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.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS COUNT II OF THE COMPLAINT OR TERMINATE THE AUTOMATIC STAY OF APPROVAL

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Defendants, Cobalt Pharmaceuticals, Inc. and Cobalt Laboratories, Inc. (collectively, "Defendants"), hereby moves the Court pursuant to Fed. R. Civ. P. 12(b)(1) for an order dismissing Count II of the Complaint or terminating the automatic stay of FDA's approval of Defendants' Abbreviated New Drug Application ("ANDA") under 21 U.S.C. §355(j)(5)(B)(iii).

Introduction

This Hatch Waxman Act case arises from Defendants' submission of an ANDA seeking FDA approval of Defendants' proposed Rosuvastatin calcium tablets ("Defendants' proposed product"). The Hatch Waxman Act provides that the mere filing of an infringement claim under 35 U.S.C. § 271(e)(2), such as in Count I of the Complaint, automatically stays FDA approval of the ANDA for a period of two and a half years or until there is a judgment.

Plaintiffs were not content, however, to enjoy what amounts to the automatic, statutorily-created, two and a half year preliminary injunction attending Count I. Rather, Plaintiffs chose to further allege in Count II that they are entitled to declaratory judgment of infringement of the same patent, but under 35 U.S.C. § 271(a).

As a matter of law, however, declaratory judgment jurisdiction requires the alleged controversy to be "immediate." In light of the automatic stay of FDA approval, there is nothing immediate about the alleged potential future infringement under 35 U.S.C. § 271(a). Accordingly, unless Plaintiffs wish to waive the automatic stay, Count II should be dismissed for lack of subject matter jurisdiction. Any other result would directly undermine the purpose and policy of the Hatch Waxman Act.

Facts

Count I of the Complaint asserts a claim of infringement under 35 U.S.C. § 271(e)(2)(A), which provides a cause of action for infringement of U.S. Patent No. RE37,314 ("the '314 patent") based on Defendants' filing of the ANDA. Defendants do not challenge the legal sufficiency of the allegations in Count I.

Count II of the Complaint, however, asserts a claim for infringement of the very same patent, but instead under 35 U.S.C. § 271(a), which provides a cause of action for infringement based on making, using or selling a patented invention in the United States. Importantly, Plaintiffs do not allege that any conduct on the part of the Defendants to date constitutes infringement under Section 271(a). This is because it is undisputed that Defendants' conduct to date falls squarely within the "safe harbor" provisions of 35 U.S.C. § 271(e)(1).

Instead, Plaintiffs merely allege that Defendants "have made substantial preparations to sell" their proposed product and "intend to commence sale of [their proposed product] immediately upon receiving approval from the FDA." Complaint at ¶¶ 28-29. These allegations are coupled with the legal conclusion that the alleged intended sale "will directly infringe, induce and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a)." Complaint at ¶ 30. Finally, Plaintiffs allege that they "have no adequate remedy at law" for the declaratory relief they seek in Count II. Complaint at ¶ 31.

Argument

I. Count II Of The Complaint Should Be Dismissed Because The Alleged Controversy Is Not Sufficiently "Immediate" To Confer Subject Matter Jurisdiction Under The Declaratory Judgment Act.

"A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, 'under all the circumstances, show that there is a substantial

controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (emphasis added).

According to Plaintiffs, the alleged "immediate" controversy will arise when Defendants sell their proposed product, after obtaining FDA approval. Complaint at ¶¶ 29-30. Plaintiffs fail to allege how "immediate" that FDA approval is likely to be.

Plaintiffs' failure to include these allegations is no mere oversight. Plaintiff could not present any specific factual allegations of "immediacy," because they knew that their assertion of infringement under Section 271(e)(2) in Count I triggered a two and a half year stay of FDA approval under the Hatch Waxman Act. *See* 21 U.S.C. §355(j)(5)(B)(iii).

Two and a half years is not "immediate" as a matter of law or common sense – especially when there is no assurance of FDA approval in the interim. For example, in *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995), the patentee sought a declaratory judgment of infringement of an untimely listed Orange Book patent. *Abbott*, 934 F. Supp. at 937-38. Although the FDA could have approved defendant's ANDA within three months from the date that plaintiff filed its complaint, the court found insufficient immediacy to confer jurisdiction under 28 U.S.C. § 2201. *Id.* The court reasoned that there no case or controversy existed because the FDA had not approved the ANDA yet at the time that Plaintiff requested declaratory judgment and there was no guarantee that such approval would be forthcoming at any particular time in the future, or ever. *Id.* at 938. See also *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 05-590-GMS, 2006 U.S. Dist. LEXIS 57469, at *9 n.3 (D. Del. Aug. 16, 2006) (finding that "the absence of FDA approval is evidence that the dispute between the parties is neither real nor

immediate.")

Here, Plaintiffs have triggered a 30 month statutory stay of FDA approval, and simply have not alleged that the FDA will ever approve the ANDA or that the approval is imminent. The possibility that the FDA might approve the ANDA over two years in the future is not sufficient to establish a case or controversy as required by 28 U.S.C. § 2201.

II. Plaintiffs' Allegation In Count II That It Lacks An Adequate Remedy At Law Is Baseless In Light Of Plaintiffs' Allegations In Count I.

In an attempt to support declaratory judgment jurisdiction for Count II, Plaintiffs allege that they "have no adequate remedy at law" for the potential future infringement of the '314 patent. Complaint at ¶ 31. This allegation is incorrect, and cannot support a finding of jurisdiction.

The allegation is wrong because Plaintiffs allege infringement of the same '314 patent in Count I of the Complaint, under Section 271(e). That section expressly provides the same injunctive remedy that Plaintiffs seek in Count II under Section 271(a). Specifically, in the event that the patent is found valid and infringed, Section 271(e) authorizes the Court to order that the effective date of Defendants' FDA approval not occur until after the '314 patent expires. 35 U.S.C. § 271(e)(4). Thus, if Plaintiffs obtain the remedy sought through Count I, Defendants would be enjoined from entering the market during the life of the patent.

III. The Court Should Not Exercise Its Discretion To Hear Count II Because To Do So Would Undermine The Purpose and Policy Of The Hatch Waxman Act.

"[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995); *see also Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991) ("When there is an

actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary.").

The protection from infringement suits until after premarket approval by the FDA is an integral part of Congress' carefully crafted compromise between brand name companies and generics in the Hatch-Waxman Amendments, the purpose of which is to speed the entry of generic drugs onto the market while protecting the intellectual property rights of brand companies. *See, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1357-58 (Fed. Cir. 2003). The Hatch-Waxman compromise provided brand companies with, among other things, a patent term extension. For their part, the generic companies received the aforementioned protection against infringement suits as well as a streamlined application process. Plaintiffs' attempt to circumvent the protection against an infringement suit prior to FDA approval threatens to destroy this compromise.

Other courts have expressed this very concern and indicated that they would decline exercising declaratory judgment jurisdiction in this circumstance. *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 939 (N.D. Ill. 1995) (noting that exercising jurisdiction would "undermine Congress' policy in enacting the [Hatch-Waxman Amendments]." and stating that even if Plaintiff had alleged facts sufficient to state that a justiciable controversy exists, the court would have declined to exercise declaratory judgment jurisdiction). In *Intermedics v. Ventritex, Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), the court voiced the same concern:

> We are concerned that if we exercise jurisdiction over declaratory relief actions in a setting like this, where we have held that defendants are entitled to protection from suit for infringement under § 271(e)(1), we will be undermining one of Congress' purposes in enacting this exemption. It appears to us that Congress intended this exemption to offer a "safe haven" to companies who

> confined their conduct to the boundaries set forth in the statute . . . [T]he promise by Congress of a safe haven could prove to be completely illusory if the courts permitted competitors to proceed full bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief. It makes little sense, and thus we assume would be inconsistent with Congress intent, to protect companies . . . from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same.

Id. at 1290.[1] The Federal Circuit affirmed *Intermedics* in an unpublished opinion, noting that "exercising jurisdiction over Intermedics' declaratory relief action would undermine the exemption [provided by Section 271(e)(1)] . . . To permit Ventritex to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Intermedics v. Ventritex, Co.*, No. 92-1076, 1993 U.S. App. LEXIS 3620, at *15 (Fed. Cir. Feb. 22, 1993).

At bottom, Count II is an attempt to circumvent the protection from infringement suits afforded by the Hatch-Waxman Amendments until after pre-market approval by the FDA. Plaintiffs have not alleged that Defendants have engaged in any conduct not protected by 35 U.S.C. 271(e). Therefore, even if there were sufficient immediacy and reality to establish an actual 35 U.S.C. 271(a) controversy, the Court should decline to exercise jurisdiction over Count II.

[1] Omitted portions of the quoted passage note that small start-up companies (like the defendant in that case) would suffer under the burden of defending declaratory judgment actions based on activities otherwise protected under 271(e)(1). The policies and purpose of the Hatch-Waxman Act, however, apply with equal vigor to any company, regardless of its pedigree or resources.

Conclusion

For the foregoing reasons, Defendants respectfully request that this Court dismiss Count II of the Complaint or terminate the stay of FDA approval of ANDA No. 79-167.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 31, 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 January 31, 2008, the attached document was Electronically Mailed the document to the following person(s):

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