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,	)	
v.	)	C.A. No. 07-811-JJF
COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES INC.,	)	
Defendants.	)	

REPLY IN SUPPORT OF COBALT'S MOTION TO DISMISS
COUNT II OF THE COMPLAINT

Richard L. Horwitz (#2246)
David E. Moore (#3983)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendants

OF COUNSEL:

Steven A. Maddox
Jeremy J. Edwards
FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007
Tel: (202) 672-5300

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INTRODUCTION

Plaintiffs cannot save their claim under Section 271(a) of the Patent Act based on pure speculation that in a little more than two years, Cobalt might obtain FDA approval of its drug, and might thereafter engage in an act of infringement under Section 271(a) by marketing its product.

This litigation arises from Cobalt's filing of an Abbreviated New Drug Application (ANDA) with a so-called "paragraph IV" certification. The Hatch-Waxman Act statutorily defined such a submission as an act of infringement under Section 271(e)(2), and thereby created a special cause of action for the benefit of Plaintiffs – the ability to sue before any actual infringement occurs under Section 271(a), and an automatic preliminary injunction in the form of a 30 month stay of FDA approval once Plaintiffs filed the case. The Act also created a statutory safe-harbor exception to Section 271(a) for experimental use of a patented invention for the preparation of a submission to the FDA.

It is indisputable that Cobalt is not alleged to have engaged in any use of the supposed invention outside the statutory safe harbor, and therefore has not engaged in any act that is even arguably infringement under Section 271(a). The gravamen of Plaintiff's argument is that some time after the 30 month stay expires, Cobalt might engage in conduct covered by Section 271(a).

Plaintiffs fail to cite any Hatch-Waxman Act case where the plaintiff was allowed to maintain a claim under Section 271(a), even though there was no allegation of any conduct outside the statutory safe-harbor. There are at least two reasons why no court has ever held that a patentee can maintain a claim Section 271(a) based only on allegations squarely within the statutory exception to that section. First, such a holding would render Section 271(e) meaningless, because every FDA applicant would be subject to declaratory judgment claims

under Section 271(e). Second, Rule 15(d) of the Federal Rules already provides for amending or supplementing pleadings to include events that occur during the course of litigation.

Finally, in light of the fact that Plaintiffs indisputably have a claim under Section 271(e), the Court may wonder why Plaintiffs have devoted so much energy asserting and defending a redundant claim under Section 271(a). We suggest the possible answer is that Plaintiffs are looking for a way around now well-settled law that there is no such thing as willful infringement in a Hatch Waxman Act case under Section 271(e)[1] – and therefore no such thing as willfulness discovery. Whatever the reason, however, Plaintiff's claim under Section 271(a) is meritless and should be dismissed.

ARGUMENT

I. Finding Declaratory Judgment Jurisdiction Here Would Eviscerate the Statutory "Safe Harbor" of 35 U.S.C. § 271(e)(2).

Plaintiffs have alleged no conduct by Cobalt that falls outside the statutory "safe harbor" of 271(e)(2). Plaintiffs merely maintain that activities protected by 271(e)(1) "are relevant to the inquiry," citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) and *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267 (D. Mass 2006). But neither *Glaxo* nor *Amgen* support Plaintiffs' extreme position.[2]

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[1] *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350 (Fed. Cir. 2004); *Boehringer Ingelheim International GMBH v. Barr Laboratories, Inc.*, C.A. No. 05-700-KAJ, 2006 U.S. Dist. LEXIS 46835, at *6 (D. Del. July 6, 2006); *Allergan, Inc. v. Alcon, Inc.*, C.A. No. 04-968-GMS, 2005 U.S. Dist. LEXIS 41834, at *6 (D. Del. July 26, 2005); *Janssen, L.P. v. Barr Labs., Inc.*, 07-1515-JAP, 2008 U.S. Dist. LEXIS 7965, at *9-12 & n.1 (D.N.J. Feb. 4, 2008) (noting "the litany of literature" explaining that the mere filing of an ANDA cannot give rise to willful infringement.")

[2] Plaintiffs also argue that the *Amgen* appeal (*Amgen Inc. v. ITC*, No 2007-1014, slip op. (Fed. Cir. March 19, 2008)) supports their position. (Opp. at 5.) But that appeal addressed the jurisdiction of the International Trade Commission, not a federal district court, and is thus inapplicable. Cobalt hereby incorporates by reference the portions of Aurobindo Pharma USA, Inc.'s Reply in support of its motion to dismiss Count II detailing this. (D.I. 33 at pp. 12-13.)

Indeed, neither *Amgen* nor *Glaxo* addresses whether conduct wholly protected under the "safe harbor" of 271(e)(1) can give rise to subject matter jurisdiction under 271(a). In *Glaxo*, the plaintiff brought a Hatch-Waxman case under 271(e)(2) alleging infringement of one patent, and also sought declaratory judgment that upon entering the market, the defendant would infringe a second patent on a method of making the drug. *Id.* at 1564. In finding declaratory judgment jurisdiction over the "future infringement" allegation relating to the "method of making" patent, the *Glaxo* court explicitly relied on evidence that defendant had engaged in conduct not covered by the safe harbor provision. *Id.* at 277-78. Notably, the defendant in *Glaxo* admitted that FDA approval was "imminent." *Id.* at 1571. Moreover, the *Glaxo* Court expressly limited its holding to "method of making" patents, which are not part of the Hatch-Waxman scheme. *Id.* at 1570-71.

Likewise, in *Amgen*, the court expressly presumed that the defendant was operating outside the safe harbor. *Id.* at 279. In its holding, the *Amgen* court expressly distinguished its facts from the situation where all of the alleged present conduct was protected by the safe harbor provision. *Id.* (contrasting *Amgen, Inc. v. Hoechst*, 2 F. Supp. 2d 104 (D. Mass. 1998)).

Unlike in *Glaxo* or *Amgen*, in the present case, plaintiffs have not alleged any conduct that falls outside the 271(e)(1) safe harbor. Unlike in *Glaxo*, plaintiffs do not seek declaratory judgment regarding a patent that is not already the subject of a 271(e)(2) claim. Finally, unlike in *Glaxo*, Cobalt has not admitted that FDA approval of its ANDA is "imminent." Accordingly, plaintiffs' reliance on those cases is misplaced.[3]

[3] Plaintiffs attempt to point to the "expanded *MedImmune* standards" as generally supporting jurisdiction over Count II. (Opp. at 3). Cobalt's motion, however, recognizes and applies *MedImmune* to show that jurisdiction is lacking. (Mot. at 2-3.)

II. Cobalt's Counterclaims Do Not Confer Jurisdiction Over Count II.

Plaintiffs argue that by asserting counterclaims of validity and unenforceability of the '314 patent, Cobalt has somehow "opened the door" to Plaintiffs' Count II. (Opp. at 4.) Plaintiffs are wrong. Cobalt asserted counterclaims regarding the '314 patent in response to the allegations of Count I under 271(e). Cobalt's '314 counterclaims are not based on 35 U.S.C. § 271(a), and do not "open the door" to declaratory judgment jurisdiction for future infringement.

The sole case cited by Plaintiffs on this point misses the mark. (Opp. at 4) (citing *Teva Pharmaceuticals USA v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007)). *Teva* did not even address declaratory judgment jurisdiction under section 271(a). Rather, *Teva* merely confirmed that a generic defendant has standing to assert counterclaims under 271(e)(5) attacking any Orange Book listed patents not asserted by a Hatch-Waxman plaintiff. *Id.* at 1334-35, 1342.

III. Plaintiffs' Own Arguments Reveal the Speculative Nature of Count II.

Having failed to allege facts in the Complaint sufficient to establish jurisdiction over Count II, plaintiffs resort to fanciful speculation to argue that remedies under Count I "may not be adequate."[4] Plaintiffs speculate that Cobalt might engage in activities that are not even associated with Cobalt's ANDA, such as inducing importation of unapproved rosuvastatin calcium from other countries, or entering into an agreement to market rosuvastatin calcium that is the subject of someone else's ANDA. (Opp. at 13.)

[4] Notably, however, because plaintiffs have not alleged any conduct by Cobalt (other than filing its ANDA) that is not protected by 35 U.S.C. § 271(e)(1), plaintiffs are entitled to nothing more than those remedies identified in section 271(e)(4). 35 U.S.C. § 271(e)(4)(C), 2nd ¶.

These musings do not appear in the Complaint, and have no factual basis in the record. Such baseless speculation only serves to underscore why declaratory judgment jurisdiction over Count II is lacking. It scarcely requires argument to show that declaratory judgment jurisdiction cannot and should not be premised on such bald conjecture.

Facts might change, and there *might* come a time in the future when plaintiffs have a factual (not speculative) basis to demonstrate a real and immediate controversy under section 271(a). If and when that day ever comes, plaintiffs can ask to supplement the Complaint pursuant to Federal Rule of Civil Procedure 15(d). Until that day, however, Count II has no place in this case.

CONCLUSION

For the foregoing reasons, this Court should Dismiss Count II of the Complaint.

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendants

OF COUNSEL:

Steven A. Maddox
Jeremy J. Edwards
FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007
Tel: (202) 672-5300

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on April 11, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on April 11, 2008, the attached document was Electronically Mailed the document to the following person(s):

Mary W. Bourke
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19899
mbourke@cblh.com

Ford F. Farabow
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
ford.farabow@finnegan.com

Charlie E. Lipsey
York M. Faulkner
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
charles.lipsey@finnegan.com
york.faulkner@finnegan.com

Henry J. Renk
Fitzpatrick, Cella, Harper & Scinto
30 Rockefeller Plaza
New York, NY 10112
hrenk@fchs.com

Thomas A. Stevens
Legal Department
AstraZeneca Pharmaceuticals
1800 Concord Pike
Wilmington, DE 19850
Thomas.Stevens@astrazeneca.com

/s/ Richard L. Horwitz
Richard L. Horwitz
David E. Moore
Potter Anderson & Corroon LLP
Hercules Plaza – Sixth Floor
1313 North Market Street
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

841808 / 32588