NOT FOR PUBLICATION **[37]**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	:	Civil Action No. 09-2445(FLW) **OPINION**

WOLFSON, United States District Judge:

In this Hatch-Waxman Act patent infringement case, Defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant") moves pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 12(b)(6) to dismiss on the grounds that this Court lacks jurisdiction over the infringement action filed by Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk" or "Plaintiffs") in connection with claim 4 of Patent No. 6,677,358 ("the '358 Patent") because Mylan is not seeking approval in its Abbreviated New Drug Application ("ANDA") to practice claim 4 and, thus, no threat of infringement could allow Plaintiffs to maintain the cause of action. The Court has considered the parties' moving, opposition, reply and sur-reply papers. For the reasons that follow, the Court grants Mylan's motion to dismiss.

I. BACKGROUND

A. The Hatch-Waxman Act

Plaintiffs filed suit under the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly referred to as the Hatch-Waxman Act.[1] The Hatch-Waxman Act was aimed at streamlining the approval process for generic pharmaceuticals. See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1344 (Fed.Cir. 2007) ("A central purpose of the Hatch-Waxman Act . . . is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'") (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)). A company seeking to market a new brand-name drug must submit a New Drug Application ("NDA"), which is generally a lengthy application that includes information about the drug such as evidence of its safety and effectiveness, and information about the patents that cover or might cover it. 35 U.S.C. § 355(b)(1). The Hatch-Waxman Act permits a manufacturer seeking to market a generic equivalent of a previously approved Food and Drug Administration ("FDA") drug to file an ANDA with the FDA to obtain approval for its generic drug, which essentially "piggyback[s] on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 441 (D.N.J. 2006) (internal citations omitted).

As part of the application process, an ANDA applicant must provide one of the following four certifications as to each patent covering the previously-approved drug: (1) that no patent information has been listed in the Orange Book (a "Paragraph I Certification"); (2) that the listed patent has now expired (a "Paragraph II Certification"); (3) that the approval be delayed until the patent expires (a "Paragraph III Certification");

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[1] 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 Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-117 Stat. 2066 (2003).

or (4) that the applicant believes to the best of his knowledge "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii) (I) - (IV). An applicant that includes a Paragraph IV Certification must give notice to "each owner of the patent that is the subject of the certification . . . and . . . the holder of the approved [NDA]." 21 U.S.C. § 355(j)(2)(B)(iii). Upon receiving notice, a patent-holder has a forty-five-day period in which to bring an action for patent infringement. See 21 U.S.C. § 355(j)(5)(B)(iii). If a patent-holder does file a lawsuit, then the FDA will not approve the ANDA until the court rules that the patent is not infringed or until thirty months have passed, beginning on the date the patent-holder received notice of the ANDA, whichever occurs first. See Id.

Significantly, however, "the four types of certifications enumerated in 21 U.S.C. § 355(j)(2)(A)(vii) are not the only mechanisms by which an ANDA applicant can address a potentially relevant patent." Apotex, Inc. v. Food & Drug Administration, 393 F.3d 210, 213-14 (D.C. Cir. 2004). Rather than submit a Paragraph IV Certification, an ANDA applicant may instead represent that it is not seeking approval for the patented method of use. 21 U.S.C. § 355(j)(2)(A)(viii). In what is commonly referred to as a "section viii statement", the ANDA applicant asserts that the "patent is inapplicable to the indication for which the drug product will be marketed." In re Neurontin Antitrust Litigation, No. 02-1390 (FSH), 2009 WL 2751029, * 2, n.11 (D.N.J. Aug. 28, 2009) (citing 21 U.S.C. § 355(j)(2)(A)(viii)). In Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004), the D.C. Circuit explained the differences between a Paragraph IV Certification and a section viii statement as follows:

> A section viii statement indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent. See 21 U.S.C. § 355(j)(2)(A)(viii). For example, if a brand-name manufacturer's patent covers a drug's use for treating depression, and the ANDA applicant seeks approval to use the drug to treat any other condition, then a section viii statement would be appropriate. Thus, whereas applicants use paragraph IV certifications to challenge the validity of admittedly applicable patents, they use section viii statements to assert that patents do not apply. The FDA has long required that for every patent ANDA applicants use either a paragraph IV certification or a section viii statement – they may not use both. As the FDA puts it, "either the applicant is seeking approval for the use claimed in the patent, or it is not." Tor-Pharm, Inc. v. Thompson, 260 F.Supp.2d 69, 77 (D.D.C. 2003) (quoting the record in that case) (internal quotation marks omitted).
>
> Paragraph IV certifications and section viii statements have quite different consequences. Applicants submitting section viii statements have no obligation to provide notice, nor must they wait thirty months for FDA approval. . . . "[T]he FDA may [thus] approve a section viii application immediately, making it an attractive route for generic manufacturers, even though a section viii statement does not entitle a successful applicant to the 180-day period of exclusivity bestowed on paragraph IV applicants."

354 F.3d at 880 (quoting Purepac Pharmaceutical Co. v. Thompson, 238 F.Supp.2d 191, 195 (D.D.C. 2002)). It is against this statutory framework that the Court now considers Mylan's motion to dismiss.

B. Procedural History and Factual Background

Novo Nordisk filed an NDA in June 1997 seeking approval for the sale of repaglinide, which the FDA ultimately approved for use in the treatment of type 2 diabetes, both as a monotherapy, as well as in combination with metformin or thiazolidinediones ("TZD's"). Compl. ¶ 12.[2] Since 1997, Novo Nordisk has manufactured and sold repaglinide under the brand name PRANDIN®. Id. at ¶ 13. On

[2] References to "Compl." are to the First Amended Complaint filed on June 26, 2009.

January 13, 2004, the United States Patent and Trademark Office issued the '358 patent, entitled "NIDDM Regimen", to Novo Nordisk A/S as assignee. Id. at ¶ 11. The listing for PRANDIN® in the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly referred to as the "Orange Book", includes the '358 patent. Id. at ¶ 14. Novo Nordisk A/S has at all times been, and continues to be, the sole owner of the '358 patent. Id. at ¶ 11. The '358 patent includes five claims:

> 1. A pharmaceutical composition comprising repaglinide and metformin together with a suitable carrier.
>
> 2. A pharmaceutical composition of claim 1 provided in the form of a tablet.
>
> 3. A pharmaceutical composition of claim 1 provided in the form of a capsule.
>
> 4. A method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin.
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> 5. A kit for use in the treatment of a patient having non-insulin dependent diabetes mellitus (NIDDM), said kit comprising an amount of repaglinide formulated for administration to said patient and an amount of metformin formulated for administration to said patient.

FAC, Ex. A, col. 10, ll. 41-56. Claims 1-3 and 5 are composition claims. Compl. ¶ 21. Claim 4, which is the subject of the instant litigation, is a method of use claim and, as stated, covers a method for the treatment of type 2 diabetes comprising administering to a patient repaglinide in combination with metformin. Id. at ¶¶ 10-12, 21.

The FDA reevaluated labeling for all oral anti-diabetic drugs in 2007. Id. at ¶ 15. Thereafter, in November 2007, the FDA directed that the indicated use of PRANDIN® be merged into a unified statement that it is to be used "as an adjunct to diet and exercise to

improve glycemic control in adults with type 2 diabetes mellitus." Id. The FDA instructed that the foregoing statement "[r]eplace all the separate indications (e.g., monotherapy, combination therapy, and initial or second-line therapy)." Id. The FDA further directed Novo Nordisk to submit revised labeling in accordance with the foregoing revised statement of use. Id. On January 11, 2008, in accordance with the FDA's directive, Novo Nordisk submitted a supplement to its NDA requesting that the label for PRANDIN® be changed. Id. at ¶ 16. Effective July 14, 2008, Novo Nordisk's revised labeling for PRANDIN® was approved. Id. The revised Indications and Usage statement now reads: "PRANDIN® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." Id. at ¶ 16. On May 6, 2009, the use code for PRANDIN® was revised to conform to the FDA's directive regarding simplified labeling for all oral antidiabetic drugs to describe its approved indication as "[a] method for improving glycemic control in adults with type 2 diabetes mellitus." Id. at ¶ 17.

Mylan filed an ANDA with the FDA, seeking approval to market a generic version of oral repaglinide tablets. Id. at ¶ 18. The ANDA initially contained only a section viii statement in connection with the '358 patent. Subsequently, however, on April 7, 2009, Novo Nordisk received a letter from Mylan indicating that the ANDA had been amended to include a Paragraph IV Certification alleging that claims 1 - 3 and 5 of the '358 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's repaglinide. Id. at ¶ 22. Mylan indicated in its April 2009 notice to Novo Nordisk that it included a section viii statement in connection with claim 4 of the '358

patent because "its [proposed] labeling does not include indications to treat diabetes with a combination of repaglinide and metformin." Id. at ¶ 22.

On May 20, 2009, Novo Nordisk filed the instant patent infringement suit under 35 U.S.C. § 271(e)(2), alleging that the filing of Mylan's ANDA for a generic version of oral repaglinide tablets infringes the '358 patent. Mylan moved to dismiss the Complaint on June 11, 2009. On June 26, 2009, while Mylan's initial motion to dismiss was pending, Novo Nordisk filed an Amended Complaint (the "First Amended Complaint" or "FAC"). Novo Nordisk alleges that "[b]ased on a May 19, 2009 discussion with the FDA, Novo Nordisk understood that the FDA would not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin, nor would it permit any ANDA filer for generic repaglinide to rely upon a Section viii statement in connection with claim 4 of the '358 patent." Compl. at ¶ 23. Novo Nordisk further alleges that the FDA issued a formal ruling in another matter which is consistent with the information provided by the FDA on May 19, 2009. Id. at ¶ 24. Novo Nordisk asserts that the "import of this ruling is that, in view of the amended use code for PRANDIN®, the FDA will not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin." Id. Novo Nordisk therefore contends that as a direct and necessary consequence, Mylan's section viii statement in connection with claim 4 of the '358 patent "is of no force and effect, and its proposed labeling will be rejected by the FDA." Compl. at ¶ 25. According to Novo Nordisk, in order to proceed with its ANDA, "Mylan *will be* required to: a) abandon its Section viii statement with respect to claim 4 and substitute a Paragraph IV certification with respect to all claims of the '358 patent;

and b) propose new labeling that includes instructions for the use of repaglinide in combination with metformin." Id. (Emphasis supplied). Accordingly, Novo Nordisk asserts a cause of action for infringement under § 271(e)(2)(A), based upon Mylan's intent to induce, promote and encourage the use of its generic repaglinide in combination with metformin for the treatment of type 2 diabetes mellitus.

Mylan subsequently filed the instant motion to dismiss. In this motion, Mylan asserts that the Court lacks jurisdiction over Novo Nordisk's assertion that the ANDA infringes claim 4 of the '358 patent. Relying on Novo Nordisk's concession in the FAC that Mylan's Paragraph IV Certification extends only to composition claims 1 – 3 and 5 of the '358 patent (FAC ¶ 22), Mylan argues that because it has submitted a section viii statement in connection with claim 4, representing that it does not intend to practice the claimed method, the ANDA upon which Novo Nordisk's only cause of action is based, creates no act or threat of infringement as to claim 4 and there is no jurisdictional basis for a patent infringement action based solely on claim 4. Moving Br. at 10-11. Further, Mylan asserts that ignoring the jurisdictional flaws of the FAC, the conclusory allegations in the FAC cannot survive the instant motion to dismiss given the fact that Novo Nordisk itself has a repaglinide-only product (i.e., PRANDIN®), and given that the FDA has expressly found that repaglinide does not need to be administered in combination with metformin, there cannot be a valid claim that Mylan's product will inevitably infringe the '358 patent. Moving Br. at 2, 16-20.

II. STANDARD OF REVIEW

A party may move for dismissal pursuant to Fed. R. Civ. P. 12(b)(1) based on lack of subject matter jurisdiction. The burden is on the plaintiff to prove that subject matter

exists. Wyeth and Cordis Corporation v. Abbott Laboratories, No. 08-0230 (JAP), 2008 WL 2036805, * 2 (D.N.J. May 8, 2008). "In Mortensen v. First Federal Sav. & Loan Ass'n, 549 F.2d 884 (3d Cir. 1977), the Third Circuit . . . divided Rule 12(b)(1) motions into two categories: facial and factual." International Development Corporation v. Richmond, No. 09-2495(GEB), 2009 WL 3818141, at * 2 (D.N.J. Nov. 13, 2009). "A facial attack on jurisdiction is directed to the sufficiency of the pleading as a basis for subject matter jurisdiction." Id. Accordingly, "the court must only consider the allegations of the complaint and documents referenced therein and attached thereto in the light most favorable to the plaintiff." Gould Electronics, Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000).

In contrast, when the court considers a factual attack on jurisdiction under 12(b)(1), ". . . the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Mortensen v. First Federal Sav. & Loan Ass'n, 549 F.2d at 891. No presumption of truthfulness attaches to the allegations of the complaint insofar as they concern subject matter jurisdiction. Id. Should factual issues arise regarding subject matter jurisdiction, the court may consider exhibits outside the pleadings. Gould Electronics, 220 F.3d at 178. "In general, when a Rule 12(b)(1) motion is supported by a sworn statement of facts, the court should treat the Defendant's challenge as a factual attack on jurisdiction." International Development Corporation v. Richmond, 2009 WL 3818141, at * 2 (quoting Med. Soc'y of N.J. v. Herr, 191 F.Supp.2d 574, 578 (D.N.J. 2002)).

"Moreover, '[w]hen a motion to dismiss is based on lack of subject matter jurisdiction pursuant to Rule 12(b)(1), as well as other Rule 12(b) defenses, the Court

should consider the Rule 12(b)(1) challenge first because, if it must dismiss the complaint for lack of subject matter jurisdiction, the accompanying defenses become moot and need not be addressed.'" Wyeth and Cordis Corporation v. Abbott Laboratories, 2008 WL 2036805, at * 2 (quoting Pashun v. Modero, No. 92-3620, 1993 WL 185323 (D.N.J. May 26, 1993)).

"A motion to dismiss for lack of ripeness is properly brought pursuant to Rule 12(b)(1)." Abraxis Bioscience, Inc. v. Navinta LLC, No. 07-1251(JAP), 2008 WL 2967034, * 2 (D.N.J. Jul. 31, 2008) (citing NE Hub Partners, L.P. v. CNG Transmission Corp., 239 F.3d 333, 341 (3d Cir. 2001)). When a motion to dismiss is brought on ripeness grounds, "a court must 'evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" Id. at * 3 (quoting Texas v. United States, 523 U.S. 296, 300-01 (1998)). The court must engage in a "multifactorial analysis":

> First, a court considers the adversity of the parties' interests. [N.E. Hub Partners, 239 F.3d at 342 (citing Step-Saver Data Sys., Inc. v. Wyse Tech., 912 F.2d 643, 647 (3d Cir. 1990))]. Second, a court must determine "the probable conclusiveness of a judgment[.]" Ibid. Third, a court ascertains "the practical utility to the parties of rendering a judgment." Ibid, (footnote omitted). If necessary, a court may consider other additional factors. Ibid. However, "[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas, supra, 523 U.S. at 300.

Abraxis Bioscience, Inc., 2008 WL 2967034, at * 3.

III. DISCUSSION

As a preliminary matter, the Court notes that is not entirely clear whether Mylan is asserting a facial or factual attack on jurisdiction under Rule 12(b)(1). As Novo Nordisk points out, "Mylan makes a facial attack on jurisdiction on the ground that "[t]he filing of

an ANDA with a section viii statement is not an act of infringement" (D's Br. at 1), but incongruently recites the standard for a factual attack on jurisdiction. Id. at 8-9." Opposition Br. at 7, n. 3. As previously noted, however, a court should treat a challenge as factual where the motion is supported by a sworn statement of facts. Med. Soc'y of N.J. v. Herr, 191 F.Supp.2d at 578 (citing Int'l Ass'n of Machinists & Aerospace Workers v. Northwest Airlines, 673 F.2d 700, 711 (3d Cir. 1982). The rationale is obvious -- where defendant proffers facts outside the pleadings in support of the 12(b)(1) motion, the challenge is undoubtedly factual as opposed to facial.

Here, the parties have both proffered numerous documents and exhibits in support of their respective positions which lead this Court to conclude that Mylan's attack must be construed as factual. Indeed, Mylan supplies the Court with several exhibits, including: (1) a copy of the '358 patent, which is the subject of the instant infringement action (Declaration of Shannon M. Bloodworth, Esq., dated July 28, 2009 ("Bloodworth Decl.") at ¶ 2, Ex. A); (2) correspondence from Mylan to Novo Nordisk, dated April 6, 2009 (Bloodworth Decl. at ¶ 3, Ex. B); (3) correspondence from Mylan to FDA's Office of Generic Drugs, submitting a Paragraph IV Certification to claims 1 - 3 and 5 of the '358 patent and a section viii statement to claim 4 of the '358 patent (Bloodworth Decl. at ¶ 4, Ex. C); (4) repaglinide product labeling submitted to the FDA with Mylan's ANDA for repaglinide tablets (Bloodworth Decl. at ¶ 5, Ex. D); (5) correspondence from the FDA to Novo Nordisk and Winston & Strawn dated December 4, 2008, granting Caraco's petition that a section viii statement be required for claim 4 of the '358 patent (Bloodworth Decl. at ¶ 6, Ex. E); (6) correspondence from the FDA to Novo Nordisk dated June 16, 2009, denying as moot Novo Nordisk's Petition for Reconsideration of the FDA's December 4,

2008 ruling (Bloodworth Decl. at ¶ 7, Ex. F); (7) Novo Nordisk's Motion to Dismiss for Lack of Jurisdiction, filed in Novo Nordisk v. Caraco Pharms. Labs., Ltd., No. 4:05 CV 40188 (E.D. Mich. July 9, 2008) (Bloodworth Decl. at ¶ 8, Ex. G); (8) a copy of House Report No. 98-857 (June 21, 1984) (Supplemental Declaration of Shannon M. Bloodworth, Esq., dated September 21, 2009 ("Supp. Bloodworth Decl.") at ¶ 2, Ex. A); (9) a copy of the FDA's *Draft Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (Supp. Bloodworth Decl. at ¶ 3, Ex. B); and (10) supplemental authority in the form of a decision issued September 24, 2009, by the Eastern District of Michigan in Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., Case No. 05-40188, 2009 U.S. Dist. LEXIS 87895 and its corresponding Order and Injunction, 2009 U.S. Dist. LEXIS 88551, issued September 25, 2009 (attached as Exhibits A and B to Mylan's October 1, 2009 sur-reply).

Likewise, in opposition to the instant motion to dismiss, Novo Nordisk supplies the Court with exhibits, including: (1) a copy of the Amended Preliminary Final Pretrial Conference Order, dated July 22, 2009, in Novo Nordisk A/S et al. v. Caraco Pharmaceutical Laboratories, Ltd. et al., Case No. 2:05 CV 40188 (E.D. Mich.) (Declaration Carrie A. Longstaff, Esq., dated September 8, 2009 ("Longstaff Decl.") at ¶ 2, Ex. A); and (2) a portion of the declaration filed by Sandoz, Inc. on June 28, 2007 in support of its motion to dismiss in Takeda Pharmaceuticals Company Ltd. Et al. v. Sandoz, Inc., Case No. 07 CV 3844 (S.D.N.Y.) (Longstaff Decl. at ¶ 3, Ex. B). While certain of the exhibits are either expressly referenced in the FAC and/or integral to the FAC such that their introduction does not implicate factual issues because the allegations

in the FAC are based thereon,[3] others clearly implicate matters outside the pleadings such that their introduction leads this Court to the inescapable conclusion that Mylan is asserting a factual attack on this Court's jurisdiction over the instant case. Moreover, Mylan is clearly disputing Novo Nordisk's factual basis for its allegations as set forth in the FAC. Specifically, Mylan challenges Novo Nordisk's assertion that the FDA will not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin, such that the FDA will require Mylan to abandon its section viii statement with respect to claim 4 and propose new labeling that includes instructions for the use of repaglinide in combination with metformin. Accordingly, the Court will evaluate the 12(b)(1) motion as a factual challenge and consider the declarations submitted by the parties.[4]

Mylan alleges that the lack of a Paragraph IV Certification as to claim 4 of the '358 patent is fatal to Novo Nordisk's FAC. Here, where patent protection for repaglinide and its primary use – the treatment of patients with type II diabetes mellitus – has expired,

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[3] It is clear that the '358 patent, attached to the Complaint, along with the April 6, 2009 correspondence from Mylan to Novo Nordisk, Mylan's Paragraph IV Certifications in connection with claims 1-3 and 5 and its section viii statement in connection with claim 4, the labeling submitted to the FDA in connection with Mylan's ANDA for repaglinide tablets, and the June 16, 2009 FDA letter ruling are expressly referenced by Plaintiff in the FAC and integral to Plaintiff's claim of infringement.

[4] "Although the court should determine subject matter jurisdiction at the outset of a case, 'the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation. See 2 James W. Moore, Moore's Federal Practice § 1230[1] (3d ed. 1997). Rather, a party may first establish jurisdiction 'by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject matter jurisdictional fact issue occurs in a comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection).' Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co., 513 U.S. 527, 537-38 (1995)." In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation, No. 09-2118, 2010 WL 902552, at * 3, n.7 (D.Del. Mar. 12, 2010).

and Novo Nordisk's sole cause of action is based upon claim 4 of the '358 patent, covering the use of repaglinide in combination with metformin, Mylan argues that its section viii statement as to claim 4 is insufficient as a matter of law to establish jurisdiction. First, citing Purepac Pharms., 238 F.Supp.2d at 195, Mylan notes that the filing of a section viii statement does not create a cause of action under the Hatch-Waxman Act. Significantly, Mylan points to the fact that Novo Nordisk itself has taken this very position in other litigation involving the '358 patent. Moving Br. at 11. Citing the matter of Caraco Pharmaceuticals Laboratories, Ltd. in the United States District Court for the Eastern District of Michigan (the "Caraco litigation"), Mylan notes that when Caraco amended its Paragraph IV Certification to a section viii statement with respect to claim 4 of the '358 patent, Novo Nordisk moved to dismiss its claim of patent infringement on claim 4, as well as Caraco's declaratory judgment counterclaims regarding claim 4 on the grounds "that there is no act of infringement upon which the Court may base jurisdiction. See Purepac, 238 F.Supp. 2d at 195 ('An applicant proceeding by means of a section viii statement . . . does not face an infringement action under 35 U.S.C. 271(e)(2)(A)')." (Bloodworth Decl. at ¶ 8, Ex. G at 9.)

Novo Nordisk counters that the filing of Mylan's ANDA is an "Act of Infringement" in that it is, under the plain meaning of Section 271(e)(2)(A), an "application under section 505(j) of the Federal Food Drug and Cosmetic Act . . . for a drug . . . the use of which is claimed in a patent." Opp. Br. at 9. Further, Novo Nordisk asserts that Mylan's concession that the filing of an ANDA with a Paragraph IV Certification constitutes a jurisdictional act of infringement under Section 271(e)(2)(A) (Moving Br. at 1) should end the inquiry into jurisdiction in light of the fact that Mylan

filed an amended ANDA in April 2009, which included Paragraph IV Certifications regarding claims 1 - 3 and 5 in connection with the '358 patent. Novo Nordisk argues that there is no language in the Hatch-Waxman Act that deprives "a court of jurisdiction where a generic company has filed an ANDA with a 'mixed' Paragraph IV certification and Section viii statement." Opp. Br. at 10. Novo Nordisk asserts that even if the Court were to "indulge" Mylan's effort to focus attention solely on its section viii statement, Mylan's argument still fails because the filing of an ANDA that *should* include a Paragraph IV Certification constitutes a jurisdictional "act of infringement" under Section 271(e)(2)(A). Quoting Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F.Supp. 2d 572, 582 (D.N.J. 2001), Novo Nordisk argues that "the face of an ANDA is not dispositive under Section 271(e)(2)(A), a jurisdictional 'act of infringement' may arise under Section 271(e)(2)(A) '*even if the ANDA included no Paragraph IV Certification at all, so long as a Paragraph IV Certification should have been included*.'" Opp. Br. at 10 (emphasis in original). Further, Novo Nordisk contends that there is little question that Mylan has engaged in "artful" drafting of its certification from the outset by submitting its ANDA with only a section viii statement and later amending the ANDA to include the Paragraph IV Certifications only as to claims 1 - 3 and 5. Novo Nordisk reasons that:

> When Mylan served notice of its Paragraph IV certification in April 2009, it triggered a 45-day window for Novo Nordisk to file suit and preserve a statutory 30-month stay of FDA approval of Mylan's ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii). If, as Mylan urges a "mixed" Paragraph IV certification and Section viii statement could deprive the Court of jurisdiction *regardless* of the propriety of the Section viii statement, the ANDA applicant could always avoid a statutory 30-month stay by the simple expedient of filing a limited (and improper) Paragraph IV certification, waiting for the 45-day window to expire, and then filing the proper Paragraph IV certification on day forty-six. Through such "artful certification," an ANDA applicant could thus unilaterally deprive

> the NDA holder of its statutory right to litigate the issue of patent infringement before the launch of the generic product. (Opp. Br. at 11-12) (emphasis in original).

There is a Chicken Little "Sky is Falling" quality to Novo Nordisk's argument. Mylan does not, as Novo Nordisk suggests, urge this Court to find that a "mixed" Paragraph IV Certification and section viii statement can deprive the Court of jurisdiction regardless of the propriety of the section viii statement. Mylan simply asserts that where it has not filed a Paragraph IV Certification with regard to the only patent claim asserted in this action – claim 4 of the '358 patent – this Court lacks jurisdiction over the infringement action involving that claim. Accordingly, the issue is whether this Court has jurisdiction over an infringement action where, although Paragraph IV Certifications have been filed in the ANDA with regard to the patent at issue, the only claim at issue in the infringement action is one for which a section viii statement has been filed. To answer that question, the Court turns to the statutory scheme that confers jurisdiction and the relevant caselaw interpreting that scheme.

A patent infringement claim is generally made against "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor[.]" 35 U.S.C. § 271(a). The Hatch-Waxman Act limits the potential patent liability for companies that seek FDA approval to market a generic version of the brand-name drug. See 35 U.S.C. §271(e)(1). Because a generic-drug manufacturer has not yet placed the drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under § 271(a). However, Section 271(e)(2)(A)

"provides a jurisdictional basis for an infringement action against the applicant where it seeks approval to market a patented product before the expiration of the patent." Janssen, L.P. v. Barr Laboratories, Inc., No. 07-1515, 2008 WL 323558, at * 2 (D.N.J. Feb. 4, 2008) (citation omitted); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). Thereby, with this provision, "Congress created a 'highly artificial act of infringement that consists of submitting an ANDA . . . 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.'" Janssen, 2008 WL 323558 at * 2 (quoting Eli Lilly, 496 U.S. at 678). Congress has extended the Court's jurisdiction over a hypothetical issue: whether the defendant's proposed generic drug would infringe on plaintiff's patent if the defendant's drug was on the market. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1366 (Fed. Cir. 2003). Section 271(e)(2)(A) "simply provides an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." Id. at 1365 (citations omitted). "The proper inquiry under 271(e)(2)(A) is 'whether if a particular drug *were* put on the market, it *would* infringe the relevant patent.'" Id. at 1366 (emphasis in original) (quoting Bristol-Myers Squibb Co. v. Royce labs., Inc., 69 F.3d 1130, 1135 (Fed.Cir. 1995)).

The Court is further guided by the thorough analysis in Eisai Co., Ltd. v. Mutual Pharmaceutical Co., No. 06-3613 (HAA), 2007 WL 4556958 (D.N.J. Dec. 20, 2007), in which the court set forth the jurisdictional contours of Section 271(e)(2)(A), as guided by controlling Federal Circuit precedent and other persuasive authority. In Eisai, the district

court considered whether it had jurisdiction to hear a claim brought under Section 271(e)(2)(A) where the ANDA filed by the company seeking to market the generic drug did not include a Paragraph IV Certification because the patent holder had inadvertently failed to list the subject patent in the Orange Book prior to the filing of the ANDA. After noting that the plain language of Section 271(e)(2)(A) does not require that an alleged infringer file a Paragraph IV Certification, the court nevertheless concluded, following an exhaustive review of federal precedent and legislative history, that "to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." Eisai, 2007 WL 4556958, at * 12. In reaching that conclusion, the Eisai court relied, in part, on Bristol-Myers Squibb Co. v. Royce labs., Inc., 69 F.3d at 1135, in which the Federal Circuit linked Section 271(e)(2)(A) to a Paragraph IV Certification as follows:

> In that action, depending upon the nature of the certification that has been filed, the district court determines the validity of the patent at issue and/or whether the drug sought to be marketed infringes the claims of that patent. "What is achieved by § 271(e)(2) [is] the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing a [paragraph IV] 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." Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). Thus, section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent. If the court determines that the patent is not invalid and that infringement would occur, and that therefore the ANDA applicant's paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires. See 21 U.S. § 355(j)(4)(B)(iii)(II); 35 U.S.C.A. § 271(e)(4)(A).

It is clear from the foregoing, that what has driven the conclusion that a Paragraph IV Certification must be filed along with the ANDA to confer jurisdiction over an infringement action under Section 271(e)(2)(A), is what that Paragraph IV Certification represents for the purposes of the infringement action, i.e., that the certification has been filed in error and that infringement would actually occur if the drug were brought to market. Here, where no Paragraph IV Certification has been filed in connection with the only claim at issue with regard to the '378 patent, the Court fails to see how the filing of the Paragraph IV Certifications in connection with claims 1 - 3, and 5 are even relevant. The fact that Mylan filed the Paragraph IV Certifications in the ANDA which is challenged simply cannot confer jurisdiction where those claims are not at issue in the infringement action. As Novo Nordisk itself recognized in the Caraco litigation, "if an ANDA applicant files a section viii statement instead of a Paragraph IV Certification, there is no act of infringement upon which the Court may base jurisdiction." Bloodworth Decl., Ex G, at 9. The filing of Paragraph IV Certifications as to claims that are not in issue in an infringement action simply cannot constitute an act of infringement upon which the Court may base jurisdiction when the claims for which they are filed have no relation to the infringement action save for the fact that they involve the patent at issue in the action and were, therefore, filed in the ANDA which is the subject of the litigation.

Returning now to Novo Nordisk's contention that an ANDA filer can thwart the protections that Congress intended to provide to patentees under the Hatch-Waxman Act by "artful drafting" in "mixed" certification cases, the Court finds no merit to that argument. As Novo Nordisk points out, the filing of an ANDA that *should* include, but does not include, a Paragraph IV Certification nevertheless constitutes an "act of

infringement" which confers jurisdiction under Section 271(e)(2)(A). In Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F.Supp. 2d 572, 582 (D.N.J. 2001), the court considered whether jurisdiction is limited in an infringement action under Section 271(e)(2)(A) to only those elements of an ANDA that were addressed in the Paragraph IV Certification and does not extend to subsequent amendments. The Ben Venue court held that such a narrow reading would undermine the purpose of Section 271(e)(2)(A). Id. at 578. The court went on to note that the Federal Circuit's statement in Bristol-Myers, 69 F.3d at 1130, that "[o]nce it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent-infringement suit",

> articulates in plain language that while the Paragraph IV Certification provides the legal trigger for an infringement action, the inquiry truly begins because the ANDA filer seeks approval to market a patented drug prior to the expiration of the relevant patent.
>
> It is possible that such a legal inquiry could begin even if the ANDA included no Paragraph IV Certification at all, so long as a Paragraph IV Certification should have been included. See Marion Merrell Dow, Inc. v. Hoechst-Roussel Pharm., Inc., 32 U.S.P.Q.2d 1156 (D.N.J.); Abbot Labs. v. Zenith labs., Inc., 934 F.Supp. 925 (N.D.Ill. 1995). In Abbott, the Court commented:
>
> > 'The proper inquiry is, should the certification have included the patent and if so, is there an infringement of the patent?' If the ANDA applicant does not certify a properly listed patent, then the patent holder still has a cause of action under § 271 (e)(2)(A).
>
> 934 F.Supp. at 936, quoting Marion Merrell Dow, 32 U.S.P.Q.2d at 1158. Since the patent holder had its patent on file in the Orange Book at the time the relevant ANDA was filed, it was immaterial for litigation purposes whether the patent was certified in the ANDA. Id.

> Although the Federal Circuit has yet to speak to this proposition, this conclusion is reasonable. Since the certification provisions exist for the benefit of the patentee, a court could conclude that a patentee should be allowed to sue for infringement as soon as the ANDA filer has left the safe harbor of § 271(e)(1) by filing a potentially infringing ANDA with the FDA, even if the artful drafting of the ANDA attempts to circumvent the required filing of a Paragraph IV Certification.

146 F.Supp.2d at 582. Were Novo Nordisk's allegations actually supportive of its contention that Mylan should have filed a Paragraph IV Certification in connection with claim 4 of the '358 patent, rather than the section viii statement that it filed with the ANDA, the Court would indeed find that it had jurisdiction to entertain Novo Nordisk's patent infringement action. Accordingly, the concerns that Novo Nordisk raises in connection with "mixed" certification cases do not pose any real danger that an ANDA applicant can deprive a patentee of the protections afforded by the Hatch-Waxman Act by artful drafting of its ANDA.[5]

The problem Novo Nordisk has here is that the allegations in the FAC simply do not support its contention that Mylan should have filed a Paragraph IV Certification, rather than the section viii statement that it actually filed with the ANDA. The allegations

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[5] Mylan counters Novo Nordisk's contention that artful drafting could potentially deprive a patentee of its rights under the Hatch-Waxman Act by citation to *FDA Draft Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications under Hatch-Waxman, as Amended by the MMA of 2003* at 9. According to Mylan, the FDA Draft Guidance establishes that a 30-month stay follows if the patent was submitted before the date that the ANDA was submitted to the FDA and the patentee initiates a patent infringement action on the patent within 45 days of the date that it receives notice of the certification. Reply Br. at 7-8. Mylan contends that because its ANDA was submitted after the listing of the '358 patent, if Mylan is indeed required to amend its statement to a Paragraph IV Certification, and Novo Nordisk files suit within 45 days, Novo Nordisk will be entitled to the 30-month stay. In light of this Court's determination that Mylan cannot deprive Novo Nordisk of the 30-month stay where a certification should include, but does not include, a Paragraph IV Certification, this Court need not reach Mylan's argument.

addressing this issue are set forth in paragraphs 23 and 24 of the FAC. As previously noted, Novo Nordisk asserts that "[b]ased on a May 19, 2009 discussion with the FDA, Novo Nordisk understood that the FDA would not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin, nor would it permit any ANDA filer for generic repaglinide to rely upon a Section viii statement in connection with claim 4 of the '358 patent." Compl. at ¶ 23. As further evidence that this is indeed the FDA's position, Novo Nordisk cites a June 16, 2009 letter ruling from the FDA noting that "[t]he import of this ruling is that, in view of the amended use code for PRANDIN®, the FDA will not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin." Id. at ¶ 24. Based on the foregoing, Novo Nordisk contends that the section viii statement is of no force and effect and Mylan's proposed labeling will be rejected with direction that the new labeling include instructions for the use of repaglinide in combination with metformin. Id. at ¶ 25.

Here, where "no presumptive truthfulness" attaches to the allegations in the complaint, Mortensen v. First Federal Sav. & Loan Ass'n, 549 F.2d at 891, this Court simply does not agree that Novo Nordisk has pled facts that would support Section 271(e)(2) jurisdiction. As Mylan points out, what is missing from the FAC is an allegation that Mylan's proposed labeling *has been rejected* by the FDA or that the FDA *has required* Mylan to modify its certification. Moreover, this Court does not agree that the June 16, 2009 letter ruling from the FDA, referenced in paragraph 24, is "consistent" with the alleged discussion Novo Nordisk had with an unnamed FDA representative. The June 16, 2009 letter ruling merely denies Novo Nordisk's Petition for Reconsideration of

its December 4, 2008 adverse ruling on mootness grounds. In the December 4, 2008 ruling, the FDA denied Novo Nordisk's Petition requesting that the FDA refrain from approving any ANDA for a repaglinide product that omits information on metformin combination therapy, finding that "a carve-out of metformin information from the drug product labeling will not compromise safety or effectiveness for the remaining, nonprotected conditions of use." Bloodworth Decl., Ex. E at 18. In the June 16, 2009 ruling, the FDA merely noted that Novo Nordisk's petition for reconsideration of its December 4 ruling was moot given that Novo Nordisk on May 6, 2009 submitted an amendment to the use code relating to the '358 patent, which was different than the use code on which the FDA had based its prior ruling. Bloodworth Decl., Ex. F at 2-3.

What is clear to this Court is that Novo Nordisk's claim is not ripe for review in that it "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas, 523 U.S. at 300. To find that the allegations in the FAC confer Section 271(e)(2) jurisdiction, this Court must look to Novo Nordisk's May 6, 2009 amendment to the use code relating to the '358 patent and surmise that the FDA will, based on that amendment, require Mylan to submit a Paragraph IV Certification and propose new labeling that includes instructions for the use of repaglinide in combination with metformin. Unless and until the FDA makes those determinations, this Court finds that the instant action is not ripe for review.

Citing a recent decision by the Eastern District of Michigan in the Caraco litigation, 2009 U.S. Dist. LEXIS 87895, at * 4, Novo Nordisk urges this Court to accept as fact that the FDA's current position is that it will not allow ANDA filers for generic repaglinide to rely upon section viii statements. Novo Nordisk's assertion is based on the

Caraco court's finding that as a result of the May 6, 2009 revision to Novo Nordisk's use code, "the FDA will no longer permit Caraco to file a 'section viii statement' carving out the patented repaglinide-metformin combination therapy as a predicate for securing approval of Caraco's ANDA to market its generic repaglinide for non-infringing uses." 2009 U.S. Dist. LEXIS 87895, at *4. However, a finding that the FDA will indeed require Mylan to amend its ANDA to include a Paragraph IV Certification in connection with claim 4 is not a *fait accompli*. As Mylan points out, the Caraco court has issued an injunction requiring Novo Nordisk to withdraw its amended use code and replace it with the original use code listing. Id. at * 5. Accordingly, this Court simply cannot find as fact that the FDA will indeed require Mylan to file a Paragraph IV Certification and propose new labeling that includes instructions for the use of repaglinide in combination with metformin. The Court therefore finds that the instant infringement action is not ripe for review.[6]

Finally, the Court notes that while the FAC includes 28 U.S.C. § 2201 among the statutes which confer subject matter jurisdiction over this action, Novo Nordisk does not appear to request declaratory relief under § 2201. Nor does Novo Nordisk respond to Mylan's contention in its moving papers that the allegations in the complaint cannot satisfy the requirements of the Declaratory Judgment Act. Consequently, this Court must presume that Novo Nordisk is not seeking relief under the Declaratory Judgment Act.

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[6] While Novo Nordisk appears to suggest that further discovery on jurisdictional facts should be permitted to the extent this Court treats Mylan's motion as a factual attack on jurisdiction (Opp. Br. at 7, n.3), the Court finds further discovery unnecessary as it is clear from the submissions of the parties, and the allegations in the FAC, that the FDA has not yet required Mylan to file a Paragraph IV Certification or revise its labeling.

IV. CONCLUSION

For the foregoing reasons, the Court grants the motion to dismiss.

/s/ Freda L. Wolfson
Honorable Freda L. Wolfson
United States District Judge

Dated: March 31, 2010