IN THE 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) ***DOCUMENT ELECTRONICALLY FILED*** **RETURN DATE: March 25, 2008**

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION

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INTRODUCTION

In opposing Defendants' motion to dismiss, Plaintiffs ignore the plain evidence that Aurobindo Pharma Limited ("Aurobindo India") alone submitted the abbreviated new drug application and paragraph IV certification that led to this case. They present no evidence that Aurobindo Pharma USA ("Aurobindo USA") actively participated in preparing or submitting the application, and they fundamentally fail to address the legal arguments presented by Defendants. Instead, Plaintiffs employ misdirection, cast aspersions on Defendants' motives, and engage in speculation about illegal importation of drugs from Canada. Defendants' motion to dismiss should be granted.

ARGUMENT

POINT I

THERE IS NO SUBJECT MATTER JURISDICTION FOR COUNT I WITH RESPECT TO AUROBINDO USA

Plaintiffs' only argument in support of subject matter jurisdiction over Count I of the Complaint (D.I. 1), the Hatch-Waxman claim, with respect to Aurobindo USA rests on the signature of an Aurobindo USA employee who fulfilled a ministerial duty under the law by acting in his individual capacity as an agent for Aurobindo India. This does not mean Aurobindo USA submitted the ANDA -- nor would it even if Aurobindo USA itself were the agent. The facts remain undisputed that Aurobindo USA had no active participation in the preparation of the ANDA or its submission to the FDA. Plaintiffs' actions show they understand this and their attempts to delay this case further by seeking additional meaningless discovery should be rejected. The Court should dismiss Count I of the Complaint against Aurobindo USA for lack of subject matter jurisdiction.

A. Aurobindo India Alone Submitted the ANDA

By the plain language of § 271(e)(2), the entity that "submits" an abbreviated new drug application ("ANDA") commits the act of infringement:

> (2) It shall be an act of infringement to *submit* -
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [i.e., an ANDA] or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (emphasis added). Here, the undisputed evidence is that Aurobindo India -- and not Aurobindo USA -- submitted the ANDA. That much was clear enough from Defendants' initial motion, and it is even more clear from the portions of the ANDA that Plaintiffs submitted to this Court. The applicant on the FDA Form 356h is Aurobindo India, not Aurobindo USA. (D.I. 28, Ex. 1.) The cover letter enclosed with the ANDA states in no uncertain terms that "*Aurobindo Pharma Limited* here with submits an" ANDA. (D.I. 28, Ex. 1.) The letter is on Aurobindo India's letterhead, and the letter and Form 356h are signed by Aurobindo India's U.S. agent -- as is required by law because Aurobindo India is a foreign entity. Other substantive portions of the ANDA provided to Plaintiffs along with the paragraph IV certification (neither of which Plaintiffs provided to the Court) similarly demonstrate that the substantive work on ANDA was prepared by Aurobindo India in India. (Pardon 3/14/08 Decl., Ex. A.)[1] The evidence unequivocally shows that Plaintiffs are wrong in their allegation that

[1] March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction.

Aurobindo USA "filed" the ANDA. The ANDA was submitted by Aurobindo India and no one else.

Contrary to Plaintiffs' assertions, the fact that Aurobindo India's U.S. agent was an employee of Aurobindo USA does not mean that Aurobindo USA submitted the ANDA. None of the documents relied upon by Plaintiffs show that Aurobindo USA acted in its corporate capacity to countersign or otherwise authorize the ANDA. To the contrary, all of the documents reference Aurobindo India as the submitter. Even the agent's email address was his personal address, not a corporate address. (D.I. 28 at Ex. 2.) The U.S. agent was an individual acting in an individual capacity as required by law, not Aurobindo USA.

B. Even if the Agent's Actions Could be Imputed to Aurobindo USA, That Does Not Mean Aurobindo USA Submitted the ANDA

Even if the agent's actions could be imputed to Aurobindo USA, that does not mean Aurobindo USA submitted the ANDA. As noted earlier, FDA regulations require a foreign entity to provide the name and address of a U.S. "agent, attorney, or authorized official" who must countersign the application. 21 C.F.R. § 314.94. Tellingly, Plaintiffs do not dispute that the purpose of the agency requirement is primarily to permit service of process. Nor do Plaintiffs dispute that it would be absurd to convert this "agency" requirement into Hatch-Waxman liability, because otherwise a party's attorney who acted as an agent could be dragged into a lawsuit as an infringer under the Hatch-Waxman Act. Instead, Plaintiffs merely claim that the FDA's interpretation of § 271(e)(2) is not entitled to deference because the statute is part of the Patent Act. (D.I. 26 at 8.)

Plaintiffs are flatly wrong. Section 271(e)(2) is part of the Hatch-Waxman Act, Pub. L. No. 98-417 (1984), and "Congress specifically authorized the FDA to engage in . . . rulemaking necessary for administration of the Act." *Apotex, Inc. v. Thompson,* 347 F.3d 1335, 1351-52

(Fed. Cir. 2003) (citing 21 U.S.C. § 355 note, Pub. L. No. 98-417, § 105, 98 Stat. 1585, 1597 (1984)). Consequently, the FDA's interpretation of this statute is entitled to deference under *Chevron U.S.A Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Apotex,* 347 F.3d at 1351-52; *cf. Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 934 (N.D. Ill. 1995) (stating that § 271(e)(2)(A) expressly incorporates § 355(j) which must be read in context with other subparagraphs of § 355).

Plaintiffs also attempt to impute the patent knowledge and bioequivalence information in the ANDA onto Aurobindo USA by arguing that the certification contained in FDA Form 356h requires that the person signing it must have substantive knowledge of the ANDA and is prepared to update the ANDA with new safety and other information as required by the FDA. (D.I. 26 at 11.) According to Plaintiffs' logic, the agent must be a scientific expert on every substantive detail of every portion of the ANDA. That would mean that if an attorney signed the ANDA as an agent of the pharmaceutical company, then the attorney must have substantive knowledge of the ANDA as well as his firm. This is an absurd result that was clearly not contemplated by Congress when it wrote the Hatch-Waxman Act or by the FDA when it drafted implementing regulations.[2]

Citing § 271(e)(2), Plaintiffs also assert that Aurobindo USA is a proper party because the purpose of the ANDA submission is to permit Aurobindo USA to "sell" rosuvastatin within the United States if the ANDA is approved. (D.I. 26 at 8.) Even if true, that is irrelevant. The plain language of the statute makes the act of *submitting* the ANDA the infringing act -- not being the beneficiary of such a submission. Plaintiffs seem to be arguing that because

[2] Similarly, signing a cover letter that merely identifies the contents of the ANDA does not mean the agent is the applicant or "submitted" the ANDA.

Aurobindo USA might benefit from Aurobindo India's submission, Aurobindo USA must have submitted the ANDA as well. Plaintiffs' logic is plainly wrong.

C. The *Lupin* Cases Require More Than an Individual's Signature to Show that the U.S. Subsidiary is an ANDA Applicant

Plaintiffs argue that this case is indistinguishable from the *Lupin* cases because Aurobindo USA is Aurobindo India's wholly owned subsidiary and markets its pharmaceutical products in the United States. (D.I. 26 at 9.) Plaintiffs again fail to produce any evidence to show that Aurobindo USA played a role similar to the U.S. subsidiary in the *Lupin* cases. For example, in *Aventis Pharma Deutschland GMBH v. Lupin Ltd*., 403 F. Supp. 2d 484 (E.D. Va. 2005), the court found that the U.S. subsidiary's "own website indicates it does much more than submit ANDA filings on behalf of its parent as it suggests." *Id.* at 493. In *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303 (D. Md. 2007), the court held that "when a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. *and is actively involved in the ANDA process*, the subsidiary also 'submits' an ANDA application." *Id.* at 306-07 (emphasis added). In these cases, therefore, both courts were persuaded that Lupin's U.S. subsidiary played a greater role than just marketing and distributing the approved generics based on facts that are not present in this case. Here, Plaintiffs have produced no evidence to show that Aurobindo USA submitted this ANDA or was *actively involved in the ANDA process.* Even if this Court accepts the legal conclusions in the *Lupin* cases, the facts in this case show only that an individual who also happens to be an employee of Aurobindo USA acted as Aurobindo India's agent in his personal capacity. That is not enough to find that he was actively involved in the ANDA process, let alone that Aurobindo USA was.

D. Asserting Count I Against Aurobindo USA is a Transparent Attempt to Obtain Personal Jurisdiction Over Aurobindo India in Delaware

Plaintiffs do not even attempt to hide their motives for dragging Aurobindo USA into this case: since personal jurisdiction over Aurobindo USA exists in Delaware, they need its presence in that case in order to try to establish some sort of corporate "alter ego" relationship for personal jurisdiction purposes so as to "hook" Aurobindo India there. (D.I. 26 at 3.) It would look odd indeed if Plaintiffs named Aurobindo USA in Delaware but not here, so Plaintiffs have named it here as well. The fact that Aurobindo USA is not truly a proper or necessary party under the Hatch-Waxman Act is verified by the fact that Plaintiffs offered, in exchange for not challenging jurisdiction in Delaware, to drop from the case the American subsidiaries of the other Delaware foreign defendants whom Plaintiffs were concerned might challenge jurisdiction there.

The law is clear. "[s]ubject matter jurisdiction *is* lacking if the alleged basis for jurisdiction 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or where such a claim is wholly insubstantial or frivolous.'" *Nesbit v. Gears Unlimited, Inc.*, 347 F.3d 73, 80 (3d Cir. 2003) (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998)) (emphasis in the original). Therefore, this Court should dismiss Count I of the Complaint against Aurobindo USA because Plaintiffs appear to seek Aurobindo USA's presence in this case (and Delaware) in order to establish personal jurisdiction over Aurobindo India in Delaware.

E. Plaintiffs' Attempt to Obtain a Continuance is Improper

Consistent with their other actions in attempting to delay this proceeding, Plaintiffs also argue that Aurobindo USA's motion to dismiss Count I is not really based on lack of subject matter jurisdiction, but rather is a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6). The reason Plaintiffs do so is because they cannot dispute the law that "a court may

inquire into jurisdictional facts without viewing the evidence in a light favorable to either party." *Nesbit*, 347 F.3d at 77. It is Plaintiffs' responsibility to demonstrate subject matter jurisdiction at all stages of the litigation, and the "jurisdictional facts" plainly demonstrate that Plaintiffs' allegations with respect to Aurobindo USA are wrong and that subject matter jurisdiction doesn't exist. Consequently, Plaintiffs seek to delay by asserting that this is not really a motion about subject matter jurisdiction.

Plaintiffs are flatly wrong. As explained earlier, the entire rationale for 35 U.S.C. § 271(e)(2) in the first place was to create "a highly artificial act of infringement" to enable the holder of a drug patent to sue the submitter of an ANDA in order to prompt a judicial resolution of the patent issue where jurisdiction to do so had previously been lacking. *Eli Lilly & Co. v Medtronic, Inc.*, 496 U.S. 661, 677-68 (1990). Discussing the statutory scheme in which an applicant who submits an ANDA certifies that the product would not infringe a valid patent and then notifies the patent holder of that certification, the Court stated:

> This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35 U.S.C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, *an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2) -- the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification* that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." § 271(e)(4)(C). Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.

Eli Lilly, 496 U.S. at 678 (emphasis added). The question whether this Court can proceed under § 271(e)(2) with respect to Aurobindo USA is plainly a question that implicates this Court's subject matter jurisdiction.

Furthermore, Plaintiffs have no basis to ask for further discovery in any event because they have had all of the discovery they need. After Aurobindo USA filed its motion to dismiss on January 31, 2008, Plaintiffs did not initially request discovery on this issue – nor is it particularly relevant. Plaintiffs first obtained an automatic extension of the deadline to respond to Monday, March 3. In the interim, Defendants agreed to limited discovery in Delaware for the purpose of enabling Plaintiffs to respond to Aurobindo India's motion to dismiss for lack of *personal* jurisdiction there. On February 28 -- two working days before their response to this motion was due -- Plaintiffs for the first time asked for documents they asserted were relevant. In the spirit of cooperation, Defendants produced documents the next day. These documents included all of the relevant initial portions of Aurobindo India's ANDA and are clearly sufficient to demonstrate that Aurobindo USA had no substantive role in the process. Plaintiffs' attempts to stave off dismissal in order to conduct more meaningless "discovery" should be rejected.

POINT II

THERE IS NO SUBSTANTIAL CONTROVERSY OF SUFFICIENT IMMEDIACY AND REALITY TO CREATE SUBJECT MATTER JURISDICTION FOR COUNT II

Plaintiffs seek to embroil both Defendants in a declaratory judgment action of patent infringement under § 271(a) based on events that Plaintiffs themselves acknowledge will occur only upon FDA approval of the ANDA and most likely after the Hatch-Waxman litigation has concluded. Plaintiffs' remaining arguments are unavailing and simply prove that they can obtain all necessary relief through the Hatch-Waxman claims in Count I.

A. Plaintiffs Admit that Declaratory Judgment Jurisdiction for Their § 271(a) Claim is Lacking

Plaintiffs' claims that there is a substantial controversy of sufficient immediacy and reality to create declaratory judgment jurisdiction for a § 271(a) claim is belied by their own words. In seeking a stay of this action, Plaintiffs themselves wrote that "Defendants do not yet have FDA approval of their ANDA. Therefore, even if this action could be resolved in Defendants favor tomorrow Defendants still could not sell their generic product." (D.I. 20-2 at 8.) Clearly, Plaintiffs themselves do not believe that Aurobindo India could sell its generic drug in the near future, so it must be true that there is no substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Plaintiffs also argue that the automatic 30-month stay of FDA approval triggered by their filing this action could be shorter if a court ruled that the '314 patent was invalid or not infringed. What does that matter? If a court so ruled, that would mean it had done so under § 271(e)(2) -- which would obviate the need for declaratory judgment jurisdiction under § 271(a) and is exactly why § 271(e)(2) was created in the first place.[3]

B. Aurobindo India Did Not "Open the Door" to a § 271(a) Action by Filing a Counterclaim to Plaintiffs' § 271(e) Action

Plaintiffs argue that Aurobindo India's counterclaim for a declaratory judgment of patent invalidity opens the door for their declaratory judgment action under § 271(a). Plaintiffs ignore the obvious: Aurobindo India's counterclaim is a counterclaim under the Hatch-Waxman Act,

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[3] Plaintiffs also incorrectly state that considering the 30-month stay would preclude a court "from exercising personal jurisdiction over a declaratory judgment action … [because] the courthouse door would be barred to ANDA applicants who, having been sued on some patents (creating a 30-month stay), wish to resolve infringement and validity issues for other non-asserted patents potentially covering the proposed generic product to avoid leaving a threat of suit upon ultimate product launch." (D.I. 26, Pls.' Resp. Br. at 17-18.) As noted in the discussion of *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007), *infra*, Plaintiffs are wrong because there is a specific statutory provision that exists to cover that scenario.

not § 271(a). That's precisely what the Supreme Court was talking about when it stated that "the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Eli Lilly*, 496 U.S. at 678.

Plaintiffs further quote *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007), out of context to support their argument. *Teva* involved declaratory judgment jurisdiction under § *271(e)(5)*, the "patent certainty" provision of the Hatch-Waxman Act, *not* § 271(a). Teva had notified Novartis that it had filed a paragraph IV certification with respect to five Novartis Orange Book patents. *Id.* at 1334. Novartis, however, only asserted one of those five patents against Teva in a Hatch-Waxman lawsuit. *Id.* at 1334-35. In return, Teva brought a declaratory judgment action on the four remaining Orange Book patents under 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) to obtain "patent certainty," as is permitted under those provisions. The Federal Circuit merely reasoned that since Novartis had created a controversy under § 271(e)(2) by suing Teva, then Teva could sue under § 271(e)(5). *Teva*, 482 F.3d at 1342. The case has nothing at all to do with § 271(a).

C. Plaintiffs' Interpretation of the § 271(e)(1) Safe Harbor Provision Eviscerates It

Section 271(e)(1) unequivocally provides a "safe harbor" for otherwise infringing activities "reasonably related to" the development of an ANDA. Plaintiffs effectively contend that the act of filing the ANDA itself establishes jurisdiction under § 271(a) because it proves that Defendants will infringe in the future. (See, e.g., reference to Defendants' purported "current activity" at D.I. 26 at 14; see also D.I. 1 at ¶ 27, which alleges that by filing the ANDA Defendants have made "substantial preparations" to infringe under § 271(a).) Plaintiffs' argument creates an exception to the safe harbor provision that would swallow the rule. If there is a safe harbor for otherwise infringing activities associated with filing a ANDA, the act of

filing it does not then automatically convert those same pre-filing activities into infringement. Under Plaintiffs' interpretation of the law, however, it would.

Plaintiffs rely on *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), to argue that activities protected from infringement under the § 271(e)(1) safe-harbor provision are relevant to establish an actual case or controversy. (D.I. 26, Pls.' Resp. Br. at 14.) Plaintiffs again disregard the facts of the case. In *Glaxo*, the plaintiff filed a declaratory judgment action under *§ 271(g)* for infringement of a "method of making" patent. Patents that cover a method of making a drug are not listed on the Orange Book and § 271(e)(2) "does not provide jurisdiction to hear infringement cases regarding claims directed to methods for making drugs." *Glaxo*, 110 F.3d at 1570. Consequently, *Glaxo* has nothing to do with § 271(e)(2) or the associated safe harbor provision of § 271(e)(1), and Plaintiffs' arguments to the contrary should be rejected.

D. Plaintiffs' Claims that Their Remedies under Count I May be Inadequate Prove the Speculative Nature of Their Claims Under Count II

Under Count I, if Plaintiffs successfully prove infringement under § 271(e)(2) they will be entitled to the remedies available under § 271(e)(4), which include an injunction prohibiting Aurobindo India from manufacturing, using, selling, offering to sell, or importing rosuvastatin in the United States. Prohibiting Aurobindo India from importing rosuvastatin would suffice to prevent it from providing rosuvastatin to Aurobindo USA for distribution within the United States. For that reason alone, Aurobindo USA does not need to be in the case.

Knowing this, Plaintiffs proceed to engage in wild speculation which in fact proves why there is no jurisdiction under Count II. For example, they state that the § 271(e)(4) remedies under Count I would not prohibit Aurobindo USA from illegally importing unapproved rosuvastatin from Canada or other countries, and that § 271(e)(4) could not prohibit Aurobindo USA from being a distributor of the product covered by another generic company's ANDA.

(D.I. 26 at 23.) Plaintiffs, however, have not alleged that Aurobindo is conducting any of these activities -- nor could they, because no evidence of any such activities exist. If Aurobindo India had never filed a paragraph IV certification, Plaintiffs could not come to this Court out of the blue to seek a declaratory judgment of infringement solely under § 271(a) based on such wild speculation. Plaintiffs are now arguing, however, that the act of filing an ANDA somehow means these unrelated things might really happen. Plaintiffs' argument is ludicrous and it proves just the opposite: they can get all the relief they need from Count I.[4]

E. At a Minimum, the Court Should Decline to Exercise its Discretion to Hear Count II

Plaintiffs argue that exercising jurisdiction over Count II will promote judicial economy. (D.I. 26 at 20-21.) Plaintiffs fail to explain how adding a second, redundant claim and an additional unnecessary party promote judicial economy. Plaintiffs' declaratory judgment action under § 271(a) would add unnecessary complexity to the case, waste judicial resources, and undermine the Hatch-Waxman Act. Accordingly, at a minimum there is no useful purpose to be served by keeping Count II in the case and the Court should decline to exercise its jurisdiction over Count II of the Complaint.[5]

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[4] Plaintiffs also rely on *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006 (N.D. Ill. 2001), to argue that declaratory judgment jurisdiction "to enjoin" future infringement was found in the context of a similarly pleaded ANDA dispute. (D.I. 26, Pls.' Resp. Br. at 17.) As noted earlier, the *Glaxo Group* case was not a § 271(e) (2) case.

[5] Plaintiffs' also rely on *Erbamont Inc. v. Cetus Corp.*, 720 F. Supp. 387 (D. Del. 1989), to persuade the Court to exercise jurisdiction in this case because it will serve a useful purpose. In *Erbamont*, the court found that an actual controversy existed because a partner of the potential infringer had already imported material that was allegedly manufactured in violation of the plaintiff's patent rights. *Id.* at 392. No such circumstances exist here.

CONCLUSION

Defendants respectfully request that the Court dismiss Count I of the Complaint against Aurobindo USA and Count II of the Complaint against both Defendants for lack of subject matter jurisdiction.

Dated: March 14, 2008.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
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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)

MARCH 14, 2008 DECLARATION OF EDWARD J. PARDON IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

I, Edward J. Pardon, do declare and state as follows:

1. I am an associate attorney at Michael Best & Friedrich LLP. I am one of the attorneys representing defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., in the above-referenced case. I submit this declaration in support of the defendants' Opposition to Plaintiffs' Motion for a Temporary Stay, filed herewith.

2. Attached hereto as Exhibit A are true and correct copies of portions of Aurobindo Pharma Ltd.'s abbreviated new drug application that were provided to Plaintiffs.

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

Dated: March 14, 2008.

Edward J Pardon

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THE 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) **CERTIFICATE OF SERVICE**

ARNOLD B. CALMANN, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the Courts of the State of New Jersey and the United States District Court for the District of New Jersey.

2. I hereby certify that on this 14th day of March, 2008, I caused the following documents to be served upon all counsel of record via ECF:

- Defendants' Reply Brief In Support of Defendants' Motion to Dismiss the Complaint;
- Declaration of Edward J. Pardon and accompanying exhibit (which was filed under seal); and
- Certificate of Service.

3. I also hereby certify that on this 14th day of March, 2008, I caused the aforementioned documents to be served via electronic mail and first class mail upon the following:

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Dated: March 14, 2008

/s/ Arnold B. Calmann
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