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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	**Civil Action No. 3:07-cv-06020 (MLC)(JJH)**
Plaintiffs,	
vs.	
AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA INC.	
Defendants.	

REPLY MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY STAY

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I. INTRODUCTION

We wish to be perfectly clear: AstraZeneca requests only that this Court grant a *temporary* stay pending the outcome of Defendants' motion to dismiss the first-filed Delaware Action and the outcome of AstraZeneca's recently filed motion with the Judicial Panel on Multidistrict Litigation ("JPMDL") to transfer this action for coordinated or consolidated pretrial proceedings to the District of Delaware, where seven related patent infringement actions are pending.[1] This *temporary* stay is meant to avoid the unnecessary duplication and inefficiencies that will arise if both the Delaware Action and this second-filed New Jersey Action continue to proceed concurrently. Discovery related to Aurobindo's motion to dismiss for lack of personal jurisdiction in the Delaware Action has commenced, and the parties have a briefing schedule. The parties will fully brief the motion by May 1, 2008. AstraZeneca's transfer motion before the JPMDL will be fully briefed by the end of April. Thus, the temporary stay will likely be of short duration.

In the meantime, the parties in the Delaware actions, including Aurobindo, are collaborating on a coordinated discovery plan for the Delaware Court's Rule 16 conference on April 10. Any discovery taken as part of that coordinated schedule in Delaware can be used interchangeably in this action if necessary. Accordingly, the temporary stay AstraZeneca seeks is not intended to forestall discovery or the advancement of this litigation. Instead, it is intended to ensure that discovery proceeds in a coordinated fashion until the Delaware Court rules on Aurobindo's motion to dismiss, and the JPMDL has had an opportunity to hear and rule on

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[1] AstraZeneca filed its transfer motion with the JPMDL, yesterday, March 13, 2008. A copy of the motion and supporting brief are attached to the Reply Declaration of Jonathan M.H. Short ("Short Reply Decl.") as Exhibit B.

AstraZeneca's transfer motion.[2] Until those things happen, AstraZeneca's litigation with Aurobindo can, and should, proceed in Delaware, coordinated with the other seven suits that involve virtually identical claims and defenses, regarding the patent asserted in this action.

The filing of protective suits in ANDA cases is an accepted procedure in this Court and other Districts. If the District of Delaware were to dismiss the Delaware Action beyond the 45 day filing period, AstraZeneca would suffer an extraordinarily harsh outcome absent this protective suit.[3] Furthermore, the first-filed rule is alive and well here in the Third Circuit, although it may not be recognized in other, less-relevant jurisdictions. Therefore, this Court is well within its power, precedent, and common sense to follow the first-filed rule.

Temporarily staying the New Jersey Action would not slow the resolution of this dispute in the slightest, as the Delaware actions are proceeding efficiently. In fact, it is odd that the Defendants want this case to proceed in New Jersey instead of Delaware, when Delaware has a documented track record of moving cases through trial significantly faster than New Jersey. (Short Reply Decl., Ex. A).

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[2] Courts in this District have temporarily stayed all litigation pending the resolution by the JPMDL of a motion, pursuant to 28 U.S.C. § 1407, for multidistrict consolidation. *See Hertz Corp. v. The Gator Corp.*, 250 F. Supp.2d 421 (D.N.J. 2003); *Egon v. Del-Val Financial Corp.*, 1991 WL 13726 (D.N.J. 1991); *Arthur-Magna Inc. v. Del-Val Financial Corp.*, 1991 WL 13725 (D.N.J. 1991).

[3] Defendants recognize the hazard of not filing within the 45 day window pursuant to 35 U.S.C. § 271(e)(2). (Def. Br. at 5). *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1297 n.5 (11th Cir. 2003) ("The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45 day window expires. The 30-month stay of FDA approval, however, will not be triggered."); *Teva Pharms. USA, Inc., v. Pfizer, Inc.*, 405 F.3d 990, 998 n.2 (Fed. Cir. 2005) ("To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section.").

II. ARGUMENT

A. Defendants Have Not Demonstrated "Exceptional Circumstances" To Warrant Departure From Application Of The First-Filed Rule

The first-filed rule is undoubtedly applicable in this case. Defendants acknowledge that in all cases of federal concurrent jurisdiction, the court that first has possession of the subject must decide it and exceptions to the first-filed rule are rare. *EEOC v. University of Pennsylvania*, 850 F.2d 969, 971, 976 (3d Cir. 1988). (Def. Br. at 4). Exceptions to that rule are few, indeed, because "[c]ourts must be presented with exceptional circumstances before exercising their discretion to depart from the first-filed rule." *EEOC*, 850 F.2d at 979.

AstraZeneca demonstrates in its opening brief that no exceptional circumstances of the type recognized by the Third Circuit exist in this case. Defendants assert nothing to the contrary—in fact, the words "exceptional circumstances" do not even appear in Defendants' opposition brief. While the first-filed rule is not rigid or inflexible and should not be mechanically applied, Defendants simply have not shown that exceptional circumstances exist in this case.

Defendants rely on *EEOC v. University of Pennsylvania* for the proposition that the Court need not apply the first-filed rule. However, the court in *EEOC* merely held that the district court did not abuse its discretion in denying a party's motion to dismiss a second-filed enforcement action, in favor of a first-filed constitutional challenge to the enforcement statute when "at least one of the filing party's motives is to circumvent local law and preempt an imminent subpoena enforcement action." 850 F.2d at 978. *EEOC*, therefore, illustrates the point that the Court should apply the first-filed rule unless exceptional circumstances exist. In *EEOC*, the Third Circuit affirmed the district court's refusal to apply the first-filed rule, finding that the University's first-filed suit in the District of Columbia was "an attempt to preempt an imminent

subpoena enforcement in the Eastern District of Pennsylvania." *EEOC*, 850 F.2d at 977. Such tactics are generally viewed as exceptional circumstances, warranting departure from the rule. *Id*. Filing a protective suit is not. *Aventis Pharma S.A. v. Sandoz Inc.*, 2007 WL 1101228, *4 (D.N.J. 2007) (recognizing that filing a second, protective suit in ANDA cases is warranted and rejecting any allegation of judge or forum shopping); *see also Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) ("Plaintiff filed the duplicate of [ANDA] actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act"). Defendants fail to show exceptional circumstances in this case. Therefore the first-filed rule should apply to avoid unnecessarily burdening the courts, parties and witnesses, and to eliminate the potential risk of conflicting pretrial rulings.

B. Defendants' Arguments Against Application Of The First-Filed Rule Fail

Instead of asserting arguments on exceptional circumstances, Defendants rely on ancillary contentions that are both unconvincing and irrelevant.

First, Defendants assert that the first-filed rule cannot apply where the same party filed both lawsuits at issue. (Def. Br. at 4). Such an assertion calls for a rigid application of the first-filed rule, rigidity that Defendants themselves criticize. Application of the first-filed rule is not foreclosed merely because AstraZeneca filed both actions. Rather, as this Court recently recognized, "cases that involve the same parties and issues are within the ambit of the [first-filed] rule." *Siemens Financial Services, Inc. v. Open Advantage M.R.I. II L.P.*, 2008 WL 564707, at *4 (D.N.J. Feb. 29, 2008) (*citing Triangle Conduit & Cable Co. v. National Electric Products Corp.*, 125 F.2d 1008, 1009 (3d Cir. 1942)); *see also The Violet Pot, LLC v. Lowe's Companies, Inc.*, 2007 WL 894187, at *2 (D.N.J. Mar. 20, 2007). This is true, even where both the first and second actions were filed by the same party. *Adams Respiratory*, 2007 WL 4284877, at *2 (refusing to depart from the first-filed rule simply because the plaintiff filed both actions). This

case involves identical parties and identical issues, and therefore warrants application of the first-filed rule. *See EEOC*, 850 F.2d at 977 (noting that application of the first-filed rule is warranted simply because a "similar" complaint had already been filed in another federal court); *Nature's Benefit, Inc. v. NFI*, 2007 WL 2462625, at *3 (D.N.J. Aug. 27, 2007) (instructing that "[n]either identical parties nor identical issues are needed, only a 'substantial overlap' is sufficient to invoke the first-filed rule); *GlaxoSmithKline Consumer Health Care, L.P. v. Merix Pharmaceutical Corp.*, 2005 WL 1116318, at * 9 (D.N.J. May 10, 2005) (noting that "[t]he critical inquiry of the first-filed rule is whether the issues substantially overlap; there is no requirement that the issues or the parties be identical"). Considering that the complaints in both the Delaware and New Jersey Actions are substantively identical, the substantial overlap threshold for application of the first-filed rule is clearly met.

Furthermore, this District has previously invoked the first-filed rule when the same party filed both the first and second-filed lawsuits. *See Martin v. Townsend*, 1990 WL 159923, at *1; 4 (D.N.J. Oct. 15, 1990) (applying the first-filed rule to dismiss the second-filed New Jersey action when the same plaintiff filed an identical complaint six weeks prior in the District of Delaware). This is directly contrary to Defendants' position.

The first-filed rule is meant to prevent the waste of judicial resources caused by duplicative litigation and to guard against the possibility of conflicting judgments. The Third Circuit long ago recognized, "Courts already heavily burdened with litigation with which they must of necessity deal should therefore not be called upon to duplicate each other's work in cases involving the same issues and the same parties." *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir. 1941) ("What has been said applies, we think, with especial force to patent suit . . . ."); *see also Continental Grain Co. v. Barge FBL-585*, 364 U.S. 19, 26 (1960) ("To permit a

situation in which two cases involving precisely the same issues are simultaneously pending in different District Courts leads to the wastefulness of time, energy, and money."); *EEOC*, 850 F.2d at 971; *Crosley Corp.*, 122 F.2d at 930; *American Cyanamid Co. v. Eli Lilly and Co.*, 903 F. Supp. 781, 787 (D.N.J. 1995) ("[f]ailure to apply the 'first-filed' rule would result in nearly identical litigation in different fora. Such duplicative litigation is precisely what the Supreme Court and numerous lower courts have attempted to avoid."). Clearly, the parties and issues here are the same. Application of the first-filed rule is therefore warranted for purposes of granting a *temporary* stay pending resolution of the jurisdictional issues in the Delaware Action. Failure to stay the New Jersey Action would, at the very least, lead to a waste of the parties' and courts' resources.[4]

The first-filed rule is applicable in Hatch-Waxman cases where the plaintiff files a protective suit in a second jurisdiction. Other federal courts have invoked the first-filed rule to stay the second-filed "protective suit" in Hatch-Waxman cases.[5] (Pl. Br., pp. 6-7) (citing *Adams Respiratory*, 2007 WL 4284877, at *2; *PDL Biopharma, Inc. v. Sun Pharm Indus., Ltd.*, 2007

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[4] For example, defendants have been attempting to push this action ahead of the main Delaware actions in an uncoordinated manner. Despite agreeing to participate with AstraZeneca and the other Delaware defendants in the upcoming April 10 Rule 16 scheduling conference in Delaware, on March 3, Defendants served document requests and interrogatories on AstraZeneca in this action, which will likely lead to uncoordinated, parallel discovery in both New Jersey and Delaware.

[5] The Eastern District of Virginia's decision *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484 (E.D. Va. 2005) does not change this outcome. The Court in *Adams* disregarded this decision because such a mechanical application of the first-filed rule was unsupported by Sixth Circuit law. *Adams Respiratory*, 2007 WL 4284877 at *2.

Additionally, Defendants attack *PDL* and *Adams* because the defendants in those cases consented to personal jurisdiction in the first-filed district. However, the Courts in *PDL* and *Adams* stayed the cases during the pendency of the defendants' motions to transfer because going forward with both actions simultaneously would waste judicial resources and present the possibility of conflicting rulings or judgments. The situations in *PDL* and *Adams* are analogous to the situation in the immediate case. The fact that the cases differ as to the type of pending motion -- motion to dismiss v. motion to transfer -- is irrelevant to the analysis.

WL 2261386, at *1 (W.D. Mich. Aug. 6, 2007); *Schering Corp. v. Caraco Pharm. Labs. Ltd.*, 2007 WL 1648908, at *1 (E.D. Mich. Jun. 6, 2007); *see also American Cyanamid*, 903 F. Supp. at 787 (noting that application of the first-filed rule is particularly appropriate in patent cases). Contrary to Defendants' position, the first-filed rule applies in Hatch-Waxman cases.

Additionally, Defendants assert that the first-filed rule is not the appropriate standard because equitable considerations must govern the analysis. (Def. Br. at 9). Defendants rely upon two cases to support that proposition. *Landis v. North American Co.*, 299 U.S. 248, 249-51 (1936) and *Dentsply International, Inc. v. Kerr Mfg.*, Co., 734 F. Supp. 656, 658-89 (D. Del. 1990).[6] However, in both *Landis* and *Dentsply*, the parties in the first-filed cases differ from the parties in the second-filed cases so the first-filed rule would not even be available. These cases are therefore distinguishable from the instant case where the parties and issues are identical.

Furthermore, the court should only entertain other considerations -- including equitable considerations -- where the overlap between the two pending cases is "less than complete," and even then only when the non-moving party has demonstrated the existence of exceptional circumstances. *GlaxoSmithKline*, 2005 WL 1116318, at *10 (finding that equitable considerations will not be given any weight unless the defendant has shown that special circumstances warrant deviation from the first-filed rule). Here, there is complete overlap between the two cases, and Defendants failed to demonstrate exceptional circumstances. Therefore, application of the first-filed rule is proper.

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[6] Defendants reference *Gold v. Johns-Mansville Sales Corp.*, 723 F.2d 1068 (3d Cir. 1983) in their citation to *Dentsply*, but this is a bankruptcy case decided before the Third Circuit's seminal ruling in *EEOC* and inapposite.

C. Granting a Temporary Stay Would Not Slow the Litigation of this Dispute

AstraZeneca's request for a *temporary* stay does not stop the progress of the litigation of the underlying dispute between AstraZeneca and the Defendants. As explained in AstraZeneca's opening brief, discovery is going forward in the Delaware Action, discovery that the parties can eventually use in whichever case eventually proceeds. (Pl. Brief, § II.A and C).

Furthermore, Defendants' conjecture that the Delaware Action would proceed slower than the New Jersey Action is unsupported by statistical data. According to the Administrative Office of the U.S. Courts, the District of Delaware proved speedier in civil cases when trials were completed. (Short Reply Decl., Ex. A). Specifically, cases took a median of 27 months for trial completion in the District of Delaware versus 36 months in the District of New Jersey. (*Id.*). This includes the time period after Judge Kent A. Jordan left the District of Delaware bench, a departure that Defendants cite as causing the docket to stagnate. (Docket No. 30-2 and 30-3).

Therefore, Defendants will not be prejudiced if the *temporary* stay is granted because the parties will continue to engage in discovery. However, contrary to Defendants' position, the dispute may take longer to resolve through trial if it remains in the District of New Jersey.

III. CONCLUSION

For the foregoing reasons, the Court should grant the requested temporary stay and enter an Order in the form proposed.

Dated: March 14, 2008

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, **Plaintiffs,** **vs.** **AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA INC.** **Defendants.**	**Civil Action No. 3:07-cv-06020 (MLC)(JJH)** **REPLY DECLARATION OF JONATHAN M.H. SHORT IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY STAY**

Jonathan M.H. Short, of full age, hereby declares as follows:

1. I am a member of the bar of this court and am associated with the firm of McCarter & English, LLP, attorneys for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha ("AstraZeneca") in this matter.

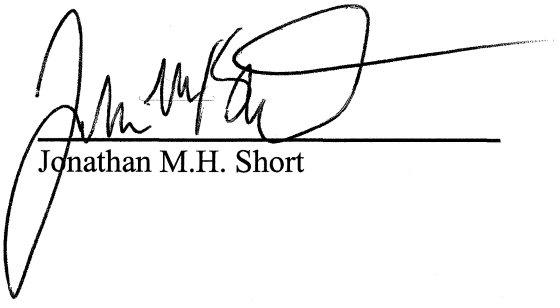
2. I submit this declaration in support of AstraZeneca's Reply Memorandum of Law in Support of Plaintiffs' Motion to Temporarily Stay These Proceedings.

3. Attached as Exhibit A hereto is a true and correct copy of 2007 Judicial Business of the United States Courts - Annual Report of the Director, Table C-10 (U.S. District Courts—Median Time Intervals from Filing to Trial of Civil Cases in Which Trials Were Completed, by District, During the 12-Month Period Ending September 30, 2007), which is publicly available at http://www.uscourts.gov/judbus2007/appendices/C10Sep07.pdf.

4. Attached as Exhibit B hereto is a true and correct copy of the Motion of AstraZeneca for Transfer of Actions to the District of Delaware Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings and accompanying documents.

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

Dated: March 14, 2008



Jonathan M.H. Short

EXHIBIT A

Table C-10.
U.S. District Courts—Median Time Intervals from Filing to Trial of Civil Cases in Which Trials Were Completed, by District, During the 12-Month Period Ending September 30, 2007

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval In Months *
TOTAL	**3,366**	**24.6**	**1,109**	**21.0**	**2,257**	**25.2**
DC	**28**	**44.0**	**12**	**44.0**	**16**	**42.0**
1ST	**157**	**29.7**	**54**	**28.0**	**103**	**29.4**
ME	9	-	3	-	6	-
MA	94	33.5	33	36.0	61	30.0
NH	7	-	1	-	6	-
RI	12	23.0	6	-	6	-
PR	35	28.0	11	21.0	24	32.0
2ND	**336**	**31.0**	**108**	**25.5**	**228**	**33.0**
CT	52	27.0	13	30.0	39	26.0
NY,N	27	40.5	4	-	23	40.0
NY,E	84	34.6	23	33.0	61	35.0
NY,S	151	25.6	61	21.0	90	29.0
NY,W	11	57.0	4	-	7	-
VT	11	19.0	3	-	8	-
3RD	**321**	**28.4**	**78**	**27.5**	**243**	**28.0**
DE	29	27.0	9	-	20	28.0
NJ	57	36.0	17	33.5	40	38.5
PA,E	104	19.4	25	15.0	79	19.5
PA,M	75	26.3	10	23.5	65	26.5
PA,W	50	33.8	15	33.0	35	34.0
VI	6	-	2	-	4	-
4TH	**229**	**17.0**	**110**	**15.4**	**119**	**18.0**
MD	40	21.5	21	17.0	19	24.0
NC,E	44	16.5	41	14.0	3	-
NC,M	6	-	5	-	1	-
NC,W	11	21.0	3	-	8	-
SC	48	18.5	11	22.0	37	18.0
VA,E	33	9.0	16	9.0	17	8.2
VA,W	25	14.5	6	-	19	16.0
WV,N	8	-	2	-	6	-
WV,S	14	21.0	5	-	9	-

Table C-10. (September 30, 2007—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval In Months *
5TH	**460**	**20.2**	**177**	**20.1**	**283**	**20.6**
LA,E	71	19.7	42	18.0	29	19.5
LA,M	15	38.0	6	-	9	-
LA,W	38	34.0	20	36.0	18	25.0
MS,N	27	23.0	5	-	22	22.5
MS,S	47	23.4	9	-	38	20.5
TX,N	49	19.4	20	16.5	29	21.0
TX,E	50	18.0	10	20.0	40	17.0
TX,S	103	20.3	41	20.0	62	19.7
TX,W	60	15.8	24	15.4	36	16.4
6TH	**267**	**26.0**	**60**	**20.0**	**207**	**27.2**
KY,E	15	24.0	1	-	14	24.0
KY,W	20	31.0	2	-	18	31.0
MI,E	74	25.8	14	16.0	60	28.7
MI,W	13	28.0	5	-	8	-
OH,N	27	20.0	6	-	21	19.0
OH,S	21	28.4	3	-	18	28.7
TN,E	31	23.0	11	18.0	20	25.0
TN,M	32	26.5	11	14.0	21	32.0
TN,W	34	23.5	7	-	27	23.0
7TH	**232**	**27.8**	**66**	**27.0**	**166**	**28.0**
IL,N	105	29.7	36	27.5	69	33.0
IL,C	24	29.0	3	-	21	31.0
IL,S	35	31.5	9	-	26	37.0
IN,N	16	21.5	1	-	15	21.5
IN,S	19	24.0	4	-	15	25.0
WI,E	9	-	6	-	3	-
WI,W	24	10.4	7	-	17	10.0
8TH	**207**	**22.1**	**57**	**21.5**	**150**	**22.3**
AR,E	64	19.7	23	19.0	41	20.0
AR,W	16	13.0	2	-	14	13.5
IA,N	9	-	3	-	6	-
IA,S	6	-	-	-	6	-
MN	27	29.0	2	-	25	31.0
MO,E	28	22.5	11	20.0	17	22.5
MO,W	20	22.0	5	-	15	25.0
NE	23	22.0	5	-	18	20.0
ND	3	-	3	-	-	-
SD	11	34.0	3	-	8	-

Table C-10. (September 30, 2007—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval in Months *	Number of Trials	Median Time Interval In Months *
9TH	**557**	**25.4**	**212**	**21.5**	**345**	**27.6**
AK	6	-	2	-	4	-
AZ	55	30.5	21	27.0	34	34.0
CA,N	73	24.9	23	20.5	50	28.0
CA,E	46	38.0	11	42.0	35	38.0
CA,C	186	21.3	78	18.7	108	24.8
CA,S	39	24.0	14	21.0	25	27.0
HI	10	17.0	5	-	5	-
ID	11	25.7	2	-	9	-
MT	11	18.0	3	-	8	-
NV	34	29.5	19	29.5	15	36.0
OR	38	25.0	11	23.0	27	27.0
WA,E	13	23.0	5	-	8	-
WA,W	32	18.0	17	18.4	15	19.0
GUAM		-	-			
NMI	3	-	1	-	2	-
10TH	**178**	**22.3**	**51**	**26.5**	**127**	**22.5**
CO	49	29.0	9	-	40	29.0
KS	27	23.0	7	-	20	22.0
NM	25	20.4	8	-	17	19.5
OK,N	12	17.0	4	-	8	-
OK,E	8	-	5	-	3	-
OK,W	18	15.0	-	-	18	15.0
UT	25	28.0	11	31.0	14	21.7
WY	14	14.5	7	-	7	-
11TH	**394**	**21.8**	**124**	**18.5**	**270**	**23.0**
AL,N	52	25.0	2	-	50	26.0
AL,M	22	16.0	6	-	16	16.0
AL,S	21	14.5	3	-	18	14.0
FL,N	19	22.0	8	-	11	22.0
FL,M	84	19.0	33	18.3	51	22.0
FL,S	116	17.9	53	17.0	63	17.4
GA,N	49	27.9	17	27.4	32	27.5
GA,M	8	-	2	-	6	-
GA,S	23	31.0	-	-	23	31.0

NOTE: INCLUDES TRIALS CONDUCTED BY DISTRICT AND APPELLATE JUDGES ONLY. ALL TRIALS CONDUCTED BY MAGISTRATE JUDGES ARE EXCLUDED. EXCLUDES THE FOLLOWING TRIALS: LAND CONDEMNATION; FORFEITURES AND PENALTY CASES; PRISONER PETITIONS (HABEAS CORPUS, MOTIONS TO VACATE SENTENCE UNDER 28 U.S.C. 2255, HEARINGS ON EVIDENTIARY MATTERS); BANKRUPTCY PETITIONS; AND THREE-JUDGE COURT CASES. FOR CIVIL CASES RESULTING IN A COMPLETED TRIAL, THE MEDIAN TIME IS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED. FOR REOPENED CIVIL CASES RESULTING IN A SECOND COMPLETED TRIAL, THE MEDIAN TIME REMAINS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED.

* TIME INTERVALS COMPUTED ONLY FOR 10 OR MORE TRIALS.

EXHIBIT B

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION	)	MDL-_____

MOTION OF ASTRAZENECA FOR TRANSFER OF ACTIONS TO THE DISTRICT OF DELAWARE PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Pursuant to 28 U.S.C. § 1407, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") move to centralize in the District of Delaware nine patent infringement actions involving AstraZeneca's patents covering its cholesterol-lowering drug CRESTOR®.

1. This litigation involves nine separate patent infringement lawsuits, each prompted by submission of an abbreviated new drug application ("ANDA") that seeks regulatory approval to market a generic version of CRESTOR®, rosuvastatin calcium, before the expiration of AstraZeneca's U.S. Patent No. RE 37,314 ("the '314 patent").

2. In the interest of judicial economy and efficiency, AstraZeneca filed seven patent actions in the United States District Court for the District of Delaware on December 11, 2007. In each of these suits, AstraZeneca requests a determination that the '314 patent is valid and

enforceable, that the Defendants' ANDA submission infringed the '314 patent, and a declaration that Defendants' future marketing of a generic rosuvastatin calcium product will infringe the patent. The five defendant groups that filed Answers in Delaware all assert counterclaims of invalidity, unenforceability, and/or non-infringement of the '314 patent in each of their respective cases.

3. Solely to protect its statutory right to a 30-month stay of ANDA approval and in the event the Delaware suit against Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. was dismissed for lack of personal jurisdiction, AstraZeneca filed a mirror-image "protective suit" against those Defendants in the United States District Court for the District of New Jersey on December 18, 2007.

4. Defendants in three of the Delaware actions, Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc.; Par Pharmaceutical, Inc.; and Sandoz Inc., filed counterclaims against AstraZeneca in Delaware, alleging invalidity and/or non-infringement of additional AstraZeneca patents covering CRESTOR®, including U.S. Patent No. 6,316,460 ("the '460 patent"). Another Delaware Defendant, Apotex, Inc., initiated a separate declaratory judgment action against AstraZeneca in the Middle District of Florida on December 31, 2007, challenging the same '460 patent. Thus, these four cases, three in Delaware and one in Florida, involve the '460 patent.

5. The Schedule of Actions summarizes the nine patent actions that are the subject of this Motion.

6. Because the actions involve common questions of fact, and centralization under § 1407 in Delaware will serve the convenience of the parties and the witnesses and promote the just and efficient conduct of this litigation, AstraZeneca hereby moves this Panel to: (1) transfer the patent actions that are currently pending in the District of New Jersey and the Middle District

of Florida to the United States District Court for the District of Delaware for pretrial purposes; (2) transfer to the District of Delaware for pretrial purposes any tag-along actions subsequently filed in another district or subsequently transferred from the District of Delaware for lack of personal jurisdiction or improper venue relating to AstraZeneca's CRESTOR® patent rights; and (3) order coordinated or consolidated pretrial proceedings for the transferred actions and the related patent actions already pending before the District Court in Delaware.

The detailed grounds for this motion are set forth in the accompanying memorandum of law.

Dated: March 13, 2008
Washington, D.C

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Schedule of Actions

CASE NAME	DISTRICT COURT	CASE NO.	JUDGE	FILING DATE	PATENTS AT ISSUE
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Mylan Pharmaceuticals Inc.	District of Delaware	1:07-cv-00805	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Sun Pharmaceutical Industries Ltd.	District of Delaware	1:07-cv-00806	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Sandoz Inc.	District of Delaware	1:07-cv-00807	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent '460 patent '618 patent '959 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Par Pharmaceutical, Inc.	District of Delaware	1:07-cv-00808	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent '460 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Apotex Inc. & Apotex Corp.	District of Delaware	1:07-cv-00809	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent

Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Aurobindo Pharma Limited & Aurobindo Pharma USA Inc.	District of Delaware	1:07-cv-00810	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Cobalt Pharmaceuticals Inc. & Cobalt Laboratories Inc.	District of Delaware	1:07-cv-00811	Hon. Joseph J. Farnan, Jr.	December 11, 2007	'314 patent '460 patent
Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha v. Aurobindo Pharma Limited & Aurobindo Pharma USA Inc.	District of New Jersey Newark Division	3:07-cv-06020	Hon. Mary L. Cooper	December 18, 2007	'314 patent
Apotex Inc. v. Astrazeneca Pharmaceuticals LP & Astrazeneca UK Limited & IPR Pharmaceuticals, Inc. & Shionogi Seiyaku Kabushiki Kaisha	Middle District of Florida	8:08-cv-213	Hon. James S. Moody, Jr.	February 13, 2008	'460 patent

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION	)	MDL-_____

BRIEF IN SUPPORT OF ASTRAZENECA'S MOTION FOR TRANSFER OF ACTIONS TO THE DISTRICT OF DELAWARE PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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In re Mirtazapine Patent Litigation,
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PDL Biopharma, Inc. v. Sun Pharm. Inds., Ltd.,
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In re Pharmastem Therapeutics, Inc., Patent Litigation,
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In re Phonometrics, Inc., Electric Long District Call Cost Computer and Recorder Patent Lit.,
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Pursuant to 28 U.S.C. § 1407, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") request transfer of two patent actions respectively from the District of New Jersey and the Middle District of Florida to the United States District Court for the District of Delaware for pretrial purposes. AstraZeneca seeks this order so that the patent actions in New Jersey and Florida may be consolidated for coordinated pretrial proceedings with related actions involving the same patents that are already pending before the District Court in Delaware.

I. FACTUAL BACKGROUND

A. The Main Delaware Actions

AstraZeneca filed seven patent infringement actions in the United States District Court for the District of Delaware on December 11, 2007, asserting infringement of U.S. Patent No. RE 37,314 ("the '314 patent"), which covers the active ingredient, rosuvastatin calcium, in AstraZeneca's highly successful cholesterol-lowering drug CRESTOR®. All seven cases raise issues of validity and enforceability of the '314 patent, and all were provoked by notices under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV notices") that these seven generic pharmaceutical companies had filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), attempting to sell a generic version of the CRESTOR® product before the expiration of the '314 patent.

All seven actions were brought in Delaware in an effort to achieve economies and efficiencies from coordinated proceedings. All seven of the defendants had contacts with Delaware, and all had previously been found to be subject to personal jurisdiction in Delaware,

admitted general presence in Delaware,[1] or consented in other cases to proceed in Delaware.[2] Two of the seven defendants have nonetheless contested the jurisdiction of the Delaware court, thereby requiring the intervention of this Panel to ensure orderly and coordinated conduct of pretrial proceedings in these cases.

The CRESTOR® patent actions currently pending in the District of Delaware are: (1) *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 1:07-vc-00805 ("the Mylan action"); (2) *AstraZeneca Pharmaceuticals LP et al.* v. *Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 1:07-cv-00806 ("the Sun action"); (3) *AstraZeneca Pharmaceuticals LP et al.* v. *Sandoz Inc.*, C.A. No. 1:07-cv-00807 ("the Sandoz action"); (4) *AstraZeneca Pharmaceuticals LP et al.* v. *Par Pharmaceutical. Inc.*, C.A. No. 1:07-cv-00808 ("the Par action"); (5) *AstraZeneca Pharmaceuticals LP et al.* v. *Apotex Inc, et al.*, C.A. No. 1:07-cv-00809 ("the Apotex action"); (6) *AstraZeneca Pharmaceuticals LP et al,* v. *Aurobindo Pharma Limited et al.*, C.A. No. 1:07-cv-00810 ("the Aurobindo action"); and (7) *AstraZeneca Pharmaceuticals LP et al.* v. *Cobalt Pharmaceuticals Inc, et al.*, C.A. No. 1:07-cv-00811 ("the Cobalt action") (collectively "the main Delaware actions").

B. The New Jersey Protective Suit

After filing the main Delaware actions, AstraZeneca filed three "protective suits." The protective suits mirrored three of the Delaware actions and were filed in the District of New

---

[1] Apotex admitted it was amendable to suit in Delaware in answering the complaint in another ANDA patent case. (Ex. 1, Answer at 3, *Allergan Inc. v. Apotex Inc.*, No. 1:07-cv-00278 (D. Del. Jun. 11, 2007) (Sleet, J.).)

[2] Aurobindo consented to jurisdiction in Delaware for purposes of litigating another ANDA patent case. (Ex. 2, Answer at 6, *Sanofi-Aventis v. Aurobindo Pharma Ltd.*, No. 1:07-cv-05807 (D. Del. Nov. 5, 2007) (Sleet, J.) ("[T]o conserve the resources of the parties and for purposes of judicial efficiency, Aurobindo Ltd. will not contest personal jurisdiction for purposes of this multi-defendant action only.").)

Jersey against the Aurobindo defendants, Middle District of Florida against Cobalt, and Northern District of West Virginia against Mylan, in anticipation that those Delaware defendants might challenge jurisdiction in Delaware.

AstraZeneca filed the protective suits solely to preserve its statutory right to a 30-month stay of ANDA approval to allow completion of the litigation if any of its Delaware suits were dismissed for lack of personal jurisdiction after the 45-day period for obtaining the stay had run. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[3] Consistent with that purpose, each protective suit was filed but not served, and each affected defendant was notified that (1) the protective suits had been filed, (2) AstraZeneca intended to serve the complaints only if it became necessary to do so, and (3) the cases would be voluntarily dismissed once jurisdiction was established in Delaware. (Ex. 3.) The defendants in the Florida and West Virginia protective suits did not contest jurisdiction in Delaware, and those actions were voluntarily dismissed.

The defendants in the New Jersey protective suit (Aurobindo) did contest jurisdiction in Delaware, answered the unserved New Jersey Complaint (*AstraZeneca Pharmaceutical LP et al. v. Aurobindo Pharma Limited et al.*, Docket No. 3:07-cv-06020 ("the New Jersey action")), and has been attempting to push proceedings in New Jersey ahead of those in the main Delaware actions in an uncoordinated manner.[4]

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[3] The prudence of filing such protective suits is well recognized. *Aventis Pharma S.A. v. Sandoz Inc.*, 2007 WL 1101228, *4 (D.N.J. 2007); *see also*, *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, 2007 WL 1648908, *2 (E.D. Mich. 2007); *PDL Biopharma, Inc. v. Sun Pharm. Inds., Ltd.*, 2007 WL 2261386, *2 (E.D. Mich. 2007); *Abbott Labs. v. Mylan Pharms., Inc.*, 2006 WL 850916, *8 (N.D. Ill. 2006).

[4] For example, Aurobindo would not agree to a stipulated stay of the New Jersey protective suit, pending resolution of its jurisdiction contest in Delaware and is actively opposing AstraZeneca's motion to stay the New Jersey protective suit. Also, despite agreeing to participate with AstraZeneca and the other Delaware defendants in the upcoming April 10 Rule 16 conference with the Delaware Court (Ex. 4), on March 3, Aurobindo served document requests and

(continued on next page)

C. The Apotex Motion to Dismiss or Transfer

No protective suit was filed against Delaware defendant Apotex, which has been actively involved in at least seven civil actions in Delaware over the last five years[5] and admitted that personal jurisdiction is proper in Delaware just ten months ago.[6] Apotex has nonetheless also challenged jurisdiction in the Delaware action and has moved to dismiss or transfer the Delaware action to the Middle District of Florida. If Apotex is successful, there will be another action based on the '314 patent pending outside the District of Delaware.

D. The Florida Declaratory Judgment Action

Apotex Inc. v. AstraZeneca Pharmaceuticals LP et al., Docket No. 8:08-cv-213, is a declaratory judgment action pending in the Middle District of Florida ("the Florida action"), relating to another patent covering AstraZeneca's CRESTOR® product, U.S. Patent No. 6,316,460 ("the '460 patent"), which claims AstraZeneca's commercial formulation of the active drug substance. As previously noted, Apotex Inc. is also a defendant in one of the Delaware actions involving the '314 patent. Counterclaims in three of the actions in Delaware also involve the '460 patent. Thus, the proper disposition of the '460 patent at issue in Florida must also be resolved in connection with the Delaware actions.

(continued from previous page)
interrogatories on AstraZeneca in the New Jersey action, which will likely lead to uncoordinated, parallel discovery in the New Jersey case.

[5] *Sanofi-Aventis et al. v. Apotex Inc. et al.*, Docket No. 07-792 (D. Del. filed December 6, 2007); *Senju Pharm. Co., Ltd. et al v. Apotex Inc. et al.*, Docket No. 07-779 (D. Del. filed November 29, 2007); *Allergan Inc. v. Apotex Inc. et al.*, Docket No. 07-278 (D. Del. filed May 21, 2007); *MedPointe Healthcare Inc. v. Apotex Inc. et al.*, Docket No. 07-204 (D. Del. filed April 17, 2007); *Merck & Co., Inc. v. Apotex Inc.*, Docket No. 06-230 (D. Del. filed April 7, 2006); *MedPointe Healthcare Inc. v. Apotex Inc. et al.*, Docket No. 06-164 (D. Del. filed March 10, 2006); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Docket No. 03-990 (D. Del. filed October 29, 2003).

[6] *See* (Ex. 1, Answer at p. 3.)

E. Possible Tag-Along Actions

AstraZeneca has received notice from two other generic drug manufacturers that they are seeking approval for a generic equivalent of the CRESTOR® product. These two manufacturers have thus far not manifested an intention to market their products before expiration of the '314 patent and, accordingly, have not been sued. Such ANDA applicants may and sometimes do amend their ANDAs to challenge patents not challenged in the original submission.[7] If either or both of these entities amend their ANDAs, there may be yet further suits on the '314 patent.

F. The Need for Coordination

1. Anticipated Discovery Complications

The subject matter of the '314 patent was invented in Japan by employees of plaintiff Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"). The four inventors of the subject matter claimed in the '314 patent reside in Japan, as do all of the Shionogi employees who were involved in procurement of patents on that subject matter. The documents relating to development of the invention and the procurement of patents on it are stored in Japan and are almost entirely in Japanese. Most, if not all, of the likely Japanese witnesses do not speak English well enough to testify in English.

2. Common Issues

In the New Jersey action, Aurobindo has alleged invalidity of the '314 patent under 35 U.S.C. §§ 102 (lack of novelty), 103 (obviousness), 112 (lack of enabling disclosure), and 251 (allegedly improper reissue patent). (Ex. 5, Answer at p. 12, the New Jersey action) The identical issues have been raised in Delaware through the pleadings of Cobalt, for example. (*See*

[7] This has already occurred in this case. For instance, while its first Paragraph IV notice did not include the '314 patent, Apotex subsequently amended its Paragraph IV notice to include the '314 patent.

Ex. 6, the Cobalt Action Answer at p. 14 ("One or more claims of the '314 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, 112 and/or 251.").) Four other Delaware defendants, Mylan, Par, Sandoz, and Sun, have similarly challenged the '314 patent. (*See* Answers in the Mylan, Par, Sandoz, and Sun Delaware actions.) While Apotex has not yet answered the Delaware Complaint, its Paragraph IV notice also alleged invalidity of the '314 patent for obviousness under 35 U.S.C. § 103 and indicated it may also allege invalidity under 35 U.S.C. §§ 102, 112, and 251.

3. Failure of Attempts at Voluntary Coordination

All of the cases are at early stages of pretrial proceedings. During a February 20, 2008 status conference in connection with the Delaware actions, all of the parties agreed that AstraZeneca and the seven Delaware defendant groups, including Apotex and Aurobindo, will proceed with the development of a coordinated discovery plan in Delaware without prejudice to any defendant's jurisdictional challenges. A proposed discovery plan is due to the Delaware Court on April 3, 2008, with a Rule 16 Conference to follow on April 10. (Ex. 7.) Limited jurisdictional discovery is underway in Delaware, involving the New Jersey and Florida litigants, Aurobindo and Apotex, respectively.

If AstraZeneca should not succeed in establishing jurisdiction in Delaware or if a jurisdictional decision is delayed, the need for transfer for coordinated pretrial proceedings has already become apparent. Aurobindo has refused to coordinate deadlines and schedules between the New Jersey and Delaware actions, attempting at each juncture to force proceedings to advance more rapidly in New Jersey than in Delaware. (See footnote 4.) AstraZeneca has filed a motion to stay proceedings in the New Jersey action pending resolution of the jurisdictional issues and this Panel's decision, and Aurobindo is participating in coordinated discovery in

Delaware without prejudice to its jurisdictional allegations. Aurobindo is opposing AstraZeneca's motion to stay the New Jersey proceedings.

II. ARGUMENT

This Panel should transfer the New Jersey action and the Florida action for coordinated or consolidated pretrial proceedings with the seven pending actions in the District of Delaware, because the actions share common questions of law and fact. Consolidation and coordination of pretrial proceedings will promote the just and efficient conduct of those actions while minimizing witness and party inconvenience. *See* 28 U.S.C. § 1407.

Here, the pending Delaware actions against Mylan, Sun, Sandoz, Par, and Cobalt, the pending Delaware and New Jersey actions against Aurobindo, the Delaware action against Apotex which it seeks to transfer to Florida, and the Florida action by Apotex, deal with multiple generic challenges to AstraZeneca's CRESTOR® patent rights. The benefits of consolidation in such cases have been recognized repeatedly by this Panel. *See In re Brimonidine Patent Litigation*, 507 F. Supp. 2d 1381, 1381 (J.P.M.L. 2007); *In re Rivastigmine Patent Litigation*, 360 F. Supp. 2d 1361, 1361-62 (J.P.M.L. 2005); *In re Mirtazapine Patent Litigation*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002). "Indeed, 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 Litigation*, 502 F. Supp.2d 1354, (J.P.M.L. 2007), citing *In re Metoprolol Succinate Patent Litigation,* 329 F. Supp.2d 1368 (J.P.M.L. 2004) (ordering transfer under Section 1407 of four actions in which the patent holder alleged infringement of two complex pharmaceutical patents).

A. The Related Actions Involve Common Questions of Fact and Law

All seven pending actions in Delaware and the New Jersey action involve nearly identical allegations by and against similarly situated defendants. Indeed, the complaints filed against the

various defendants are substantially the same, each alleging infringement of the '314 patent based on submission of an ANDA specifying use of rosuvastatin calcium as the active pharmaceutical ingredient. The '314 patent encompasses that active ingredient.

As set forth in § I.F.2., above, the issues raised in the New Jersey action against Aurobindo and the Delaware action against Apotex, which Apotex asks to be transferred to Florida, are wholly subsumed within the issues that must be resolved in Delaware. These issues arise in the technically complex field of medicinal chemistry and implicate the scope and content of the cholesterol-lowering prior art, the level of ordinary skill in that field, the predictability or lack thereof of the effect of changes in chemical structure on the biological properties of therapeutic drugs, and objective evidence of nonobviousness. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.,* 492 F.3d 1350, 1355 (Fed. Cir. 2007). The allegations under 35 U.S.C. § 251 implicate the actions and intent of individuals in procuring the original patent, the propriety of "reissuing" that patent as the '314 patent, and the details of the associated procedures in the U.S. Patent and Trademark Office.

Regarding the Florida action, Apotex there advances allegations of non-infringement of the '460 patent similar to those brought by Par and Sandoz in their Delaware counterclaims against AstraZeneca. Indeed, the Florida action is just the type of action that Apotex would have brought against AstraZeneca as a counterclaim in the District of Delaware if Apotex had answered the complaint instead of filing a motion to dismiss or transfer the action for lack of personal jurisdiction. Moreover, because the '460 patent is directed to a formulation of rosuvastatin calcium, it is logically linked to the '314 patent that is directed to rosuvastatin calcium itself, and both patents cover AstraZeneca's commercial CRESTOR® product.

B. Transfer and Consolidation Will Serve the Convenience of the Parties and Promote the Just and Efficient Conduct of the Related Actions

As demonstrated above, the actions in Delaware share factual and legal questions with the New Jersey and the Florida actions. Experience has taught trial courts that significant documentary and testimonial evidence pertinent to those questions, such as the state of the prior art, the prosecution history, and the development of the invention, will overlap within the cases. *See, e.g., Magnavox Co. v. APF Elec., Inc.*, 496 F. Supp. 29, 33 (N.D. Ill. 1980) (consolidating three patent actions to prevent duplicative efforts by the court and counsel, noting probability that "the same documents and technical drawings will be solicited from the plaintiffs" and the likelihood "that defendants will want to depose the same persons."); *Sage Prod., Inc. v. Devon Indus., Inc.,* 148 F.R.D. 213, 215 (N.D. Ill. 1993) (consolidating two patent actions so "duplication of effort will be avoided as will the delay and expense of proceeding with separate depositions and separate motion schedules.").

This Panel has had much the same experience. *See In re Amoxicillin Patent and Antitrust Litig.*, 449 F. Supp. 601, 603 (J.P.M.L. 1978) (ordering transfer and consolidation of patent actions noting "the strong likelihood that discovery concerning these questions will be both complicated and time-consuming."); *In re Desloratadine*, 502 F. Supp.2d at 1355-56 (centralizing actions "expected to share factual questions with respect to the [] patent's validity and enforceability, among other things" in the district that "already encompasses all defendants, and [where] the common party patentholder is located"); *In re Metoprolol,* 329 F. Supp.2d at 1369-70 (holding centralization of four patent infringement actions dealing with validity of two complex pharmaceutical patents was appropriate); *In re FMC Corporation Patent Litigation*, 422 F. Supp. 1163, 1165 (J.P.M.L. 1976) (holding that transfer was "necessary" for patent litigations "involv[ing] common factual questions concerning the validity of the patent."); *In re*

Pharmastem Therapeutics, Inc., Patent Litig., 360 F. Supp. 2d 1362, 1364 (J.P.M.L. 2005) (ordering transfer and consolidation of patent actions that could be "expected to share factual and legal questions concerning such matters as the technology underlying the patents, prior art, claim construction and issues of infringement involving the patents."); *In re Phonometrics, Inc., Elec. Long Dist. Call Cost Computer and Recorder Patent Lit.*, 1997 WL 83673, *1 (J.P.M.L. 1997) (consolidating 21 separate actions that "will likely share questions concerning such matters as patent validity, prior art, obviousness and interpretation of the claims of the patent").

The logic underlying these district court and Panel decisions applies even more strongly in this case. Many of the documents and deposition witnesses that may be sought in discovery are located in Japan, where rosuvastatin was discovered. The logistical and language obstacles likely to be encountered in that process are immense. It is particularly important in such circumstances to avoid, to the extent possible, inconsistent document production obligations, inconsistent discovery deadlines, and multiple depositions of non-English-speaking witnesses.

Consolidation of these proceedings will conserve judicial resources by providing for a single judicial resolution of all such questions. Consolidation also will eliminate the possibility of inconsistent pretrial rulings in the consolidated actions. *In re Rivastigmine*, 360 F. Supp. 2d at 1361 ("Centralization under Section 1407 is necessary in order to . . . prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claims construction"); *see also In re FMC*, 422 F. Supp. at 1165 (preventing inconsistent pretrial rulings is a factor supporting consolidation). As this Panel has noted, "transfer under Section 1407 has the benefit of placing all actions . . . before a single judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs while ensuring that common parties are not

subjected to discovery demands which duplicate activity that has already occurred or is occurring in other actions." *In re Pharmastem,* 360 F. Supp. 2d at 1364.

C. The District of Delaware Is the Appropriate Transferee Forum

The District of Delaware is the best forum for transfer and consolidation of these related actions. Five of these related patent cases are already pending in Delaware without jurisdictional challenge and are certain to remain there. Those cases have been assigned to Judge Farnan, who already has experience in the field of cholesterol-lowering drug patents through his supervision of ANDA litigation relating to Lipitor®. *See Pfizer Inc. v. Ranbaxy*, (03-209-JJF) (consolidated); *Pfizer Inc. et al. v. Ranbaxy Laboratories Limited et al.*, (07-138-JJF); *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, (07-360-JJF); and *Pfizer Inc. v. Cobalt Pharmaceuticals, Inc.*, (07-790-JJF).

All of the Delaware actions have been assigned to Magistrate Judge Stark for pretrial proceedings. And while the Delaware court is currently awaiting Senate confirmation of one district judge, the vacancy has not deleteriously affected average case pendencies in the district. The average time from filing to trial in Delaware is 27 months, compared, for example, to 36 months for the District of New Jersey. *See* judicial statistics compiled at Federal Court Management Statistics located at http://www.uscourts.gov/cgi-bin/cmsd2007.pl, last visited on March 11, 2008. Indeed, pursuant to Judge Stark's instructions, all of the defendants are currently engaged in shaping a coordinated discovery plan in Delaware.

Domestic discovery related to the '314 and '460 patents also points all cases toward Delaware. Documents relevant to secondary considerations of nonobviousness of the '314 patent, such as the commercial success of CRESTOR®, are located at AstraZeneca facilities in Delaware. Employees likely to be witnesses related to the substance of those documents are also in Delaware. Moreover, the '460 formulation patent was invented at AstraZeneca facilities in

Delaware by two AstraZeneca employees. Those employees are likely witnesses relating to the '460 counterclaims in Delaware and Apotex's Florida declaratory judgment action. Documents relating to the formulation development and the inventors' discovery are similarly in Delaware. Virtually all domestic discovery related to the '314 and '460 patents is found in Delaware, making it the most convenient forum for discovery related to the '460 patent.

In addition, the U.S. marketing arms of both Apotex and Aurobindo are Delaware corporations for whom Delaware is a legally appropriate forum. Both parent corporations are foreign entities for whom the Delaware court is no less convenient than any alternative forum. Indeed, both foreign corporations are already litigating ANDA patent cases in Delaware. (*See supra* notes 1 and 2.) Noteworthy in this regard is Aurobindo's acknowledgement in accepting Delaware jurisdiction in *Sanofi-Aventis v. Aurobindo Pharma Ltd.*, No. 1:07-cv-5807 (D. Del.), that it had done so "to conserve the resources of the parties and for purposes of judicial efficiency." (Answer at 6, Nov. 5, 2007.) Further, the remaining parties are proceeding without objection in Delaware.

D. Relation to Pending District Court Motions

In a telephone conference held in the Delaware cases on February 20, 2008 by Magistrate Judge Stark, AstraZeneca stated its intention to file this motion to transfer the New Jersey and Florida actions to Delaware for pretrial purposes. AstraZeneca there stated it would do so without waiting for resolution of the jurisdictional issues in Delaware so as to avoid any delay in commencement of consolidated discovery. If, by the time this motion is heard, jurisdiction has been established in Delaware as to both Aurobindo and Apotex, this motion will be moot as to them.

E. Tag-Along Actions

Because there are at least two other generic manufacturers planning to market a generic version of CRESTOR®, there is a concrete prospect that additional suits on the '314 patent will be filed. A transfer order in the pending cases will provide a framework within which to quickly consolidate such additional cases as "Tag-along Actions" under Rule 7.4, Rules of Procedure of J.P.M.D.L.

III. CONCLUSION

For the reasons stated above, transfer of the New Jersey action and the Florida action to the District of Delaware for coordinated pretrial proceedings with at least five other actions pending in that court will reduce duplicative discovery of common questions of fact, will serve the convenience of parties and witnesses, and will promote the just and efficient conduct of these actions. Accordingly, the Panel should grant the requested motion for transfer and consolidation.

Dated: March 13, 2008
Washington, D.C

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BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION	)	MDL-_____

ASTRAZENECA'S REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Pursuant to Rule 16.1(b) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation (the "Panel"), AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha, collectively "AstraZeneca," submits this oral argument request in support of its Motion for Transfer and for Coordinated or Consolidated Pretrial Proceedings. Oral argument should be heard so that the parties can respond directly to the Panel's inquiries about the motion. There are nine separate actions, eight party groups, and many counsel. Oral argument will ensure that the Panel has access to the views of all parties regarding the propriety of consolidation, transfer, and the proposed transferee district.

Dated: March 13, 2008
Washington, D.C

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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: 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.

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA INC., MYLAN PHARMACEUTICALS INC., PAR PHARMACEUTICAL, INC., RANBAXY INC., RANBAXY LABORATORIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LTD, TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMA INC. and TORRENT PHARMACEUTICALS LIMITED, Defendants.	CIVIL ACTION NO. 07-572 GMS

ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND JURY DEMAND OF DEFENDANT AUROBINDO PHARMA LTD. TO PLAINTIFFS' COMPLAINT

Defendant Aurobindo Pharma Ltd. ("Aurobindo Ltd."), by and through the undersigned attorneys, answers the Complaint of Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis US") as follows:

PARTIES

COMPLAINT:

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: Aurobindo Ltd. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies all such allegations.

JURISDICTION AND VENUE

COMPLAINT:

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

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo Ltd. admits that subject matter jurisdiction over Plaintiffs' infringement claim on the patents-in-suit is proper for claims directed to Aurobindo Ltd. and denies that subject matter jurisdiction exists over Plaintiffs' infringement claim on the patents-in-suit directed to Aurobindo USA. Aurobindo Ltd. denies the remaining allegations of Paragraph 16.

COMPLAINT:

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.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that these allegations are directed towards a Defendant other than Aurobindo Ltd. and an answer by Aurobindo Ltd. is required, Aurobindo Ltd. denies the allegations of this Paragraph. As to Aurobindo Ltd., to the extent an answer is required, Aurobindo Ltd. denies the factual allegations in Paragraph 17. While Aurobindo Ltd. denies that it is subject to personal jurisdiction in this District, to conserve the resources of the parties and for purposes of judicial efficiency, Aurobindo Ltd. will not contest personal jurisdiction for purposes of this multi-defendant action only. Aurobindo Ltd. denies the remaining allegations of this Paragraph.

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December 18, 2007

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Via Federal Express & E-Mail

AstraZeneca Pharmaceuticals LP, et al. v.
Mylan Pharmaceuticals Inc., Docket No. 07-805;
Sun Pharmaceutical Industries Ltd., et al., Docket No. 07-806;
Sandoz Inc., Docket No. 07-807;
Par Pharmaceutical, Inc., Docket No. 07-808;
Apotex Inc., et al., Docket No. 07-809;
Aurobindo Pharma Ltd., et al., Docket No. 07-810; and
Cobalt Pharmaceuticals, Inc., et al., Docket No. 07-811

FINNEGAN
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Dear Counsel:

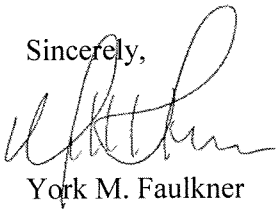
AstraZeneca and Shionogi ("Plaintiffs") recently filed the above-referenced actions in the U.S. District Court for the District of Delaware, alleging infringement of U.S. Patent No. RE 37,314, based on Abbreviated New Drug Applications submitted to the U.S. Food and Drug Administration. We represent Plaintiffs in those actions.

In an effort to simplify and expedite resolution of these issues, we have brought suit against each defendant in Delaware, where we believe personal jurisdiction is proper. To facilitate the efficient advancement of the actions, please confirm whether your respective clients will agree to consolidation of these actions.

We recognize that your clients have previously litigated in Delaware and assume that they will be content to do so again due to the efficiencies involved. In some instances, Plaintiffs either have or will file protective suits in alternative jurisdictions. We do not intend to serve the complaints in the protective suits, unless it becomes necessary to do so. Once these actions are underway in Delaware, Plaintiffs will dismiss the corresponding protective suits in the alternative jurisdictions.

We look forward to hearing from each of you and receiving the defendants' agreement to consolidate the actions in Delaware.

Sincerely,



York M. Faulkner

cc: Mary W. Bourke, Esq.

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

- - -

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., Defendant.	:	CIVIL ACTION NOS. 07-805 (JJF-LPS)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES INC., CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	:	and 07-806 (JJF-LPS)

- - -

Wilmington, Delaware
Wednesday, February 20, 2008 at 3:04 p.m.
TELEPHONE CONFERENCE

- - -

BEFORE: HONORABLE **LEONARD P. STARK**, U.S. MAGISTRATE JUDGE

- - -

(***Captions continue on page two***)

Brian P. Gaffigan
Registered Merit Reporter

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SANDOZ, INC., Defendant.	:	CIVIL ACTION NOS. 07-807 (JJF-LPS)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	:	and 07-808 (JJF-LPS)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. APOTEX INC., and APOTEX CORP., Defendants.	:	and 07-809 (JJF-LPS)

(*Captions continue on page three*)

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LTD., and AUROBINDO PHARMA USA, INC., Defendants.	:	CIVIL ACTION NOS. 07-810 (JJF-LPS)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. COBALT PHARMACEUTICALS, INC., and COBALT LABORATORIES, INC., Defendants.	:	and 07-811 (JJF-LPS)

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- oOo -

P R O C E E D I N G S

(REPORTER'S NOTE: The following telephone conference was held in chambers, beginning at 3:04 p.m.)

THE COURT: Good afternoon, counsel. This is Judge Stark. This is the time, as you know, for the status conference in seven different actions, all related. They have our civil case numbers beginning with 07-805 and ending 07-811.

I want to begin by learning who is on the call. So first, for AstraZeneca and the plaintiffs, who do I have on the line?

MS. BURKE: Good afternoon, Your Honor. This is Mary Burke from Connolly Bove representing the plaintiffs AstraZeneca and Shionogi. With me on the phone are Charley Lipsey and York Faulkner from Finnegan Henderson, Henry Renk from Fitzpatrick and Tom Stevens from AstraZeneca.

THE COURT: And who will be speaking for AstraZeneca plaintiffs on the call?

MR. LIPSEY: Your Honor, this is Charley Lipsey; and I'll be speaking for AstraZeneca.

THE COURT: Okay. Great. Is that all of the plaintiffs or are there other counsel for other plaintiffs?

MR. LIPSEY: That's it, Your Honor.

THE COURT: Okay. Great. Now, in Action No. 805 for the Mylan defendants, who is on the call?

MS. MAZZOCHI: Good afternoon, Your Honor, this is Deanne, D-E-A-N-N-E, Mazzochi, M-A-Z-Z-O-C-H-I, from the law firm Rakoczy Molino Mazzochi & Siwik in Chicago. Also with me from our firm is Tara Raghavan; and our local counsel is also here, and I'll have her introduce herself.

MS. MATTERER: Good afternoon. This is Mary Matterer from the law firm of Morris James.

THE COURT: Okay. And Ms. Mazzochi will be the

one speaking for the Mylan defendants?

MS. MAZZOCHI: Yes, Your Honor.

THE COURT: Okay. Thank you. And in Action No. 806, who is on the call for the Sun defendants?

MR. DROBNY: Good afternoon, Your Honor, this is Dane, D-A-N-E, Drobny, D-R-O-B-N-Y, at Winston & Strawn, as well as my partner, Chuck Klein.

MR. SEAMAN: And locally, John Seaman at Abrams & Laster.

THE COURT: Okay. And Mr. Drobny, you will be the one speaking?

MR. DROBNY: Yes, Your Honor.

THE COURT: Then Action No. 807, for the Sandoz defendants, who is on the call?

MR. PAVANE: Your Honor, this is Martin Pavane, P-A-V-A-N-E. And with me on the call is Darren Mogil, M-O-G-I-L; and in Delaware George Seitz, S-E-I-T-Z. And I will be speaking for the Sandoz defendants.

THE COURT: Great. Thank you very much.

In Action 808, that's the Par defendants. Who is on the call for them?

MR. BROWN: This is Dan Brown from Frommer Lawrence & Hague in New York representing Par. With me here in New York is Nick Giove from our firm; and in Delaware, Fred Cottrell from Richards Layton & finger.

THE COURT: Okay. And Mr. Brown, you will be the one speaking; correct?

MR. BROWN: Yes.

THE COURT: For the Apotex defendants in Action 809.

MR. HORWITZ: Your Honor, it's Rich Horwitz here in Wilmington at Potter Anderson; and with me from Welsh Katz, Robert Breisblatt, Laurie Haynie and Aron Carnahan; and I believe Mr. Breisblatt or Ms. Haynie will take the lead.

THE COURT: Mr. Breisblatt or Ms. Haynie, which one will it be?

MR. BREISBLATT: Your Honor, it will be Ms. Haynie doing the talking, but if there is no objection, I might chirp in from time to time.

THE COURT: Okay. We'll see how much chirping is necessary.

Okay. In Action 810, the Aurobindo defendants.

MR. KIRK: Your Honor, this is Richard Kirk from Bayard, P.A. here in Wilmington. My colleagues are Thomas Heneghan, H-E-N-E-G-H-A-N, Jeffrey Ward, and Edward Pardon, P-A-R-D-O-N, from Michael Best & Friedrich; and Mr. Heneghan will be our spokesman.

THE COURT: Okay. Thank you. And last, but not least, the Cobalt defendants in Action 811.

MR. HORWITZ: Your Honor, it's Rich Horwitz again. And with me for Cobalt, Steve Maddox from Foley & Lardner in DC.

THE COURT: Okay. And Mr. Maddox, you will be speaking for Cobalt?

MR. MADDOX: Yes, sir.

THE COURT: All right. Well, thank you, counsel. I have a court reporter with me. Obviously, it's imperative that before you speak, please identify yourselves so we can keep track of who is speaking, of course.

So as I understand it, all seven of these actions involve AstraZeneca and related entities as the plaintiffs. All seven of the cases claim that ANDA applications infringe the '314 patent and they all further are seeking a declaratory judgment of infringement pursuant to 35 U.S.C., Section 271(a). All of these cases, all seven have been assigned to Judge Farnan; and he, in turn, has referred them to me for all purposes, all pretrial purposes through, and including, the pretrial conference.

Have I said anything yet that is incorrect or that anybody disagrees with? Let me start with Mr. Lipsey.

MR. LIPSEY: No, Your Honor. You have it right so far.

THE COURT: And do any of the defense counsel think I have gotten anything wrong yet?

Okay. I'm hearing nothing so I will take that as a no. Thank you.

All right. Well, as I further understand, Mr. Lipsey, it appears that in five of the seven actions, there have been answers and counterclaims and by stipulation which I have ordered, AstraZeneca will be replying to any counterclaims by March 21st, 2008. Is that correct?

MR. LIPSEY: That is correct.

THE COURT: And, further, it appears that there are four actions which have motions to dismiss and with one exception, AstraZeneca will be replying to those motions by March 20th of this year, and the one exception is that Aurobindo has one motion to dismiss regarding the alleged lack of personal jurisdiction and a related joinder issue for which you are not going to respond until April 21st, 2008. Do I have that right, Mr. Lipsey?

MR. LIPSEY: Yes, Your Honor. That is correct. Two of those motions bear on whether the parties will be here in Delaware with us for trial. One of them is the Aurobindo motion you mentioned to which we have an agreement with Aurobindo for some limited jurisdiction discovery leading to our response on April 21st. There is a similar motion by Apotex and we have opened negotiations with Apotex hoping to get at least that motion on the same or approximately the same schedule as we have with Aurobindo,

and we will be chatting with them in the coming days trying to work that out.

THE COURT: Okay. Well, sticking with you, Mr. Lipsey, what, if anything, do the plaintiffs suggest I do with respect to scheduling at this point?

MR. LIPSEY: Well, we obviously were hoping to conduct all seven cases in the same court. All seven defendants appear to have contacts with Delaware. All seven defendants had conducted their ANDA litigation business before. We obviously would like to follow that through.

There is obviously a certain amount of jurisdictional discovery we would like to take in order to tee those issues up. We would like not to delay everybody in the process of doing that. In part, even if we were to lose on the in personam jurisdiction issue on one or both of these defendants, we are planning on filing shortly a motion before the Multi-District Panel to send such actions as may not be here at least for pretrial discovery. And that being the case, we figure it highly likely that discovery is going to go forward in this court no matter what the outcome of those motions is.

What we would like is to have a series of Rule 26(f) conferences with counsel for the defendants during March where we can frame a discovery plan. An important component for us will be some kind of protection built in

there to deal with complex cases with multiple parties where we have some hopefully common discovery propounded, hopefully a lead counsel identified, hopefully some rational limits on interrogatories and depositions and deposition time; the sort of thing that is normally done in complex litigation. And we would propose then to have a Rule 16 conference with Your Honor in mid-April or thereabouts.

The Multi-District Panel, the next hearing that we can hope to get from them is in May, I am told, so it's almost certain that issue will be heard, if not resolved, by then. What we are hoping is the two defendants that are currently challenging jurisdiction will be invited to, and would accept, the right to participate in framing the discovery plan here without prejudice to their positions on in personam jurisdiction so their input can be had and they can enjoy such discovery as is available here while we're sorting out the jurisdictional issues.

So that, in a somewhat long winded form, is what we would propose.

THE COURT: Okay. I appreciate that background, and I think I understand where you are coming from. I think the best way to get all the defense positions and responses to that -- generally, the topic is scheduling, but I do want to hear specifically of what you think of what Mr. Lipsey has proposed -- is I'm just going to go in order of the

cases by number. So we'll start with the Mylan defendants, and I believe that is Ms. Mazzochi.

MS. MAZZOCHI: Yes. Good afternoon, Your Honor. Deanne Mazzochi. The general rule with this many defendants, we're certainly not going to be looking to do duplicative discovery. I think that we would certainly be willing to work with the other defendants to try to find areas where we do have some common ground so that we're not duplicating discovery; but by the same token, Mr. Lipsey talked about rational limits on depositions and interrogatories. My understandings is while the '314 patent is at issue in all of the cases, there are additional patents that are at issue in some cases and not in others. I believe there are some pending declaratory judgment claims by the other defendants to bring in other patents. So we just would want to make sure that there is no prejudice to any party in terms of being able to pursue discovery and that limits aren't going to be placed on any particular party for discovery.

Well, let me put it this way. I just don't want the defendants to be treated as if they are all one defendants with common interests because I think that there are going to be instances where the parties' common interests or the defendants' common interests are going to diverge.

THE COURT: Well, if I understood Mr. Lipsey, I think he intends to have separate Rule 26 conferences with each of the defendants. And I guess that would ultimately result in either multiple scheduling orders or at least one proposed scheduling order where the parties tried to agree on as much as they can but would presumably preserve the opportunity for each of the different defendants to indicate their specific individual needs on any particular type of discovery.

MS. MAZZOCHI: Right.

MR. LIPSEY: If I may, Charles Lipsey again. I actually was proposing meeting with all the defendants in which we could hash out exactly the kind of issue that just got raised. There may well be some individual needs that would have to be addressed, but I would hope to get some agreement amongst all of the defendants at least on how we're going to handle the common discovery.

THE COURT: Okay. I guess I didn't mean to impose whether it would be one meeting or seven meetings or some other number but that there would be a chance for all the defendants together, or individually, to air with the plaintiff what their view was on discovery and ultimately that would result in a document that I would see which would hopefully agree on most or all of the discovery issues, and to the extent that it didn't, we would have obviously the

scheduling conference and I would have to make some decisions.

Is that a fair characterization, Mr. Lipsey?

MR. LIPSEY: Absolutely, Your Honor.

THE COURT: And I think with that clarification, Ms. Mazzochi, that would not be shutting down your client from raising whatever issues they have. Am I right about that?

MS. MAZZOCHI: Right. I would hope not.

THE COURT: Okay. Was there anything more you wanted to add, Ms. Mazzochi?

MS. MAZZOCHI: No, Your Honor.

THE COURT: All right. For Sun, is it Mr. Drobny?

MR. DROBNY: Yes, Your Honor. And with Your Honor's clarification, we have no issues with what the plaintiffs have proposed.

THE COURT: Okay. For Sandoz, Mr. Pavane?

MR. PAVANE: Yes, we too are in agreement.

THE COURT: Okay. Mr. Brown for Par?

MR. BROWN: Likewise.

THE COURT: Okay. Was it Mr. Haynie for Apotex?

MS. HAYNIE: That was Ms. Haynie.

THE COURT: I apologize.

MS. HAYNIE: That's fine. With the

understanding there would no prejudice to our position, we would be willing to engage in preliminary discussions. However, we feel we should also mention we have filed a declaratory judgment action in the Middle District of Florida on a different patent, although it's related to the same underlying drug. It's a different patent, the '460 patent that we have filed in Florida. So that could raise different issues for our client.

THE COURT: Has that case proceeded at all yet?

MS. HAYNIE: No, it has not been answered yet. The answer is due March 26th.

MR. LIPSEY: Your Honor, Charles Lipsey again. That is one we would be approaching the judicial panel in Multi-District Litigation to send up here in the event that it needs to be litigated.

THE COURT: Okay. Thank you. But, Ms. Haynie, with my understanding at least that there is this other action out there which may cause some complications with you and your client, you are willing to sit down and talk with Mr. Lipsey about the possibility of a discovery plan and such here.

MS. HAYNIE: Yes. Under the conditions he discussed, yes.

THE COURT: For Aurobindo, is it Mr. Heneghan?

MR. HENEGHAN: Thank you, Your Honor. Our

situation is a little bit different in that we have the case pending here and the identical case is also pending in New Jersey. And unlike the situation with Apotex where the defendants filed its declaratory judgment in a different jurisdiction, the case in New Jersey was actually filed against us by the same plaintiffs on the exact same legal theory, the same patent. In fact, the complaints are word for word the same with the exception that the caption that identifies the court. That case already has an initial scheduling conference set for the end of March and it's going forward.

That being said, and without waiving any of our arguments on personal jurisdiction, we would be willing to cooperate in some sort of discussion about consolidating discovery regardless of how the cases go forward. I just want to make sure the court was aware that the situation with our motion to dismiss on personal jurisdiction is a little different in that it's a threshold issue that would possibly just take us out of Delaware completely.

With that being said, we are willing to cooperate in working together on a common discovery plan.

THE COURT: Okay. Thank you for that.

Mr. Lipsey, did you want to say anything about whether the New Jersey action impacts anything of this at this time?

MR. LIPSEY: Well, the New Jersey action is the other one that we would approach the Multi-District Panel on. And just to explain, that was what is called in this business a protective suit which we did not serve. Our intention was to proceed there only if the court were to determine that we did not have personal jurisdiction here in Delaware because there are substantive rights that turn on having the case pending. And while the court has the power to transfer it to where it should be, and we would expect that would happen if we were to be wrong on the jurisdictional issue, that suit was filed out of an abundance of caution. The answer was filed even without it being served. I don't want to wait until we resolve the jurisdictional issue here to approach the Multi-District Panel just because it takes so long to get on the docket there. So basically what we would like to do is proceed basically in parallel to fight the jurisdictional issue here. Hopefully, that will moot out the pleading that we filed with the Multi-District Panel.

THE COURT: I understand that. Okay. Finally, for Cobalt, was it Mr. Maddox?

MR. MADDOX: Yes, Your Honor. I beg your pardon?

THE COURT: I was just going to ask your position on meeting and talking about a discovery plan and

all that.

MR. MADDOX: My position is we've got the right sequence. I think everyone on this phone has been through these cases before, and it would be a miracle if there were no issues for you to resolve at a Rule 16 conference. And so I would propose that the sequence makes sense. The timing, I don't think we really need to wait until mid-to-late April for that. I think March is a long month. We can get a lot done there, and maybe have it at the end of March or beginning of April.

THE COURT: Okay. I won't, at this point, give up on the possibility of a miracle, but I certainly won't hold my breath for it. I appreciate the warning.

Well, just looking at my schedule, I could schedule a scheduling teleconference for the morning of April 4th, if you folks could get together and have your meeting or meetings and get me your proposal which outline any objections let's say by a week before that, which would be March 28th.

Mr. Lipsey, could you work with that schedule?

MR. LIPSEY: I unfortunately, have a deposition scheduled on the 4th. It might be a little easier if we could talk and make sure that we can get that covered for -- I am absolutely free on the 10th. I don't know whether that is something I can suggest.

THE COURT: No, I could do the morning of the 10th. And if I could get your submission a week before, by the 3rd?

MR. LIPSEY: Okay. That's fine with us. Is that okay with everybody else?

THE COURT: Anybody who has a problem with that date, please let me know by your name.

MR. HENEGHAN: Judge, this is Tom Heneghan on behalf of Aurobindo. We don't have a problem with that as long as it's clear we're happy to participate without any prejudice to our motion on personal jurisdiction.

THE COURT: Yes, nobody is waiving any rights or prejudicing any rights or at least that is not the intent. All I'm having you do is agree to talk without prejudice to your rights and to jointly submit something to me on April 3rd setting out a schedule or schedules, and everybody can again preserve their rights in writing in that filing and certainly should set out any objections that they have, and then we'll talk on April 10th and I'll try to resolve things.

With that background and understanding, does anybody have any objection to the timing of April 3rd for the submission and April 10th, let's say 10:00 a.m., for the teleconference?

Okay. I'm not hearing any objections.

MR. BREISBLATT: None, Your Honor. Robert Breisblatt for Apotex. The submission you want on April 3rd, do you want a single position with each parties or do you want each party to do their own submission?

THE COURT: I would prefer to have a single submission that laid out everybody's position, but I'd like to leave it to the discretion of all of you. My preference is one that assumes the document I would get would be something that would be manageable and would focus me on where there are disputes, and hopefully there aren't too many. If that assumption turns out to be incorrect and seven separate submissions are going to be, the parties feel, more appropriate, I want to leave you the opportunity to do that.

Is that enough guidance or do you need me to be more definitive?

MR. BREISBLATT: No, I think that is fine, Your Honor. Again, Bob Breisblatt. I think what I have seen lately where there are multiple defendants and a single plaintiff, and there isn't major agreement between the two, is that there is two submissions, one from the plaintiff and one from the defendants, and where the defendants have differing positions, they're placed in the defendants' order as well but if you would prefer a single, we can obviously do it that way.

THE COURT: Okay. So my preference is a single. If it's not going to be one, obviously two is better than seven, but I will accept up to eight different submissions, if need be, but I want them on April 3rd. And I am trusting the parties will work with their best good faith efforts to keep the submissions to the minimum number necessary to set out everybody's position for me. Okay?

Is there anything further?

MR. HENEGHAN: Judge, this is Tom Heneghan.

THE COURT: Yes.

MR. HENEGHAN: I just have a question. With all the advent of all the electronic filing we're doing these days, is there anything other than just filing it electronically that you want? Do you want a copy served to chambers or is the regular electronic filing sufficient? I'm just not sure what your preference is.

THE COURT: Yes. If you could deliver a courtesy copy, hand deliver a courtesy copy to chambers, that is very helpful even in the era of e-filing. I appreciate you asking.

Is there anything further that we should discuss at this point from anybody?

MR. LIPSEY: Charley Lipsey again. Not for the plaintiffs.

THE COURT: Okay. Any defendants want to speak

now?

I'm hearing silence again. Okay. I will take that as we've covered what we can cover today. I appreciate everybody's time, and I'll look for one or more submissions on April 3rd and we'll get an order out scheduling a scheduling teleconference for the morning of April 10th at 10:00 a.m., and I will look forward to that and thank you all for your time.

(The attorneys respond, "Thank you, Your Honor.")

THE COURT: Okay. Good-bye.

(Telephone conference ends at 3:29 p.m.)

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC., Defendants.	Case No. 07-CV-06020 (MLC)(JJH) **DEMAND FOR JURY TRIAL** ***DOCUMENT ELECTRONICALLY FILED***

DEFENDANT AUROBINDO PHARMA LIMITED'S ANSWER TO THE COMPLAINT

Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

10. Plaintiffs purport and claim to own, and to have the right to enforce the '314 patent.

11. On or about December 18, 2007, Plaintiffs sued Defendants in this District alleging infringement of the '314 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT I

(Declaratory Judgment of Invalidity of the '314 Patent)

12. Aurobindo India re-asserts and re-alleges paragraphs 1-11 of this Counterclaim as if fully set forth herein.

13. There is an actual, substantial, and continuing justiciable case or controversy between Aurobindo India and Plaintiffs regarding the invalidity of the '314 patent, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. A declaration of rights between the parties is both appropriate and necessary to establish that the '314 patent is invalid and therefore cannot be infringed by Aurobindo India.

14. The claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code, including §§ 102, 103, 112, and 251 thereof.

15. Aurobindo India is entitled to a judicial declaration that the claims of the '314 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo India respectfully requests:

A. That the Complaint filed by Plaintiffs against Aurobindo India be dismissed in its

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LIMITED, and IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	)	
Plaintiffs,	)	C.A. No. 07-811-JJF
v.	)	
COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES INC.,	)	
Defendants.	)	

DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants, Cobalt Pharmaceuticals, Inc. and Cobalt Laboratories, Inc. (collectively, "Defendants"), hereby answer the Complaint filed by AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "Plaintiffs"), as follows:

Nature of the Action

1. Defendants admit that the Complaint purports to state a civil action for infringement of U.S. Patent No. RE37,314 ("the '314 patent") under 35 U.S.C. § 271(e) and (a). Defendants admit that the Complaint purports to relate to Abbreviated New Drug Application ("ANDA") No. 79-167 filed by Cobalt. Defendants deny each and every remaining allegation contained in paragraph 1 of the Complaint.

Parties

2. Defendants lack sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 2 of the Complaint and, therefore, deny each and every allegation in paragraph 2 on that basis.

25. This Court can and should declare the rights and legal relations of the parties regarding the '314 and '460 patents pursuant to, *inter alia*, 28 U.S.C. §§ 2201 and 2202 and 21 U.S.C. § 355(c)(3)(D)(i)-(ii) and 35 U.S.C. § 271(e)(5).

26. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because each conducts substantial business in, and has regular and systematic contact with, this District, including conduct related to the marketing, distribution and/or sale of its pharmaceutical products in this District.

27. This Court also has jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by filing numerous lawsuits in this District.

28. This Court also has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because each Plaintiff has consented to jurisdiction by bringing in this District an action against Cobalt which arises from the same events as these Counterclaims.

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

First Claim for Relief: Declaratory Judgment of Invalidity of the '314 Patent

30. Defendants/Counterclaim-Plaintiffs assert and reallege paragraphs 1 through 29 of the instant Counterclaims as if fully set forth herein.

31. One or more claims of the '314 patent would have been obvious to one of skill in the relevant art in light of the prior art at the time the application from which the '314 patent issued was filed.

32. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '314 patent are invalid under at least one of 35 U.S.C. §§ 102, 103, 112, and/or 251.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Mylan Pharmaceuticals Inc., Defendant.	Civ. No. 07-805-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sun Pharmaceutical Industries Ltd., Defendant.	Civ. No. 07-806-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sandoz Inc., Defendant.	Civ. No. 07-807-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Par Pharmaceutical Inc., Defendant.	Civ. No. 07-808-JJF-LPS
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Apotex Inc. and Apotex Corp., Defendants.	Civ. No. 07-809-JJF-LPS
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.	Civ. No. 07-810-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,

Plaintiffs,

v.

Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc.,

Defendants.

Civ. No. 07-811-JJF-LPS

ORDER

At Wilmington this **21st** day of **February, 2008**.

IT IS ORDERED that a Rule 16 scheduling teleconference has been scheduled for **April 10, 2008 at 10:00 a.m.** with Magistrate Judge Stark. **Plaintiff's counsel shall initiate the teleconference call to 302-573-4573.** Attached to this Order is a draft copy of the Magistrate Judge's Rule 16 Scheduling Order and Final Pretrial and Trial Management Order. Counsel shall confer regarding proposed dates in the scheduling order and shall submit their proposal(s) no later than **April 3, 2008**.

Delaware counsel are reminded of their obligations to inform out-of-state counsel of this Order. To avoid the imposition of sanctions, counsel shall advise the Court immediately of any problems regarding compliance with this Order.

UNITED STATES MAGISTRATE JUDGE

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION	)	MDL - _____

Proof of Service

I hereby certify that a copy of the foregoing Motion, Brief, Schedule of Actions and accompanying Exhibits were served on March 13, 2008 by First Class Mail on the Courts and by First Class Mail and Electronic Mail on Counsel as follows:

Clerk, District of Delaware
Wilmington, DE
(First Class Mail only)

Clerk, District of New Jersey
Newark, NJ
(First Class Mail only)

Clerk, Middle District of Florida
Tampa, FL
(First Class Mail only)

Defendants

Apotex Inc. & Apotex Corp.
D. Delaware, C.A. No. 07-809
M.D. Florida, C.A. No. 8:08-cv-00213

Counsel

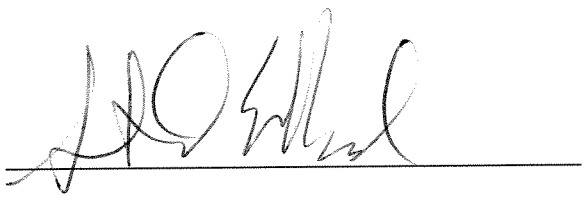
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, **Plaintiffs,** **vs.** **AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA INC.** **Defendants.**	**Civil Action No. 3:07-cv-06020 (MLC)(JJH)**

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of Plaintiffs' Reply Brief in Support of its Motion to Stay with supporting papers were caused to be served on March 14, 2008, upon the

following via ECF and/or Overnight Mail:

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