UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NOVO NORDISK A/S and
NOVO NORDISK, INC.,

Plaintiffs,

-vs-

Case No. 05-40188
Hon: AVERN COHN

CARACO PHARMACEUTICAL
LABORATORIES, LTD. and
SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.
_____/

MEMORANDUM AND ORDER DENYING PLAINTIFFS' MOTION TO DISMISS FOR LACK OF JURISDICTION[1]

I.

This is a patent case. It involves the diabetes drug repaglinide marketed by plaintiffs Novo Nordisk A/S and Novo Nordisk, Inc. (Novo) under the trade name Prandin. Novo's patent for repaglinide, U.S. Pat. No. RE37,035 (the '035 patent), expired on March 14, 2009. Novo also holds a patent on the combination of repaglinide and metformin, U.S. Pat. No. 6,677,358B1 (the '358 patent) which does not expire until 2018. As will be explained, this case began in 2005 when Novo sued Caraco Pharmaceutical Laboratories, Ltd (Caraco) and Sun Pharmaceutical Industries, Inc. (Sun) claiming infringement of the '358 patent when Caraco applied to the FDA to market a generic version of repaglinide. Caraco and Sun countersued for declaratory relief, raising issues including validity, enforceability, and misuse.

[1]Ordinarily, the Court would hold a hearing on this matter. However, upon review of the parties' papers, the Court finds that oral argument is not necessary. See E.D. Mich. LR 7.1(f)(2).

After five years of litigation, one appeal, and a three-week bench trial on the issues of patent validity and enforceability, a decision on which is pending, Novo has moved to dismiss the case for lack of subject matter jurisdiction. Although Novo alleged in its complaint that an actual controversy existed because of Caraco's conduct before the FDA, it now says that jurisdiction is lacking because of Caraco's later actions before the FDA. For the reasons that follow, Novo's motion is DENIED.

II.

In analyzing jurisdictional questions in declaratory judgment actions, there is no bright-line rule. MedImmune Inc. v. Genentech Inc., 549 U.S. 118, 127 S.Ct. 764, 771 (2007). Instead, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id.

A party claiming declaratory judgment jurisdiction has the burden to establish the existence of such jurisdiction. See Benitec Austl., Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1344 (Fed. Cir. 2007).

III.

The background of the case, including the process of certification of a generic drug, is described in several decisions of the Court reported at 450 F. Supp. 2d 757 (E.D. Mich. 2006) and 2009 WL 2769855 (E.D. Mich. Aug. 31, 2009). Background is also set forth in the Court of Appeals for the Federal Circuit's decisions reported at 601 F.3d 1359 (Fed. Cir. 2010) and --- F.3d ----, 2010 WL 2990968 (Fed. Cir. July 29, 2010). What follows is background relevant to the instant motion.

A.

First, as to the statutory framework, this case falls under the Hatch-Waxman Act, which amended the Federal Food, Drug, and Cosmetic Act, Pub.L. No. 52-675, 52 Stat. 1040 (1938), (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)) (the "FDCA"). Under the FDCA, the FDA is responsible for determining whether a generic drug product should be approved for sale to the public. 1 U.S.C. § 355(a). Under Hatch-Waxman, a pharmaceutical manufacturer, such as Caraco, seeking expedited FDA approval to market a generic version of a patented drug may submit an abbreviated new drug application ("ANDA"). 21 U.S.C. § 355(j). An applicant submitting an ANDA must certify one of four things: (1) that the drug for which the ANDA is submitted has not been patented (a "paragraph I" certification); (2) that any patent on such drug has expired (a "paragraph II" certification); (3) the date on which the patent on such drug will expire, if it has not yet expired (a "paragraph III" certification); or (4) that the patent on such drug "is invalid or that it will not be infringed by the manufacture, use, or sale of the new drug" for which the ANDA is submitted (a "paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

When an applicant submits an ANDA that contains a paragraph IV certification, it must give the owner of the relevant patent notice of the certification. 21 U.S.C. § 355(j)(2)(B). Importantly, inclusion of a paragraph IV certification in an ANDA is deemed an act of infringement. The statute, referring to an ANDA containing a paragraph IV certification, states: "It shall be an act of infringement" to submit an application under 21 U.S.C. § 355(j) "for a drug claimed in a patent ... if the purpose of such submission is to obtain approval ... to engage in the commercial manufacture, use,

or sale of [the] drug ... before the expiration of [the] patent." 35 U.S.C.A. § 271(e)(2)(A).

If the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA "shall be made effective immediately" unless the patent owner brings an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B). 21 U.S.C. § 355(j)(4)(B)(iii). Hatch-Waxman further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval of the ANDA. Id. The suspension continues-and the FDA cannot approve the ANDA-until the earliest of three dates: (I) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that is thirty months from the patent owner's receipt of notice of the filing of the paragraph IV certification. 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. 271(e)(4)(A).

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.Cir. 2002)). Finally, a section viii statement, unlike a paragraph IV certification, does not constitute an act of infringement sufficient to invoke subject matter jurisdiction under Hatch-Waxman. See Purepac, 238 F. Supp. 2d at 195.

B.

Second, as to the facts of this case, in February 2005, Caraco submitted an

ANDA, seeking to market a generic version of repaglinide. Caraco included in its ANDA a "paragraph IV certification" stating that all five claims of the '358 patent were invalid and thus not infringed by Caraco's attempt to manufacture a generic repaglinide.

On April 2, 2005, the FDA acknowledged receipt of Caraco's ADNA and Paragraph IV certification. See Ex. 16 of Joint Appendix. Caraco also notified Novo of the certification as required.

In June 2005, Novo sued Caraco for infringement and later added Sun as a defendant. Novo claimed that Caraco's anticipated manufacture of repaglinide would infringe the '358 patent because the label would suggest the use of repaglinide with metformin. Both Caraco and Sun counterclaimed that the '358 patent was invalid, unenforceable, and would not be infringed by the sale of generic repaglinide.

Meanwhile, in August 2007, the FDA notified Caraco that its ADNA had been "tentatively approved." In the correspondence, the FDA noted that because there was a patent dispute involving the '358 patent, Caraco's application could not be finally approved. The FDA specifically referenced the lawsuit filed by Novo against Caraco. Ex. 21 of Joint Appendix.

On April 2, 2008, Caraco submitted an amendment to its ADNA, proposing that it be allowed to redact references in its label to the combination of repaglinide with metformin. In this filing, Caraco was attempting to submit a split certification, encompassing both a paragraph IV certification and a section viii certification. As noted in the Federal Circuit's decision:

> . . .at the FDA's urging [Caraco] sought a paragraph IV certification as to the drug product claims of the '358 patent, and a section viii certification as to the method claim.

Novo v. Caraco, 601 F.3d at 1379 n.16 (Dyk, dissenting) (emphasis added). See also Ex. 10 of Joint Appendix.

This point is critical inasmuch as Novo's motion is grounded on the premise that in seeking the amendment with the section viii certification, Caraco "dropped" its paragraph IV certification and, in so doing, the basis for subject matter jurisdiction was lost. This is a faulty premise. Novo did not abandon, drop, replace or otherwise waive the paragraph IV certification. This is clear when the record is further examined.

In May 2009, Novo submitted an amended use code for the '358 patent which the FDA approved.[2] Specifically, Novo changed the use code from "U-546–use of repaglinide in combination with metformin to lower blood glucose" to U-968–a method for improving glycemic control in adults with type 2 diabetes mellitus." As the case history shows, the propriety of Novo changing the use code was hotly litigated with Novo eventually prevailing in the Federal Circuit.

The FDA then notified Caraco that it would not approve a section viii statement in light of Novo's amended use code. The FDA later instructed Caraco to change its ADNA to add back in the information about the combination of repaglinide and metformin, which essentially mooted Caraco's efforts at a section viii statement.

All of this is spelled out in a May 26, 2010 letter from Caraco to the FDA in which Caraco states in relevant part:

---

[2]Shortly after Caraco sought the amendment, on July 9, 2008, Novo filed its first motion to dismiss for lack of subject matter jurisdiction. Following a status conference, Novo withdrew the motion. Novo refiled the motion after the proofs were submitted in the validity trial. The Court has already commented on the peculiar circumstances of Novo's filing in the Memorandum and Order of September 16, 2010. See Doc. No. 503.

> . . . it is Caraco's understanding that FDA has currently decided to reject the proposed section viii statement with regard to claim 4 of the '358 patent and, therefore the FDA is now deeming Caraco's ANDA to contain a paragraph IV certification as of the time of tentative approval. Caraco may ultimately need to maintain its paragraph IV certification as to all claims of the '358 patent to obtain final approval. However, it is currently maintaining that certification under protest.

Ex. 4 of Joint Appendix. While Novo says that these statements mean Caraco was trying to "revive" its paragraph IV certification, that is not the case. Rather, these statements merely reconfirm that Caraco was pursuing both a paragraph IV certification and a section viii statement with respect to the '358 patent. When the section viii statement was rejected (because Novo was successful in obtaining an amended use code), the paragraph IV certification was still in place. At that point, Caraco's ANDA contained only the paragraph IV certification, which Caraco has continued to pursue.

C.

In the end, the fact is that there has always been a substantial controversy between the parties over the '358 patent. Caraco's paragraph IV certification is still pending before the FDA. Caraco's filing of the ANDA was an act of infringement sufficient to invoke subject matter jurisdiction. That dispute continues to date.

SO ORDERED.

S/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: October 6, 2010

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, October 6, 2010, by electronic and/or ordinary mail.

S/Michael Williams
Relief Case Manager, (313) 234-5160