO PUT A REASONABLE TIME TO DISCOVERY AND OTHER TRIAL MATTERS AND TRY TO GET THIS CASE TRIED WITHIN A REASONABLE PERIOD OF TIME.

IF, FOR EXAMPLE, THE COURT IN ILLINOIS DOES NOT RULE, IF THE INFORMATION WE HAVE ISN'T ACCURATE OR IF THE COURT HAS SOME DIFFICULTY WITH SOME ASPECT OF THE OPINION IT IS WRITING, IT COULD BE MONTHS, THREE MONTHS, FOUR MONTHS, FIVE MONTHS THAT THERE IS A DELAY IN THAT DECISION, THAT, OF COURSE, WOULD HAVE A TREMENDOUS IMPACT ON US HERE BECAUSE WE ARE READY AND PREPARED TO GO FORWARD.

REALISTICALLY, THE CASE IN VIRGINIA IS NOT GOING TO GO FORWARD -- IF THE COURT IN ILLINOIS DENIES IT TO GO FORWARD, THEN WE GO THERE. IF THE COURT GOES AHEAD AND CONCLUDES THERE IS NO JURISDICTION THERE, THEN WE GO HERE.

SO IT IS VERY CLEAR THAT WAITING AROUND IS PROBABLY NOT IN ANYBODY'S INTEREST, CERTAINLY NOT IN ANDRX'S INTEREST. AND THIS CASE WILL LITERALLY LANGUISH AND BE IN A STAMPED PATTERN FOR A CONSIDERABLE PERIOD OF TIME UNLESS THE COURT IN ILLINOIS RULES.

SO WE WOULD SUGGEST THAT IF THE COURT IS INCLINED

TO WAIT, THAT WE PUT A VERY, VERY SHORT TIME FRAME HERE SO WE DON'T GET CAUGHT IN A SITUATION WHERE A DELAYED RULING COULD LITERALLY STOP THIS CASE COLD IN ALL COURTS FOR A CONSIDERABLE PERIOD OF TIME, AND TIME IS OF THE ESSENCE IN THIS TYPE OF LITIGATION.

THE COURT: THANK YOU, MR. ISICOFF. WELL, FIRST OF ALL, I DO NOT KNOW -- WHO WAS THE JUDGE IN THE NORTHERN DISTRICT OF ILLINOIS?

MR. ISICOFF: JUDGE HIBLER, I BELIEVE.

MR. DALY: YES. WILLIAM HIBLER, YOUR HONOR.

THE COURT: HIBLER?

MR. DALY: YES.

THE COURT: I HAVE A FEELING THAT HE IS PREPARED TO RULE. I ABHOR UNUSUAL DELAY IN THIS COURT. AND MOST OF MY COLLEAGUES FEEL THE SAME WAY. WE SOMETIMES GET A LITTLE BIT IMPATIENT WITH OUR OWN CIRCUIT COURT, BECAUSE IT SEEMS ON OCCASION TO TAKE THEM MUCH LONGER TO ALREADY MAKE UP THEIR MINDS, ALBEIT THEY MUST EITHER AGREE OR AGREE TO DISAGREE.

IN ANY EVENT, LET ME ASSURE YOU, FIRST OF ALL, I AM GOING TO GRANT THE MOTION TO STAY. I AM GOING TO STAY THIS WILL MATTER FOR 30 DAYS APPROXIMATELY. LET'S SEE.

[PAUSE]

YES. RESET THIS HEARING -- IF HE HAS DENIED THE MOTION OR IF HE HAS GRANTED IT -- ALL RIGHT, SO THAT I CAN

TALK WITH COUNSEL ABOUT PRECISELY WHAT THEIR NEXT DISCLOSABLE MOVES ARE, IF YOU WILL.

LET ME ALSO ASSURE YOU THAT THIS DELAY WILL NOT IN MY OPINION OPERATE TO THE PREJUDICE OF ANYONE FOR THE SIMPLE REASON THAT WE HAVE MADE, I BELIEVE, GREAT STRIDES IN THE NINE YEARS OR SO THAT I HAVE NOW BEEN ON THIS BENCH IN MOVING OUR CIVIL CALENDARS.

WHEN I CAME ON THIS BENCH IN 1991, THE ROUTINE TIME PERIOD BEFORE A CIVIL CASE OF ANY KIND COULD GET TO TRIAL WAS THREE YEARS. MY CASES NOW PROCEED TO TRIAL WITHIN A YEAR FROM CONFERENCE, AND THAT IS BECAUSE I HOLD THE PARTIES TO THE DEADLINES SET IN THE ORDER THAT I WILL ISSUE.

NOW, I SAID 30 DAYS. IT MIGHT BE 29 OR 31 OR 26, SOMETHING OF THAT NATURE, DEPENDING UPON WHETHER IT FALLS ON A WEEKEND OR ON A DAY THAT I WOULD OTHERWISE BE UNAVAILABLE. SO IT WILL BE WITHIN THAT FRAME WORK, WITHIN THOSE PARAMETERS.

AND IF THE MOTION IS GRANTED, MOTION TO DISMISS, YOU MAY ANTICIPATE WE WILL BE READY FOR THE FINAL STATUS CONFERENCE. ALL RIGHT.

IT IS AN INTERESTING QUESTION. UNFORTUNATELY -- I SAY "UNFORTUNATELY" -- FOR THIS COURT THERE MAY BE MANY SIMILAR CASES. SO PROBABLY THE SOONER THIS PARTICULAR ASPECT GENRE OF CASE, IF YOU WILL, IS ADDRESSED, THE

BETTER, BECAUSE AT LEAST THERE WILL BE A PRECEDENT. VERY WELL. IS THERE ANYTHING ELSE WE CAN TALK ABOUT TODAY?

MR. ISICOFF: NO, YOUR HONOR.

MR. GOODWIN: NO.

THE COURT: ALL RIGHT. THANK YOU VERY MUCH FOR YOUR APPEARANCE AND YOUR REPORT. I WISH YOU WELL. HAVE A NICE DAY.

[PROCEEDINGS CONCLUDED]

C E R T I F I C A T E

I HEREBY CERTIFY THAT THE FOREGOING IS AN ACCURATE TRANSCRIPTION OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

7/17/00
DATE FILED

Randall J. Belsvik

RANDALL J. BELSVIK, RPR
OFFICIAL COURT REPORTER
99 N.E. 4TH STREET, SUITE 1027
MIAMI, FL 33131 305-523-5178

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 IN SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER OR STAY

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), pursuant to Local Rule 7.1.B, hereby file this Request for Oral Argument In Support of Plaintiffs' Motion to Transfer or Stay and state as follows:

1. On January 8, 2008, sanofi-aventis filed a Motion to Transfer or Stay requesting that the Court transfer this action to the District of Delaware where an identical, parallel, first-filed action and two related cases involving 13 additional defendants are currently pending. Alternatively, sanofi-aventis requested that the Court stay the case in this forum pending the resolution of any venue issues raised with respect to the first-filed action in the Delaware court by Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex"). Such a stay would not prejudice any party as sanofi-aventis and Apotex would continue to litigate their claims and defenses in the Delaware action while avoiding the costly and unnecessary duplication of pretrial efforts by the parties and two separate courts.

2. Plaintiffs desire a hearing because oral argument will provide an opportunity to explain the procedural posture of the related Delaware actions as well as Plaintiffs' need to file the second action in this district to preserve their rights to a stay of generic approval pending the resolution of their patent infringement claims.

3. Oral argument will also provide an opportunity for Plaintiffs to describe in detail why the public's interest in patent certainty necessitates litigations involving multiple defendants to be conducted by one court in order to ensure consistent judgments. Likewise, Plaintiffs expect to explain how the complexities of the patent issues at bar, and the wide-ranging discovery that Plaintiffs expect Defendants to seek, necessitate coordinated proceedings with Plaintiffs' claims against 13 other defendants in order to promote judicial economy.

4. Lastly, oral argument will permit the parties to update the Court on the status of the first-filed Delaware action.

5. Oral argument would be helpful to the Court in considering the legal issues that underlie Plaintiffs' Motion to Transfer or Stay; such issues include the necessity for patentees to file multiple parallel actions in different jurisdictions in order to secure the protections afforded by the Hatch-Waxman Act and how courts may ensure that the proper priority is given to the patentee's choice of forum and first-filed actions.

6. Moreover, oral argument would be helpful to the Court, as a hearing will provide the Court with an opportunity to question counsel regarding the complex nature of the factual and procedural history that necessitated the Plaintiffs filing of this second parallel action, including the interplay between the Hatch-Waxman Act and those facts.

7. Plaintiffs estimate that the parties would require 10 minutes per side for oral argument.

WHEREFORE, Plaintiffs respectfully request that the Court allow oral argument on Plaintiffs' Motion to Transfer or Stay.

Dated: January 8, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

s/ Alfred J. Saikali
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
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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)

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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 TO STAY CERTAIN DEADLINES SET IN THE COURT'S JANUARY 3, 2008 ORDERS AND PLAINTIFFS' REPLY TO DEFENDANTS' COUNTERCLAIMS AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully file this Motion to Stay Certain Deadlines Set In The Court's January 3, 2008 Orders and Plaintiffs' Reply to Defendants' Counterclaims. Plaintiffs also request expedited review of this motion, in light of the immediately pending deadlines. In support of this motion, sanofi-aventis states as follows:

1. This is a patent infringement action brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for Defendants Apotex Inc. and Apotex Corp.'s (collectively "Apotex") infringement of Plaintiff sanofi-aventis's U.S. Patent No. 4,661,491 ("the '491 patent") through their submission of Abbreviated New Drug Application ("ANDA") No. 79-013 seeking FDA approval to market a generic version of sanofi-aventis's branded drug product Uroxatral®.

2. The parties' claims and defenses in this action are identical to those of a previously-filed parallel action pending in Delaware, *sanofi-aventis et al. v. Apotex Inc. et al.,*

Civil Action No. 07-792 (GMS) (MPT), United States District Court for the District of Delaware.

3. Because Defendants did not timely consent to personal jurisdiction in Delaware, Plaintiffs were forced to bring a second suit in this district in order to preserve their rights under the Hatch-Waxman Act. Without filing this second-filed action, Plaintiffs' ability to obtain a statutory stay of approval by the FDA for Defendants' proposed generic product pending the outcome of its patent claims would have been jeopardized.

4. On December 28, 2007, Defendants answered the complaint in this action, though it had not been served by Plaintiffs, and alleged a number of counterclaims. One business day later, on January 2, 2008, Defendants amended their answer and counterclaims in this action and filed their answer and counterclaims in the Delaware action.

5. On January 3, 2008, the Court issued a Scheduling Order, Pretrial Order Setting Conference, Scheduling Order Setting Trial, and Order Referring Case To Mediation setting the following deadlines on or before January 31, 2008:

(a) Party conference by January 17, 2008;

(b) Selection of a mediator by January 17, 2008; and

(c) Join additional parties or amend the pleadings by January 31, 2008.

6. Sanofi-aventis's reply to Defendants' counterclaims is also due on January 17, 2008.

7. On January 8, 2008, Plaintiffs moved the Court to transfer this action to the District of Delaware, or in the alternative, stay this action pending the resolution of any venue disputes by that first-filed court.

8. The course of these proceedings is likely to differ significantly depending on the outcome of Plaintiffs' pending Motion to Transfer or Stay. As such and in light of the likelihood

that Plaintiffs' pending motion may not be resolved until after January 31, Plaintiffs request that the Court stay the court scheduled events occurring before January 31, 2008 as well as Plaintiffs' reply to Defendants' counterclaims until 10 days after an order is issued on Plaintiffs' Motion to Transfer or Stay. It is within the Court's discretion to grant the requested stay which will prevent duplicative pretrial proceedings pending the resolution of the parties' venue disputes without any prejudice to the parties, who may still litigate their claims and defenses in Delaware.

9. Counsel for Plaintiffs certify that pursuant to S.D. Fla. L.R. 7.1A3(a) we have met and conferred with counsel for Defendants on January 7, 2008 in an effort to resolve the issues raised by this motion. The parties were unable to resolve such issues.

WHEREFORE, sanofi-aventis respectfully requests that the Court stay the Court scheduled events occurring before January 31, 2008 set in the January 3, 2008 Pretrial Orders, as well as sanofi-aventis's reply to Defendants Apotex Inc. and Apotex Corp.'s counterclaims until 10 days after an order is issued on Plaintiffs' Motion to Transfer or Stay filed on January 8, 2008. Additionally, sanofi-aventis respectfully requests that the Court expedite its review of this motion and the schedule for the parties' briefing. Without such expedited treatment, it is unlikely that the Court will be able to rule on this motion before the deadlines Plaintiffs seek to stay have already passed.

MEMORANDUM OF LAW

Based on the current schedule, the parties must conduct their party conference, select a mediator, and join any additional parties/amend the pleadings and Plaintiffs must reply to Defendants' counterclaims by January 31, 2008. Plaintiffs' pending Motion to Transfer or Stay may obviate the need for the parties to conduct any of these activities should the Court transfer this action to the District of Delaware or stay pending the disposition of any transfer requests brought by Defendants in that forum. Staying the current deadlines in this action will save the

parties considerable time and resources, but will not prejudice their interests as they can continue to litigate their identical claims and defenses in the first-filed Delaware action.

BACKGROUND

After bringing a first-filed action in the District of Delaware against Apotex for its infringement of the '491 patent on December 6, 2007, sanofi-aventis was forced by Apotex's failure to timely consent to personal jurisdiction in that venue to bring this second-filed action to protect its right to a 30-month stay of FDA approval of Apotex's proposed generic product. Apotex filed its Answers and Counterclaims in this action on December 28, 2007, asserting invalidity and non-infringement of the '491 patent in its defenses and counterclaims as well as counterclaims alleging that the claims of a second sanofi-aventis patent, U.S. Patent No. 6,149,940, are invalid and not infringed by Apotex's proposed generic product. On the next business day, Apotex amended its Answer and Counterclaims in this case and filed substantially identical answers and counterclaims in the first-filed Delaware action. In its answer in Delaware, Apotex agreed that it would not contest personal jurisdiction and that venue was appropriate, yet claimed that this District was a more convenient forum.

In response, sanofi-aventis filed a Motion to Transfer or Stay these proceedings on January 8, 2008, requesting that the Court transfer these proceedings to the first-filed District of Delaware, where the same issues are pending in three litigations against Apotex and 13 other Defendants and that are before the same Judge and Magistrate Judge. Previously, the Court issued a set of scheduling orders on January 3, setting a number of fast approaching deadlines, including the party conference and selection of a mediator by January 17 and the deadline to join additional parties or amend the pleadings by January 31. Additionally, sanofi-aventis's reply to Apotex's counterclaims is currently docketed for January 17.

ARGUMENT

Should the Court grant Plaintiffs' Motion to Transfer or Stay, there will be no further proceedings in this District, or at least none until the issue of venue is resolved in the Delaware action, thereby obviating the need for the parties to conduct a party conference, select a mediator, join additional parties or amend the pleadings as those activities will occur in the District of Delaware in coordination with the related actions pending in that district. Similarly, there would be no need for sanofi-aventis to reply to Apotex's counterclaims in this Court.

If the Court does not stay these dates, the parties may be forced to duplicate their pretrial efforts, thereby wasting time and resources. For example, the party conference will require the parties to meet and confer on a wide-range of issues concerning pretrial activities and trial and to prepare a joint discovery plan. If the Motion to Transfer or Stay is granted and the case proceeds in the District of Delaware, the parties efforts will be wasted as they will likely have to confer with defendants in the related Delaware action concerning the case schedule, discovery limitations, and other pretrial issues. Similarly, if the Motion to Transfer or Stay is granted, the time and expense associated with contacting and retaining a mediator would be of little use in the District of Delaware, where coordination with 13 other defendants would need to occur again.

The requested stay would not prejudice either party because even if the requested stay is granted and subsequently sanofi-aventis's motion is denied, any delay in the proceedings will have been minimal. Sanofi-aventis filed its Motion to Transfer or Stay on January 8, 2008. Assuming the parties take the maximum time accorded to them under the local rules to brief the motion, the Court would still be able to rule on that motion as early as February 7, 2008. If the Court denies the motion, the party conference could proceed within a month from the date originally set by the Court.

CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Court stay all deadlines currently set for January 31, 2008 or prior until 10 days after the resolution of Plaintiffs' Motion to Transfer or Stay.

Dated: January 8, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

s/ Alfred J. Saikali_____
Alfred J. Saikali
Fla. Bar No.: 178195
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470
asaikali@shb.com
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
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Telephone: 305.358.5171
Facsimile: 305.358.7470

Attorneys for Plaintiffs

SERVICE LIST

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

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

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

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

VIA CM/ECF

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO STAY CERTAIN DEADLINES SET IN THE COURT'S JANUARY 3, 2008 ORDERS AND PLAINTIFFS' REPLY TO DEFENDANTS' COUNTERCLAIMS

THIS CAUSE is before the Court on Plaintiffs' Motion to Stay Certain Deadlines Set In the Court's January 3, 2008 Order Setting Conference and Plaintiffs' Reply to Defendants' Counterclaims, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiff's Motion To Stay the January 3, 2008 Pretrial Order Setting Conference And Its Reply To Defendants' Counterclaims is GRANTED.

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

Honorable Federico A. Moreno
United States District Court Judge

FILING FEE $35.00 PAID In Forma Pauperis 472512 Clarence Maddox, Clerk

FILED by DKTG D.C. JAN - 9 2008 CLARENCE MADDOX CLERK U.S. DIST. CT. S.D. OF FLA. - MIAMI

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. /

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 Gerald J. Flattmann, Jr., 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 Gerald J. Flattmann, Jr. to receive electronic filings in this case, and in support thereof states as follows:

1. Gerald J. Flattmann, Jr. 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 and the District of Columbia.

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, Gerald J. Flattmann, Jr. has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. Gerald J. Flattmann, Jr., 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 Gerald J. Flattmann, Jr. at e-mail address: gflattmann@kirkland.com.

WHEREFORE, Alfred J. Saikali moves this Court to enter an Order permitting Gerald J. Flattmann, Jr. 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 Gerald J. Flattmann, Jr.

Dated: January 9, 2008

LAW OFFICES
SHOOK, HARDY & BACON LLP
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
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a copy of the foregoing was faxed and mailed this 9th day of January, 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 GERALD J. FLATTMANN, JR.

Gerald J. Flattmann, Jr., 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 and the District of Columbia.

Dated: January 8, 2008

Gerald J. Flattmann, Jr.
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022-4611
(212) 446-4800

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Limited Appearance. Consent to Designation and Request to Electronically Receive Notices of Electronic Filings was served by U.S. Mail on January 8, 2008, on all counsel or parties of record on this service list.

Gerald J. Flattman, Jr.

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 GERALD J. FLATTMANN, JR., 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 Gerald J. Flattmann, Jr. 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 Gerald J. Flattmann, Jr. 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. Gerald J. Flattmann, Jr. 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 Gerald J. Flattmann, Jr. at gflattmann@kirkland.com.

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

_____
FEDERICO A. MORENO
United States District Court Judge

Copies furnished to:

Alfred J. Saikali, Esq.
Shook Hardy & Bacon LLP
Miami Center, Suite 2400
201 S. Biscayne Blvd.
Miami, Florida 33131

Stephen J. Bronis, Esq.
Jennifer Coberly, Esq.
Zuckerman Spaeder LLP
201 S. Biscayne Blvd.
Suite 900
Miami, Florida 33131

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 CONTINUE PRETRIAL DEADLINES AND TRIAL

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 with respect to *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (GMS) (MJT) and *sanofi-aventis and sanofi-aventis U.S. LLC, v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT) currently pending in the District Court for the District of Delaware. I submit this declaration in support of Plaintiffs' Motion to Continue Pretrial Deadlines and Trial and have personal knowledge of the facts set forth herein.

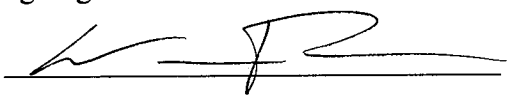
1. Attached hereto as Exhibit 1 is a true and accurate copy of a letter dated January 4, 2008 from William T. Vuk to Robert B. Breisblatt and Steven J. Bronis.

2. Attached hereto as Exhibit 2 is a true and accurate copy of a letter dated January 7, 2008 from Steven F. Feldman to William T. Vuk.

3. Attached hereto as Exhibit 3 is a true and accurate copy of a letter dated January 7, 2008 from William T. Vuk to Steven E. Feldman.

4. Attached hereto as Exhibit 4 is a true and accurate copy of a letter dated January 14, 2008 from Steven E. Feldman to William T. Vuk.

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



William T. Vuk

January 15, 2008
New York, New York

EXHIBIT 1

KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

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

212 446-4800

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Facsimile:
212 446-4900

January 4, 2008

By Electronic Mail
Robert B. Breisblatt, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
rbreisblatt@welshkatz.com

Stephen J. Bronis
Zuckerman Spaeder LLP
201 South Biscayne Blvd., Suite 900
Miami, Florida 33131
sbronis@zuckerman.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Robert and Stephen:

I write to request that Apotex agree to transfer the above referenced matter to the District of Delaware in order to be joined with the first filed action *sanofi-aventis et al. v. Apotex Inc. et al.*, C.A. No. 07-792 (GMS). Alternatively I request that Apotex agree to stay the action pending the resolution of Apotex's as yet unfiled motion to transfer the first-filed Delaware action to the Southern District of Florida and/or sanofi-aventis's as yet unfiled motion to dismiss the Florida action in favor of the Delaware action or, in the alternative, to transfer it to the District of Delaware.

In light of the Court's scheduling order, please let me know if you are available to discuss this issue as well as other potential motion practice today or on Monday January 7th.

Sincerely,

William T. Vuk

cc (via email):
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.
Jack Blumenfeld, Esq.

EXHIBIT 2

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Attorneys at Law
120 SOUTH RIVERSIDE PLAZA · 22ND FLOOR
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TELEPHONE (312) 655-1500
FACSIMILE (312) 655-1501

www.welshkatz.com

Steven E. Feldman
sefeldman@welshkatz.com
Direct Dial (312) 526-1551

January 7, 2008

Via Electronic Mail (wvuk@kirland.com) &
Confirmation by U.S. Mail

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Re: ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Dear William:

We acknowledge receipt of your January 4, 2008 correspondence. We do not agree to transfer the above-captioned case to Delaware. Nor do we agree to a stay of the Florida action pending resolution of any motions to transfer. Sanofi is obligated under the Hatch-Waxman Act to "reasonably cooperate in expediting the action." *E.g.*, 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, we believe that Sanofi should dismiss its Delaware lawsuit against our clients in favor of the Florida action, which necessarily will proceed more quickly to resolution. Please let us know whether your client will agree to dismissal of the Delaware complaint.

I am available this afternoon (after 2pm (CST)) to discuss this and other issues related to the Court's scheduling order.

Very truly yours,

WELSH & KATZ, Ltd.

By: 
Steven E. Feldman

SEF/mh
cc: Alfred J. Saikali, Esq. (asikali@shb.com)
Stephen J. Bronis, Esq. (sbronis@zuckerman.com)
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)
Sherry L. Rollo, Esq. (srollo@welshkatz.com)

EXHIBIT 3

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
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212 446-4800

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Facsimile:
212 446-4900

January 7, 2008

By Electronic Mail
Steven E. Feldman, Esq.
Welsh & Katz, LTD.
120 South Riverside Plaza
Chicago, Illinois 60606
sefeldman@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 Steven:

I write to memorialize our meet and confer discussion from earlier today related to the above matters.

In light of sanofi-aventis's first-filed Delaware action, sanofi-aventis requested that the parties meet and confer on the disposition of the second-filed Florida action in an attempt to avoid any unnecessary motion practice before the Court. Specifically, we asked that Apotex agree to the dismissal of the Florida action, transfer to Delaware, or stay pending the disposition of any venue issues in Delaware. Because Apotex has refused to agree that the identical claims and counterclaims of the Delaware and Florida actions should proceed in Delaware along with sanofi-aventis's claims against 13 other defendants, we are left with no choice but to seek relief from the Court.

The following summary confirms the results of the parties' meet and confer today. Please let me know if there is anything you disagree with.

Dismissal or Stay of Claims/Counterclaims Pending In Florida: You confirmed that Apotex would not consent to the dismissal of all claims and counterclaims pending in Florida. You also confirmed that Apotex would not stay any aspect of the second-filed Florida action pending the resolution of any motions that either party might bring.

sanof-aventis's Dismissal of Their Claims Pending In Delaware: I informed you that sanofi-aventis would not consent to your request to dismiss the claims pending against Apotex in Delaware.

KIRKLAND & ELLIS LLP

Apotex's Motion to Transfer You confirmed that Apotex intends to file a motion to transfer the first-filed Delaware action to the Southern District of Florida because the Southern District of Florida is a more convenient forum. You explained that Florida is a more convenient venue because Apotex Corp. is headquartered in Florida and, while you could not identify any, you are certain there are potential witnesses/deponents who reside in Florida. You also explained that at this time you were unaware as to whether any Research and Development related to Apotex's generic alfuzosin hydrochloride tablets occurred in Florida. Additionally, you stated that Apotex believes that the second-filed Florida action will be adjudicated faster then the first-filed action in Delaware because Apotex would be on its own against sanofi-aventis as opposed to in one coordinated action in Delaware involving 13 other defendants. You further stated that the Florida Courts issuance of a scheduling order, which I noted was pro forma, setting trial for May 2008 supports the conclusion that the action in Florida would proceed faster then the first-filed Delaware action. At this time, you do not know when Apotex will bring this motion. You also noted that Apotex would not agree to stay the Florida action pending resolution of Apotex's Motion to Transfer. I confirmed that sanofi-aventis would oppose Apotex's motion.

sanofi-aventis's Motion to Transfer and Stay: You confirmed that Apotex would oppose any motion to transfer the second-filed Florida action to Delaware that sanofi-aventis might bring.

The '940 Patent: I notified you that sanofi-aventis does not believe the '940 patent is in dispute against Apotex. You stated that based upon the recent *Forest Labs.* decision you disagreed. However, I informed you that I was unaware of any such decision and you identified no such decision.

Sincerely,

William T. Vuk

cc (via email):
Jack Blumenfeld, Esq.
Stephen J. Bronis, Esq.
Richard L. Horwitz, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

EXHIBIT 4

WELSH & KATZ, LTD.

Attorneys at Law

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Steven E. Feldman
sefeldman@welshkatz.com
Direct Dial (312) 526-1551

January 14, 2008

Via Electronic Mail (wvuk@kirland.com) &
Confirmation by U.S. Mail

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Re: ***Sanofi-Aventis et al. v. Apotex Inc. et al.***
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Dear William:

We acknowledge receipt of your January 11, 2008 letter. We do not agree to delay resolution of this matter in the manner that you suggest. We would be amenable to extending the discovery and other deadlines in the case consistent with a trial date in November or December, 2008.

We would like to schedule a discovery conference with you or whoever has authority to discuss this matter with us on Monday so that we can begin proceeding with Rule 26(a)(1) disclosures and discovery as required by the Court's scheduling Order. As I mentioned in our previous discussion, we also would like to move forward with having a Protective Order entered in the case and exchange our lists of acceptable mediators. With respect to the Protective Order we suggest adopting (with appropriate modification to account for the parties here) the Protective Order that currently is in place Medpointe v. Apotex case, which our respective firms are handling. We also would like to obtain copies of materials with obvious relevance to this litigation such as an identification of patent claims that you are asserting against the Apotex parties; copies of Sanofi's INDA and 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. We will of course make our ANDA available to you once the Protective Order is implemented.

Please let me know when you are available to have this discussion.

Very truly yours,

WELSH & KATZ, Ltd.

By: Steven E. Feldman

SEF/mh
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
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 CONTINUE PRETRIAL DEADLINES AND TRIAL AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to continue the pretrial deadlines and trial date set forth in its January 3, 2008 orders and set this case on a "Complex Track" under L.R. 16.1.A. This is a complex, international action for patent infringement brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act based on the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of Plaintiffs' innovator drug Uroxatral®. Plaintiffs expect that discovery and other pretrial activities must extend well past the current May 2008 trial date to ensure that complete disclosures under all applicable rules are made in a fair and equitable manner, and the parties and the Court address the following complexities:

- A specialized *Markman* hearing for the Court to define the meaning of the asserted patent claim(s);
- Discovery concerning over 25 years of research and product development conducted overseas;
- Review of millions of pages of potentially relevant documents, many in foreign languages;

- Compliance with the EU privacy directive;
- Numerous depositions requiring the assistance of interpreters;
- Discovery under the Hague Convention or other evidence gathering treaties;
- Extensive expert discovery concerning the infringement, validity, and enforceability of the patents-in-suit; and
- Approximately 10 days of trial.

Consequently, Plaintiffs ask that the Court continue the completion of fact discovery to December 2008 and trial to September 2009 in the interests of justice so that the parties may fully and completely develop their claims and defenses in light of those disclosures through claim construction, expert discovery, and summary judgment motion practice prior to trial.

Counsel for Plaintiffs certify that pursuant to Local Rule 7.1.A.3(a) it has met and conferred with counsel for Defendants in an effort to resolve the issues raised by Plaintiffs' Motion to Continue Pretrial Deadlines and Trial. The parties were unable to resolve those issues.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully requests that the Court enter an Order granting Plaintiffs' Motion to Continue Pretrial Deadlines and Trial.

MEMORANDUM OF LAW

I. Background

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 (issued April 28, 1987) ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000) ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[1] Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the

[1] 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.

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.

On or about August 15, 2007, Plaintiffs received notice that Defendant Apotex Inc. had 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, as amended, seeks FDA approval for the commercial manufacture, use, offer for sale and sale of a generic version of Uroxatral® prior to the expiration of the '491 and '940 patents. In its notice to Plaintiffs, Defendant Apotex Inc. stated that it had filed a certification under § 505(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the proposed tablets did not infringe any valid claim of the '940 patent. In a second notice received by Plaintiffs on or about October 25, 2007, Apotex Inc. stated that it had filed an additional paragraph IV certification that its product would not infringe any valid claim of the '491 patent. Defendant Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its paragraph IV certifications to the FDA.

In response to the second notice, Plaintiffs filed suit against Defendants for their infringement of the '491 patent in the District of Delaware within 45 days of receiving notice of the paragraph IV certification as required by the Hatch-Waxman Act to receive a 30-month stay of generic approval. Defendants ignored Plaintiffs' request to consent to personal jurisdiction in Delaware within the 45-day window, thereby forcing Plaintiffs to file the present suit in a forum where they were confident that Apotex Inc. and Apotex Corp. would not contest personal

jurisdiction.[2] Shortly after this complaint was filed, Defendants did in fact agree not to contest jurisdiction in Delaware, but refused to confirm that agreement in writing so that Plaintiffs could voluntarily withdraw this action until filing their answer to the Delaware complaint. Defendants answered the complaint in this action without service, and only one business day before answering the complaint in Delaware, denying infringement of the '491 patent and counterclaiming for noninfringement and invalidity of both the '491 patent and the '940 patent—defenses and counterclaims identical to their allegations in Delaware. Consequently, Plaintiffs have filed a motion to transfer this action to Delaware, Plaintiffs' forum of choice and the first-filed forum, where it can proceed with the identical parallel action against Defendants and two related actions against 13 other defendants accused of infringing the '491 and/or '940 patents based on their ANDAs for generic versions of Uroxatral®. The pleading phase of all three related actions in the District of Delaware is complete and the parties now await an order setting the initial case management conference.

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2 Courts have recognized that it is unclear whether a patentee 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 Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006). 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.

On January 3, 2007, the Court issued a Scheduling Order in the present action setting various pretrial and trial dates that fall under the Expedited Track of L.R. 16.1.A.2(a), including March 27, 2008 for the completion of all discovery in less than 90 days from the order and May 27, 2008 for the start of trial in less than five months from the order. The Court issued a number of other orders on January 3 relating to the Scheduling Order, including a Pretrial Order Setting Conference, a Scheduling Order Setting Trial, and an Order Referring Case to Mediation.

On January 11, 2008, Plaintiffs asked Defendants to jointly move the Court to set this case on a Complex Track under L.R. 16.1.A. or otherwise meet and confer on the schedule set by the Court's January 3 order.[3] Defendants responded on January 14, 2008 that it did not agree to Plaintiffs' request to move the case to the Complex Track, but, conceding that this case should not be expedited, stated that they were "amendable to extending the discovery and other deadlines in the case consistent with a trial date in November or December, 2008." Ex. 4, 01/14/08 S. Feldman ltr to W. Vuk.

As the parties will discuss the other issues set forth in the Court's January 3 Pretrial Order Setting Conference, Scheduling Order Setting Trial, and Order Referring Case to Mediation during the initial party conference, Plaintiffs do not address those issues here and instead focus

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[3] Defendants refused Plaintiffs' request to stay the party conference and other dates set by the Court pending the disposition of Plaintiffs' Motion to Transfer or Stay so that the parties and the Court could avoid spending time and resources on pretrial activities that will be duplicated in the Delaware action. Ex. 1, 01/04/08 W. Vuk ltr to R. Breisblatt and S. Bronis; Ex. 2, 01/07/08 S. Feldman ltr to W. Vuk; Ex. 3, 01/07/08 W. Vuk ltr to S. Feldman (True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Motion To Continue Pretrial Deadlines And Trial). Consequently, Plaintiffs filed their Motion to Stay Certain Deadlines Set In the Court's January 3, 2008 Orders and Plaintiffs' Reply to Defendants' Counterclaims on January 9 asking the Court to stay the initial party conference, deadline to select mediator, deadline to add parties and/or amend pleadings, and response date for Plaintiffs' reply to Defendants' counterclaims until 10 after the disposition of the transfer motion. The Court has not yet ruled on this motion.

on the appropriate track for this action under L.R. 16.1.A.2 and the major dates incident to that track as outlined in the current Scheduling Order.

II. The Court Should Place This Action On A Complex Track

The current Scheduling Order sets the close of discovery within three months and trial within five months of the order thus placing this action on an Expedited Track, which, generally applies to "relatively non-complex" cases in which discovery can be completed within three to six months and trial is only expected to take one to three days. *See* L.R. 16.1.A.2(a). Alternatively, the Court may place this action on a Complex Track, the designation for cases that require over 10 days of trial and a discovery period of nine months to a year. *See* L.R. 16.1.A.2(c). Under L.R. 16.1.A.3, the Court must consider at least the following elements in evaluating and assigning cases to a specific track for discovery and trial: "the complexity of the case, number of parties, number of expert witnesses, volume of evidence, problems locating or preserving evidence, time estimated by the parties for discovery and time reasonably required for trial." Considering each of these factors and the issues discussed above, the Complex Track is more appropriate for this action.

Typically, the resolution of patent cases is exceedingly complex and time consuming. For example, discovery concerning patent infringement allegations covers everything from the conception and reduction to practice of the patented inventions, their prosecution at the patent office, activities and publications alleged to be prior art to those inventions, secondary indicia of non-obviousness, such as the commercial success of products embodying the patent claims, and the design, operation and manufacture of the accused products. These issues can be complicated further in ANDA litigations that may involve many years of clinical trials and regulatory files for the referenced products. Other pretrial proceedings are also onerous. For example, patent cases require the Court to itself become an expert in the technology at issue, usually necessitating

competing technology tutorials from both sides. Additionally, these cases require specialized *Markman* hearings in which a court will construe the meaning of various terms and phrases of the asserted patent claims. A court's *Markman* ruling is critical to the resolution of a patent action as it sets forth the definitions of the claims that the parties must use in their infringement and validity cases, and is often the culmination of extensive briefing and expert analysis. The parties then use the court's definitions of the claims during expert discovery, summary judgment, and trial.

These complexities certainly apply to the case at bar. The parties are spread throughout the United States and internationally. The patents-in-suit generally relate to a method for using alfuzosin to treat dysuria and pharmaceutical compositions containing that active ingredient. On their face, the patents-in-suit claim priority to foreign patent applications from 1985 and 1996 and 1997 respectively. Based on the development of the patented technology, the patent prosecutions, and the prior art cited by Defendants and the other defendants in the Delaware actions to date, Plaintiffs expect Defendants to seek discovery dating back to the 1970s on activities that occurred largely outside of the United States. Furthermore, the FDA approval for Uroxatral® was based on years of clinical trials and regulatory filings; again Plaintiffs expect that Defendants will seek documents and deposition testimony on these complex and wide-reaching matters. The Court will have to become an expert in the technology at issue and conduct a *Markman* hearing after extensive claim construction briefing by the parties. The parties will then need time to apply the Court's definitions of the claims to the facts during expert discovery, summary judgment, and in preparing their respective cases for trial to establish whether Defendants' proposed generic product practices the claimed inventions and whether those inventions were anticipated or rendered obvious by the alleged prior art.

Moreover, to the extent that the Court does not transfer this action to the District of Delaware, Plaintiffs must separately proceed against Defendants and the 13 other defendants in that district, conducting separate discovery and other pretrial activities on the same patent issues.[4] In view of these issues and the specific complications discussed below, Plaintiffs expect that fact discovery will take almost a year to complete even with only two defendants in this case, and that the parties and the Court will need an additional nine months to conduct claim construction, expert discovery, summary judgment, and trial.

A. Volume of Documents

Based on Plaintiffs' investigation to date concerning the allegations made by Defendants in this action and the 13 accused infringers in the related Delaware actions, Plaintiffs expect to review millions of pages of documents for production in this action. These documents cover certain research and development activities concerning alfuzosin dating back 25 years, including its use in treating various disorders as well as the formulations developed to administer the active ingredient to patients, prosecution of the patents-in-suit and the applications to which they claim priority, the design and results of a number of clinical trials studying alfuzosin treatments, regulatory filings leading to the approval of Uroxatral® by the FDA, and the marketing of that product in the United States. Indeed, Defendants have already informed Plaintiffs that, at minimum, they will request "copies of Sanofi's INDA and 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." *See* Ex. 4, S.

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[4] In the event that the Court denies Plaintiffs' motion to transfer, Plaintiffs would intend to petition the Judicial Panel on Multidistrict Litigation to consolidate this action with the three Delaware actions for purposes of pretrial discovery given the identity of patent claims and substantial identity of defenses asserted by all 15 defendants in these actions.

Feldman 01/14/08 ltr to W. Vuk. Plaintiffs also expect that Defendants will review and produce a large number of documents concerning their study of Uroxatral®, the patents-in-suit and the alleged prior art, their development of the proposed generic product, studies and clinical trials concerning that product, and their preparation and filing of ANDA 79-013.

B. Problems Locating Evidence

Based on Plaintiffs' investigation to date of these issues, the documents Defendants are likely to seek are spread across at least the United States and France at various locations where Plaintiffs have conducted various activities concerning the development and study of alfuzosin and Uroxatral®. Plaintiffs' expect to spend a great deal of time at considerable expense to locate and collect the documents from facilities in the United States and abroad in order to review them for production as many have been archived and are no longer in active use. Complicating matters further is that many documents Defendants expect to seek were kept by predecessor companies to sanofi-aventis and sanofi-aventis U.S. LLC using systems that are either obsolete or no longer in use.

C. Compliance with EU Data Privacy Directive

Many of the documents Defendants will likely seek are located in France that are subject to the privacy directives of that territory and the European Union. *See generally* Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data (Oct. 24, 1995), *available at* http://www.cdt.org/privacy/eudirective/EU_Directive_.html. The directive prohibits the transfer of personal data[5] to non-European Union countries that do not

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[5] Article 2(a) of the Directive defines "'personal data 'shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be

(Continued…)

provide what the European Union deems to be the "adequate" standards for privacy protection, including the United States. As a result, Plaintiffs may not just ship all potentially relevant documents to the United States for review where litigation vendors and other duplicating and processing resources are more plentiful than in countries such as France where discovery is considerably less expansive than in the United States. To the extent that this information must be produced, Plaintiffs expect that the time necessary to complete discovery will be lengthened by their efforts to comply with the directive.

D. Foreign Language Issues

Many of the documents potentially relevant to the parties' claims and defenses in this action are in French and other foreign languages and will require additional time to review due to translation issues. Moreover, the parties may need to obtain certified translations of documents for use as exhibits at deposition, in their motion practice, and at trial. Finally, Plaintiffs expect that many of the witnesses in this action will require interpreters at both deposition and trial. These issues are expected to lengthen both the discovery period and trial.

E. Hague Convention

To the extent that Defendants seek discovery outside of the United States, particularly from third parties, Defendants may have to resort to requesting documents and deposition testimony under the Hague Convention or other evidence gathering treaties, a lengthy process in which it will likely be forced to first seek relief from this Court through the issuance of letters rogatory followed by efforts to enforce those letters in foreign jurisdictions.

F. Number of Depositions

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identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity."

Considering that there are eight inventors named on the patents-in-suit and a variety of other witnesses with knowledge of the alleged prior art, Uroxatral® and the proposed generic product, as well as various marketing and regulatory issues, Plaintiffs' expect that the parties will collectively require at least 30 fact depositions in this action. As discussed above, many of the witnesses are located outside of the United States and some may not fall within the power of the federal courts. Many are not fluent in English and will require interpreters. Moreover, a number of potential witnesses 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.

G. Expert Discovery

Additionally, the parties will likely engage in extensive expert discovery in light of what they learn during the fact discovery described above. In view of the claims and defenses alleged to date, the parties' experts may opine on issues concerning the construction of the asserted claim terms, the infringement of those claims by Defendants' proposed generic product, and the validity of those claims in light of the activities and publications that Defendants will allege to be prior art. The experts on both sides, which may range from urologists, organic chemists, pharmacists, pharmacologists, to economists, will need to review a considerable number of documents and deposition transcripts and exhibits to evaluate the parties' claims prior to forming and communicating their expert opinions.

H. Length of Trial

Plaintiffs anticipate that it will take approximately 10 days for the Court to try this case given the number of claims associated with the complex technology at issue, the formulation and

administration of the proposed generic product, the infringement of the patent claims by that product, the alleged invalidity of those claims, and the foreign language issues addressed above.

III. Proposed Schedule

Based on these factors, as well as the fact that this action involves one ANDA with two plaintiffs and two defendants, Plaintiffs propose the general schedule outlined below.

Deadline	Proposed Complex Track	Current Expedited Track
Conference and selection of a mediator to be completed no later than:	Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay	January 17, 2008
Deadline to join additional parties or to amend pleadings [without leave of the Court]:	Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay	January 31, 2008
Deadline to complete fact discovery	December 23, 2008	
Markman hearing and technology tutorial	February 3-4, 2009	
Deadline to complete expert discovery	Within 90 days of *Markman* order	
Deadline to complete all discovery:	Within 90 days of *Markman* order	March 27, 2008
Deadline for the filing of all motions for summary judgment:	Within 10 days of the close of expert discovery	April 10, 2008
Deadline for the filing of pretrial motions, including motions *in limine* and *Daubert* motions:	August 11, 2009	April 28, 2008
Mediation to be completed no later than:	August 11, 2009	April 28, 2008
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	August 26, 2009	May 7, 2008
Defendants' witness and	August 28, 2009	May 9, 2008

Deadline	Proposed Complex Track	Current Expedited Track
exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:		
Pretrial stipulation to be filed by:	September 1, 2009	May 13, 2008
Calendar Call at 2:00 P.M. on:	September 9, 2009	May 20, 2008
Trial set for the two-week period commencing:	September 15, 2009	May 27, 2008

IV. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court place this action on a Complex Track and continue the pretrial deadlines and trial accordingly.

Dated: January 15, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

s/ Alfred J. Saikali_____
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Fla. Bar No.: 178195
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470
asaikali@shb.com
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 15, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
Alfred J. Saikali (Florida Bar No.: 178195)
E-mail: asaikali@shb.com
SHOOK, HARDY & BACON L.L.P.
201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
Telephone: 305.358.5171
Facsimile: 305.358.7470

Attorneys for Plaintiffs

SERVICE LIST

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

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

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

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

VIA CM/ECF

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO CONTINUE PRETRIAL DEADLINES AND TRIAL

THIS CAUSE is before the Court on Plaintiffs' Motion to Continue Pretrial Deadlines and Trial, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiffs' Motion to Continue Pretrial Deadlines and Trial is GRANTED.

THIS COURT issues this Order in accordance with S. D. Fla. L. R. 16.1. The parties shall comply with the following deadlines.

Conference and selection of a mediator to be completed no later than:	**Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay**
Deadline to join additional parties or to amend pleadings [without leave of the Court]:	**Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay**
Deadline to complete fact discovery	**December 23, 2008**

Markman hearing and technology tutorial	**February 3-4, 2009**
Deadline to complete expert discovery	**Within 90 days of *Markman* order**
Deadline to complete all discovery:	**Within 90 days of *Markman* order**
Deadline for the filing of all motions for summary judgment:	**Within 10 days of the close of expert discovery**
Deadline for the filing of pretrial motions, including motions *in limine* and *Daubert* motions:	**August 11, 2009**
Mediation to be completed no later than:	**August 11, 2009**
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	**August 26, 2009**
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	**August 28, 2009**
Pretrial stipulation to be filed by:	**September 1, 2009**
Calendar Call at 2:00 P.M. on:	**September 9, 2009**
Trial set for the two-week period commencing:	**September 15, 2009**

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

_____
Honorable Federico A. Moreno
United States District Court Judge

FILING FEE
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In Forma Pauperis 973233
Clarence Maddox, Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

2008 JAN 15 AM 10: 31
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FL.-MIAMI

CASE NO.: 07-61800 CIV-MORENO

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

Plaintiffs,

v.

APOTEX, INC. and
APOTEX, CORP.,

Defendants.

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

In accordance with Local Rule 4.B 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 Steven E. Feldman, Esquire, of the law firm of Welsh & Katz, Ltd., for purposes of limited appearance as co-counsel on behalf of Defendants herein, in the above-styled case only, and pursuant to Rule 2B, Southern District of Florida, CM/ECF Administrative Procedures, to permit Steven E. Feldman, to receive electronic filings in this case, and in support thereof states as follows:

1. Steven E. Feldman, is not admitted to practice in the Southern District of Florida and is a member in good standing of The Illinois Bar.

2. Movant, Jennifer Coberly, Esquire, of the law firm of Zuckerman Spaeder LLP, 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, Steven E. Feldman has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. Steven E. Feldman 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 Steven E. Feldman at email address: sefeldman@welshkatz.com.

WHEREFORE, Jennifer Coberly moves this Court to enter an Order permitting Steven E. Feldman to appear before this Court on behalf of Defendants for all purposes relating to the proceedings in the above-styled matter and directing the Clerk to provide notice of electronic filings to Steven E. Feldman.

DATED this 14 day of January, 2008.

Respectfully submitted,

Walter J. Taché
Florida Bar No. 028850
wtache@zuckerman.com
Jennifer Coberly
Florida Bar No. 930466
jcoberly@zuckerman.com
Zuckerman Spaeder LLP
201 South Biscayne Blvd., Suite 900
Miami FL 33131
Tel: (305) 358-5000
Fax: (305) 579-9749

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. mail to Alfred J. Saikali, Shook Hardy & Bacon, LLP 200 South Biscayne Blvd., Suite 2400, Miami, Florida 33131 on this 14 day of January, 2008.

By: _____
Jennifer Coberly

CERTIFICATION

I, Steven E. Feldman, Esq., hereby certify that I am a member in good standing of the Bar of the State of Illinois, that no disciplinary proceedings or charges have been instituted against me, and that I have studied and am familiar with the Local Rules of this Court.

Dated this 2nd day of January, 2008.

By: _____
STEVEN E. FELDMAN, ESQ.

Certificate of Admission
To the Bar of Illinois

I, Juleann Hornyak, Clerk of the Supreme Court of Illinois, do hereby certify that

Steven Eric Feldman

has been duly licensed and admitted to practice as an Attorney and Counselor of Law within this State; has duly taken the required oath to support the CONSTITUTION OF THE UNITED STATES and of the STATE OF ILLINOIS, and also the oath of office prescribed by law, that said name was entered upon the Roll of Attorneys and Counselors in my office on November 9, 1995 and is in good standing, so far as the records of this office disclose.

In Witness Whereof, I have hereunto
placed my hand and affixed the seal
of said Supreme Court, at Springfield,
in said State, this Tuesday, January 08, 2008.

Juleann Hornyak

Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO.: 07-61800 CIV-MORENO

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

Plaintiffs,

v.

APOTEX, INC. and
APOTEX, CORP.,

Defendants.

ORDER GRANTING MOTION FOR LIMITED APPEARANCE OF STEVEN E. FELDMAN, 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 Steven E. Feldman, Esq., and Consent to Designation, requesting, pursuant to 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 Steven E. Feldman, Esq., 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. Steven E. Feldman, Esq., is

granted to appear and participate in this action on behalf of Defendants, Apotex, Inc. and Apotex, Corp. The Clerk shall provide electronic notification of all electronic filings to Steven E. Feldman, at sefeldman@welshkatz.com.

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

United States District Judge
Federico Moreno

Conformed Copies to:

All Counsel of Record

FILING FEE
PAID
In Forma Pauperis
Clerk Maddox, Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Miami Division

FILED by SK D.C.
DKTG
JAN 15 2008
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

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 Alexis Gorton, 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 Alexis Gorton to receive electronic filings in this case, and in support thereof states as follows:

1. Alexis Gorton 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, Alexis Gorton has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. Alexis Gorton, 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 Alexis Gorton at e-mail address: agorton@kirkland.com.

WHEREFORE, Alfred J. Saikali moves this Court to enter an Order permitting Alexis Gorton 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 Alexis Gorton.

Dated: January 15, 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)
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a copy of the foregoing was faxed and mailed this 15th day of January, 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 ALEXIS GORTON

Alexis Gorton, 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 11, 2008

Alexis Gorton
agorton@kirkland.com
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022-4611
(212) 446-4800

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Limited Appearance. Consent to Designation and Request to Electronically Receive Notices of Electronic Filings was served by U.S. Mail on January 15th, 2008, on all counsel or parties of record on this service list.

Alfred J. Saikali, Esq.
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
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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 ALEXIS GORTON, 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 Alexis Gorton 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 Alexis Gorton 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. Alexis Gorton 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 Alexis Gorton at agorton@kirkland.com.

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

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies furnished to:

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