

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, :  
 ASTRAZENECA UK LIMITED, :  
 IPR PHARMACEUTICALS, INC., and :  
 SHIONOGI SEIYAKU KABUSHIKI :  
 :  
 Plaintiffs, :  
 v. : MDL NO. 08-1949-JJF-LPS  
 : Civ. Act. No. 07-810-JJF-LPS  
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 :  
 AUROBINDO PHARMA LIMITED, and :  
 AUROBINDO PHARMA USA, INC., :  
 :  
 Defendants. :

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Attorneys for Plaintiff.

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Attorneys for Defendants.

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**MEMORANDUM OPINION**

February 25, 2009  
 Wilmington, Delaware.

  
Farnan, District Judge.

Pending before the Court is an Objection To The Report And Recommendation Of The Magistrate Judge On Aurobindo Pharma USA Inc.'s Motion To Dismiss Pursuant To Fed. R. Civ. P. 12(b)(1) (D.I. 74) filed by Defendants.<sup>1</sup> For the reasons discussed, the Court will overrule the Objection and adopt the disposition of the Motion To Dismiss recommended by the Magistrate Judge in his Report and Recommendation.

#### **I. Parties' Contentions**

By their Objection, Defendants contend that Plaintiffs' Section 271(e)(2) claim alleged in Count I of the Complaint against Aurobindo Pharma USA, Inc. ("Aurobindo USA") should be dismissed for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), because Aurobindo USA did not prepare or file the Abbreviated New Drug Application ("ANDA") giving rise to the Section 271(e)(2) claim and had no substantive knowledge of the ANDA. Aurobindo USA is a wholly owned subsidiary of Aurobindo Pharma Limited ("Aurobindo Pharma"), and Defendants contend that Aurobindo Pharma was the only entity responsible for preparing and filing the ANDA. Although an employee of Aurobindo USA signed the ANDA pursuant to 21 C.F.R. 314.50(a)(5)<sup>2</sup>, Defendants

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<sup>1</sup> The Report and Recommendation of the Magistrate Judge can be found at 2008 WL 5046424 (D. Del. Nov. 24, 2008).

<sup>2</sup> When a foreign entity like Aurobindo Pharma submits an ANDA, 21 C.F.R. § 314.50(a)(5) requires the ANDA to be

contend that his signature was in his individual capacity as an agent for Aurobindo Pharma and not as an agent for Aurobindo USA.

Defendants contend that the Magistrate Judge erroneously applied the framework for dismissal under Federal Rule of Civil Procedure 12(b)(6), instead of the standards under Rule 12(b)(1), which resulted in the Magistrate Judge's decision to accept as true Plaintiffs' jurisdictional allegations. Defendants contend that in raising their Rule 12(b)(1) argument, they are attacking the factual basis for Plaintiffs' assertion of jurisdiction, and therefore, the Magistrate Judge is under no duty to accept those facts as true and may consider evidence outside the pleadings to ensure that the Court has subject matter jurisdiction.

In response, Plaintiffs contend that the limitations set forth in Section 271(e)(2) are not jurisdictional, and therefore Rule 12(b)(1) is not the appropriate standard to apply in evaluating Defendants' Motion To Dismiss. Plaintiffs contend that the Magistrate Judge correctly applied Rule 12(b)(6), and under this rule, Plaintiffs have sufficiently pled the elements of a Section 271(e)(2) claim. In the alternative, Plaintiffs contend that, even if the standards for a Section 12(b)(1) factual attack on jurisdiction are applied, the facts demonstrate that Aurobindo USA submitted the ANDA because its employee (1)

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"countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States."

countersigned the ANDA, (2) signed a cover letter for the application inviting the FDA to direct questions regarding the submission to him at his Aurobindo USA offices, (3) used the address and telephone number for Aurobindo USA, and (4) did not receive any compensation from Aurobindo Pharma for any individual services provided to it and received only his salary from Aurobindo USA.

## **II. Standard of Review**

When reviewing the decision of a magistrate judge on a dispositive matter, the Court conducts a de novo review. 28 U.S.C. § 636(b)(1)(B); Fed. R. Civ. P. 72(b)(3). A motion to dismiss is a dispositive matter. Id. The court may accept, reject, or modify the recommendations of the magistrate judge. The court may also receive further evidence or return the matter to the magistrate judge with instructions for proceeding. Id.

## **III. Discussion**

The threshold issue presented by the parties is whether the Magistrate Judge erred in applying the standard of review under Rule 12(b)(6) to Defendants' Motion To Dismiss. Application of Rule 12(b)(6) required the Magistrate Judge to construe the allegations of the Complaint as true, and this construction of the Complaint clearly mandated a decision against Defendants on the Motion. Indeed, Defendants make no argument in their Objection that the Complaint's allegations, if accepted as true,

are insufficient to establish either jurisdiction or the elements of the Section 271(e)(2) claim. Rather, the crux of Defendants' argument is that they have raised a factual dispute which required the Magistrate Judge to go beyond the allegations of the pleadings.

Section 271(e)(2) has been described as the "jurisdictional hook" by which a party creates a case or controversy for the purposes of resolving disputes concerning patent infringement and/or validity<sup>3</sup>, but the Federal Circuit has also stated that "Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word." Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1330 (Fed. Cir. 2003). Rather, the Court's subject matter jurisdiction over a Section 271(e)(2) claim still flows from 28 U.S.C. 1338(a), and the Court is unaware of any decisions construing the limitations provided in Section 271(e)(2) as jurisdictional.

In Litecubes, LLC v. Northern Light Prods., Inc., 523 F.3d 1353, 1357 (Fed. Cir. 2008), the Federal Circuit recognized that the boundary between subject matter jurisdiction and the elements of a claim are "often-confused" and turned to the bright line

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<sup>3</sup> See, e.g., Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) (stating that "§ 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity").

rule set forth in Arbaugh v. Y&H Corp., to determine whether the prerequisites of Section 271(a) were jurisdictional requirements or the elements of a claim. 546 U.S. 500, 516 (2006). In Arbaugh, the Supreme Court stated:

If the Legislature clearly states that a threshold limitation on a statute's scope shall count as jurisdictional, then courts and litigants will be duly instructed. . . . But when Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as non-jurisdictional.

Id. The Federal Circuit applied this test in Litecubes and concluded "that Congress has not clearly stated that any of the limitations in § 271 are jurisdictional." 523 F.3d at 1366 (emphasis added). While it is true that the Federal Circuit's statement was made in the context of Section 271(a) specifically, the Court, reviewing the legislative history of Section 271(e)(2), finds no evidence that Congress intended the elements of that section to be jurisdictional prerequisites. This conclusion is consistent with the Federal Circuit's approach to Section 271(e)(2) in Allergan, which recognizes Section 1338(a) as the basis for this Court's jurisdiction. 324 F.3d at 1330 ("In short, Section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed.") (emphasis added).

Accordingly, the Court is persuaded that the issue of whether Aurobindo USA submitted the ANDA application for purposes

of Section 271(e)(2) is a question that goes to the merits of one of the elements of Plaintiffs' infringement claim under Section 271(e)(2).<sup>4</sup> Having reached this conclusion, the Court further concludes that the Magistrate Judge did not err in reviewing the issues raised in Defendants' Motion To Dismiss under the standard of review for Rule 12(b)(6). As the Federal Circuit explained, "[s]ubject matter jurisdiction does not fail simply because the plaintiff might be unable to ultimately succeed on the merits," and "a failure to prove the allegations alleged in a complaint require a decision on the merits, not a dismissal for lack of subject matter jurisdiction." *Id.* at 1360-1361. Because the allegations of the Complaint, accepted as true, state both the

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<sup>4</sup> Even if the Court's conclusion is overstated and the elements of Section 271(e)(2) have a jurisdictional component, it is the Court's view, that these elements at least overlap with both the jurisdictional issue and the merits of the claim. In these circumstances, the Court "should either employ the standard applicable to a motion for summary judgment (if the material facts are undisputed) or leave the jurisdictional determination to trial." See James Wm. Moore, 2 Moore's Federal Practice 12.30[3] (3d ed. 2008); Charles Alan Wright & Arthur R. Miller, 5B Federal Practice & Procedure § 1350 ("If, however, a decision of the jurisdictional issue requires a ruling on the underlying substantive merits of the case, the decision should await a determination of the merits either by the district court on a summary judgment motion or by the fact finder at the trial."). The determination of which procedure should be applied; however, should, in the first instance, be determined by the Magistrate Judge in the context of a properly filed summary judgment motion so that the Magistrate Judge can determine whether the facts alleged are subjected to a genuine material dispute such that trial is required, or whether they are not in dispute such that adjudication by way of summary judgment is appropriate.

prerequisites for the exercise of the Court's subject matter jurisdiction under Section 1338(a), as well as the elements for a Section 271(e)(2) claim, the Court concludes that the Magistrate Judge's decision on Defendants' Motion To Dismiss was not erroneous.<sup>5</sup>

#### **IV. Conclusion**

For the reasons discussed, the Court will overrule Defendants' Objection and adopt the disposition of the Motion To Dismiss recommended by the Magistrate Judge in his Report and Recommendation.

An appropriate Order will be entered.

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<sup>5</sup> As discussed in footnote 3 *infra*, the Court's decision has no bearing on a properly filed summary judgment motion, which must be considered by the Magistrate Judge, in the first instance.