IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, and THE BRIGHAM AND WOMEN'S HOSPITAL, INC.	)	C.A. No. 10-338 (RBK-KW)
Plaintiffs,	)	**PUBLIC VERSION**
v.	)	
APOTEX CORP.,	)	
Defendant.	)	

REPLY TO PLAINTIFF'S ANSWERING BRIEF TO APOTEX CORP.'S MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(1) AND FED. R. CIV. P. 12(b)(6)

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I. INTRODUCTION

The Plaintiffs have failed to state a claim against Apotex Corp. because an applicant for an Abbreviated New Drug Application ("ANDA") cannot infringe an Orange-Book-listed[1] patent without certifying that the patent is invalid or not infringed. Infringement under 35 U.S.C. § 271(e)(2)(A) requires that an ANDA applicant seek approval to market a drug or a use of a drug prior to the expiration of a patent that claims that drug or use. For an Orange-Book-listed patent, a certification that the patent is invalid or not infringed is necessary to seek approval for a drug or claimed use of a drug prior to patent expiry. Because ANDA No. 79-145 does not contain such a certification, this Court should dismiss the Complaint.

The Hatch-Waxman Act[2] established a statutory framework that enables generic drug manufacturers to bring safe, efficacious, low-cost drugs to market. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (2008). This framework makes it an act of infringement to submit an ANDA seeking approval to market an FDA-approved drug prior to the expiration of a patent that claims that drug or a use of that drug. 35 U.S.C. § 271(e)(2). Under this framework, an ANDA applicant can submit one of four certifications with respect to each patent that claims the FDA-approved drug or a use of that drug. 21 U.S.C. § 355(j)(2)(A)(vii). The certification made by the ANDA applicant determines when the FDA may approve the ANDA.

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[1] The "Orange Book" is the name commonly used to refer to a U.S. Food and Drug Administration publication entitled the "Approved Drug Products With Therapeutic Equivalence Evaluations." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (2008). This publication lists patents identified by an applicant for a new drug as covering the drug or a use of the drug identified in the new drug application ("NDA"). *See id.*; *see also* 21 U.S.C. § 355(b)(1).

[2] "The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003)." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 n.1 (2008).

21 U.S.C. § 355(j)(5)(B). Of the four available certifications, two allow the FDA to approve an ANDA prior to the expiration of a patent that claims the FDA-approved drug or a use of that drug. *Id.* One effectively states that the Orange Book does not list any patent that claims the FDA-approved drug or a use of that drug for which the applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii)(I). This is a Paragraph I certification, and the FDA may immediately approve an ANDA containing this type of certification. 21 U.S.C. § 355(j)(5)(B)(i). This type of certification permits FDA-approval of an ANDA prior to the expiration of a non-Orange-Book-listed patent that claims the FDA-approved drug or a use of that drug. This case does not implicate this type of certification because the Orange Book lists the asserted patents.

The other is a Paragraph IV certification, which states that an Orange-Book-listed patent is invalid or will not be infringed by the drug described in the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The FDA may approve an ANDA containing this type of certification immediately unless the patent owner or NDA holder files an infringement action within forty-five days of receiving notice that the ANDA applicant filed a Paragraph IV certification.[3] 21 U.S.C. § 355(j)(5)(B)(iii). If an action is timely filed, ANDA approval is automatically stayed thirty months unless a court finds the patent invalid, unenforceable, or not infringed before the automatic stay ends. *Id.* This type of certification also permits FDA-approval of an ANDA prior to the expiration of a patent that claims the FDA-approved drug or a use of that drug.[4]

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[3] An ANDA applicant must notify the patent owner and NDA holder that it filed a Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B).

[4] An ANDA applicant may also certify that the Orange-Book-listed patent that claims the FDA-approved drug or a use of the FDA-approved drug has expired ("Paragraph II" certification) or that the applicant is not seeking ANDA approval prior to the expiration of the Orange-Book-listed patent ("Paragraph III" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(II). These certifications do not permit FDA-approval prior to patent expiry. 21 U.S.C. § 355(j)(5)(B)(i)-(ii)

In this case, the Plaintiffs allege that Apotex Corp. submitted an ANDA that seeks approval to market rosuvastatin calcium for uses claimed in two Orange-Book listed patents prior to their expiration. Because the Orange Book lists each asserted patent, however, a Paragraph IV certification with respect to each patent is necessary to seek approval for the uses claimed in those patents prior to their expiration. The Plaintiffs have not alleged that Apotex Corp. submitted a Paragraph IV certification with respect to either patent. Nor could they, as Apotex Corp. has not done so. Absent such allegations, the Plaintiffs have failed to present a justiciable case or controversy. Therefore, this Court should dismiss this action for lack of subject matter jurisdiction. Alternatively, this Court should dismiss this action for failure to state a claim.

II. ARGUMENT

A. A Paragraph IV certification is necessary to state a claim for infringement of an Orange-Book-listed patent under § 271(e)(2).

The Plaintiffs' patent infringement allegations are wholly insubstantial and frivolous because the Plaintiffs have not alleged that Apotex Corp. submitted a Paragraph IV certification concerning either Orange-Book-listed patent asserted here. A Paragraph IV certification is the only way an ANDA applicant may seek approval to commercially manufacture, use, or sell an FDA-approved drug prior to the expiration of an Orange-Book-listed patent that claims that drug or a use of that drug for which the ANDA seeks approval. *See Caraco Pharm. Labs, Ltd.*, 527 F.3d at 1283. Therefore, an ANDA applicant cannot infringe an Orange-Book-listed patent under § 271(e)(2)(A) unless the applicant submits a Paragraph IV certification for that patent.

This is required by statute, as § 271(e)(2)(A) inherently requires that an ANDA applicant submit a Paragraph IV certification to infringe an Orange-Book-listed patent. The plain language of § 271(e)(2)(A) requires (1) one to submit an application under section 505(j) of the

Food, Drug, and Cosmetic Act (2) seeking approval to commercially manufacture, use, or sell a drug prior to the expiration of a patent that claims that drug or a use of that drug. 35 U.S.C. § 271(e)(2)(A). Under § 505(j), the FDA can approve—and therefore an ANDA applicant may seek—ANDA approval prior to the expiration of a patent that claims the FDA-approved drug or a use of that drug in two instances. *See* 21 U.S.C. § 355(j)(5)(B) (establishing effective approval date of ANDA based on certification filed with ANDA). One instance concerns patents listed in the Orange Book; the other does not. *Id.*

Accordingly, Congress drafted § 271(e)(2) to limit infringement to those instances under § 505(j) in which an ANDA applicant may seek approval prior to the expiration of a patent that claims the FDA-approved drug or a use of that drug. Rather than explicitly state all elements required to infringe under § 271(e)(2), Congress referenced the submission of "an application *under* section 505(j) of the Federal Food, Drug, and Cosmetic Act." *See* U.S.C. § 271(e)(2)(A) (emphasis added). This reference expressly incorporates § 505(j) into § 271(e)(2), and requires that courts read these two sections together. When read together, the submission of an ANDA containing a Paragraph IV certification with respect to an Orange-Book-listed patent is an infringing act. This is what Congress intended, and its inclusion of "under section 505(j) of the Federal Food, Drug, and Cosmetic Act" shows that Congress drafted the statute accordingly.

Indeed, § 505(j) and § 271(e)(2)(A) must be construed together because they are *in para materia*. *See Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1564 (Fed. Cir. 1995). Statutory construction requires courts to look at the plain language of a statute and then construe the statute according to traditional tools of statutory construction. *Id.* One tool of statutory construction applicable here is that courts should construe statutes *in para materia* together. *Id.* This rule is a "logical extension of the principle that individual sections of a single statute should

be construed together." *Erlenbaugh v. U.S.*, 409 U.S. 239, 244 (1972). And this rule is particularly applicable when the two statutes serve the same function and were enacted by the same legislative body at the same time. *Id.* at 244-45. Here, Congress enacted §§ 271(e)(2) and 505(j) as part of the Hatch-Waxman Act. One of the purposes of the Hatch-Waxman Act is to facilitate the early resolution of patent disputes between patent owners and NDA holders on the one hand, and generic drug companies on the other. *See Caraco Pharm. Labs, Ltd.*, 527 F.3d at 1283. And the Act did just that—it created an artificial act of patent infringement based on the submission of an ANDA seeking approval prior to the expiration of a patent that claims the FDA-approved drug or a use of that drug. *Id.*

For Orange-Book-listed patents, a Paragraph IV certification is the only way to trigger liability under § 271(e)(2)(A). *See Caraco Pharm. Labs, Ltd.*, 527 F.3d at 1283. Congress specified in § 505(j) when an ANDA applicant may seek approval to market an FDA-approved drug or a use of that drug claimed in an Orange-Book-listed patent. To seek approval to market an FDA-approved drug or a use of that drug *before* an Orange-Book-listed patent that claims that drug or that use expires, an ANDA applicant must certify that the patent is invalid or the drug or use described in the ANDA will not infringe the patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) *and* 21 U.S.C. § 355(j)(5)(B). There is no other way to obtain FDA approval for that drug or for that use prior to the expiration of an Orange-Book-listed patent that claims that drug or use.[5] Therefore, an ANDA applicant can only infringe an Orange-Book-listed patent when the applicant submits a Paragraph IV certification concerning that patent.

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[5] An ANDA applicant may seek approval to market an FDA-approved drug claimed in an Orange-Book-listed *after* the patent expires by submitting either a Paragraph II certification or a Paragraph III certification.

B. The standard for infringement of Orange-Book-listed patents under § 271(e)(2) advanced by the Plaintiffs is incorrect.

Infringement under § 271(e)(2) requires a Paragraph IV certification for Orange-Book-listed patents. Nonetheless, the Plaintiffs contend that a Paragraph IV certification is sufficient, but not necessary to state a claim for patent infringement under § 271(e)(2). But the Hatch-Waxman Act, which requires a Paragraph IV certification to seek approval to market a drug or use of a drug claimed in an Orange-Book-listed patent prior to patent expiry, belies the Plaintiffs' contention. And the cases cited by the Plaintiffs do not hold otherwise.

For example, in *Impax Labs. v. Aventis Pharm., Inc.*, the Federal Circuit heard an appeal concerning an action seeking a declaratory judgment that an ANDA applicant had not infringed a patent that claimed a drug or the use of that drug under § 271(e)(2)(A). 468 F.3d 1366, 1372-73 (Fed. Cir. 2006). The Orange Book did not list the asserted patent in *Impax*. *Id.* Therefore, a Paragraph IV certification was not necessary. In fact, the ANDA applicant in *Impax* pleaded in its amended complaint that it sought approval to engage in the commercial manufacture or sale of a drug prior to the expiration of a patent that claimed a drug or the use of that drug. Amended Complaint at ¶ 13, *Impax Labs. v. Aventis Pharm., Inc.*, C.A. No. 02-581-JJF (D. Del. Mar. 14, 2003) (available as 2003 WL 24307203 (2003)). Moreover, the ANDA applicant in *Impax* did not contest the facts concerning infringement in the underlying district court action. *Impax Labs. v. Aventis Pharm., Inc.*, 235 F. Supp. 2d 390, 392 (D. Del. 2002). These facts render *Impax* inapplicable to this case. More importantly, in contrast to *Impax*, the Plaintiffs in this case have asserted Orange-Book-listed patents against Apotex Corp. Therefore, *Impax* is inapposite.

The *Glaxo Group Ltd. v. Apotex, Inc.* cases cited by the Plaintiffs are similarly distinguishable, as the asserted patents in those cases were not listed in the Orange Book either. *See* 376 F.3d 1339, at 1344 (Fed. Cir. 2004). In *Glaxo Group Ltd.*, the asserted patents

concerned "old antibiotics" approved under a repealed provision of the Federal Food, Drug, and Cosmetic Act. *Id.* The old antibiotics provision did not require patent owners or NDA holders to list patents in the Orange Book and did not require ANDA applicants to file a certification with respect to patents that claim the proposed generic drug. *Glaxo Group Ltd.* 376 F.3d at 1344. Given these facts, the district court in the underlying action reasoned that allowing the plaintiffs' declaratory judgment action to proceed best served the purposes of the Hatch-Waxman Act. *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 779 (N.D. Ill. 2003). That is not the case here because the Hatch-Waxman Act established a framework to resolve Orange-Book-listed patent disputes. Collectively, these cases cited by the Plaintiffs are not applicable here because they establish only that a Paragraph IV certification may not be necessary to state a claim for infringement of a patent that the Orange Book does not list.[6]

The cases cited by the Plaintiffs that deal with Orange-Book-listed patents are also inapplicable. In *Bayer Healthcare, LLC v. Norbrook Labs. Ltd.*, the district court relied on an old antibiotics case to decide whether to allow an action under § 271(e)(2)(B)[7] to proceed. Nos. 08-C-0953 and 09-C-0108, 2009 WL 6337911, at *8-9 (E.D. Wis. Sept. 24, 2009) (citing *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 828-29 (N.D. Ill. 2009). It questioned whether the applicant properly withdrew its Paragraph IV certification, and reasoned that the application still sought approval to use the drug for the patented use. *Id.* at *10-11. That is not the case here, as ANDA No. 79-145 has never contained a Paragraph IV certification with respect to the asserted patents. Further, the Plaintiffs do not contend that ANDA No. 79-145

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[6] *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 828-29 (N.D. Ill. 2009), which is another case cited by the Plaintiffs that concerns old antibiotics, is equally unapt.

[7] In *Bayer Healthcare, LLC*, the district court treated an application based on the Generic Drug and Patent Term Restoration Act as it would have treated an ANDA. *See, e.g.*, *2-3.

presently seeks—or has ever sought—to use rosuvastatin calcium for a use claimed in the asserted patents. For these reasons, *Bayer Healthcare, LLC* is inapposite.

The Plaintiffs also cite a hearing transcript from *Bristol-Myers Squibb Co. v. Mylan Pharms., Inc.*, which is neither precedential nor persuasive. To the extent the district court in *Bristol-Myers Squibb Co.* relied on the Federal Circuit's *Impax* decision, *Bristol-Myers Squibb Co.* does not apply to this case involving Orange-Book-listed patents for the reasons discussed above. (*See* D.I. 24, Exhibit 4 to Severance Decl., at 11:5-6.) Further, the decision in *Bristol-Myers Squibb Co.* is unconvincing. Although it correctly notes that the judge in *Bristol-Myers Squibb Co.* did not think that one needs an Orange Book listing to bring an action under § 271(e)(2)(A), (D.I. 23, Pls. Ans. Brief, at 14), the Plaintiffs' brief fails to mention that the judge went on to question whether that was ultimately correct. (D.I. 24, Exhibit 4 to Severance Decl., at 4:23-5:5.) In *Bristol-Myers Squibb Co.*, the judge explained that he considered the facts before him, was reluctant to dismiss the case, and would "deny the motion to dismiss without saying there's no required orange book listing." *Id.* at 5:3-6:3.

The district court's reticence in *Bristol-Myers Squibb Co.* was well-founded as the statutory framework established by the Hatch-Waxman Act indicates that infringement under § 271(e)(2) requires that an ANDA applicant submit a Paragraph IV certification with respect to an Orange-Book-listed patent. ANDA No. 79-145 does not contain a Paragraph IV certification with respect to either asserted patent. As a result, there is no basis for the Plaintiffs' allegations.

C. [redacted]

Because infringement under § 271(e)(2)(A) requires that an ANDA applicant seek approval to market a drug for an FDA-approved use prior to the expiration of a patent that claims that use, [redacted]

[redacted] This is an unremarkable contention, as the ANDA applicant decides: whether to submit an ANDA; which FDA-approved drug or use it will seek approval for; and, based on the type of certification it submits for an Orange-Book-listed patent, when it seeks approval. Just as it determines whether to submit an ANDA, [redacted] This is what the Hatch-Waxman Act permits, and indeed, encourages. Thus, an ANDA applicant can unilaterally decide whether it will avoid infringing a patent. Specifically, an ANDA applicant can elect to submit a Paragraph III certification [redacted]

[redacted]

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[8] [redacted]

In addition, the Plaintiffs should have known that there was no basis for their patent infringement claims because they did not receive notice that ANDA No. 79-145 contains Paragraph IV certifications for the asserted patents. Here, the Plaintiffs received a copy of ANDA No. 79-145 in a prior action. Prior to filing this Complaint, the Plaintiffs could have asked for any amendments to ANDA No. 79-145. They did not. Even though documents from the prior action formed the basis of their Complaint, the Plaintiffs did not make a reasonable inquiry as to whether ANDA No. 79-145 sought approval for the uses claimed in the asserted patents. Despite the lack of a Paragraph IV certification for either asserted patent, the Plaintiffs filed this action. [redacted] Apotex Corp. respectfully asks this Court to dismiss the Plaintiffs' Complaint.

III. CONCLUSION

The Plaintiffs have failed to allege a valid claim for patent infringement under § 271(e)(2) because they have not—and cannot—allege that ANDA No. 79-145 contains a Paragraph IV certification related to either of the two Orange-Book-listed patents asserted here. The Plaintiffs' formulaic recitations cannot overcome this shortcoming. As a result, the Complaint does not present a justiciable Article III case or controversy. Even if it did, it does not state a claim for patent infringement under § 271(e)(2). Not only is there no Paragraph IV certification, [redacted] Therefore, this Court should dismiss the Complaint with prejudice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on November 16, 2010, 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.

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