NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., Plaintiff, v. SANDOZ INC, Defendant.	Civil Action No. 12-3289 (PGS) **MEMORANDUM DECISION**

SHERIDAN, U.S.D.J.

Presently before the Court are two motions to dismiss, asserted by two separate sets of defendants in two separate patent litigations initiated by plaintiff Merck Sharp & Dohme Corporation ("Merck" or "Plaintiff"). In both lawsuits, Merck is asserting that the defendant generic drug companies infringed two of its patents: U.S. Patent No. 5,591,336 ("the '336 patent") and U.S. Patent No. 5,716,942 ("the '942 patent"). Defendants are Accord Healthcare, Inc., Accord Healthcare, Inc. USA, and Intas Pharmaceuticals Ltd. (collectively "Accord") in the matter captioned *Merck Sharp & Dohme Corp. v. Accord Healthcare, Inc. USA, et al.*, No. 12-cv-3324, and Sandoz Inc. ("Sandoz") in the above captioned matter (Accord and Sandoz collectively, "Defendants"). In both matters, Defendants have moved to dismiss only with respect to the '942 patents. For the reasons set forth below, both motions are denied.

I

A pharmaceutical company is required to submit a New Drug Application ("NDA") to the Federal Food and Drug Administration ("FDA") before introducing a new drug into interstate commerce. *See* 21 U.S.C. § 355(a). The NDA must, *inter alia,* identify any patents for "which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). When an NDA is approved by the FDA, this patent information is published in an official FDA publication entitled the *Approved Drug Products with Therapeutic Equivalence Evaluations,* known as the "Orange Book." *Merck & Co., Inc. v. Hi-Tech Pharmacal, Inc.,* 482 F.3d 1317, 1319 (Fed. Cir. 2007).

Generic drug manufacturers may subsequently file an Abbreviated New Drug Application ("ANDA") for FDA approval of a generic version of a drug approved under an NDA. 21 U.S.C. § 355(j). An ANDA filer must submit, *inter alia,* one of four certifications with respect to each patent listed in the Orange Book by the NDA holder. 21 U.S.C. § 355(j)(2)(A)(vii). The type of certification at issue here is a "paragraph IV certification," where the ANDA filer, for each of the patents listed in the Orange Book by the NDA holder, certifies "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A paragraph IV certification requires a generic applicant to make an early disclosure to the patentee of its detailed legal and factual basis for a patent challenge to a listed patent. 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), 355(j)(2)(B)(i), (iv). A paragraph IV certification also can result in an automatic stay of FDA approval pending litigation, referred to as a "30-month stay." *See* 21 U.S.C. § 355(j)(5)(B)(iii). The central question before the Court is whether a paragraph IV

certification is necessary in order for a District Court to assert jurisdiction over a claim pursuant to 35 U.S.C. § 271(a).

II

Merck is the owner of the two patents at issue in this litigation: the '336 patent and '942 patent. The '336 patent claims, among other things, the composition of matter fosaprepitant dimeglumine, the active ingredient in the drug products at issue in the litigation. The '942 patent is directed to a method of use of fosaprepitant. Merck holds a NDA for an injectable form of fosaprepitant dimeglumine used for the prevention of retching and vomiting associated with cancer chemotherapy. The drug is sold by Merck as EMEND for Injection.

Merck's NDA includes two dosage strengths of EMEND, 115 mg and 150 mg. For the 115 mg strength, Merck submitted information to the FDA concerning related patents, which included the '336 and '942 patents. Thereafter, upon approval of the 115 mg NDA in 2008, the '336 and '942 patents were listed in the Orange Book in the entry for that NDA. Later Merck filed a supplement to its NDA adding the 150 mg dosage strength and submitted similar patent information to the FDA, again listing both the '336 and '942 patents. However, upon approval of the NDA for the 150 mg dose, only the '336 patent was listed in the Orange Book.[1] Any reference to the '942 patent was excluded. The omission was corrected in April 2012, shortly before the filing of this lawsuit, but after submission of Defendants' ANDAs. Therefore, at the time Defendants submitted their ANDAs, the adjacent entries in the Orange Book appeared as follows:

[1] The parties dispute the reasons for the '942 patent's absence from the 150 mg listing in the Orange Book, but this dispute is not material to this motion.

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
FOSAPREPITANT DIMEGLUMINE - EMEND						
N022023 001	5552570	Mar 04, 2014	U-950		NCE	Jan 25, 2013
	5538982	Jul 23, 2013	U-950			
	5691336	Mar 04, 2019	DS DP			
	5716942	Feb 10, 2015	U-950			
	7214692	Sep 18, 2012	U-950			
FOSAPREPITANT DIMEGLUMINE - EMEND						
N022023 002	5691336	Mar 04, 2019	DS DP		D-126	Nov 12, 2013
					NCE	Jan 25, 2013

The top entry, for the 115 mg dosage strength, lists both the '942 patent and the '336 patent, among others. But appearing directly below that, the entry for the 115 mg dosage strength listed only the '336 patent.

Defendants filed ANDAs only for the 150 mg dosage strength but not for the 115 mg dosage strength. Because the '336 patent was listed in the Orange Book entry for the 150 mg dosage strength at the time Defendants submitted their ANDAs, Defendants were required to, and did, make paragraph IV certifications that the '336 patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDAs were submitted. Accordingly, the present case involves an automatic stay of FDA approval based on the '336 patent infringement claim. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Because the '942 patent was not listed in the Orange Book at the time Defendants submitted their ANDAs, Defendants did not make paragraph IV certifications that the '942 patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDAs were submitted.

Nevertheless, despite the absence of paragraph IV certifications with respect to the '942 patent, Merck's complaint alleges that Defendants seek approval to engage in the use and sale of a drug product claimed in both the '336 and '942 patents, and the use or sale of a drug product the use of which is claimed in the '336 and '942 patents, before the expiration of those patents, and have therefore infringed both patents under 35 U.S.C. § 271(e)(2)(A).

Defendants claim, however, that a generic drug applicant must file a paragraph IV certification with respect to a patent in order for a NDA holder to state a claim for infringement of that patent under 35 U.S.C. § 271(e)(2)(A) and to give rise to a District Court's subject matter jurisdiction over that claim. Relying on two unpublished decisions from this Court, Defendants contend that Merck failed to list the '942 patent in the Orange Book, as such no paragraph IV certification was involved, and therefore no subject matter jurisdiction over the '942 patent claims arose. *See Eisai Co. v. Mutual Pharmaceutical Co.*, Civ. Action No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.*, Civ. Action No. 09-2445, 2010 WL 1372437 (D.N.J. Mar. 31, 2010).

Plaintiff does not dispute the District of New Jersey cases upon which Defendants rely; but Plaintiff argues that more recent precedent of the Federal Circuit controls. According to Plaintiff, the Federal Circuit has ruled that a paragraph IV certification is not a requirement as a matter of law for subject matter jurisdiction or for the court to reach the merits of a claim under 35 U.S.C. § 271(e)(2)(A). *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012).

III

On a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), the Court is required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party. *See, e.g., Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949-50, 173 L. Ed. 2d 868 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 (3d Cir. 1994). A complaint should be dismissed only if the alleged facts, taken as true, fail to state a claim.

Iqbal, 129 S. Ct. at 1950. The question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail. *Semerenko v. Cendant Corp.*, 223 F.3d 165, 173 (3d Cir. 2000), *cert. denied, Forbes v. Semerenko*, 531 U.S. 1149, 121 S. Ct. 1091, 148 L. Ed. 2d 965 (2001).

IV

The Court finds that it has subject matter jurisdiction over Merck's claim of patent infringement with respect to the '942 patent. 28 U.S.C. § 1338 grants federal courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents." The Complaint alleges jurisdiction under 28 U.S.C. § 1338 and causes of action for patent infringement arising under 35 U.S.C. § 271(e)(2), which is an Act of congress relating to patents. Therefore, the Court has subject matter jurisdiction.

Defendants' arguments that paragraph IV certifications are needed with respect to the '942 patent are belied by the plain language of 35 U.S.C. § 271, and by Federal Circuit and District of New Jersey case law. The existence of subject matter jurisdiction depends on whether the cause of action alleged in the Complaint is one that arises under the patent laws. The Federal Circuit recently rejected the argument by a generic drug company that "§ 271(e)(2) creates a case or controversy only if the accused ANDA contains a Paragraph IV certification." *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1375 (Fed. Cir. 2012). "'[S]ection 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed.' In other words, the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and the threshold jurisdictional determination does not depend on the ultimate merits of the claims." *Id.* at 1377 (quoting *Allergan, Inc. v. Alcon Laboratories,*

Inc., 324 F.3d at 1330); *see also Abraxis Bioscience Inc. v. Navinta LLC*, Civ. No. 07-1251, D.I. 50 (D.N.J. Oct. 9, 2007) (Pisano, J.) (finding that jurisdiction under § 271(e)(2) is focused on the hypothetical question of whether, "if the defendant's proposed generic drug was on the market, would it infringe on the plaintiff's patent."). Accordingly, Merck's allegations of patent infringement are sufficient for this Court to exercise its subject matter jurisdiction.

The court also finds that Merck has adequately stated claims of patent infringement with respect to the '942 patent. "It shall be an act of infringement to submit an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." Nothing in the plain language suggests that infringement actions against ANDA filers must be based only on Orange Book listed patents. As Defendants cannot dispute that their ANDAs are for drugs the use of which are claimed in Merck's '942 patent, Merck has properly alleged a claim of patent infringement within the statutory requirements.

This decision rests on the concept of judicial efficiency and common sense. Merck alleges infringement of both the '336 and '942 patents based on ANDAs filed by Defendants. While both patents are listed in the Orange Book for the 115 mg dosage strength, the entry for the 150 mg dosage strength only listed the '336 patent at the time Defendants' ANDAs were filed. Because of their admission that they filed paragraph IV certifications against the '336 patent, Defendants do not seek dismissal of the '336 patent infringement claim. Yet Defendants have alleged the same defenses and will have to present the same case in order to prevail on both claims. The overlap weighs in favor of trying the two infringement claims together. In addition,

the purpose of 35 U.S.C. § 271(e) – to promote the early resolution of patent disputes relating to an ANDA – are implicated here with respect to both the '336 and the '942 patents.

For the reasons stated, *supra*, Defendants' motions to dismiss the second count of the Complaints are denied. The Court will issue appropriate orders.

PETER G. SHERIDAN, U.S.D.J.

February 4, 2013