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

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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)

PACER Service Center

Transaction Receipt

06/18/2008 08:42:32

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

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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 Sherry L. Rollo, 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 Sherry L. Rollo, to receive electronic filings in this case, and in support thereof states as follows:

1. Sherry L. Rollo, 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, Sherry L. Rollo has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. Sherry L. Rollo 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 Sherry L. Rollo at email address: srollo@welshkatz.com.

WHEREFORE, Jennifer Coberly moves this Court to enter an Order permitting Sherry L. Rollo 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 Sherry L. Rollo.

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, Sherry L. Rollo, 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: _____
SHERRY L. ROLLO, ESQ.

Certificate of Admission To the Bar of Illinois

I, Juleann Hornyak, Clerk of the Supreme Court of Illinois, do hereby certify that

Sherry Lee Rollo

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 4, 2004 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 Friday, January 04, 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 SHERRY L. ROLLO, 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 Sherry L. Rollo, 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 Sherry L. Rollo, 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. Sherry L. Rollo, 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 Sherry L. Rollo, at srollo@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

Case 0:07-cv-61800-FAM Document 16 Entered on FLSD Docket 01/16/2008 Page 1 of 7

FILING FEE $ 175-
PAID 97346
In Forma Pauperis
Clarence Maddox, Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Miami Division

FILED by DKTG D.C.
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 William T. Vuk, 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 William T. Vuk to receive electronic filings in this case, and in support thereof states as follows:

1. William T. Vuk 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, William T. Vuk has made payment of this Court's $75 admission fee. A certification in accordance with Rule 4B is attached hereto.

4. William T. Vuk, 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 William T. Vuk at e-mail address: wvuk@kirkland.com.

WHEREFORE, Alfred J. Saikali moves this Court to enter an Order permitting William T. Vuk 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 William T. Vuk.

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)
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 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 WILLIAM T. VUK

William T. Vuk, 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

William T. Vuk
wvuk@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 15, 2008, on all counsel or parties of record on this service list.

Alfred J. Saikali, Esq.
asaikali@shb.com
SHOOK HARDY & BACON LLP
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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 WILLIAM T. VUK, 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 William T. Vuk 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 William T. Vuk 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. William T. Vuk 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 William T. Vuk at wvuk@kirkland.com.

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

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Alfred J. Saikali, Esq.
asaikali@shb.com
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UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

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

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER GRANTING MOTION FOR LIMITED APPEARANCE

THIS CAUSE came before the Court upon Plaintiffs' Motion for Limited Appearance, Consent to Designation and Request to Electronically Receive Notices of Filing **(D.E. No. 10)**, filed on **January 9, 2008**.

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

ADJUDGED that the motion is GRANTED. Gerald J. Flattmann, Jr. is admitted for the purposes of limited appearance as co-counsel on behalf of the Plaintiffs and is permitted to receive electronic filings in the above-styled action.

DONE AND ORDERED in Chambers at Miami, Florida, this 17th day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

PLAINTIFFS' REPLY TO DEFENDANTS APOTEX INC. AND APOTEX CORP.'S AMENDED COUNTERCLAIMS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC, for their Reply to the numbered paragraphs of the Counterclaims of Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex"), hereby state as follows:

1. Admitted, upon information and belief.

2. Admitted, upon information and belief.

3. Admitted.

4. Admitted.

5. Admitted that Apotex purports to state declaratory judgment counterclaims that 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), and the Medicare Prescription Drug, Improvement, and Modernization Act of

2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003), but denied that there is any factual or legal basis for these counterclaims.

6. Admitted that the Court has jurisdiction over the subject matter of the counterclaims related to the '491 patent, but denied that such jurisdiction exists for the counterclaims related to the '940 patent.

7. Plaintiffs do not contest personal jurisdiction in this Court for this Action; to the extent that Paragraph 7 contains any other or further allegations, they are superfluous allegations to which no response is required.

8. While Plaintiffs do not dispute this judicial district is a possible venue for this action, they believe that the District of Delaware is a more convenient venue; therefore on January 8, 2008, Plaintiffs respectfully moved this Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action against Apotex, Civil Action No.07-792 (GMS) (MPT), has been pending since December 6, 2007 in front of the same Judge and Magistrate Judge as two related actions involving the same patent(s), claims and defenses against 13 other defendants, Civil Actions Nos.07-572 (GMS) (MPT) and 07-574 (GMS) (MPT), that have been pending since September 21, 2007.

9. Admitted.

10. Admitted that sanofi-aventis is the assignee of the '491 patent and has a right to enforce the '491 patent.

11. Admitted, except denied that the ‘940 patent issued to anyone named Busto Arisizio.

12. Admitted that sanofi-aventis is an assignee and exclusive licensee of the '940 patent and has a right to enforce the '940 patent.

13. Admitted that the '491 patent and the '940 patent are listed in the Orange Book for Uroxatral®, and that sanofi-aventis U.S. is the holder of New Drug Application No. 21-287.

14. Admitted that plaintiffs have sued other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets for infringement of the '940 patent; otherwise denied.

15. Admitted.

16. Admitted.

17. Admitted.

18. Admitted, except denied that Apotex served its Paragraph IV certification letter, dated October 25, 2007, on or about October 15, 2007.

19. Admitted.

20. Admitted that sanofi-aventis has sued Apotex for infringement of the '491 patent in this District, but denied that Apotex has a reasonable apprehension of being sued by sanofi-aventis for alleged infringement of the '940 patent; to the extent that Paragraph 20 contains any other or further allegations, they are superfluous allegations to which no response is required.

21. The allegations of Paragraph 21 of Apotex's Counterclaims set forth legal conclusions and characterizations to which no response from sanofi-aventis is required. To the extent a response is necessary, sanofi-aventis denies the allegations of Paragraph 21.

22. Admitted, except denied that there is any justiciable controversy as to the validity or infringement of the '940 patent.

23. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-22 as though set forth specifically herein.

24. Denied.

25. Denied.

26. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-25 as though set forth specifically herein.

27. Denied.

28. Denied.

29. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-28 as though set forth specifically herein.

30. The '940 patent is not currently in dispute and therefore no response from sanofi-aventis as to the allegations contained within Paragraph 30 is necessary. To the extent a response is necessary, sanofi-aventis denies Paragraph 30.

31. Denied.

32. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-31 as though set forth specifically herein.

33. The '940 patent is not currently in dispute and therefore no response from sanofi-aventis as to the allegations contained within Paragraph 33 is necessary. To the extent a response is necessary, sanofi-aventis denies Paragraph 33.

34. Denied.

Wherefore, Plaintiffs deny that Apotex Inc. or Apotex Corp. is entitled to any relief, either as prayed for in their Counterclaims or otherwise. Plaintiffs further deny each allegation contained in Apotex Inc. and Apotex Corp.'s Counterclaims that was not specifically admitted, denied, or otherwise responded to in this Reply to Defendant Apotex Inc. and Apotex Corp.'s Counterclaims.

Without prejudice to the denials set forth in its Reply to Defendant Apotex Inc. and Apotex Corp.'s Counterclaims, and without admitting any allegations of the Counterclaims not otherwise admitted, Plaintiffs assert the following defenses to the Counterclaims: (1) Subject matter jurisdiction does not exist for Apotex's counterclaims directed toward the '940 patent; and (2) This second-filed action should be transferred to the more convenient venue of the District of Delaware where an identical, parallel, first-filed action against Apotex has been pending since December 6, 2007 in front of the same Judge and Magistrate Judge as two related actions against 13 other defendants that have been pending since September 21, 2007.

Dated this 17th day of January 2008.
Miami, Florida

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 17, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali_____
Alfred J. Saikali (Florida Bar No.: 178195)
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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)

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 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 OF CONTINUANCE AND ORDER REVISING PRETRIAL DEADLINES

THIS CAUSE came before the Court upon Plaintiffs' Motion to Continue Pretrial Deadlines and Trial **(D.E. No. 12)**, filed on **January 15, 2008**.

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

ADJUDGED that for good cause shown, the motion is **GRANTED** as follows.

(1) TRIAL DATE - The trial is **CONTINUED** from the two-week period of **May 27, 2008**, to the two-week period of **October 6, 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, September 30, 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.

(3) PLAINTIFF'S WITNESS AND EXHIBIT LISTS - Plaintiff shall provide

Defendant, by either fax or hand delivery, a copy of Plaintiff's Witness List and a copy of Plaintiff's Exhibit List no later than **Wednesday, September 17, 2008, at 5:00 P.M.**

(a) PLAINTIFF'S WITNESS LIST - Plaintiff's Witness List shall include all the witnesses, both lay and expert, that Plaintiff intends to call at trial. Plaintiff's 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) PLAINTIFF'S EXHIBIT LIST - Plaintiff's Exhibit List shall include all the exhibits that Plaintiff intends to use at trial. Plaintiff's 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.* Plaintiff's 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 *Plaintiff reserves the use of any other relevant evidence*. Exhibits omitted from the list will not be allowed at trial.

(4) DEFENDANT'S WITNESS AND EXHIBIT LISTS - Defendant shall provide Plaintiff, by either fax or hand delivery, a copy of Defendant's Witness List and a copy of Defendant's Exhibit List no later than **Friday, September 19, 2008, at 5:00 P.M.**

(a) DEFENDANT'S WITNESS LIST - Defendant's Witness List shall include only those additional lay and expert witnesses not included on Plaintiff's Witness List. Witnesses listed by Plaintiff will be available for both parties and should not

be re-listed on Defendant's Witness List. Defendant's 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 Defendant's Witness List and not listed on Plaintiff's Witness List will not be allowed at trial.

(b) DEFENDANT'S EXHIBIT LIST - Defendant's Exhibit List shall include only those additional exhibits that Defendant wishes to introduce at trial which are not on Plaintiff's Exhibit List. Defendant's 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.* Defendant's 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 *Plaintiff reserves the use of any other relevant evidence.* Exhibits omitted from Defendant's Exhibit List and not listed on Plaintiff's Exhibit List will not be allowed at trial.

(5) PRETRIAL STIPULATION - Pursuant to S.D. Fla. L.R. 16.1.E., the parties shall file a Pretrial Stipulation no later than **Tuesday, September 23, 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.

(6) OTHER PRETRIAL DEADLINES -

(a) Discovery - The parties shall complete all expert and non-expert discovery no later than **August 6, 2008**.

(b) Summary Judgment - The parties shall file all motions for summary judgment no later than **August 20, 2008**.

(c) Pretrial Motions - The parties shall file all other pretrial motions no later than **September 5, 2008**.

(7) PREVIOUS SCHEDULING ORDERS - This Order shall supercede only the inconsistent provisions of previous Scheduling Orders.

DONE AND ORDERED in Chambers at Miami, Florida, this 22nd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

Shook, Hardy & Bacon L.L.P.®
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Alfred J. Saikali

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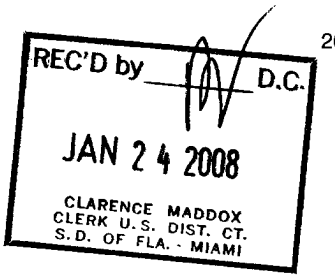
January 18, 2008



VIA U.S. MAIL

Clerk of Courts
United States District Court
Southern District of Florida
301 North Miami Avenue
Miami, FL 33128

Re: Sanofi-Aventis et. al. vs. Apotex Inc. et. al.
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Sir/Madam Clerk:

Pursuant to the Court's January 3, 2008, Order Referring Case to Mediation in the above-referenced matter, I am writing to inform the office of the Clerk of the Court that while the parties have not yet reached an agreement as to a mediator for this case; the parties have exchanged proposed mediators and are continuing to meet and confer to select a mediator. The parties are hopeful that the issue will be resolved early next week.

Please contact me if you have any questions or concerns.

Sincerely,

Alfred J. Saikali

AJS:igo
cc: Jennifer Coberly, Esq.

557552v1

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.
_____/

THE APOTEX DEFENDANTS' MOTION FOR ENTRY OF A PROTECTIVE ORDER AND INCORPORATED MEMORANDUM OF LAW

The Apotex Defendants move pursuant to Fed. R. Civ. P. 26 for entry of the proposed Protective Order attached hereto as Exhibit A. Apotex submitted this proposed protective order to counsel for Sanofi on January 17, 2008. Apotex's proposed Protective Order is substantively identical (with appropriate modification to account for the parties here) to a protective order that Sanofi's lawyers recently negotiated with Apotex's counsel in another ANDA case involving a different plaintiff. Nevertheless, Sanofi has refused to agree to Apotex's proposed protective order or to propose an alternative protective order that it finds acceptable. Discovery is underway and the entry of a Protective Order is necessary to provide the timely exchange of documents.

I. Delaying The Entry Of A Protective Order Only Delays Discovery

There is no dispute that a Protective Order is necessary to protect the interests of both parties and is a staple of almost every patent case. *See Karolewicz v. Drummond Press, Inc.,* 2007 U.S. Dist. LEXIS 51818 (M.D. Fla. 2007) (finding protective orders frequently entered in

patent infringement cases stating "it has become apparent the issuance of a protective order is necessary to facilitate the flow of discovery and preserve material worthy of protection."). This case involves confidential and proprietary drug formulations, research materials and other information that is not generally known to competitors. The Court has set a discovery cut-off date of August 6, 2008 and a trial date in October, 2008. *See* Revised Scheduling Order of 1/22/08 (Dkt. 23). Given the quick pace of this litigation, a Protective Order is needed now so that discovery can proceed and these deadlines can be met.

The parties already have had their Rule 26(f) conference and have exchanged Rule 26(a)(1) disclosures (although no documents have yet been produced). On January 18, 2008, Apotex served document requests on Sanofi and will soon be serving interrogatories and other discovery requests on Sanofi. Sanofi's responses, due February 18, 2008, no doubt will include objections that the requests call for documents containing confidential and sensitive information unless a Protective Order is entered. In fact Sanofi already has refused to produce, even on a provisional attorney's eyes only basis, any core documents underlying its claims in this case, such as Sanofi's New Drug Applications, lab notebooks, research notes, data and memoranda underlying the development of the drug product and method that are the subjects of Sanofi's patents in suit.

II. Apotex's Proposed Protective Order Is Substantially Identical to A Protective Order To Which Sanofi's Counsel Previously Agreed

Although Apotex's proposed protective order is essentially identical to that which Sanofi's counsel previously agreed in another currently pending ANDA litigation, Sanofi has nevertheless refused to agree to this one, stating that it is not yet "prudent" to negotiate and enter into a Protective Order until its motion to transfer is decided. Sanofi's counsel also characterized negotiations over a Protective Order at this time as premature, nevermind that the Court has set

an August, 2008 discovery cut-off and an October trial date, and the parties already have had their Rule 26(f) conference. *See* Fed. R. Civ. P. 26(d). Discovery in this case is not optional. Sanofi chose to sue Apotex for patent infringement here. Even though it is based in France, Sanofi still is subject to the Rules of Civil Procedure. Regardless of whether this litigation remains before the Southern District of Florida or is transferred to the District of Delaware, Sanofi will be subject to the same discovery. There simply is no reason to delay the entry of a Protective Order and discovery in this matter. Sanofi's intransigence on the protective order only serve to delay the litigation process and operate in opposition to the requirements imposed by the *Hatch-Waxman Act*, that the parties to an ANDA action "reasonably **cooperate** in **expediting** the action." 21 USC §355(j)(5)(B)(iii) (emphasis added).

Sanofi also has suggested in discussions with Apotex's counsel that the "EU Data Privacy Directive" may have some impact on the Protective Order. This is nonsense. Sanofi has failed to identify any specific provisions of the proposed Protective Order that are contrary to the EU Data Privacy Directive, despite being invited on multiple occasions to do so. Furthermore, in another currently pending ANDA litigation between Sanofi and Apotex, the Protective Order includes no mention of the EU Data Policy Directive. Finally, Apotex suggested that to the extent that Sanofi has concerns about the EU Data Privacy Directive, it should propose some language dealing with the issue. That Sanofi has refused to do so speaks volumes of the true dilatory nature of this objection.

Sanofi's counsel has not engaged in meaningful efforts to negotiate a Protective Order and cooperate in moving discovery along. Sanofi's counsel simply rejected Apotex's proposal without making a suggestion of an acceptable Protective Order. Apotex believes the Protective

Order proposed is reasonable, fair and will protect the interests of both parties. As such, Apotex requests the Court enter the Protective Order.

Pursuant to Local Rule 7.1(A)(3), Counsel for the movant has conferred with all parties or non-parties who may be affected by the relief sought in the motion in a good faith effort to resolve the issues raised in the motion and has been unable to do so.

III. Conclusion

For the foregoing reasons, Apotex requests the Court enter the Protective Order attached hereto as Exhibit A.

Dated: January 25, 2008

Respectfully submitted,

s/. Jennifer Coberly
Stephen J. Bronis
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Fax: 312-655-1501

Attorneys for Apotex Corp and Apotex Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing 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

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

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO TRANSFER OR STAY

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") respectfully submit this memorandum in opposition to Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") Motion to Transfer or Stay and Supporting Memorandum of Law.

Litigation in this Florida action is now well underway. This Court already has set a discovery schedule with a discovery cut-off of August 6, 2008 and a trial date of **October 6, 2008.** *See* January 22, 2008 Order (Dkt. No. 23). The parties in Florida already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and begun serving discovery. By contrast, other than initial pleadings, the Delaware action has not yet begun.

One of the primary purposes of the *Hatch-Waxman* Act is to expedite resolution of patent disputes involving drug products in order to facilitate the public's access to less expensive generic drugs. 21 USC §355(j)(5)(B)(iii) (parties required to "reasonably cooperate in expediting the action."); H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at p. 28, *reprinted in*

1984 U.S.C.C.A.C. 2647. Allowing the case to remain in Florida will accomplish that goal. However, transferring this case to Delaware will needlessly slow the resolution of this matter.

Sanofi cannot satisfy its heavy burden of showing Delaware is the more convenient forum. In fact, all relevant factors indicate Florida is the much more convenient and logical forum for this action. One of the Defendants, Apotex Corporation, which will market and sell the allegedly infringing drug product, has its headquarters in Florida. *See* Declaration of Tammy McIntire, attached hereto as Exhibit A at ¶4. Sanofi has accused Apotex Corp. of aiding and abetting, inducing and contributing to the infringement of its patent. Fla. Compl. ¶15 (Dkt.1). While Apotex disputes these accusations (and does not believe they state a claim for infringement under 35 U.S.C. §271(e)(2)), the situs of these alleged acts, and any Apotex Corp. documents and witnesses, necessarily would be Florida.

None of the parties have active operations in Delaware. Apotex Corp.'s operations are located in Florida. Apotex, Inc., whose act of filing an abbreviated new drug application ("ANDA") to market a generic version of an approved drug is the alleged act of infringement under 35 U.S.C. §271(e)(2), is a Canadian company whose operations are based in Canada. *See* Declaration of Bernice Tao attached hereto as Exhibit B at ¶¶4, 6. Sanofi-Aventis U.S., who presently markets the drug at issue here, is located in New Jersey. Its parent, Sanofi-Aventis, which purports to own the patents in suit, is located in France. None of the acts accused of infringement here have any connection to Delaware. None of the documents necessary as evidence for this matter are located in Delaware. (Exhibit A at ¶7; Exhibit B at ¶9). None of the potential witnesses are located in Delaware. (Exhibit A at ¶ 6; Exhibit B at ¶8).

The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C., which courts have recognized is not a significant factor in the §1404

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

Sanofi's reliance on the Delaware litigation having been filed mere days before this litigation is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues.

Accordingly, the Court should refuse to transfer this litigation to Delaware and allow this matter to proceed at the expedited pace in Florida.

ARGUMENT

I. Sanofi's Arguments Ignore that Proceeding In Florida Would Expedite Resolution Of This Action

As noted above, the Hatch-Waxman Act requires the parties to an ANDA action to cooperate with each other in expediting the resolution of the action. 21 USC § 355 (j)(5)(B)(iii) ("In such an action, each of the parties shall reasonably cooperate in expediting the action."). Apotex requested that Sanofi agree to proceed in Florida based on the expedited trial date. Sanofi refused and filed its motion to transfer. The Court should enforce the intent of the Hatch-Waxman Act and allow this litigation to proceed in the most expeditious fashion, which means keeping this case in Florida. *See In re Barr Labs., Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991) (noting Congress enacted the Hatch-Waxman Act to "get generic drugs into the hands of patients at reasonable prices – fast.").

There can be no dispute that proceeding with this case in Florida will expedite this litigation. This Court has entered a Scheduling Order setting a discovery schedule and a trial

date in October 2008, and discovery already is underway in this case. *See* January 22, 2008 Order (Dkt. 23).

Sanofi's contention that the scope of discovery requires this matter to proceed on a slower track is now moot. As stated in Sanofi's motion for transfer at pg. 17, Sanofi requested the court to place this action on a complex track under Local rule 16.1.A. *See Plaintiffs' Motion to Comtinue Pretrial Deadlines and Trial and Supporting Memorandum of Law* (Dkt. 12). The Court was presented with Sanofi's arguments relating to the complex nature of this case and scope of discovery as well as Sanofi's request to extend the end of discovery an additional 13 months (April, 2009) and extending the trial date from May, 2008 to September, 2009. (Dkt. 12). The Court nevertheless granted only a short extension with the close of discovery in August, 2008, a dispositive motion deadline of August 20, 2008 and a trial date of October 6, 2008. (Dkt. 23).

Transferring this litigation to Delaware, as Sanofi suggests, where Sanofi has sued 13 other ANDA holders for the infringement of not only the '491 patent but also the '940 patent, will only slow the adjudication process. Although Sanofi has not yet sued Apotex for the infringement of the '940 patent, Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe that patent because Apotex's proposed drug product is **different** from what is claimed in the '940 patent. In fact, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Delaware defendants, and that the Delaware litigation against Apotex – whether alone or in combination with other ANDA

holders – will not be in a position where discovery would be done less than seven months from now, and trial would occur less than nine months from now.[1]

Because of these differences transfer to Delaware and consolidation on the infringement issues likely will cause delay, as the parties and the Court sort out the issues of competitive sensitivity and confidentiality amongst the other generic defendants and their competing ANDA products. All of this delay is avoided if the case remains here in Florida.

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

II. All Relevant Factors Weigh Against Transfer To Delaware

The factors dictated by 28 U.S.C. §1404 also favor keeping this case in Florida. Specifically, §1404 requires the Court to consider the location of evidence, the convenience of the parties, the convenience of the witnesses and the interests of justice. Sanofi, as the moving party, has the burden of showing Delaware as the more appropriate venue under the factors. *Central Money Mortg. Co. v. Holman*, 122 F. Supp. 2d 1345, 1346 (M.D. Fla. 2000) ("[T]he movant has the burden of persuading the trial court that transfer of venue should be granted."). The public and private interest factors considered are outlined in the Southern District of

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

Florida's decision in *Jewelmasters, Inc. v. May Dep't Stores*, 840 F. Supp. 893, 895 (S.D. Fla. 1993):

> The idea behind § 1404 (a) is that where a 'civil action' to vindicate a wrong -- however brought in a court -- presents issues and requires witnesses that make one District Court more convenient than another, the trial judge can, after findings, transfer the whole action to the more convenient court." *Continental Grain Co*., 364 U.S. at 26. To determine the appropriateness of such a transfer, the Court must weigh a variety of factors, including (1) the convenience of the parties; (2) the convenience of the witnesses; (3) the relative ease of access to sources of proof; (4) the availability of process to the presence of unwilling witnesses; (5) the cost of obtaining the presence of the witnesses; and (6) the public interest.

Sanofi does not satisfy its burden by showing Delaware is a more convenient forum. Weighing the relevant interests renders Florida the more appropriate forum. With respect to the public's interest, the public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). The above-quoted sections of the Hatch-Waxman Act dealing with the parties' obligation to expedite resolution of this matter further dictate that Florida is the appropriate forum for this action.

Further, Sanofi's arguments concerning conservation of judicial resources through combining this action with the other cases pending in Delaware are illusory. Transferring a case set on a 9-month track to trial to a jurisdiction where it will be joined with 13 other cases involving a number of different infringement issues, and where no trial date has been set will not conserve judicial resources. The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C. Neither company has active

operations in Delaware. Apotex Corp.'s headquarters is located in Florida and Apotex, Inc. is located in Canada. Sanofi-Aventis U.S. is located in New Jersey and its parent, Sanofi-Aventis is located in France. Although the Defendants' state of incorporation is not irrelevant to a transfer inquiry, it certainly is not dispositive. *Mentor Graphics Corp. v. Quickturn Design Systems, Inc.,* 77 F.Supp.2d 505, 509 FN 6 (D. Del. 1999) ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive."). In fact, a defendant's place of incorporation is not mentioned in §1404 or among the six factors outlined by the Southern District of Florida in considering a motion to transfer. *Jewelmasters, Inc.*, 840 F. Supp. at 895.

The operative facts giving rise to this litigation are centered in Florida, Canada, France, and New Jersey, *not* Delaware. 17 Moore's Federal Practice 3d, § 111.13(1)(d) at 111-71 ("If none of the operative events in the lawsuit took place in the district in which the action was originally filed, a motion to transfer to the district in which the events occurred is likely to succeed…."). None of the alleged infringing activities took place in Delaware. (Exhibit A at ¶ 6-8). The filing of the ANDA with Paragraph IV certification was the purported act of infringement prompting this litigation and was initiated from Canada. (Exhibit A at ¶ 5-7; Exhibit B at ¶ 6-9). None of the documents relevant to this litigation are in Delaware. (Exhibit A at ¶ 7; Exhibit B at ¶ 9). The ANDA filing, Paragraph IV Certification, and further correspondence with the FDA are the operative facts and documents relevant to this litigation, all of which originated from or are located in Canada or Florida.

The convenience of the witnesses also favors transfer to Florida. *Amersham Pharmacia Biotech v. Perkin-Elmer Corp.*, 11 F. Supp. 2d 729, 730 (S.D.N.Y. 1998) ("Evaluation of the first two factors [(1) the convenience of witnesses; (2) the location of relevant documents and

relative ease of access to sources of proof] is typically dependent, moreover, on identification of the fourth factor, the "locus of the operative facts."). All persons knowledgeable Apotex Corp.'s alleged acts of infringement are located in Florida. Accordingly, Florida is a more convenient and logical forum for this litigation.

Without any legitimate basis to support transferring this case to Delaware, Sanofi instead tries to shift the burden to Apotex to establish that the case should remain in Florida. For example, Sanofi attempts to compare this case to that of *Alcon Mfg., Ltd. v. Apotex Inc.,* No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007), where Apotex filed a motion to transfer venue from the Southern District of Indiana to the Southern District of Florida. However, *Alcon*, is nothing like the present case – most significantly, Alcon (unlike Sanofi) did not sue Apotex in the Southern District of Florida. Further, in the *Alcon* case Apotex was the moving party and therefore had the burden of persuading the Indiana court to transfer the case away from the plaintiff's chosen forum. Here, Sanofi is the moving party and chose to sue Apotex here. Unlike the situation in *Alcon* the parties already have engaged in the litigation process and begun discovery in Florida. There has been no such progression in Delaware. In any event, Sanofi, not Apotex, carries the burden of establishing transfer is appropriate. It has failed to do so.

III. Plaintiffs Voluntarily Chose Florida As A Forum And The First-Filed Rule Does Not Apply

Sanofi chose Florida as a proper forum to litigate this lawsuit. Sanofi's contention that this lawsuit was only filed as a protective measure because it feared the Delaware action would be dismissed for lack of personal jurisdiction does not change this. Far from being a persuasive reason to transfer the litigation to Delaware, Sanofi's professed reason for suing in Florida is

indicative that Florida "is clearly the better forum, as all parties agree that both jurisdiction and venue lie here." *Aventis Pharma Deutschland GMBH v. Lupin Ltd,* 403 F.Supp.2d 484, 490 (E.D. Va. 2005); *see also Bristol-Myers Squibb Co. v. Andrx Pharms.*, No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (rejecting argument that second-filed lawsuit in the Southern District of Florida should not proceed because patentee only filed there out of fear that the situs of the first filed action would not have jurisdiction over one of the parties).

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

Sanofi's attempt to rely on the Delaware lawsuit's filing date being a few days before this case as a basis for transferring this litigation is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues. *Aventis*, 403 F. Supp.2d at 489 (E.D. Va. 2005) (explaining that the first-filed rule does not apply where the "Plaintiffs filed the same case against the same Defendants in two different courts."); *Employers Reins. Corp. v. MSK Ins., Ltd.*, No. Civ. 01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003) (declining to apply first-to-file rule, noting rule applies to "*party* who files first"); *see also* ("*Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-CV-04700-HAA-ES (D.N.J.) Dkt. No. 14, Nov. 16 ,2006 Order at 2). (Exhibit C.) Rather, it most often applies to situations where two opposing parties race to different courthouses to file suits

against each other, a situation not present here. *See, e.g., Serco Serv. Co. v. Kelley Co.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995); *Aventis,* 403 F. Supp. 2d at 489-90 (E.D. Va. 2005).

The cases Sanofi cites are factually opposite to the instant situation, and therefore offer no support for their assertion. For instance, *Philibert v. Ethicon, Inc.,* 2005 WL 525330 (S.D. Fla. Jan. 14, 2005), was cited by Sanofi for the proposition that a transfer to the first-filed forum where identical claims were pending would serve the interests of justice. Sanofi, however, fails to mention that the court only found the first-filed rule applied after determining that the Defendant, the moving party, did not show that the balance of convenience tipped in favor of transfer. *Philibert,* 2005 WL 525330 at *2. Additionally, Sanofi cites *Cordis Corp. v. Siemens-Pacesetter, Inc.,* 682 F.Supp. 1200 (S.D. Fla. 1987) to emphasize that a Plaintiff need not show a change of circumstances when moving to transfer. Sanofi omits the following facts. There were not two identical lawsuits pending. Plaintiff had originally filed suit naming an additional Defendant which destroyed jurisdiction in the transferee state. Only after dropping the additional defendant and gaining appropriate jurisdiction in the transferee state did the Plaintiffs request transfer. Most importantly, the Defendants admitted that all Defendant witnesses would be in the transferee state and the situs of the events leading to the lawsuit occurred in the transferee state.

None of these cases are factually applicable to the instant situation where Plaintiff filed two identical lawsuits, the convenience of the parties and witnesses and the situs of material events clearly weighs in favor of retaining the case in Florida and the expedited docket in Florida serve the interest of justice. The first filed rule is not absolute, and is subsidiary to the balancing of convenience and other interests. *Serco*, 51 F.3d at 1039. Thus, "'the trial court's discretion tempers the preference for the first-filed suit, when such preference should yield to the forum in which all interests are best served.'" (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931,

938 (Fed. Cir. 1993)). For example, in *Aventis*, in rejecting the plaintiffs' first filed argument, the court explained that "its primary concern is to 'expedite the action' as directed by *21 U.S.C. § 355(c)(3)(C)*." *Aventis*, 403 F. Supp.2d. at 490. There, the appropriate venue was determined to be the location (Virginia) of the second filed action where the person who was designated to accept service of process in the Paragraph IV certification letter was located. *Id.* at 488. Similarly here, Apotex, Inc.'s paragraph IV letter designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf.

Adams similarly holds that the first-filed rule does not apply in a situation such as this, where the ANDA filer was sued in two different jurisdictions by the same patentee. There, the patentee (like Sanofi here), filed identical patent infringement actions against the ANDA-filer in both New Jersey and Pennsylvania. The ANDA-filer immediately answered and counterclaimed in Pennsylvania and consented to proceed there. The patentee objected. Invoking the first-filed rule, the patentee moved to stay the Pennsylvania action that it voluntarily filed, and asked the New Jersey Court to enjoin the Pennsylvania court from proceeding. The patentee's arguments were rejected and the second-filed Pennsylvania action was permitted to continue.

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

Id.

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

> . . . I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which the Plaintiff almost exclusively relies – applies in the unique circumstances presented here . . . . I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and

> then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial.

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

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

IV. The Court Should Deny A Stay Of Litigation And Proceed With The Scheduling Order

Sanofi's alternative request that the Court stay this litigation and allow the Delaware action to move forward likewise should be denied. For all the reasons stated above this is will not serve the interests of justice. There is no rational reason to stay this litigation, which already is proceeding toward trial later this year, and allow the Delaware action to proceed. After receiving the Court's revised scheduling order of January 22, 2008 (Dkt. 23), Apotex moved the Delaware Court to transfer that case down to Florida or stay it pending resolution of this proceeding. With briefing on the transfer issue nearly complete and a trial date and discovery schedule already in place here, Apotex respectfully requests that this Court take the lead on deciding the transfer issue and deny Sanofi's motion so that the Delaware Court will have the benefit of this Court's ruling and accord it comity.

CONCLUSION

For the foregoing reasons, Sanofi's motion to transfer or stay its own Florida action should be denied together with such other relief as is appropriate under the circumstances.

Dated: January 28, 2008

Respectfully submitted,

s/. Jennifer Coberly
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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 was served by mail on January 28, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs,	)	Case No. 07 C 792 Judge Sleet
vs.	)	
APOTEX INC. and APOTEX CORP., Defendants.	)	

DECLARATION OF TAMMY McINTIRE

I, Tammy McIntire declare as follows:

1. I am President of Apotex Corp.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. Apotex Corp. is a Delaware corporation whose headquarters and principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. Apotex Corp. does not have any employees located in Delaware.

5. To the extent any Apotex Corp. employees are knowledgeable about ANDA No. 79-013 they are employed at the Florida location.

6. To the extent Apotex Corp. has any documents relevant to ANDA No. 79-013 they are located at Apotex Corp.'s Florida location.

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

Dated: January 23, 2008

Tammy McIntire

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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840408 / 32533

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, vs. APOTEX INC. and APOTEX CORP., Defendants.	)	Case No. 07 C 792 Judge Sleet

DECLARATION OF BERNICE TAO

I, Bernice Tao declare as follows:

1. I am the Director, Regulatory Affairs U.S. for Apotex Inc. In that role, I am familiar with the various pending ANDA's that Apotex Inc has pending in the United States including ANDA 79-013.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. Apotex Inc. is a Canadian corporation whose headquarters and principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. Apotex Inc. is in the business of developing and manufacturing quality generic pharmaceuticals.

5. Apotex Inc. prepared and filed ANDA 79-013 from its offices in Canada.

6. Apotex Inc. does not have any employees located in Delaware.

7. To the extent any Apotex Inc. employees are knowledgeable about ANDA No. 79-013 they are employed at the Canadian location.

8. To the extent Apotex Inc. has any documents relevant to ANDA No. 79-013 they are located at Apotex Inc.'s Canadian location.

9. Apotex, Inc.'s paragraph IV letters designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: January 23, 2008

Bernice Tao

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
HAROLD A. ACKERMAN
SENIOR JUDGE

UNITED STATES DISTRICT COURT
POST OFFICE BOX 999
NEWARK, NEW JERSEY 07101-0999

November 16, 2006

TO ALL COUNSEL OF RECORD

Re: *Adams Respiratory Therapeutics, Inc. v. Mutual Pharm. Holdings Co.,* Civil Action No. 06-4700

Dear Counsel:

I have reviewed the letters from counsel regarding Plaintiff's request that this Court hold an immediate status conference "to resolve issues relating to an identical case pending in the Eastern District of Pennsylvania." (Pl.'s Letter to Court 11/9/06 at 1.) After careful consideration, this Court denies Plaintiff's request.

Plaintiff Adams Respiratory Therapeutics, Inc. ("Adams") filed the instant action in this Court on October 2, 2006. Prior to filing its Complaint in this Court, Adams learned that Defendant Mutual Pharmaceutical Holdings, Co. ("Mutual") had challenged this Court's personal jurisdiction in an unrelated case, *Eisai Co., Ltd. v. Mutual Pharmaceutical*, Civ. No. 06-3613 (D.N.J. filed August 3, 2006). As Adams notes, Eisai's response to Mutual's personal jurisdiction challenge has been stayed pending jurisdictional discovery.

Understandably concerned that a successful challenge to the personal jurisdiction of this Court by Mutual in the *Eisai* action conceivably could cause Adams problems in its own suit against Mutual, Adams filed an identical action in the Eastern District of Pennsylvania two days after filing in this Court. This was necessary, from Adams's viewpoint, to preserve "certain substantive rights provided under the Hatch-Waxman Act." (Pl.'s Letter to Court 11/9/06 at 2.) Subsequent to filing in Pennsylvania, Adams moved that court to stay proceedings there pending the outcome of the jurisdictional issue in this Court. The Eastern District of Pennsylvania denied the motion to stay and the case is proceeding apace in that District.

Adams requests that I exercise my discretion as the Court in which the first action was filed and enjoin the Eastern District of Pennsylvania from proceeding with the case filed in that jurisdiction. (Pl.'s Letter to Court 11/9/06 at 3 (citing *Triangle Conduit & Cable, Inc. v. National Electric Prod. Corp.*, 125 F.2d 1008, 1009-10 (3d Cir. 1942); *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir. 1941)).) While I recognize that I have the power to direct the Eastern District of Pennsylvania to stay its related, subsequently-filed proceeding, I decline to exercise that power.

The "first-filed rule" is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient. *See Triangle*, 125 F.2d at 1008-09 (reversing district court of first-filed case for not enjoining second case filed by *defendant* in another district).

Presumably, Adams would like me to decide the *Eisai v. Mutual* personal jurisdiction issue, which would give Adams some indication of whether it would prevail on the same issue, especially now that Mutual has raised the same personal jurisdiction issue in the *Adams v. Mutual* case as well. If Adams were satisfied with my ruling in the *Eisai v. Mutual* case, then, ostensibly, it would voluntarily dismiss the Pennsylvania action and proceed with its identical case in this Court. Alternatively, now that Mutual has moved this Court to dismiss for lack of personal jurisdiction, it would be of great benefit to Adams if I decided that motion out of turn.

With respect to the *Eisai v. Mutual* motion, I cannot decide a motion that has not been fully briefed and that is stayed pending jurisdictional discovery. With respect to the more recently filed motion by Mutual in this case, I am disinclined to make any decision of such importance in haste. Moreover, as I am sure counsel can appreciate, my docket contains many other motions that were filed well in advance of this one that are of equal importance to the respective parties. While I am sympathetic to Adams's predicament, the situation is of its own making. If Adams wants to proceed in its first choice of forum, it knows how to unilaterally effectuate that circumstance.

This Court hereby DENIES Adams's request for an immediate status conference and hereby DENIES Adams's request that this Court enjoin the Eastern District of Pennsylvania action.

SO ORDERED

s/ Harold A. Ackerman
U.S.D.J.

HAA:amb

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ADAMS RESPIRATORY THERAPEUTICS, INC.	:	**CIVIL ACTION**
Plaintiff,	:	
	:	
v.	:	**NO. 06-4418**
	:	
PHARMACEUTICAL HOLDINGS CORP., et al.	:	
Defendants	:	
	:	

ORDER

AND NOW, this 2nd day of November, 2006, it is **ORDERED** as follows:

1. Plaintiff's Motion to Stay (Doc. No. 18), filed on October 24, 2006, is **DENIED**. Plaintiff brings this action under the Hatch-Waxman Act, asking me to conclude that Defendants' intended manufacture and sale of a generic drug would violate Plaintiff's patent for the drug "Mucinex." See 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiff filed the instant Complaint only two days after filing a nearly-identical Complaint in the District of New Jersey. Adams Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Civ. Action No. 2:06-cv-04700-HAA-MF (D. N.J., filed October 2, 2006). Defendants have disputed jurisdiction in New Jersey, but concede that jurisdiction exists here. Plaintiff has explained that it filed in this Court so that it will have a "back-up" forum in the unlikely event that the New Jersey Court determines after Plaintiff's statutory forty-five day window has elapsed that the District of New Jersey is without jurisdiction to hear Plaintiff's first-filed action. See 21 U.S.C. § 355(j)(5)(B)(iii) (to stay FDA final approval of generic drug application, patent owner must bring suit within forty-five days of receiving notice that generic drug applicant has filed a certification that the patent is invalid or

not infringed). Plaintiff now seeks a stay of the instant matter, pending the New Jersey Court's decision on jurisdiction. Should that Court determine it is without jurisdiction, Plaintiff would then seek to proceed against Defendants in this Court.

Defendants vigorously contend that Plaintiff seeks a stay solely for delay, so that Plaintiff can take advantage of Hatch-Waxman's thirty month non-compete period. See id. (if patent owner files suit within forty-five day window, FDA will place a thirty-month automatic stay on approval of generic drug application, unless the Court issues a decision before expiration of thirty-month period). Plaintiff responds with equal vigor that Defendants have filed an Answer, Counterclaim, and Summary Judgment Motion (before Plaintiff even served the instant Complaint) to create the false impression that the action before me is well on its way to conclusion.

Without impugning the motives of Plaintiff or Defendants, I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which Plaintiff almost exclusively relies – applies in the unique circumstances presented here. The decisions Plaintiff has cited – in which the "first-filed" rule is applied – are inapposite. See Semmes Motors, Inc. v. Ford Motor Co., 429 F.2d 1197 (2d Cir. 1970) (plaintiff filed two cases in different districts, and defendant moved to stay); Old Charter Distillery Co. v. Continental Distilling Corp., 59 F. Supp. 528 (D. Del. 1945) (plaintiff filed two cases in different districts, and second court granted plaintiff's motion to stay after first court ruled that it had jurisdiction). I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial. Accordingly, I will deny the Motion to Stay.

2. Defendants' Motion for Summary Judgment (Doc. No. 10), filed on October 17, 2006, is **DENIED WITHOUT PREJUDICE** because it is premature. Defendants are free to renew their Motion at the close of discovery or at another appropriate time.

3. Defendants' Motion for Leave to File Trade Secrets and Confidential Business Information Under Seal (Doc. No. 11), filed on October 17, 2006, is **GRANTED**.

4. The Declarations of Harry G. Brittain and Robert Dettery, along with the attached exhibits, shall be maintained under seal and shall not be made available to the public, except as provided by subsequent Order of this Court.

5. Defendants shall file, as soon as practicable, a public record version of the Declarations of Harry G. Brittain and Roberty Dettery with redactions of the portions of the declarations that contain the trade secret and confidential business information.

6. Defendants' Counterclaim (Doc. No. 4), filed on October 10, 2006, appears to turn entirely on the viability of Plaintiff's patent. Accordingly, resolution of the merits of Plaintiff's Complaint should precede resolution of the Counterclaim. Thus, Defendants' Counterclaim is **STAYED** pending resolution of the Plaintiff's claims.

IT IS SO ORDERED.

/s Paul S. Diamond, J.

_____

Paul S. Diamond, J.

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 OF REFERRAL TO MAGISTRATE JUDGE SIMONTON OF MOTION FOR ENTRY OF A PROTECTIVE ORDER

THIS CAUSE came before the Court upon a *sua sponte* review of the record.

PURSUANT to 28 U.S.C. § 636(b)(1)(A) and the Magistrate Judge Rules of the S.D. Fla. L.R., the above-captioned Cause is referred to **United States Magistrate Judge Andrea M. Simonton** to submit an Order to this Court on **The Apotex Defendants' Motion for Entry of a Protective Order (D.E. No. 25-1), filed on January 25, 2008**. The Court notes that this Cause is currently scheduled for trial for the two-week period beginning **May 27, 2008**.

All motions for extension or enlargement of time that relate to such motion are included with this referral. Any applications for extension or modification of pretrial deadlines or the trial date shall be made to the District Judge.

It shall be the responsibility of the respective parties in this case to note on all motions and submissions pertaining to the referenced matters the name of Magistrate Judge Andrea M. Simonton.

An additional courtesy copy of all materials necessary to the resolution of the referred matters shall be directed to the Magistrate Judge Simonton's Chambers.

DONE AND ORDERED in Chambers at Miami, Florida, this 31st day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

United States Magistrate Judge Andrea M. Simonton

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 CORRECTING PREVIOUS ORDER REFERRING MOTION

THIS CAUSE came before the Court upon a *sua sponte* review of the record. In this Court's Order of Referral to Magistrate Judge Simonton of Motion for Entry of a Protective Order **(D.E. No. 27)**, filed on **January 31, 2008**, the trial date was noted as **May 27, 2008**. While this was the initial trial date set by the Court, the Court later granted a motion for a continuance and continued the trial date to **October 6, 2008**. Therefore, the Order of Referral should reflect a trial date of **October 6, 2008**.

DONE AND ORDERED in Chambers at Miami, Florida, this 31st day of January, 2008.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

DEFENDANTS' MOTION FOR EXTENSION OF TIME TO COMPLY WITH REQUIREMENTS OF LOCAL RULE 16.1 OR, IN THE ALTERNATIVE, TO FILE UNILATERAL SCHEDULING REPORT AND PROPOSED SCHEDULING ORDER

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby submit their motion for an extension of time to comply with Local Rule 16.1 or, in the alternative, to file their unilateral Scheduling Report, and in support state as follows:

1. This Court ordered the parties to file a joint scheduling report as required by Local Rule 16.1 no later than January 31, 2008.

2. Apotex has attempted to comply with the Court's Order, but has been unable to do so.

3. Despite several telephone conferences, email communications, and the exchange of draft reports, the parties have not been able to agree on the contents of the report.

4. Specifically, the parties have diametrically opposed views as to whether the report should be treated as an argumentative brief.

5. Apotex believes the above circumstances provide good cause to extend the time in which the parties must comply with the requirements of Local Rule 16.1 for at least seven (7)

days, to allow further time for the parties to reach a mutual understanding.

6. In the alternative, Apotex has attached a unilateral Scheduling Report, and requests authority to file the same in lieu of the Joint Conference Report called for by Local Rule 16.1 and the Court's Order.

7. Because the Court has already filed a scheduling order, Apotex has not attached a new proposed order.

WHEREFORE, Plaintiffs request that the Court enter an order extending the time to comply with the requirements of Local Rule 16.1 for at least seven (7) days or, in the alternative, authorizing them to file a unilateral Scheduling Report in lieu of the Joint Conference Report required by Local Rule 16.1, and for such further relief as the Court deems appropriate.

Dated: January 31, 2008

Respectfully submitted,

s/. Jennifer Coberly

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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 February 1, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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Attorneys for Plaintiffs,
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,	)	
	)	Case No. 07C61800-FAM
Plaintiffs,	)	
vs.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

APOTEX SCHEDULING REPORT

Pursuant to Fed. R. Civ. P. 26(f) and Local Rule 16.1 for the Southern District of Florida, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") hereby submit this Report of the Scheduling Conference of the Parties. Sanofi's positions are stated to the best of Apotex's knowledge and belief, but Apotex anticipates the Plaintiffs will seek leave to file a unilateral report.

A. Meeting

Pursuant to Federal Rule of Civil Procedure 26(f) and this Court's Local Rule 16.1, a meeting was held via teleconference on January 15, 2008. The meeting was attended by: Steven E. Feldman and Jennifer R. Coberly, for Apotex; and William Vuk, Alexis Gorton and Alfred J. Saikali for Sanofi-Aventis and Sanofi-Aventis U.S. L.L.C.

Additionally, counsel for the parties have conferred via telephone and written correspondence both before and after January 15, 2008 in an effort to agree on the issues discussed below.

B. Likelihood of Settlement

Counsel for the parties have discussed the possibility of settlement but no formal discussions have been held. The parties will continue to discuss settlement options in the future and will advise the Court of any further developments.

C. Likelihood of Appearance of Additional Parties

At this time the parties do not anticipate seeking to join any additional parties.

D. Proposed Time Limits on the Time: The parties were unable to agree on a joint discovery plan and therefore propose the following separate plans to the Court:

Apotex's Proposal:

This Court has entered two scheduling orders. The first on January 3, 2008 (Dkt. 4) and a revised Order of Continuance and Order Revising Pretrial Deadlines on January 22, 2008 (Dkt. 23). The following reiterates the current Court ordered deadlines, with which Apotex concurs, and also proposes a few additional deadlines (in bold) that Apotex believes are appropriate for this case:

Apotex's Proposal:

Deadline	Schedule	Source
Trial set for the two-week period commencing:	October 6, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Calendar Call	September 30, 2008, at 2:00 p.m.	Court Order of Jan. 22, 2008 (Dkt. 23)
Expert Depositions Completed	**September 29, 2008**	**Apotex proposed date**
Pretrial stipulation to be filed by:	September 23, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	September 19, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	September 17, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Rebuttal Expert Reports	**September 15, 2008**	**Apotex proposed date**
Deadline for the filing of pretrial motions:	September 5, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Deadline for the filing of all motions for summary judgment:	August 20, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Initial Expert Reports On Issues Where Party Has Burden of Proof	**August 18, 2008**	**Apotex proposed date**
Deadline to complete all **fact** discovery:	August 6, 2008	Court Order of Jan. 22, 2008 (Dkt. 23), modified to include Apotex's proposal to limit deadline to "fact discovery"
Mediation to be completed no later than:	April 28, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Deadline to join additional parties or to amend pleadings [without leave of the Court]:	January 31, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Fed. R. Civ. P. 26(a)(1) disclosures	The parties exchanged Fed. R. Civ. P. 26(a)(1) disclosures on January 17, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Interpretation of Disputed Patent Claim Language		**Apotex proposes that disputed patent claim language be interpreted either in conjunction with summary judgment motions that are filed or as part of the trial on the merits**

Sanofi's Proposal:

Deadline	Sanofi-aventis's Original Proposal Under the Complex Track	sanofi-aventis's Revised Proposal Under the Complex Track	Current Schedule
Trial set for the two-week period commencing:	September 15, 2009	June 8, 2009	October 6, 2008
Calendar Call at 2:00 P.M. on:	September 9, 2009	June 2, 2009	September 30, 2008
Pretrial stipulation to be filed by:	September 1, 2009	May 25, 2009	September 23, 2008
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	August 28, 2009	May 22, 2009	September 19, 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 20, 2009	September 17, 2008
Mediation to be completed no later than:	August 11, 2009	May 5, 2009	April 28, 2008
Deadline for the filing of pretrial motions, including motions *in limine* and *Daubert* motions:	August 11, 2009	May 5, 2009	September 5, 2008
Deadline for the filing of all motions for summary judgment:	Within 10 days of the close of expert discovery	Within 10 days of the close of expert discovery	August 20, 2008
Deadline to complete all discovery:	Within 90 days of *Markman* order	Within 75 days of *Markman* order	August 6, 2008
Deadline to complete expert discovery	Within 90 days of *Markman* order	Within 75 days of *Markman* order	
Markman hearing and technology tutorial	February 3-4, 2009	January 22, 2009	
Deadline to complete fact discovery	December 23, 2008	November 18, 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	Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay	January 31, 2008

E. Proposals for the formulation and simplification of issues, including the elimination of frivolous claims or defenses, and the number and timing of motions for summary judgment or partial summary judgment.

Apotex's Proposal:

Apotex believes that two issues: (1) whether it infringes U.S. Patent No. 6,149,940 (Sanofi has not disputed this[1], but asserts that there is no subject matter jurisdiction to decide this issue); and (2) whether Apotex's filing of an ANDA can constitute an exceptional case are susceptible to early adjudication in this matter. Apotex will be in a position to file appropriate motions to resolve these issues within the next 30 days.

Sanofi's Proposal:

Sanofi proposes that the parties each be permitted to file one summary judgment motion that shall be served and filed within 10 days of the close of expert discovery.

F. The necessity or desirability of amendments to the pleadings:

At this time, the parties do not anticipate any amendments to the pleadings.

G. The possibility of obtaining admissions of fact and of documents, electronically stored information or things which will avoid unnecessary proof, stipulations regarding authenticity of documents, electronically stored information or things, and the need for advance rulings from the Court on admissibility of evidence.

[1] *See* Plaintiffs' Motion To Transfer or Stay and Supporting Memorandum of Law (Dkt. 5) at pg. 6.

The parties will cooperate to identify facts that may be established or documents that may be authenticated by stipulation, in order to avoid the need for advance rulings on admissibility of evidence, but at this time, the parties have insufficient information to identify such facts and/or documents. The parties have briefly discussed the procedure and format to be used for exchanging electronic information and will continue to work together with respect to this issue. The parties have insufficient information at the present time to make any informed suggestions regarding the avoidance of unnecessary proof but will continue to work together with respect to the issue.

H. Suggestions for the avoidance of unnecessary proof and of cumulative evidence.

At this time, the parties do not have any suggestions for the avoidance of unnecessary proof other than attempting to obtain appropriate stipulations regarding the authenticity of documents. However, the parties will use their best efforts to avoid unnecessary proof and cumulative evidence.

I. Suggestions on the advisability of referring matters to a Magistrate Judge or Special Master.

At this time, the parties do not believe that reference to a Magistrate Judge or Special Master is necessary or advisable.

J. A preliminary estimate of the time required for trial.

At the present time, the parties agree with the Court's estimate that it will require no more than 10 days for this action to be tried.

K. Requested date or dates for conferences before trial, a final pretrial conference and trial

The Court's Scheduling Order currently sets the final Pretrial Conference for September 30, 2008 and trial for a two week period commencing on October 6, 2008.

Apotex's Proposal:

The Court has scheduled a final Pretrial Conference be held on September 30, 2008 at 2:00 p.m.. and a two week trial beginning on Apotex proposes no changes to those dates, but does note that October 8-9 is the Jewish Holiday of Yom Kippur and accordingly requests that trial not be held on those two days.

Sanofi's Proposal:

Sanofi proposes that given the complexities and volume of anticipated discovery in this action that this case be assigned to a Complex Track. Based on assignment to the Complex Track, Sanofi proposes that the final pretrial conference be held on June 2, 2009 and that trial commence on June 8, 2009.

L. Any other information that might be helpful to the Court in setting the case for status or pretrial conference.

Apotex's additional information:

On January 25, 2008, Apotex filed a Motion for Protective Order (Dkt. 25) with the Court. The Court's entry of the Protective Order will allow discovery to proceed at a faster and more efficient pace.

Sanofi's additional information:

Sanofi would like to inform the Court that it intends on petitioning the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer and consolidate this action with the three first-

filed 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. Sanofi further intends to move this Court for a stay of the proceedings pending the Panel's resolution of Sanofi motion to transfer and consolidate.

Dated: January 31, 2008

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 February 1, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

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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 FILE SCHEDULING REPORT AND PROPOSED SCHEDULING ORDER

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to enter the Scheduling Report and Proposed Scheduling Order attached hereto at Exhibits 1 and 2 respectively, and in support of their motion state as follows:

1. The parties were required to file a joint scheduling report pursuant to Local Rule 16.1 and the orders of the Court by January 31, 2008.

2. To date, the parties have held numerous telephonic meet and confers concerning the joint scheduling report and have exchanged various drafts and emails reflecting their respective revisions.

3. Counsel for the parties were engaged in a telephonic meet and confer on these issues when Defendants unilaterally, and with only minutes notice, filed Defendants' Motion for

Extension of Time to Comply with Requirements of Local Rule 16.1 or, In the Alternative, to File Unilateral Scheduling Report and Proposed Scheduling Order. *See* D.I. 29.[1]

4. During the meet and confer, Defendants identified the specific portions of the draft joint scheduling report that they found objectionable: (1) the Preliminary Statement; (2) Plaintiffs' proposal under Section D with the exception of the chart of proposed dates; and (3) Plaintiffs' proposal under Section E with the exception of Plaintiffs' position with respect to the number of summary judgment motions. Plaintiffs agreed to clearly indicate these objections in the report, but Defendants still refused to sign and file the report jointly.

5. Following the meet and confer, and as discussed by the parties during the call, Plaintiffs revised the draft report. Plaintiffs moved the Preliminary Statement to Section K under Plaintiffs' additional information and added language indicating which portions of Sections D and E Defendants objected to even though these sections were already clearly marked as Plaintiffs' proposals and not an agreement between the parties. The Status Report attached at Exhibit 1 reflects these revisions. Defendants did not respond to Plaintiffs' request to sign and file the revised report jointly.

---

[1] The report attached at Exhibit A to Defendants' motion is not actually "unilateral" because it purports to memorialize the parties' agreements and Plaintiffs' proposals. Moreover, the report reflects numerous omissions and inaccuracies and does not even correctly describe the meet and confer process: (1) Defendants removed language describing the background of the case, pending motions, including Plaintiffs' intent to file an opposition to Defendants' motion for a protective order, in this Court and the parallel Delaware action, and portions of Plaintiffs' proposals from Sections D and E; (2) under Section A, Defendants do not fully describe the meet and confer process and inaccurately list the attorneys present for the meeting listed; (3) Section E does not include Plaintiffs' position that the issues raised by Defendants are not easily resolved; (4) Section I inaccurately states that Plaintiffs agreed that referral to a Magistrate Judge or Special Master would not be "advisable"; and (5) Section J inaccurately implies that Plaintiffs agreed that trial could take less than 10 days.

6. 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 File Status Report and Proposed Scheduling Order. 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 File Status Report and Proposed Scheduling Order.

Dated: January 31, 2008

Respectfully submitted,

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

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 31, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

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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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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.
_____/

SCHEDULING REPORT

Pursuant to Local Rule 16.1 for the Southern District of Florida, for the purposes prescribed by Federal Rule of Civil Procedure 26(f), Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this Scheduling Report which sanofi-aventis understands reflects the parties' respective positions on the form and content of the report as of the parties' most recent meet and confer on these issues.

A. Meeting

Pursuant to this Court's Local Rule 16.1 for the purposes prescribed by Federal Rule of Civil Procedure 26(f), a meeting was held via teleconference on January 15, 2008. The meeting was attended by: William T. Vuk and Alfred J. Saikali for sanofi-aventis and Steven E. Feldman and Jennifer R. Coberly, for Apotex On January 17, 2008, the parties exchanged the information required pursuant to the Order Setting Conference in that sanofi-aventis served its disclosures pursuant to that Order and Apotex served its Initial Disclosures pursuant to Fed. R.

Civ. P. 26(a)(1). Then, on January 29, 2008, counsel for the parties held another meet and confer conference to further discuss the Rule 16.1 issues addressed below. The meeting was attended by: William T. Vuk, Alexis Gorton and Alfred J. Saikali for sanofi-aventis and Steven E. Feldman and Jennifer R. Coberly, for Apotex. To the extent the parties were unable to reach an agreement with respect to a particular issue, both parties' proposals are set forth.

B. Likelihood of Settlement

Counsel for the parties have discussed the possibility of settlement but no formal discussions have been held. The parties will continue to discuss settlement options in the future and will advise the Court of any further developments.

C. Likelihood of Appearance of Additional Parties

At this time the parties do not anticipate seeking to join any additional parties.

D. Proposed Limits on the Time:[1] The parties were unable to agree on a joint discovery plan and therefore propose the following separate plans to the Court:

sanofi-aventis's proposal: Sanofi-aventis proposes that the Court place this action on a Complex Track and set November 18, 2008 as the deadline to complete fact discovery 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 complexities inherent in this case. The Court's current schedule sets the close of both fact and expert discovery within approximately seven months and trial within nine months of the date of the Scheduling Order; thus the action is on the Standard Track, which, generally applies to "a case requiring three to ten days of trial" in which discovery can be completed within six to nine months. *See* L.R. 16.1.A.2(b). Examination of the factors

[1] The parties have discussed this document in detail and counsel for Apotex has informed sanofi-aventis's counsel that it objects to sanofi-aventis's inclusion of all text under "D. Proposed Limits on Time" other than the chart.

under L.R. 16.1.A.3, which include "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" demonstrate that the Complex Track is more appropriate for this action in which the following complexities and discovery related issues are anticipated:

- 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, located at least in France and the United States;
- 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;
- Approximately 10 days of trial; and
- That independent of this action, sanofi-aventis will proceeding with pretrial activities in Delaware against 13 additional defendants, including depositions of many of the same employees.

Based on the information set forth above, sanofi-aventis submits the below chart comparing sanofi-aventis's original and revised proposals with the Court's current schedule.

Deadline	sanofi-aventis's Original Proposal Under the Complex Track	sanofi-aventis's Revised Proposal Under the Complex Track	Current Schedule
Trial set for the two-week period commencing:	September 15, 2009	June 8, 2009	October 6, 2008
Calendar Call at 2:00 P.M. on:	September 9, 2009	June 2, 2009	September 30, 2008
Pretrial stipulation to be filed by:	September 1, 2009	May 25, 2009	September 23, 2008
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	August 28, 2009	May 22, 2009	September 19, 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 20, 2009	September 17, 2008
Mediation to be completed no later than:	August 11, 2009	May 5, 2009	April 28, 2008
Deadline for the filing of pretrial motions, including motions *in limine* and *Daubert* motions:	August 11, 2009	May 5, 2009	September 5, 2008
Deadline for the filing of all motions for summary judgment:	Within 10 days of the close of expert discovery	Within 10 days of the close of expert discovery	August 20, 2008
Deadline to complete all discovery:	Within 90 days of *Markman* order	Within 75 days of *Markman* order	August 6, 2008
Deadline to complete expert discovery	Within 90 days of *Markman* order	Within 75 days of *Markman* order: reports from the party with the burden of proof within 21 days of *Markman* ruling; rebuttal reports to be served 14 days later.	
Markman hearing and technology tutorial	February 3-4, 2009	January 22, 2009: opening brief filed on December 18, 2008, responsive brief filed on January 5, 2009 and	

Deadline	sanofi-aventis's Original Proposal Under the Complex Track	sanofi-aventis's Revised Proposal Under the Complex Track	Current Schedule
		reply brief filed on January 12, 2009	
Deadline to complete fact discovery	December 23, 2008	November 18, 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	Within 10 days of disposition of Plaintiffs' Motion to Transfer or Stay	January 31, 2008

Apotex's Proposal:

This Court has entered two scheduling orders. The first on January 3, 2008 (Dkt. 4) and a revised Order of Continuance and Order Revising Pretrial Deadlines on January 22, 2008 (Dkt. 23). The following reiterates the current Court ordered deadlines, with which Apotex concurs, and also proposes a few additional deadlines (in bold) that Apotex believes are appropriate for this case:

Apotex's Proposal:

Deadline	Schedule	Source
Trial set for the two-week period commencing:	October 6, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Calendar Call	September 30, 2008, at 2:00 p.m.	Court Order of Jan. 22, 2008 (Dkt. 23)
Expert Depositions Completed	**September 29, 2008**	**Apotex proposed date**
Pretrial stipulation to be filed by:	September 23, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	September 19, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	September 17, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Rebuttal Expert Reports	**September 15, 2008**	**Apotex proposed date**
Deadline for the filing of pretrial motions:	September 5, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Deadline for the filing of all motions for summary judgment:	August 20, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Initial Expert Reports On Issues Where Party Has Burden of Proof	**August 18, 2008**	**Apotex proposed date**
Deadline to complete all **fact** discovery:	August 6, 2008	Court Order of Jan. 22, 2008 (Dkt. 23), modified to include Apotex's proposal to limit deadline to "fact discovery"
Mediation to be completed no later than:	April 28, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Deadline to join additional parties or to amend pleadings [without leave of the Court]:	January 31, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Fed. R. Civ. P. 26(a)(1) disclosures	The parties exchanged Fed. R. Civ. P. 26(a)(1) disclosures on January 17, 2008	Court Order of Jan. 22, 2008 (Dkt. 23)
Interpretation of Disputed Patent Claim Language		**Apotex proposes that disputed patent claim language be interpreted either in conjunction with summary judgment motions that are filed or as part of the trial on the merits**

E. Proposals for the formulation and simplification of issues, including the elimination of frivolous claims or defenses, and the number and timing of motions for summary judgment or partial summary judgment.[2]

sanofi-aventis's Proposal:

Sanofi-aventis sets forth below the issues that currently need to be decided in this matter. At this time, sanofi-aventis has not identified any opportunities for narrowing these issues, but will continue to discuss the possibility of narrowing any of these issues with Apotex and will inform the Court if any issues are so narrowed. Sanofi-aventis disagrees with Apotex that there are any issues that could be readily resolved.

1) Whether Apotex has infringed, induced infringement or contributed to the infringement of one or more claims of the '491 patent.

2) The injunctive relief to which sanofi-aventis is entitled, if Apotex is found to have infringed, induced infringement, or contributed to the infringement any of the claims of the '491 patent.

3) Whether Apotex is entitled to a declaration of non-infringement with respect to any valid or enforceable claim of the '491 patent.

4) Whether Apotex is entitled to a declaration of invalidity with respect to the '491 patent.

5) The construction of the claims of the '491 patent.

6) Whether the Court has subject matter jurisdiction over Apotex's counterclaims related to the '940 patent;

7) Whether Apotex is entitled to a declaration of non-infringement with respect to any valid or enforceable claim of the '940 patent.

[2] The parties have discussed this document in detail and counsel for Apotex has informed sanofi-aventis's counsel that it objects to sanofi-aventis's inclusion of all text under "E. Proposals for the formulation and simplification of issues . . ." other than as it relates to summary judgment motions.

8) Whether Apotex is entitled to a declaration of invalidity with respect to the '940 patent.

9) The construction of the claims of the '940 patent.

10) Whether this case is exceptional under 35 U.S.C. § 285.

11) Whether either party is entitled to an award of its attorney fees, costs and expenses.

Sanofi-aventis proposes that the parties each be permitted to file one summary judgment motion that shall be served and filed within 10 days of the close of expert discovery.

Apotex's Proposal:

Apotex believes that two issues: (1) whether it infringes U.S. Patent No. 6,149,940 (Sanofi has not disputed this[3], but asserts that there is no subject matter jurisdiction to decide this issue); and (2) whether Apotex's filing of an ANDA can constitute an exceptional case are susceptible to early adjudication in this matter. Apotex will be in a position to file appropriate motions to resolve these issues within the next 30 days.

F. The necessity or desirability of amendments to the pleadings:

At this time, the parties do not anticipate any amendments to the pleadings.

G. The possibility of obtaining admissions of fact and of documents, electronically stored information or things which will avoid unnecessary proof, stipulations regarding authenticity of documents, electronically stored information or things, and the need for advance rulings from the Court on admissibility of evidence.

The parties will cooperate to identify facts that may be established or documents that may be authenticated by stipulation, in order to avoid the need for advance rulings on admissibility of evidence, but at this time, the parties have insufficient information to identify such facts and/or documents. The parties have briefly discussed the procedure and format to be used for

[3] *See* Plaintiffs' Motion To Transfer or Stay and Supporting Memorandum of Law (Dkt. 5) at pg. 6.

exchanging electronic information and will continue to work together with respect to this issue. The parties have insufficient information at the present time to make any informed suggestions regarding the avoidance of unnecessary proof but will continue to work together with respect to the issue.

H. Suggestions for the avoidance of unnecessary proof and of cumulative evidence.

At this time, the parties do not have any suggestions for the avoidance of unnecessary proof other than attempting to obtain appropriate stipulations regarding the authenticity of documents. However, the parties will use their best efforts to avoid unnecessary proof and cumulative evidence.

I. Suggestions on the advisability of referring matters to a Magistrate Judge or Special Master.

To date, the Court has referred Apotex's motion for entry of a protective order the Magistrate Judge. At this time, the parties do not believe that reference of other matters to a Magistrate Judge or Special Master is necessary but will continue to discuss the issue and inform the Court accordingly.

J. A preliminary estimate of the time required for trial.

sanofi-aventis's Position:

At the present time, sanofi-aventis estimate that it will require 10 days for this action to be tried.

Apotex's Position:

At the present time, Apotex agrees with the Court's estimate that it will require no more than 10 days for this action to be tried.

K. Requested date or dates for conferences before trial, a final pretrial conference and trial

The Court's Scheduling Order currently sets the final Pretrial Conference for September 30, 2008 and trial for a two week period commencing on October 6, 2008. At the present time, the parties do not believe that an interim status/pretrial conference is necessary, but will continue to discuss this issue and inform the Court accordingly.

sanofi-aventis's Proposal:

Sanofi-aventis proposes that given the complexities and volume of anticipated discovery in this action that this case be assigned to a Complex Track. Based on assignment to the Complex Track, Sanofi proposes that the final pretrial conference be held on June 2, 2009 and that trial commence on June 8, 2009.

Apotex's Proposal:

The Court has scheduled a final Pretrial Conference be held on September 30, 2008 at 2:00 p.m.. and a two week trial beginning on Apotex proposes no changes to those dates, but does note that October 8-9 is the Jewish Holiday of Yom Kippur and accordingly requests that trial not be held on those two days.

L. Any other information that might be helpful to the Court in setting the case for status or pretrial conference.

Sanofi-aventis's additional information:

Case background: This is an action brought by sanofi-aventis under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for the infringement of U.S. Patent No. 4,661,491 ("the '491 patent"), listed in the FDA's *Approved Drug Products With Therapeutic Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, by

Apotex's filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Apotex argues that its proposed generic product will not infringe the '491 patent and that the '491 patent is invalid. Apotex additionally seeks declaratory judgments that the '491 patent will not be infringed by Apotex's proposed generic product and that the '491 patent is invalid. Sanofi-aventis denies Apotex's claims and allegations related to the '491 patent. Apotex also has filed counterclaims seeking declaratory judgments that U.S. Patent No. 6,149,940 ("the '940 patent"), a second patent listed in the Orange Book for Uroxatral®, will not be infringed by Apotex's proposed generic product and that the '940 patent is invalid. Sanofi-aventis asserts that subject matter jurisdiction is lacking for Apotex's counterclaims related to the '940 patent. Sanofi-aventis otherwise denies Apotex's claims and allegations with respect to the '940 patent.

Sanofi-aventis filed the present action on December 10, 2008 and there currently is pending in the District of Delaware an identical action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), filed by sanofi-aventis on December 6, 2008 involving the same parties, claims and defenses. Additionally, two related actions, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT), against thirteen additional defendants[4] and involving similar claims and defenses were filed by sanofi-aventis on September 21, 2007. All three related actions in the District of Delaware are pending before the same Judge and Magistrate Judge.

[4] The thirteen additional defendants named in the Complaints filed in Delaware are: Actavis South Atlantic LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc., Barr Laboratories, Inc., Mylan Pharmaceuticals Inc., Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited , Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd.

Motions Currently Pending in the Present Action: On January 8, 2008, sanofi-aventis moved to transfer the present action to Delaware or to stay the present action pending the disposition of any transfer issues raised by Apotex in Delaware. Apotex filed its opposition to that motion on January 28, 2008. Sanofi-aventis will file and serve its reply brief by February 7, 2008. No decision has been issued.

Also on January 8, 2008, sanofi-aventis moved to stay certain deadlines set in the Court's January 3, 2008 Orders. Sanofi-aventis understands that no decision has been issued. Apotex disagrees and maintains that the Amended Scheduling Order addressed this motion.

On January 25, 2008, Apotex moved for the entry of a protective order. Sanofi-aventis will file and serve its opposition to that motion by February 11, 2008. No decision has been issued.

Motion Currently Pending in the Delaware Action: On January 24, 2008, Apotex moved to transfer the Delaware action to Florida or to stay the Delaware action pending final resolution of the present action in Florida. Sanofi-aventis will file and serve its opposition to that motion by February 11, 2008. No decision has been issued.

Anticipated Motion to the Judicial Panel on Multidistrict Litigation: Sanofi would like to inform the Court that it intends on petitioning the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer and consolidate this action with the three first-filed 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. Sanofi further intends to move this Court for a stay of the proceedings pending the Panel's resolution of Sanofi motion to transfer and consolidate.

Apotex's additional information:

On January 25, 2008, Apotex filed a Motion for Protective Order (Dkt. 25) with the Court. The Court's entry of the Protective Order will allow discovery to proceed at a faster and more efficient pace.

Dated: January 31, 2008

Respectfully submitted,

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

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 31, 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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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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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 SCHEDULING ORDER

Based upon a conference between the parties, it is hereby:

ORDERED AND ADJUDGED as follows:

1. This case shall be assigned to the Complex Track and be given the following schedule:

Event	Deadline
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	November 18, 2008
Markman hearing and technology tutorial	January 22, 2009
Deadline to complete expert discovery	Within 75 days of *Markman* order
Deadline to complete all discovery:	Within 75 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	May 5, 2009

Event	Deadline
Daubert motions:	
Mediation to be completed no later than:	May 5, 2009
Plaintiffs' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	May 20, 2009
Defendants' witness and exhibit lists to be served by fax or hand delivery no later than 5:00 P.M. on:	May 22, 2009
Pretrial stipulation to be filed by:	May 25, 2009
Calendar Call at 2:00 P.M. on:	June 2, 2009
Trial set for the two-week period commencing:	June 8, 2009

2. **Markman Proceedings:** A Markman hearing and technology tutorial will be held on January 22, 2009. The parties shall abide by the follow briefing schedule: opening brief is due on December 18, 2008, responsive brief is due on January 5, 2009 and reply brief is due on January 12, 2009.

3. **Expert Discovery:** The deadline to complete Expert Discovery is 75 days from the issuance of a Markman ruling. Reports from retained experts required by Fed. R. Civ. P. 26(a)(2) shall be served from the party with the burden of proof within thirty days of the Court issuing a Markman ruling, rebuttal expert reports shall be served twenty-one days later. All expert depositions must be completed within 75 days of the issuance of a Markman ruling.

4. **Summary Judgment Motions:** Each party is permitted to serve one summary judgment motion that must be filed within 10 days of the close of expert discovery.

5. **Mediation:** Mediation shall occur by May 5, 2009.

6. **Joinder of other Parties:** All motions to join other parties shall be filed within 10 days of the disposition of Plaintiffs' Motion to Transfer or Stay.

7. **Amendment of the Pleadings:** The parties may amend their pleadings without leave of Court within 10 days of the disposition of Plaintiffs' Motion to Transfer or Stay.

8. **Pretrial Motions:** All pretrial motions, including any motions in limine, shall be filed by _____.

9. **Resolution of Pretrial Motions:** All pretrial motions shall be resolved by _____.

10. **Final Pretrial Conference:** A final pretrial conference shall be held on _____.

11. **Trial Commencement:** This case is scheduled for trial commencing _____.

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Magistrate Simonton
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. /

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO FILE SCHEDULING REPORT AND PROPOSED SCHEDULING ORDER

THIS CAUSE came before the Court upon Plaintiffs' Motion to File Scheduling Report and Proposed Order **(D.E. No. __)** filed on **January 31, 2008.**

THE COURT has considered the motion and Plaintiffs' opposition, and being otherwise fully advised in the premises, it is

ADJUDGED that for good cause shown, the motion is **GRANTED** as follows:

Plaintiffs' request to file a scheduling report and proposed scheduling order is granted.

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

_____
FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

DECLARATION OF ALEXIS GORTON IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION TO STAY PENDING JPML DECISION

I, Alexis Gorton, declare:

I am an attorney with the law firm Kirkland & Ellis LLP, counsel for sanofi-aventis and sanofi-aventis U.S. LLC in this action. I submit this declaration in support of Plaintiffs' Emergency Motion to Stay Pending JPML Decision. I have personal knowledge of the facts set forth herein.

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

2. Attached hereto as Exhibit 2 is a true and accurate copy of Apotex Inc. - Corporate Info, http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes (last visited February 7, 2008).

3. Attached hereto as Exhibit 3 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.

4. Attached hereto as Exhibit 4 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.

5. Attached hereto as Exhibit 5 is a true and accurate copy of the Complaint, without exhibits, dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC*, *et al.*, Civil Action No. 07-572 (GMS) (MJT), in the District Court for the District of Delaware.

6. Attached hereto as Exhibit 6 is a true and accurate copy of the Complaint, without exhibits, dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Barr Laboratories, Inc.*, Civil Action No. 07-574 (GMS) (MJT), in the District Court for the District of Delaware.

7. Attached hereto as Exhibit 7 is a true and accurate copy of a letter dated October 1, 2007 from William T. Vuk to Bernice Tao.

8. Attached hereto as Exhibit 8 is a true and accurate copy of the Complaint, without exhibits, dated December 6, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT), in the District Court for the District of Delaware.

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 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.

11. Attached hereto as Exhibit 11 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.

12. Attached hereto as Exhibit 12 are true and accurate copies of Defendants Apotex Inc.'s and Apotex Corp.'s Motion to Transfer, Or In the Alternative, to Stay and Opening Brief In Support of Motion to Transfer In Favor of Pending Florida Jurisdiction, Or In the Alternative to Stay the Delaware Litigation, without exhibits, dated January 24, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT), in the District Court for the District of Delaware.

13. Attached hereto as Exhibit 13 is a true and accurate copy of Plaintiffs' Answering Brief In Opposition to Defendants' Motion to Transfer In Favor of Pending Florida Jurisdiction, Or In the Alternative to Stay the Delaware Litigation, without exhibits, dated January 31, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-792 (GMS) (MJT), in the District Court for the District of Delaware.

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

s/ Alexis Gorton

Alexis Gorton

February 7, 2008
New York, New York

EXHIBIT 1

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

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

PLAINTIFFS' MOTION TO TRANSFER
AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-*

aventis et al. v. Actavis South Atlantic LLC et al., No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT), pending in that District. A list of the four pending actions identifying all parties and the presiding judges is attached hereto as the Schedule of Actions.

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

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

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

3. In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed

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

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

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

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

7. Given that personal jurisdiction could be exercised against all 15 potential defendants in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against the 13 defendants it elected to sue at that time[1] for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[2]

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

9. In response to Apotex Inc.'s second Paragraph IV Certification, dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex Inc. and Apotex Corp. (collectively "Apotex") in Delaware on December 6, 2007 for infringement of the '491 patent. That action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge.

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[1] At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product.

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

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

11. Under the Hatch-Waxman Act, a patentee has a strict statutory 45-day window in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired.

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

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

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

14. Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware.

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

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

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

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

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

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

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

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

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

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

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

Dated: February 1, 2008

Respectfully submitted,

Gerald J. Flattmann, Jr./AB

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

SCHEDULE OF ACTIONS

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

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

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

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

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I. INTRODUCTION

Sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions against 13 defendants that have been pending in Delaware since September 2007, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT).[1]

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

II. BACKGROUND

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

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

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

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

In the Summer of 2007, nine separate Abbreviated New Drug Applications ("ANDAs") for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Each of these ANDAs seeks the FDA approval necessary for the submitting entity or entities to engage in the commercial manufacture, use and sale of generic copies of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the submitting entity or entities included an allegation under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of

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

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

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

Because personal jurisdiction exists over all of the entities involved in the submission of the infringing ANDAs and Paragraph IV Certifications in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) (the "Actavis Dkt.") and 07-574 (GMS) (MPT) (the "Barr Dkt.") on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective Paragraph IV Certifications.[3] *See* Complaints (Actavis Dkt. 1; Barr Dkt. 1).[4] At the time of the filing the first two Delaware complaints, Apotex's ANDA only included a Paragraph IV Certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis did not file an action against Apotex for infringement of the '940 patent. Sanofi-aventis then received a second Paragraph IV Certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced the first-filed action, Civil Action No. 07-792 (GMS) (MPT) (the "Apotex DE Dkt."), against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent.

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

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

See Complaint (Apotex DE Dkt. 1). On January 2, 2008, Apotex answered the complaint and conceded that jurisdiction and venue were proper in Delaware:

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

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

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

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

Labs. v. Mylan Pharm., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).[5] Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. Prior to filing the Delaware actions, however, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct and/or representations made in their respective Paragraph IV Certification letters. Sanofi-aventis's concerns appeared justified when Apotex, Aurobindo, Mylan, Sun, and Torrent refused to consent to jurisdiction in Delaware during sanofi-aventis's strict 45-day window in which to bring suit.

The law remains unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8. The consequences of losing the protections of the Hatch-Waxman Act, however, are clear and are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate

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

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

The District of Delaware can properly exercise personal jurisdiction over all 15 defendants in the three first-filed Delaware actions. Given the uncertain consequences surrounding the unlikely, but possible dismissal of any defendant from one of the Delaware actions, sanofi-aventis had no choice but to bring second-filed actions in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. As a result, sanofi-aventis brought second-filed actions within the statutory 45-day window against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007 and against Apotex on December 10, 2007. The second-filed suits against Aurobindo, Mylan, Sun, and Torrent have each been dismissed, leaving Apotex as the lone outstanding second-filed suit. [6]

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

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,[7] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. (*See* Ex. G,

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

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

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

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

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

duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts.

III. SUMMARY OF THE ARGUMENT

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

IV. ARGUMENT

A. The Applicable Standard

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

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

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

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

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

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

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

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

"[T]ransfer under Section 1407 does not require a complete identity or even a majority of common factual or legal issues as a prerequisite to transfer." *See In re Acacia Media Techs. Corp. Patent Litig.*, 360 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005). Here, however, the common issues of law and fact will predominate because all four actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product, and many of the defendants have raised the same defenses and counterclaims. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations where "[i]n each action [the patentee] has asserted that a proposed generic product infringes its patent...."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (ordering consolidation of three patent infringement actions where "[a]ll three actions involve one or more patents related to...[the branded pharmaceutical] product sold by [the plaintiff]."). The defendants may have slightly different formulations or base their obviousness arguments on different combinations of

prior art, but that is not justification for denying a request for transfer and consolidation. *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("Several opposing defendants argue that centralization is not warranted in light of the fact that issues of patent infringement are unique in each action, because each defendant's allegedly infringing formulation is different. We disagree.").

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

Similarly, because the validity of both patents are challenged in each case, both courts may be required to address the state of the science and the knowledge of one of ordinary skill in the art at the relevant time, and the scope and content of each prior art reference asserted with respect to each asserted claim from the patents. Again, these factors warrant transfer and consolidation. *See, e.g.*, *In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976) (holding that common issues of validity "justify transfer."); *In re Nabumetone Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998) (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin Patent Litig.*, MDL

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

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

In sum, given the numerous questions of fact and law that are common to all four actions, transfer and consolidation under Section 1407(a) is appropriate and should be granted. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355; *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361; *In re Acacia Media Techs. Corp.*, 360 F. Supp. 2d at 1379.

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

Transfer and consolidation of the actions will also promote the just and efficient conduct of the actions, satisfying the second requirement of Section 1407(a) . As the Supreme Court noted, "Patent infringement litigation often raises difficult technical issues that are unfamiliar to the average trial judge." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank.*, 527 U.S. 627, 651 (1999). Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency. *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

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

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

Second, consolidation will prevent inconsistent pretrial rulings. For example, consolidation will prevent inconsistent claim construction rulings. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the judge to decide). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming. Without consolidation, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings. This is precisely the scenario that Section 1407 was designed to avoid. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (stating that centralization will "prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim construction;"); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Third, consolidation will result in a more efficient discovery schedule for the parties and the court, avoiding duplicative written discovery, document productions, discovery motions and the like. Given that the same patents are at issue in all four of sanofi-aventis's actions, that the defendants' products are all generic versions of the same Uroxatral® brand product, and the substantial overlap of the defenses in each action, the scope of discovery will substantially overlap in the four actions. *In re Burke, Inc., Pers. Mobility Vehicle Patent Litig.*, MDL No. 809, 1989 U.S. Dist. LEXIS 13662, at *2 (J.P.M.L. Aug. 22, 1989) (consolidating infringement

actions involving a single patent "to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary").

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

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

Transfer and consolidation of the actions will be most convenient for the parties and witnesses. Consolidation will serve as a cost-saving measure to the parties by avoiding duplicative discovery and other pretrial burdens in relation to common issues. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 ("[c]entralization under Section 1407 will eliminate duplicative discovery… and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same); *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001) (explaining that centralization would effectuate "an overall savings of cost and a minimum of inconvenience to all concerned" with the pretrial activities). Transfer and consolidation will "ensure that discovery will transpire but once and, at the same time, will also streamline the rest of the pretrial process through the involvement and supervision of only a single judge in a single district." *In re Celotex Corp. "Technifoam" Prods. Liab. Litig.*, 68 F.R.D. 502, 504 (J.P.M.L. 1975).

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

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

Transfer and consolidation will also avoid subjecting witnesses to multiple depositions on identical subject matter. *See In re M3Power Razor Sys. Mktg. & Sales Prac. Litig.*, 398 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004) ("Section 1407 will offer the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to accommodate all parties' legitimate discovery needs while ensuring that common party and witnesses are not subjected to discovery demands that duplicate activity that will or has occurred in other actions."). Sanofi-aventis expects that the parties will require at least 100 fact depositions.[9] Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications that may impact their ability to travel for deposition. These factors will lengthen both the individual depositions themselves as well as the time necessary to coordinate and complete all fact deposition discovery. The burden on the witnesses of being subjected to two depositions, that may require multiple days of testimony, compels the consolidation of these four actions.

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

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

category of documents related to its claims and defenses are located in Canada, not Florida. *See* Initial Disclosures (Ex. I). Furthermore, both Apotex Inc. and Apotex Corp. have litigated in the Delaware court on at least five separate occasions. (Ex. E, F). In any case, because consolidation by the Panel would be for pretrial proceedings only, the consolidation will not necessarily require Apotex's witnesses to travel to Delaware for depositions or otherwise. *See, e.g. In re MLR, LLC, Patent Litig.*, 269 F. Supp. 2d 1380, 1381 (J.P.M.L. 2003).

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

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

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

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

Mirtazapine Patent Litig., 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, the Panel has stated that it is appropriate that the action be consolidated in the district where the most broadly-based and earliest-filed action is pending. *See In re Regents of Univ. of California*, 964 F.2d 1128, 1136 (Fed. Cir. 1992).

In view of these policies, the District of Delaware is the only forum situated to promote the interests of justice, efficiency, and convenience to all of the parties. The Delaware actions were earliest filed with two of the suits being filed against 13 defendants nearly three months before the Florida action was filed against just two related defendants. The first-filed Delaware actions also encompass all 15 defendants, making them the most broadly-based of the actions. *Id.* Because sanofi-aventis's first-filed Delaware actions are already pending against all defendants in that district, it is most efficient to keep the cases there. Again, Apotex has conceded that jurisdiction and venue are proper in Delaware and has failed to identify any witnesses or documents relating to sanofi-aventis's action against Apotex that are located in Florida. These factors weigh considerably in favor of transfer of the Florida action to the District of Delaware for consolidation with the first-filed Delaware actions.

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

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

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

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

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

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

V. CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Panel transfer *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON, pending in the Southern District of Florida to the District of Delaware, and consolidate that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Labs, Inc.*, No. 07-574 (GMS) (MPT), pending in that District.

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Respectfully submitted,

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153 East 53rd Street
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Attorneys for sanofi-aventis and sanofi-aventis U.S. LLC

EXHIBIT 2

THE APOTEX GROUP
CANADA'S PHARMACEUTICAL COMPANIES

Banner image for the corporateinformation page

Select a Country

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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



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 3

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 4

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.

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 5

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
CLERK

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.

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Dated: September 21, 2007

EXHIBIT 6

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

Dated: September 21, 2007

EXHIBIT 7

KIRKLAND & ELLIS LLP
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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 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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

COMPLAINT

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

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December 6, 2007

EXHIBIT 9

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December 6, 2007

By Federal Express
and Electronic Mail

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Chairman & C.E.O.
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Tammy McIntyre
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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/ng

William T. Vuk

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

Jack Blumenfeld, Esq.
Morris Nichols Arsht & Tunnell

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ANSWER OF APOTEX INC. AND APOTEX CORP.
TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufacturers numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufacturers numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used "throughout the United States", and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs' Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 ("the '491 patent") and that a copy of the '491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 et seq.

Jurisdiction and Venue

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

ANSWER: Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufacturers numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court's personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent

infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia,* its systematic and continuous contacts with Delaware, including through its sister corporation and agent Apotex Corp.

ANSWER: For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

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

ANSWER: Apotex Corp. does not dispute the Court's jurisdiction over it.

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

ANSWER: Apotex, Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action, but believe that the Southern District of Florida is a more convenient venue and that this case should be transferred there and joined with the copending civil action no. 07 C 61800 (S.D. Fla.), in which Apotex, Inc. and Apotex Corp. already have filed answers and counterclaims.

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended

release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

ANSWER: Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

Acts Giving Rise to this Action
Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses to the Complaint:

FIRST DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted.

Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.

3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food,

Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).

7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District and because Apotex Corp. is incorporated in this District.

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

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491 ("the '491 patent"), entitled "ALFUZOSINE COMPOSITIONS AND USE" to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 ("the '940 patent") entitled "TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE" to Lauretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in'940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the '940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The '491 patent and the '940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the '940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.'s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use of sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the'940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s

ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-infringement of the '940 Patent)

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets,

10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;

(b) Declaring that the claims of the '491 patent are invalid;

(c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;

(d) Declaring that the claims of the '940 patent are invalid;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and

(f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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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 11

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.

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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.

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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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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

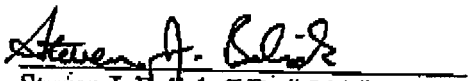
(b) Awarding TorPharm its reasonable attorneys' fees and costs of this action; and,

(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 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MOTION TO TRANSFER, OR IN THE ALTERNATIVE, TO STAY

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") respectfully move this Court, pursuant to 28 U.S.C. § 1404, for an Order transferring this litigation to the Southern District of Florida where an identical lawsuit is pending. Alternatively, Apotex moves for an Order staying this litigation until a resolution is reached in Florida. The grounds for this Motion are fully set forth in Apotex's Opening Brief in Support filed contemporaneously herewith.

Apotex conferred with Plaintiffs regarding this Motion; Plaintiffs will oppose the Motion.

Respectfully submitted,

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Dated: January 24, 2008
843768 / 32533

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ORDER

Having considered Defendants Apotex Inc. and Apotex Corp.'s Motion to Transfer, Or In The Alternative, To Stay, it is hereby ORDERED this _____ day of _____, 2008 that the Motion is GRANTED. This Civil Action is hereby TRANSFERRED to the Southern District of Florida.

_____
UNITED STATES DISTRICT JUDGE

843781

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BACKGROUND

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

I. STATUTORY AND REGULATORY BACKGROUND

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

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

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

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

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

II. STATEMENT OF FACTS

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

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

ARGUMENT

I. PROCEEDING IN FLORIDA WOULD EXPEDITE RESOLUTION OF THIS ACTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Id.

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

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

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

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

CONCLUSION

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

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Dated: January 24, 2008
844301 / 32533

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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

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

NATURE AND STAGE OF THE PROCEEDINGS

This is an action brought under the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. The pleading stage of this action is complete and the parties await an order setting the initial case management conference from the Court.

SUMMARY OF THE ARGUMENT

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

Rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions. Apotex has failed to identify a single witness or document located in Florida. Instead, Apotex admits that it prepared and filed its ANDA from its offices in Canada. Moreover, the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum in which they proceed.

If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of judicial resources as well as the resources of the parties on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses. Apotex's strategy would not only impact the parties in this case, but also the 13 additional defendants now before the Court where sanofi-aventis's other related patent infringement actions will proceed regardless of what happens with respect to sanofi-aventis's claims against Apotex. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and retain this case so that all claims for patent infringement against all 15 defendants may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

STATEMENT OF FACTS

I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. *See* D.I.

1 ¶ 1. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in New Jersey. *See* D.I. 1 ¶ 2.

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

II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." D.I. 1 ¶ 11. It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] D.I. 8 ¶ 12. Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287. D.I. 1 ¶ 11; D.I. 8 ¶ 13.

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1 True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Answering Brief In Opposition To Defendants' Motion To Transfer In Favor Of Pending Florida Jurisdiction, Or In The Alternative To Stay The Delaware Action.

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

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

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

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

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

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

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

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

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

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

patent in this District on December 6, 2007. D.I. 1. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

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

Despite having previously admitted personal jurisdiction in several prior actions in this forum,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. H, 12/06/07 W. Vuk ltr to B. Sherman. It was only after the 45 days had run that Apotex stated that it would not contest jurisdiction in Delaware. Ex. I, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the Delaware complaint and conceded that jurisdiction and venue were proper in this forum:

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

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

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

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before Your Honor and Magistrate Judge Thynge. As of January 7, 2008, all 15 defendants, including Apotex, had filed their answers and counterclaims and sanofi-aventis had filed all of its replies.

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

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

Although sanofi-aventis believed that this Court could properly exercise personal jurisdiction over Apotex, the Southern District of Florida was the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct

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

and representations made in Apotex's certification letters. *See* Exs. B, C. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring the second-filed Florida action within the 45-day window on December 10, 2007. [6] Ex. M, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

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

Ex. M ¶ 19 (emphasis added). Plaintiffs never served the Florida complaint on Apotex. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing before answering in Florida so that sanofi-aventis could voluntarily dismiss that complaint. Plaintiffs have since moved to transfer the Florida action to this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. N, Plaintiff's Florida Motion To Transfer Or Stay.

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

It is now clear that Apotex sought to make an end run around Plaintiffs' choice of this forum. Apotex filed its Answer and Counterclaims in the Florida action on December 28, 2007, one business day before answering the first-filed Delaware complaint.[7] *See* Ex. O, Florida Answer And Counterclaims; Ex. P, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that Florida is "more convenient" with the "fact" that the Florida action has progressed farther than the Delaware actions, arguing that the Florida action is well underway even though the Florida court has not held its initial case management conference and the parties have only exchanged initial disclosures. Ex. Q, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. R, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. S, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1). Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. Q. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have been rejected.

ARGUMENT

I. All Relevant Factors Favor Proceeding In Delaware In Coordination With Related Claims Against 13 Other Defendants

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might

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

have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Jumara v. State Farm Ins. Co.*, 55 F. 3d 873, 879 (3d Cir. 1995). In the Third Circuit, courts consider both private and public interests in this balancing:

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

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

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

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

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

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

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

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Sanofi-aventis had a rational and legitimate reason to choose the District of Delaware because it was the district where Plaintiffs could bring each of the 15 ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. *Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at *2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where plaintiff had a rational and legitimate reason to sue defendants in the forum because, *inter alia*, all parties were subject to personal jurisdiction in that forum); *see also Joint Stock Soc'y v. Heublein, Inc.,* 936 F. Supp. 177, 187 (D. Del. 1996). This District is also where two of the parties, Apotex Corp. and sanofi-aventis U.S. LLC, are incorporated. *See Auto. Techs.*, 2006 WL 3783477 at *2.

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

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

For example, the court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay its second-filed "protective action" based on the "first-filed" rule. No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007). ANDA filer Sun opposed the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *Id.* at *2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

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

Id. (emphasis added). "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay. *Id.*; *Abbott*, 2006 WL 850916 at *8 ("The [Hatch-Waxman Act] is silent, and the courts have not clarified, whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired.").

Courts in the Third Circuit have made similar findings. For example, in *Celgene Corp. v. Abrika Pharm., Inc.,* plaintiffs brought suit for patent infringement under the Hatch-Waxman Act against defendants in the District of New Jersey. No. 06-5818, 2007 WL 1456156, at *1 (D.N.J. May 17, 2007). Plaintiffs filed a nearly identical action two days later in the District of Delaware. *Id.* Recognizing plaintiffs' choice of forum and the first-filed rule, the court declined to transfer the first-filed New Jersey action to Delaware where "Plaintiffs had a legitimate reason to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants." *Id* at *4*; see also Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *cf. Medpointe Healthcare Inc. v. Cobalt Pharm. Inc.,* No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008) (denying transfer from the first-filed forum even though plaintiff had filed both the initial ANDA patent infringement action and the second "protective" suit against the same defendant). The court went on to note that plaintiffs had filed the New Jersey action first, and as here, had not served the complaint in the second-filed Delaware action, "indicating a clear preference that the case move forward in New Jersey." *Id.* Judge Robinson agreed and dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'" *Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007).

The facts here are identical in all relevant respects to those in *PDL* and *Celgene.* Sanofi-aventis was forced by Apotex's refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in Florida. *See, e.g.,* Ex. H; Ex. M ¶ 19. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex Corp.'s incorporation here and Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge jurisdiction. *See* Ex. G; D.I. 7. Apotex can hardly argue that sanofi-aventis's filing of parallel actions are motivated by bad faith or forum shopping. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should move forward with this action in Plaintiffs' forum of choice and not allow Apotex's gamesmanship to dictate where Plaintiffs' claims will proceed.

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

This case is readily distinguishable from *Lupin.* As an initial matter, precedent from this District clearly shows that the first-filed rule is certainly not subject to the mechanical limitation imposed by the *Lupin* court. *See, e.g., Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007); *see also Airport Investors Ltd. P'ship, Inc. v. Neatrour,*

No. 03-831 GMS, 2004 WL 225060, at *2 (D. Del. Feb. 3, 2004) (recognizing that, although not addressed by the parties, "the 'first-filed' rule of this Circuit likely dictates" transfer of the second-filed Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants). Moreover, defendants in *Lupin* contested jurisdiction in the first-filed forum; here, Apotex has stated that it will not contest jurisdiction in Delaware. *Aventis*, 403 F. Supp. 2d at 490; D.I. 7 ¶¶ 7-8, 10. And here, there are related actions pending in this first-filed forum that will proceed regardless of where the Apotex case is tried—a key fact not at issue in *Lupin.* Finally, Plaintiffs have made clear that their sole reason for filing in Florida was to protect their rights due to the ambiguities concerning personal jurisdiction challenges in ANDA cases. Ex. M ¶ 19. District courts post-*Lupin*, such the *PDL*, *Celgene*, and *Abbott* courts discussed above, have clearly recognized the need for filing protective suits under the Hath-Waxman Act and have expressly rejected the Virginia court's limitation on the first-filed rule. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.,* No. 1:07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (refusing to apply the *Aventis* court's "mechanical limitation" and noting "the harsh outcome should [the first-filed forum] dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay" of the second-filed action).

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

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

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

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

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997). Courts have found that the interests of justice are best served when all of a patentees' claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Apotex brushes aside these significant considerations with general claims that the generic products and defenses in the related Delaware actions may

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

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

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.,* a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at *1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at *2; *Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had

not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the court held that all the parties would benefit because:

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

Id. at 888 (internal quotations omitted).

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

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

arguments advanced by each defendant are unpersuasive. *See* D.I. 11 at 7-8. Based on the invalidity arguments presented by defendants in their paragraph IV certification letters, it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each of the proposed generic products is a purported once-a-day formulation referencing Plaintiffs' Uroxatral® product, including its proposed indication. As the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer would lead to multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the defendants may seek discovery. Additionally, transfer would likely lead to duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Florida would force two courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products. *See Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (staying second-filed action pending resolution of jurisdictional issues in first-filed court, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary" where claims against 19 other ANDA defendants were pending in the first-filed forum).

Finally, retaining this case will prevent potentially inconsistent rulings on critical issues such as claim construction, the validity of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to claim construction, where inconsistent rulings could result in the same claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MLR, LLC v. U.S. Robotics Corp.,* No. 02 C 2898, 2003 WL 685504, at *1-2

(N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

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

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

This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art,

and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, this case will take a significant amount of time to resolve regardless of where it proceeds. Any additional time spent litigating does not necessitate transfer from Plaintiffs' choice of forum in light of the juridical economy and witnesses convenience benefits to retaining the case in this District for coordination with the other two related cases.

Moreover, getting low-cost drugs to market is not the only goal of the Hatch-Waxman Act. Rather, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharm. USA, Inc. v. Pfizer, Inc.,* 395 F. 3d 1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 343; *Ben Venue Labs.,* 146 F. Supp. 2d at 579. Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple forums, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market. This result would run counter to the intent of Congress and frustrate a key purpose of the Hatch-Waxman Act.

In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing the Florida action while seeking to delay this case is motivated by the potential for significant financial gain to Apotex if it is able to enter the market with a generic copy of sanofi-aventis' Uroxatral® without competition from the other defendants.[10] Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to continue to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex purposes to espouse. Indeed, the resolution of Plaintiffs' claims will best be expedited under the Hatch-Waxman Act through cooperation between Plaintiffs and all 15 defendants to conduct discovery and other pretrial proceedings in an efficient and coordinated manner.

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

Finally, Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in that district. D.I. 11 at 2, 10; D.I. 7 ¶ 10; Ex. P ¶ 19. As the moving party, Apotex bears the burden of demonstrating that this factor, in the balance of the *Jumara* standard, so strongly favors transfer that Plaintiffs' choice of forum should be disturbed. Apotex doesn't even come close.

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

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

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

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

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

None of these facts weigh in favor of transfer under the *Jumara* convenience factors. Although Apotex has failed to name any witnesses or identify their locations in Florida, it is reasonable to assume that any such witnesses are likely employees of Apotex and could be made available for trial in either Florida or Delaware. *See Jumara,* 55 F. 3d at 879 (stating that the convenience of witnesses is only considered "to the extent that the witnesses may actually be unavailable for trial in one of the fora."); *Pernod,* 2006 WL 3755452 at *3; *Auto. Techs.,* 2006 WL 3783477, at *2 ("Further, as this court has previously held, a flight to Delaware is not an onerous task warranting transfer."); *see also Abbott*, 2006 WL 850916, at *7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). To the extent Apotex contends there are third parties with relevant knowledge in Florida, it has made no showing of who those witnesses are or that they would be unwilling or unable to travel to Delaware for trial; obviously, the parties can work together on a discovery schedule that

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

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

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

to transfer. *See, e.g., ZF Meritor LLC v. Eaton Corp.,* Civ. No. 06-623-SLR, slip op. at 3, (D. Del. June 13, 2007) (refusing to transfer where "[d]efendant is a billion-dollar company with nationwide operations that has litigated in Delaware on multiple occasions."); *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, Civil Action No. 03-1047 GMS, slip op. at 4 (D. Del. Mar. 5, 2004) ("Moreover, short of invoking judicial estoppel, the court finds many of the Defendants' arguments in favor of these factors to be disingenuous considering that [one of Defendants] have brought infringement actions in the District of Delaware on five previous occasions in the last three years."); *see also Abbott,* 2006 WL 850916, at *8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint). In addition, Apotex Corp. is a Delaware corporation. Having enjoyed the benefits of doing business under Delaware law, it cannot complain about proceeding in this judicial forum. Based on these facts, Apotex can surely be expected to bear any minimal, unsupported inconvenience of proceeding in Delaware as it would be greatly outweighed by the burden on sanofi-aventis of proceeding in two separate fora for discovery and other pretrial proceedings, as well as the burden on sanfoi-aventis's and third party witnesses who will likely be called for deposition by Apotex in Florida and by the other 13 defendants in Delaware.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to the Southern District of Florida. *See Alcon*, 2007 WL 854026 at *2-3. The *Alcon* court rejected Apotex's arguments, including its convenience claims. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally. Thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon,* 2007 WL 854026, at *2-3. Second,

Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.*

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

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

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

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

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

CONCLUSION

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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January 31, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
Kenneth L. Dorsney, Esquire
POTTER ANDERSON & CORROON LLP

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

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

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully move the Court to stay all proceedings in this action until the Judicial Panel on Multidistrict Litigation ("the Panel") decides Plaintiffs' motion to transfer this case to the District of Delaware pursuant to 28 U.S.C. § 1407 for consolidation with the parallel, first-filed action against Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") and Plaintiffs' claims against 13 other ANDA defendants for coordinated pretrial proceedings. *See* Ex. 1, JPML Motion and Supporting Brief.[1] Judicial resources will be wasted, inconsistent rulings may result, and sanofi-aventis will be significantly and unfairly prejudiced if this action continues, but is subsequently transferred by the Panel. Conversely, the limited stay requested by Plaintiffs will

[1] True and correct copies of the exhibits cited herein are attached to the accompanying Declaration of Alexis Gorton In Support of Plaintiffs' Emergency Motion to Stay Pending JPML Decision.

not prejudice Apotex as the parties will continue to litigate their claims and defenses in Delaware—the requested transferee forum—in coordination with the 13 other defendants. As various motions now pending before the Court may become moot or otherwise require reconsideration and the parties are engaging in pretrial activities that will likely be redone if the Panel grants Plaintiffs' motion, Plaintiffs request that the Court waive the time requirements of S.D. Fla. L.R. 7.1 and grant an immediate hearing on this motion pursuant to S.D. Fla. L.R. 7.1.E.

In support of their motion and request for an immediate hearing, Plaintiffs state as follows:

1. This is a second-filed action based on Defendants' infringement of United States Patent No. 4,661,491 ("the '491 patent"), a patent assigned to Plaintiff sanofi-aventis which is listed in the FDA's Orange Book for Plaintiff sanofi-aventis U.S. LLC's drug Uroxatral®, by Defendants' Abbreviated New Drug Application ("ANDA") which seeks FDA approval for the commercial manufacture, sale and use of a generic version of that drug.

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

3. On February 1, 2008, Plaintiffs submitted for filing with the Panel a motion for transfer and consolidation pursuant to 28 U.S.C. § 1407. In that motion, Plaintiffs asked the Panel to transfer this action to the District of Delaware and to consolidate it with the three

actions currently pending in that district, including Plaintiffs' case against Defendants, for coordinated pretrial proceedings. Plaintiffs' motion was docketed by the Panel on February 5 and assigned MDL No. 1941.

4. The Panel will likely grant Plaintiffs' motion as each of the relevant factors considered under 28 U.S.C. § 1407 favor transfer and consolidation. First, all four actions involve common questions of law and fact, including the infringement and validity of the '491 and '940 patents. Second, transfer and consolidation will promote the just and efficient conduct of the four actions as only one judge will be required to manage discovery and conduct other pretrial activities and will avoid the potential for inconsistent rulings between this Court and the Delaware court on critical issues such as claim construction. Third, transfer and consolidation will be most convenient to the parties and witnesses as they will only have to conduct discovery, or appear for deposition, in one forum on a unified schedule. Finally, transfer will further the goals of the Hatch-Waxman Act as all 15 ANDA defendants will be on equal footing, proceeding on a unified schedule in one court.

5. Further, the Panel is likely to order that all four actions should proceed in Delaware as it is the forum in which the most broadly-based and earliest-filed actions, and where Plaintiffs' claims against all 15 defendants, are pending.

6. The Court should exercise its discretion and issue an immediate stay of all proceedings in this action pending the Panel's decision. First, a stay will conserve judicial resources as this Court will not have to become an expert in the technology at issue or manage discovery and other pretrial activities, including ruling on the various motions pending before the Court, that may be reconsidered or vacated if the Panel grants Plaintiffs' motion. Second, a stay will prevent inconsistent rulings between this Court and the Delaware court. Third, a stay will

prevent the parties from having to conduct discovery and other pretrial activities in two separate courts and will avoid sanofi-aventis's and third party witnesses, many of whom are likely located outside of the United States, from having to appear for deposition on multiple occasions. Finally, there is no hardship to Defendants as Plaintiffs' requested stay can be lifted as soon as the Panel decides Plaintiffs' motion and the parties can continue to litigate their claims and defenses in Delaware while this action is stayed. In any event, any claimed hardship by Defendants would be greatly outweighed by the conservation of judicial resources, potential for inconsistent rulings, and hardship to Plaintiffs and the witnesses if this action proceeds.

7. Plaintiffs have requested a stay through the emergency motion procedure of S.D. Fla. L.R. 7.1.E so that the Court may waive the time requirements of S.D. Fla. L.R. 7.1 and grant an immediate hearing on this issue. This expedited procedure is necessary as there are various motions pending before the Court, including Plaintiffs' Motion to Continue Pretrial Deadlines and Trial (D.I. 12), Defendants' Motion for Protective Order (D.I. 25), Defendants' Motion for Extension of Time to File Joint Scheduling Report (D.I. 29), and Plaintiffs' Motion For Leave to File Scheduling Report and Proposed Scheduling Order (D.I. 30). Without a stay, the Court and the parties will waste time and resources addressing these issues that will become moot or may otherwise be reconsidered if the Panel grants Plaintiffs' motion. Moreover, the parties will have to continue to engage in various other pretrial activities that will likely have to be redone in coordination with the 13 additional defendants in Delaware.

8. Pursuant to S.D. Fla. L.R. 7.1.A.3(a), Plaintiffs' counsel conferred with Defendants' counsel in a good faith effort to resolve the issues raised by this Motion. No resolution was obtained.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully request that the Court enter an Order granting Plaintiffs' Emergency Motion to Stay Pending JPML Decision. Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC further request that the Court, pursuant to S.D. Fla. L.R. 7.1.E, waive the time requirements of S.D. Fla. L.R. 7.1 and grant an immediate hearing to address the issues presented herein.

MEMORANDUM OF LAW

The four actions subject to Plaintiffs' JPML motion all involve the same patents and ANDAs filed for the same reference product. The Panel is likely to grant Plaintiffs' motion because the cases clearly involve common questions of law and fact, such as the infringement and validity of the patents-in-suit, and consolidation will promote a just and efficient resolution of Plaintiffs' disputes with all 15 defendants and best serve the convenience of the parties and witnesses as they will only have to participate in discovery and other pretrial activities in one forum on a unified schedule. Moreover, the Panel is likely to consolidate the actions in Delaware, where the most broadly-based and earliest-filed actions are currently pending.

Consequently, the Court should exercise its discretion and stay the present action pending the Panel's decision. Without a stay, this Court will have to expend valuable judicial resources becoming an expert on the technology at issue and in managing discovery and other pretrial activities. A stay will not only preserve these resources, but will avoid the potential for inconsistent rulings with the Delaware court on key issues such as claim construction. Without a stay, the parties will be forced to participate in discovery in two separate fora and sanofi-aventis's and third party witnesses may be called for deposition at various times by both Apotex in Florida and the other 13 defendants in Delaware. There is no hardship to Apotex to weigh against these

considerations as this case is in its early stages, the stay can be lifted as soon as the Panel decides Plaintiffs' motion, and the parties can continue to move forward in the Delaware action.

Finally, there is good cause for the Court to consider this motion on an emergency basis because it will conserve the Court's and the parties' resources as there are various pending motions that will become moot or require reconsideration if the Panel grants Plaintiffs' motion and the parties are currently engaging in pretrial activities that will likely have to be redone in coordination with the 13 other defendants in the related Delaware actions.

BACKGROUND

I. The Parties, Patents and Products

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. Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] 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.

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

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. 2, The Apotex Group Corporate Info.

Apotex notified sanofi-aventis by letter dated August 14, 2007 that it had filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval for the commercial manufacture, use and sale of a generic version of Uroxatral® and a "paragraph IV certification" alleging that the proposed product would not infringe any valid claim of the '940 patent. Ex. 3, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG. Apotex subsequently notified sanofi-aventis by letter dated October 25, 2007 that it had amended its ANDA to include a paragraph IV certification against the '491 patent. Ex. 4, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG. Sanofi-aventis received notification of eight other ANDA filings during the Summer of 2007; each included paragraph IV certifications against the '491 and/or '940 patents. 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).

II. Delaware Actions

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 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. *See* Ex. 5, Delaware Complaint No. 07-572; Ex. 6, Delaware Complaint No. 07-574.

Sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent shortly thereafter in response to its paragraph IV certification against that patent.[3] Ex. 8, Apotex Delaware Complaint. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge. Though Apotex refused to consent to jurisdiction in Delaware until after sanofi-aventis's 45-day window to bring suit expired, Apotex's answer in Delaware confirms that it will not contest jurisdiction and that Delaware is an appropriate venue for this action. *See* Ex. 9, 12/06/07 W. Vuk ltr to B. Sherman; Ex. 10, Apotex Delaware Answer.

III. Florida Action

Apotex's refusal to consent to jurisdiction in Delaware within the 45-day window, despite having previously proceeded in several prior actions without contesting personal jurisdiction,[4]

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[3] 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. 7, 10/01/07 W. Vuk ltr to B. Tao.

[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has proceeded in the District of Delaware without contesting jurisdiction. *See* Ex. 11, Compilation of

forced sanofi-aventis to file a second suit in this District where it knew Apotex would not contest jurisdiction based on prior litigation conduct and representations made in its notice letters. D.I. 1¶ 19. Without this second-filed "protective" suit, sanofi-aventis may have been barred from bringing any action under the Hatch-Waxman Act, and thus lose the 30-month stay of generic approval, if Apotex successfully challenged jurisdiction in Delaware.[5] Sanofi-aventis's intent on this point was clear from the filing of the complaint December 10, 2007. *See* D.I. 1¶ 19.

IV. The Parties' District Court Motions to Transfer or Stay

In response to Apotex's consent to jurisdiction in Delaware, sanofi-aventis moved to transfer this action to that first-filed forum or, in the alternative, to stay this action pending resolution of the venue issues raised by Apotex in the Delaware court. D.I. 5-1. Apotex has opposed that motion and has also moved the Delaware court to transfer its action here; sanofi-aventis has opposed that motion. D.I. 26-1; Ex. 12, Apotex's Delaware Motion to Transfer; Ex. 13, Plaintiffs' Delaware Opposition. The briefing on both motions will be complete in the next week.

V. Plaintiffs' JPML Motion

On February 1, 2008, sanofi-aventis submitted for filing with the Panel a motion to transfer and consolidate this matter pursuant to 28 U.S.C. § 1407. Ex. 1. In that motion, sanofi-

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Apotex Delaware Complaint and Answers. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. *Id.*

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

aventis asked the Panel to transfer this action to the District of Delaware and to consolidate it with the parallel first-filed action against Apotex and two related actions against the 13 other ANDA defendants, pending in that District. The Panel docketed Plaintiffs' motion on February 5 and assigned the matter MDL No. 1941.

ARGUMENT

The Court has the power to stay this action and should exercise its discretion to do so until the Panel decides Plaintiffs' motion for transfer and consolidation. *See Landis v. No. Am. Co.*, 299 U.S. 248, 254 (1936) (noting that the power to stay "is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants."). As the Court has recognized, "[i]t is common practice for courts to stay an action pending a transfer decision by the JPML." *Bonenfant v. R. J. Reynolds Tobacco Co.*, No. 07-60301-Civ., 2007 WL 2409980, at *1 (S.D. Fla. July 31, 2007) (citing *Republic of Venez. v. Phillip Morris Cos., Inc.*, No. 99-0582-Civ., 1999 WL 33911677, at *1 (S.D. Fla. Apr. 28, 1999) ("granting a stay pending the JPML's decision of the Motion to Transfer and Consolidate")); *see also Rivers v. Walt Disney Co.*, 980 F. Supp. 1358, 1362 (C.D. Cal. 1997) (noting that "it appears that a majority of courts have concluded that it is often appropriate to stay preliminary pretrial proceedings while a motion to transfer and consolidate is pending with the MDL Panel"); 15 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice and Procedure* § 3866.1 (3d ed. 1998) ("[D]istrict courts often will exercise their discretionary power to stay the proceedings before them with regard to a variety of matters pending a decision by the Panel regarding the transfer of a case, especially when such a stay would further the policies of judicial economy, efficiency, and consistency that are deeply embedded in the federal multidistrict litigation statute."). In fact, courts commonly stay such actions because "[a] stay pending the [JPML]'s decision can increase the efficiency and

consistency, particularly when the transferor court believes that a transfer order is likely and when the pending motions raise issues likely to be raised in other cases as well." *Bonenfant*, 2007 WL 2409980, at *1 (quoting *Manual for Complex Litigation* § 22.35 (4th ed. 2004)). Here a stay will conserve judicial resources, prevent inconsistent rulings, and avoid the burden to the parties of proceeding in this action in the likely event that the Panel grants Plaintiffs' motion. *See Rivers*, 980 F. Supp. at 1360 (explaining that the court, in ruling on a motion to stay, "should consider three factors: (1) potential prejudice to the non-moving party; (2) hardship and inequity to the moving party if the action is not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases are in fact consolidated"); *Mathern v. Wyeth*, No. Civ.A.04-2116, 2004 WL 1922028, at *1 (E.D. La. Aug. 25, 2004) (finding that a stay pending transfer to an MDL would promote judicial efficiency and avoid conflicting rulings).

I. The Panel Will Likely Transfer This Action To Delaware For Consolidated Pretrial Proceedings

In evaluating a motion for transfer and consolidation, the Panel considers whether the actions sought to be consolidated involve common questions of fact, whether consolidation will promote a just and efficient resolution of the parties' disputes, and whether transfer and consolidation will best serve the convenience of the parties and witnesses. *See* 28 U.S.C. § 1407; *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) ("[W]e find that these three actions involve common questions of fact, and that centralization under Section 1407 in the [first-filed District] will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."). As each of these considerations weigh in favor

of transfer here, the Panel is likely to grant Plaintiffs' motion and transfer this action to Delaware for consolidation with the three cases currently pending in that forum.[6]

First, all four actions share common issues of law and fact as they each relate to the infringement and validity of the '491 and/or '940 patents and proposed generic versions of Uroxatral®. *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005) (stating that, because all three actions sought to be consolidated involved claims that generic products infringed one or more of the same patents, "[t]he actions can thus be expected to share factual and legal questions . . . ."); *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("Several opposing defendants argue that centralization is not warranted in light of the fact that issues of patent infringement are unique in each action, because each defendant's allegedly infringing formulation is different. We disagree."); *In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976) (holding that common issues of validity "justify transfer"). Second, transfer and consolidation will promote the just and efficient conduct of the actions as only one court will be required to manage discovery and conduct other pretrial proceedings while becoming an expert in the technology at issue to perform those functions. It will also prevent inconsistent rulings on critical issues such

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[6] The Panel will likely consolidate all four actions for pretrial proceedings in the District of Delaware. *See In re Desloratadine Patent Litig*, 502 F. Supp. 2d at 1355 (noting that actions should be centralized in the district that will best "serve the convenience of the parties and witnesses and promote the just and efficient conduct of th[e] litigation."). The Panel has previously recognized the advantage of consolidating cases in a district where one of the actions is pending. *See, e.g., In re Mirtazapine Patent Litig.*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, the Panel has stated that it is appropriate that the actions be consolidated in the district where the most broadly-based and earliest-filed action is pending. *See In re Regents of Univ. of Cal.*, 964 F.2d 1128, 1136 (Fed. Cir. 1992). Here, the earliest-filed and most broadly based suit is against 12 defendants and is pending in Delaware—the first-filed forum for all of Plaintiffs' claims concerning the patents-in-suit.

as claim construction which could lead to the same terms having different meanings for different defendants. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will . . . prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim construction; and conserve the resources of the parties, their counsel and the judiciary."). Third, transfer and consolidation will be most convenient to the parties and witnesses as they will only have to conduct discovery, or appear for deposition, in one forum on a unified schedule. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will eliminate duplicative discovery . . . ."); *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001) (explaining that centralization would effectuate "an overall savings of cost and a minimum of inconvenience to all concerned").

Moreover, transfer and consolidation will further the goals of the Hatch-Waxman Act as all 15 ANDA defendants will proceed on the same schedule and footing in one forum. *See In re Gabapentin*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (transferring and consolidating ANDA actions and dismissing as "misplaced" the defendants' argument that "transfer will engender further delays in a litigation in which time is of the essence"); *In re Nabumetone Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (same).

II. A Stay In This Case Will Promote Judicial Efficiency And Avoid Inconsistent Rulings

A single district court will preside over all pretrial proceedings if the Panel grants Plaintiffs' motion. Without a stay, this Court will invest substantial time and energy in making pretrial rulings that may be reconsidered or vacated if the Panel grants Plaintiffs' motion. As one district court noted in granting a motion to stay pending the Panel's decision: "If the MDL

motion is granted, all of the Court's time, energy, and acquired knowledge regarding this action and its pretrial procedures will be wasted." *U.S. Bank v. Royal Indem. Co.*, No. CIV.A.3:02-CV-0853-P, 2002 WL 31114069, at *2 (N.D. Tex. Sept. 23, 2002). Thus, the Court should not expend resources "familiarizing itself with the intricacies of a case that would be heard by another judge" who will likely have to replicate the efforts of this Court." *Rivers*, 980 F.Supp at 1360-61. By way of example, the transferee court will have to set a schedule for discovery and other pretrial proceedings for Plaintiffs and all 15 ANDA defendants. Consequently, any schedule set by this Court based on the parties' requests will have to be reconsidered. *See* D.I. 12; D.I. 29; D.I. 30. Likewise, the transferee court will have to reconsider or vacate any protective order entered by this Court to account for the needs of not only sanofi-aventis and Apotex, but also the other 13 defendants in the related Delaware actions. *See* D.I. 25.

A stay would also eliminate the potential for conflicting pretrial rulings between this Court and the Delaware court on key issues such as claim construction. *See Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft*, 48 F. Supp. 2d 37, 43 (D.D.C. 1999) (finding that a stay pending an MDL decision would "eliminate the potential for conflicting pretrial rulings."). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming, Without a stay, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings which could lead to the same claim terms have different meanings for different defendants. If this case is transferred, the transferee judge

may still modify or rescind any orders made by the transferor courts. *See Astarte Shipping Co. v. Allied Steel & Export Serv.*, 767 F.2d 86, 87 (5th Cir. 1985) (noting that "[t]he transferee district court has the power and the obligation to modify or rescind any order in effect in the transferred case which it concluded are incorrect); *Weinke v. Microsoft Corp.*, 84 F. Supp. 2d 989, 990 (E.D. Wis. 2000) (granting motion to stay "in the interest of judicial economy and to avoid inconsistent results"); *D's Pet Supplies, Inc. v. Microsoft Corp.*, Nos. 99-76056, 99-76086, 99-76202, 00-70481, 2000 WL 34423492, at *1 (E.D. Mich. May 19, 2000) (staying proceedings to serve the interests of justice and minimize the risk of inconsistent rulings).

III. The Balance Of Hardships In This Case Clearly Warrants A Stay

Sanofi-aventis will be substantially prejudiced if it is forced to simultaneously litigate pretrial matters in two courts in parallel. *See Am. Seafood v. Magnolia Processing, Inc.*, Nos. 92-1030, 92-1086, 1992 WL 102762, at *2 (E.D. Pa. May 7, 1992) (holding that "[t]he duplicative motion practice and discovery proceedings demonstrate that judicial economy and prejudice … weigh heavily in favor of [a] stay"). Without the protection of a stay, sanofi-aventis will be required to seek and provide the same discovery twice and engage in other duplicative pretrial activities. The result will be undue hardship to sanofi-aventis, especially if this action proceeds on a different schedule than the Delaware action where the other 13 ANDA defendants will have to continue to participate.

Staying this case will also avoid subjecting witnesses to multiple depositions on identical subject matter. Sanofi-aventis expects that Plaintiffs and the 15 ANDA defendants will require

upwards of 100 fact depositions.[7] Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications. These factors will lengthen both the individual depositions themselves as well as the time necessary to coordinate and complete all fact deposition discovery. Duplicating these efforts in two fora would burden the witnesses and lead to the unnecessary expenditure of the resources of the courts and sanofi-aventis and courts consistently acknowledge that duplicative litigation is burdensome and supports a stay. *See, e.g., I.A. Durbin, Inc. v. Jefferson Nat'l Bank*, 793 F.2d 1541, 1551-52 (11th Cir. 1986) (noting that "[t]rial courts are afforded broad discretion in determining whether to stay or dismiss litigation in order to avoid duplicating a proceeding already pending in another federal court"); *Gov't of Virgin Is. v. Neadle*, 861 F. Supp. 1054, 1055 (M.D. Fla. 1994) (noting that the general principle of the standard for granting a stay of related proceedings "is to avoid duplicative litigation"); *Anderson v. Merck & Co. Inc.*, 417 F. Supp. 2d 842, 849 (E.D.Ky. Feb. 28, 2006) (staying proceedings to "'provide for the convenience of the parties and witnesses and ... promote the just and efficient conduct' of complex matters") (quoting 28 U.S.C. § 1407).

While sanofi-aventis faces a substantial risk of prejudice in the absence of a stay, the risk of prejudice to Apotex is minimal, especially given that the requested stay will be in effect only until the Panel issues its decision. Thus, there will be no indefinite delay in the litigation. *See Republic of Venez.*, 1999 WL 33911677, at *1 (finding no prejudice by the granting of a brief

[7] It is likely that the parties will seek deposition testimony from the eight inventors named on the patents-in-suit and a variety of other witnesses with knowledge of the alleged prior art, Urotraxal®, the proposed generic products, including the decision to file, the preparation and submissions of each of the nine ANDAs, the research, development and formulation pertaining to the proposed generic products, as well as marketing and regulatory issues.

stay pending the Panel's decision). Additionally, the short duration of the stay is particularly harmless in light of the fact that this action is at an early stage. For example, the parties have not had their initial case management conference with the Court and discovery has been limited to the exchange of initial disclosures and Apotex's service of document requests. Moreover, the parties' claims and defenses will proceed in the Delaware action, where all 15 defendants will continue to participate. Thus, Apotex will suffer no significant prejudice by a limited delay in pretrial proceedings in this forum pending the Panel's ruling. Indeed, the prejudice to Plaintiffs and the witnesses that would result if these proceedings continue would far outweigh any harm that Apotex may claim.

IV. The Court Should Consider This Motion On An Emergency Basis

There is good cause for the Court to treat this motion on an emergency basis under S.D. Fla. L.R. 7.1.E. First, there are various motions currently pending before the Court that will likely be mooted or require reconsideration if the Panel grants Plaintiffs' motion for transfer and consolidation. For example, three of the parties' pending motions address the schedule for discovery and other pretrial proceedings in this case. D.I. 12; D.I. 29; D.I. 30. If the Panel grants Plaintiffs' motion and consolidates all four actions for pretrial proceedings, the transferee court will have to set a new schedule for discovery, claim construction, and other pretrial activities for Plaintiffs and all 15 defendants regardless of the forum in which the cases are consolidated. Thus, the Court should not expend time and resources to consider the parties' competing proposals and set a schedule which will have to be reconsidered or vacated by the transferee court. Likewise, Plaintiffs and all 15 defendants in the four actions will have to meet and confer on the terms of a suitable Protective Order, meaning that any such order entered by this Court would again be reconsidered or vacated. *See* D.I. 25.

Second, the parties are currently conducting pretrial activities that will likely have to be redone upon consolidation by the Panel, including meet and confers concerning the procedures and form of electronic discovery and the exchange of discovery requests and responses. This is particularly true if the transferee forum has guidelines for the parties to use in their discussions concerning electronic discovery and sets limits on discovery requests that would effect all 15 defendants collectively. *See* Ad Hoc Comm. for Elec. Discovery of the U.S. District Court for the District of Delaware, Default Standard for Discovery of Electronic Documents (E-Discovery"), available at http://www.ded.uscourts.gov/OrdersMain.htm (last visited Feb. 7, 2008).

Thus, waiving the time requirements under S.D. Fla. L.R. 7.1 and holding an immediate hearing on Plaintiffs' motion to stay will conserve the time and resources of the both the Court and the parties so that these activities can temporarily be stayed pending the Panel's decision.

CONCLUSION

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

Dated: February 7, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 7, 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.

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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
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(Miami Division)

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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' EMERGENCY MOTION TO STAY PENDING JPML DECISION

THIS CAUSE is before the Court on Plaintiffs' Emergency Motion to Stay Pending JPML Decision, filed on February 7, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiffs' Emergency Motion to Stay Pending JPML Decision is GRANTED. This Civil Action is hereby STAYED until the Judicial Panel on Multidistrict Litigation renders a decision in MDL No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

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

Honorable Federico A. Moreno
United States District Court Judge

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

PLAINTIFFS' REQUEST FOR ORAL ARGUMENT ON
PLAINTIFFS' EMERGENCY MOTION TO STAY PENDING JPML DECISION

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC, pursuant to S.D. Fla. L.R. 7.1B, respectfully request oral argument on Plaintiffs' Emergency Motion to Stay Pending JPML Decision. Plaintiffs' motion addresses the complex factual and procedural history that lead to Plaintiffs filing of this action as well as their motion with the Judicial Panel on Multidistrict Litigation. Oral argument would be helpful as it would provide the parties with an opportunity to address these issues, and respond to the Court's questions on them, as well as the likelihood that the Panel will transfer this action to Delaware and the impact that transfer will have on the ongoing activities of the Court and the parties if this action is not stayed.

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

Dated: February 7, 2008

Respectfully submitted,

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I HEREBY CERTIFY that on February 7, 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.

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SERVICE LIST

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

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

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

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

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
/

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER OR STAY

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this reply brief in further support of their motion to transfer this action to the District of Delaware, where an identical, first-filed action against Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") and Plaintiffs' claims against 13 other defendants for infringement of the patents-in-suit are pending. Contrary to Apotex's assertions, various courts, including this District, have applied the first-filed rule where plaintiffs brought identical actions against the same defendants in different districts. The courts have also expressly recognized the need for bringing second-filed "protective" suits, such as this action, in ANDA litigation due to the ambiguities concerning jurisdictional challenges under the Hatch-Waxman Act and the serious risks patentees face if their first-filed actions are dismissed—namely the loss of the 30-month stay of generic approval while a patent litigation is pending. As discussed below, the balance of relevant factors does not favor deviation from the uniformly applied first-filed rule. Moreover, this rule not only applies to the merits of the venue dispute, but also dictates that the

second-filed court should defer to the first-filed court on where the actions should proceed. The Court should therefore not "take the lead" as Apotex suggests, but should stay this action pending Delaware's ruling on venue if it decides not to transfer the case at this time.[1]

I. The First-Filed Rule Applies Even When Plaintiff Brings Both ANDA Actions

As discussed in Plaintiffs' motion, Delaware is Plaintiffs' forum of choice and the first-filed forum, not only for the Apotex action, but also for their claims against 13 other ANDA defendants which must proceed in Delaware regardless of where this case is tried. D.I. 5-1 at 11-12. Apotex ignores the forum of choice factor, including the fact that a plaintiff's choice of forum should rarely be disturbed unless outweighed by other considerations, and incorrectly states that the "first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues." *See* D.I. 26-1 at 9. Courts have routinely rejected such arguments, transferring, dismissing, or staying second-filed ANDA cases in recognition of the jurisdictional ambiguities of the Hatch-Waxman regime and the serious risks to patentees if their first-filed actions are dismissed. *See* D.I. 5-1 at 11-12, 18-20.[2]

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[1] True and accurate copies of the Exhibits 1-19 cited herein are attached to the Declaration of William T. Vuk in Support of Plaintiffs' Motion to Transfer or Stay. D.I. 6. True and accurate copies of Exhibits 20-23 cited herein are attached to the accompanying Declaration of Alexis Gorton in Support of Plaintiffs' Motion to Transfer or Stay.

[2] *See, e.g.,* 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 (granting limited stay of second-filed ANDA action while first-filed court decided jurisdictional issues); *PDL Biopharma, Inc. v. Sun Pharm. Ind., Ltd.,* No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007) (staying second-filed ANDA action and recognizing the need for "protective" suits as a successful jurisdictional challenge in the first-filed court could preclude the patentee from bringing any suit under the Hatch-Waxman Act); *Celgene Corp. v. Abrika Pharms., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (dismissing second-filed action because the court was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'"); *Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (staying second-filed ANDA action while first-filed court, where claims against 19 other ANDA defendants were pending, decided jurisdictional issues, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary"); *Celgene Corp. v. Abrika Pharms., Inc.,* No. 06-5818, 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007)

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

This case is readily distinguishable from *Lupin.* As an initial matter, precedent from this District shows that the first-filed rule is certainly not subject to the mechanical limitation imposed by the *Lupin* court. *See* Ex. 19 at 12-13; *Manuel v. Convergys Corp.,* 430 F.3d 1132, 1135, 1135-38 (11th Cir. 2005); *Philibert v. Ethicon, Inc.,* No. 04-81101-CIV, 2005 WL 525330, at *1 (S.D. Fla. Jan 14, 2005).[3] Moreover, defendants in *Lupin* contested jurisdiction in the first-filed forum; here, Apotex has stated that it will not contest jurisdiction in Delaware. *Aventis*, 403 F. Supp. 2d at 488; Ex. 12 ¶¶ 7-8, 10. And here, there are related actions pending in the first-filed forum that will proceed regardless of where the Apotex case is tried—a key fact not at issue

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(denying motion to transfer first-filed action where "Plaintiffs had a legitimate reason to file a similar, even identical action in [the second-filed forum], in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California 'in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application' sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *Abbott Labs. v. Mylan Pharms., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006); *cf. Medpointe Healthcare Inc. v. Cobalt Pharms. Inc.,* No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008).

[3] Apotex does not address *Manuel* and does not contest that the *Philibert* court applied the first filed rule even though plaintiffs filed two identical actions. D.I. 26-1 at 10. Rather, Apotex merely points out that the *Philibert* court did not deviate from the first-filed rule because the moving party did not show the balance of convenience favored transfer. *See id.* Here the Court should not deviate from the first-filed rule as the balance of factors supports transfer.

in *Lupin.* 403 F. Supp. 2d at 489 (noting that "the first to file rules applies in context not present in this case [where] one patent is involved but there are multiple defendants in different forums. . . ."). Finally, Plaintiffs have made clear that their sole reason for filing in Florida was to protect their right to a 30-month stay in the event that the Delaware action was dismissed for lack of personal jurisdiction. Ex. 16 ¶ 19. District courts post-*Lupin*, such as the *PDL*, *Celgene*, and *Abbott* courts, have recognized the need for filing ANDA "protective" suits and have expressly rejected *Lupin's* limitation on the first-filed rule. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.,* No. 1:07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (refusing to apply the *Lupin* court's "mechanical limitation" and noting "the harsh outcome should [the first-filed forum] dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay" of the second-filed action).

Apotex's reliance on *Adams Respiratory Therapy v. Mut. Pharm. Holdings*, Civil Action No. 06-4700 HAA, slip op. (D.N.J. Nov. 16, 2006), is also misplaced. D.I. 26-1 at 11-12. The primary concern of the *Adams* court was judge shopping. D.I. 26-4 at 2. Here, Plaintiffs were not judge shopping, but were merely trying to ensure that their claims would go forward with the protections afforded to them under the Hatch-Waxman Act if Apotex successfully challenged personal jurisdiction in Delaware. Plaintiffs' intention was clear—they sought Apotex's consent to jurisdiction in Delaware prior to filing the Florida action and never served the Florida complaint. Exs. 9, 16 ¶ 19; *Celgene*, 2007 WL 1456156 at *4 (noting a clear indication that plaintiffs preferred the first-filed forum as they did not serve the second-filed complaint). And as in *Lupin*, the *Adams* court did not appreciate the serious consequences patentees face due to the jurisdictional ambiguities under the Hatch-Waxman regime if they do not file second, "protective" suits in certain circumstances. Moreover, the *Adams* opinion has not been followed

in the issuing forum. *See Celgene*, 2007 WL 1456156, at *1, 4.[4]

II. Without Transfer, Two Courts Must Squander Scarce Judicial Resources Conducting Identical Pretrial Activities

Apotex's contention that transfer "will not conserve judicial resources" defies all logic. *See* D.I. 26-1 at 6. Regardless of where Plaintiffs' claims against Apotex proceed, the two related actions against 13 additional defendants for infringement of the same two patents based on ANDA filings for the same reference product at issue here must go forward in Delaware. D.I. 5-1 at 10, 14. Without transfer both this Court and the Delaware court will be forced to become experts in the technology at issue, manage discovery, and conduct pretrial proceedings on identical or similar issues. D.I. 5-1 at 14-15. Apotex brushes aside these significant considerations with general claims that the generic products and defenses in the related Delaware actions may be different rendering the benefits of transfer "illusory." *See* D.I. 26-1 at 4-6. Based on the invalidity arguments presented by all 15 defendants in their paragraph IV certification letters it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each ANDA references Plaintiffs' Uroxatral® product, including its proposed indication. As the issues with respect to the reference product and the patents-in-suit are identical, failure to transfer would lead to multiple depositions of the same witnesses concerning Plaintiffs' research and development, patent prosecution and regulatory and marketing activities. Moreover, transfer will avoid potentially inconsistent pretrial rulings, such as on claim construction which could result in identical claim terms having different meanings for different defendants. D.I. 5-1 at 15.

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[4] The other cases cited by Apotex are no more persuasive. *See* D.I. 26-1 at 9-10. For example, in *Bristol-Myers Squibb Co. v. Andrx Pharms., LLC,* the court transferred to the district in which the ANDA was created, a fact not present here as discussed below. No. 03 Civ. 2503(SHS), 2003 WL 22888804, at *3 (S.D.N.Y. Dec. 5, 2003). Moreover, that case did not involve two-related, pending actions in the transferor forum and predates the various opinions cited above that have recognized the need to file "protective" suits in ANDA actions.

III. Any Alleged Inconvenience To Apotex Is Greatly Outweighed By The Hardships To The Parties and Witnesses of Proceeding In Two Separate Fora

Apotex also argues that the convenience of the witnesses weighs against transfer, but does not support its contention. *See* D.I. 26-1 at 7-8. For example, Apotex states that Apotex Corp., located in Florida, "will market and sell the allegedly infringing []product" citing the declaration of Apotex Corp.'s president, Tammy McIntire. D.I. 26-1 at 2. Nothing in Ms. McIntire's barely two-page declaration, however, supports this allegation. D.I. 26-2. In fact, she does not identify a single event, witness, or document with any connection to Florida that is relevant to this case.[5] The declaration submitted by Apotex Inc.'s director of regulatory affairs, Bernice Tao, does not say much more. D.I. 26-3. The sole link to Florida provided by Ms. Tao is that Apotex listed Ms. McIntire in Weston, Florida as the agent for service in Apotex Inc.'s paragraph IV certification letters.[6] *Id.* ¶ 9. As discussed in Plaintiffs' motion, the same Apotex convenience arguments were rejected by the court in *Alcon Mfg., Ltd. v. Apotex Inc.,* No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026, *2-3 (S.D. Ind. Mar. 14, 2007). D.I. 5-1 at 16-17.[7]

Ms. Tao's declaration confirms that Apotex "prepared and filed ANDA 79-013 from its offices in Canada." D.I. 26-3 ¶ 5.[8] It is therefore likely that the witnesses with knowledge of

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[5] Instead, Ms. McIntire merely says that :"To the extent any Apotex Corp. employees are knowledge about ANDA No. 79-013 they are employed at the Florida location;" and "[t]o the extent Apotex Corp. has any documents relevant to ANDA No. 79-013 they are located at Apotex Corp.'s Florida location. D.I. 26-2 ¶¶ 5, 6.

[6] Likewise, Apotex also failed to list any witnesses or documents located in Florida in its initial disclosures. Ex. 21, Defendants Apotex's Initial Disclosures.

[7] Apotex argues that *Alcon* is inapposite because, *inter alia*, Plaintiffs bear the burden of proof with respect to this motion, but does not deny the fact that it is making the same convenience arguments in this case that were rejected in *Alcon*. *Compare* D.I. 26-1 at 8 *to* D.I. 5-1 at 16-18.

[8] Likewise, Canada, not Florida, appears to be the situs of operative events concerning Apotex that lead to the litigation. D.I. 11 at 10-11. *Compare Alcon Mfg., Ltd. v. Apotex Inc.,* No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026, at *2-3 (S.D. Ind. Mar. 14, 2007) (finding that operative events took place where Apotex prepared its ANDA and where plaintiffs conducted research and development) *to Bristol-Myers*, 2003 WL 22888804, at *3 (noting that the design and

Apotex's study of Uroxatral®, its research, development and testing of its proposed generic product, and its study of the patents-in-suit and the prior art cited in its notice letters are located in Canada and will have to travel for deposition and trial whether this case proceeds in Delaware or Florida. To the extent any witnesses are actually present in this District, they are likely employees of Apotex and there is nothing to indicate that they would be unable to travel to Delaware. *See 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.").

Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA cases, including at least one as a plaintiff, without complaint. *See* Exs. 1, 8. In addition, Apotex Corp. is a Delaware corporation. Ex. 12 ¶ 4. Accordingly, Apotex can surely be expected to bear any minimal, unsupported inconvenience of proceeding in Delaware as it would be greatly outweighed by the burden on sanofi-aventis of proceeding in two separate fora for discovery and other pretrial proceedings, as well as the burden on sanofi-aventis's and third party witnesses who will likely be called for deposition by Apotex in Florida and by the other 13 defendants in Delaware.

IV. Transfer Would Further the Goals of the Hatch-Waxman Act

Apotex repeatedly argues that the Court must retain this action to further the Hatch-Waxman Act's goal of getting low-cost drugs into the hands of consumers. *See, e.g.,* D.I. 26-1 at 3. What Apotex fails to mention is that this is not the only goal of the Hatch-Waxman Act. Rather, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.,* 395 F. 3d

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development of the allegedly infringing product occurred in the second-filed forum).

1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act.

In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing this case while seeking to delay the Delaware action is motivated by the potential for significant financial gain to Apotex if it is able to enter the market with a generic copy of Uroxatral® without competition from the other defendants.[9] Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex proposes to espouse. Indeed, the resolution of Plaintiffs' claims will best be expedited through cooperation between Plaintiffs and all 15 defendants, including Apotex, in Delaware to conduct discovery and other pretrial proceedings in an efficient and coordinated manner.

Moreover, and contrary to Apotex's assertion, litigation in this District is not "well

[9] Apotex's delay is evidenced by the timing of its motion to transfer in Delaware. Apotex first alerted the Delaware court that it preferred this District on January 2, 2008. Ex. 12 ¶ 10. Apotex then confirmed during a meet and confer with Plaintiffs on January 7 that it would move to transfer the Delaware action to this District. Ex. 14. But Apotex waited another three weeks before filing its motion, after the parties exchanged their local rule disclosures in Florida and it was entitled to serve document requests in this action. *See* Ex. 22, Apotex's DE Motion.

underway." D.I. 26-1 at 1. The parties have only exchanged initial disclosures and Apotex has served document requests. While the Court's scheduling order has set trial for October 2008, Plaintiffs have renewed their request that the Court place this case on a complex track and extend the dates for the close of fact discovery and trial to November 2008 and June 2009 respectively so that the parties may conduct discovery in a fair and efficient manner to fully develop their claims and defenses in advance of trial. D.I. 30-2 at 2-5. Moreover, any delay in resolution of Plaintiffs' claims against Apotex is greatly outweighed by the factors discussed above.

V. Staying This Action Pending the Delaware Court's Resolution of Venue Issues Will Avoid Wasting the Resources of the Court's and the Parties

Plaintiffs' motion requests that, if the Court does not transfer this case, the current action be stayed pending resolution of any venue issues raised by Apotex in the Delaware court. D.I. 5-1 at 1, 18-20. Since Plaintiffs filed their motion, Apotex moved to transfer the first-filed action to this District or to stay the Delaware action indefinitely pending final resolution of this case. D.I. 26-1 at 12; Ex. 22. The briefing on that motion is nearly complete as Plaintiffs filed their opposition on January 31 and Apotex's reply is due next week. Ex. 23, Plaintiffs' DE Opposition.

Apotex asks the Court to "take the lead on deciding the transfer issue and deny Sanofi's motion so that the Delaware Court will have the benefit of this Court's ruling and accord it comity." D.I. 26-1 at 12. It is not surprising that Apotex cites no authority in support of its request. The first-filed rule applies not only to the merits of a venue dispute, but also establishes that the second-filed court should defer to the first-filed court on where the action should proceed. *See, e.g., Cadle Co. v. Whataburger of Alice, Inc.,* 174 F.3d 599, 606 (5th Cir. 1999); *Tiber Labs., LLC v. Cypress Pharms., Inc.,* No. 2:07-CV-0014-RWS, 2007 WL 3216625, at *2 (N.D. Ga. May 11, 2007). The briefing on Apotex's motion to transfer in Delaware will be completed in the next week. The Court should exercise its discretion to grant a limited stay so

that the first-filed Delaware court can decide whether it will retain the parallel action against Apotex or transfer to this District in order to avoid wasting judicial resources and the burden to the parties of proceeding in two separate courts. *See, e.g.,* Ex. 19; *PDL*, 2007 WL 2261386, at *2; *Schering Corp.,* 2007 WL 1648908, at *3; *Abbott.,* 2006 WL 850916, at *8.

Plaintiffs also note that since filing their motion, they have also moved the Judicial Panel on Multidistrict Litigation to transfer this action to the District of Delaware for consolidated pretrial proceedings with the first-filed, parallel action of this case and the two other cases pending in that district against 13 other defendants. Ex. 20, Plaintiffs' JPML Motion and Brief. As the Court has recognized, "[i]t is common practice for courts to stay an action pending a transfer decision by the JPML." *Bonenfant v. R. J. Reynolds Tobacco Co.*, No. 07-60301-CIV, 2007 WL 2409980, at *1 (S.D. Fla. July 31, 2007). Thus, the pending JPML motion provides additional support for Plaintiffs' request for a limited stay. *See, e.g., U.S. Bank v. Royal Indem. Co.*, No. Civ.A.3:02-CV-0853-P, 2002 WL 31114069, at *2 (N.D. Tex. Sept. 23, 2002) ("If the MDL motion is granted, all of the Court's time, energy, and acquired knowledge regarding this action and its pretrial procedures will be wasted."); *Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft*, 48 F. Supp. 2d 37, 43 (D.D.C. 1999) (finding that a stay pending an MDL decision would "eliminate the potential for conflicting pretrial rulings.").

Dated: February 7, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 7, 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.

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SERVICE LIST

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

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

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