IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(RICHMOND DIVISION)

Glenmark Generics Ltd., and Glenmark Generics Inc., USA, *Plaintiffs*, v. Ferring B.V., *Defendant.*	CASE NO. 3:14-cv-00422-HEH U.S. District Judge Henry E. Hudson

MEMORANDUM IN SUPPORT OF DEFENDANT'S
MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendant Ferring B.V. ("Ferring") respectfully submits this memorandum in support of its motion to dismiss Plaintiffs Glenmark Generics Ltd. and Glenmark Generics Inc., USA's (collectively, "Glenmark") complaint.

I. INTRODUCTION

No actual controversy exists between Glenmark and Ferring. Glenmark frames its complaint as a request for a declaratory judgment of unenforceability of U.S. Patent No. 7,022,340 ("the '340 patent"). As Glenmark admits in its complaint, however, Ferring statutorily disclaimed every claim of the '340 patent before Glenmark filed this complaint, and the effect of this disclaimer is that the '340 patent is viewed as never having existed. Glenmark thus asks this Court to engage in a substantive analysis of a non-existent patent. Because there is no patent to adjudicate, there cannot be any real controversy between the parties over the '340 patent.

Accordingly, this Court lacks subject matter jurisdiction and, moreover, Glenmark's complaint fails to state a claim. Ferring thus respectfully requests that the Court dismiss Glenmark's complaint.

II. BACKGROUND

A. The Hatch-Waxman Framework

This action arises under the Hatch-Waxman Act,[1] a statute that governs (among other things) the approval of generic versions of previously approved innovator drugs. Before an innovator pharmaceutical company, such as Ferring, can get a new drug approved by the U.S. Food & Drug Administration ("FDA"), the company must submit a New Drug Application ("NDA") containing comprehensive clinical evidence showing the drug's safety and efficacy. These studies take many years and millions of dollars to complete. An applicant seeking to market a generic version of a previously approved innovator drug, however, can bypass the clinical trials required of the innovator company and instead file an Abbreviated New Drug Application ("ANDA"). *See generally* 21 U.S.C. § 355(j). An ANDA applicant is allowed to rely on the testing in the innovator company's NDA and must prove only that its generic drug product is "bioequivalent" to the NDA product. *See* 21 U.S.C. § 355(j)(2)(A).

The Hatch-Waxman Act requires NDA applicants and NDA holders to identify to the FDA all patents that cover the drug or the use of the drug. 21 U.S.C. § 355(b)(1). The FDA then lists these patents in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." With respect to each patent that claims the drug listed in the NDA, an ANDA application must include a certification that:

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[1] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

I. Such patent information has not been filed;

II. Such patent has expired;

III. The applicant does not seek approval of its ANDA before such patent expires; or

IV. Such patent is invalid or will not be infringed by the manufacture, use, or sale of the ANDA applicant's generic drug (a so-called "Paragraph IV certification").[2]

21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The Hatch-Waxman Act creates incentives for generic applicants to challenge patents by awarding the first ANDA applicant to make a Paragraph IV certification a period of 180 days of regulatory exclusivity before any subsequent Paragraph IV filers can receive FDA approval for their ANDA products. 21 U.S.C. § 355(j)(5)(B)(iv).

B. The Facts of This Case

Ferring holds NDA No. 021795 for desmopressin acetate tablets, 0.1 and 0.2 mg. Ferring's NDA was approved by the FDA on May 8, 2008. As required by the Hatch-Waxman Act, Ferring identified the '340 patent to the FDA. The FDA listed the '340 patent in the Orange Book for Ferring's NDA No. 021795. Glenmark states in its complaint that, in 2010, it filed ANDA No. 201-831 seeking approval to market a generic desmopressin acetate tablet product and included a Paragraph IV certification as to the '340 patent. (Dkt. 1, ¶ 25.) Ferring did not file suit against Glenmark on the basis of Glenmark's Paragraph IV certification. (Dkt. 1, ¶ 26.)

On April 11, 2014, Glenmark filed a declaratory judgment action against both Ferring and Sanofi-Aventis U.S. LLC ("Sanofi") in the U.S. District Court for the District of New Jersey. Sanofi also holds an NDA for desmopressin acetate tablets, 0.1 and 0.2 mg (NDA No. 019955). In its complaint in the District of New Jersey, Glenmark sought a declaration that the '340 patent

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[2] Glenmark's complaint incorrectly states that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) requires a certification that the patent is "invalid, unenforceable or will not be infringed." (Dkt. 1, ¶ 12.) The statute refers only to invalidity and non-infringement and does not mention unenforceability.

is invalid or that Glenmark's ANDA product has not infringed, does not infringe and will not infringe the claims of the '340 patent.

On May 14, 2014, Ferring filed in the U.S. Patent and Trademark Office ("USPTO") a statutory disclaimer under 35 U.S.C. § 253 disclaiming every claim of the '340 patent, thus dedicating the patent to the public. (Dkt. 1, Ex. 2.) As Glenmark admits in its complaint, Ferring also requested that the FDA delist the '340 patent from the Orange Book listing for Ferring's NDA. (Dkt. 1, ¶ 34.) The Orange Book website entry for Ferring's NDA No. 021795 now states that there "are no unexpired patents for this product in the Orange Book Database."[3] The Orange Book listing website also reflects a request by Sanofi to delist the '340 patent from Sanofi's NDA.[4]

After Ferring disclaimed the '340 patent and requested that the FDA delist the patent from the Orange Book entry for Ferring's NDA, Glenmark voluntarily dismissed its declaratory judgment action in the District of New Jersey as to both Sanofi and Ferring. Although Glenmark was aware that the '340 patent no longer existed because of the disclaimer, Glenmark nonetheless filed this action against Ferring (but not Sanofi) seeking a declaration of unenforceability of the non-existent '340 patent. Glenmark now asserts that there exists "an actual, substantial, and continuing justiciable case or controversy between Ferring and Glenmark regarding the unenforceability of the '340 patent," a patent Glenmark admits is properly viewed as having never existed.

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[3] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021795&Product_No=001&table1=OB_Rx (last accessed on July 30, 2014).

[4] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=019955&Product_No=001&table1=OB_Rx (last accessed on July 30, 2014).

III. ARGUMENT

A. Article III of the U.S. Constitution Requires That an Actual Case or Controversy Exist Between the Parties

An actual case or controversy must exist between the parties in order for this Court to have jurisdiction under Article III of the U.S. Constitution. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-28 (2007). The U.S. Supreme Court has stated that, in order for a declaratory judgment action to satisfy Article III's case or controversy requirement, the dispute between the parties must be "definite and concrete, touching the legal relations of parties having adverse legal interests," must be "real and substantial," and must "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.* at 127 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). "Basically, 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.* (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added).

The party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95 (1993) (citing *Aetna Life Ins. Co.*, 300 U.S. at 240-42). Additionally, district courts "possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act." *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581, 591 (4th Cir. 2004) (quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995)). This is true "even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Id.*

B. Glenmark's Declaratory Judgment Claim Should Be Dismissed for Lack of Subject Matter Jurisdiction Because There Is No Actual Case or Controversy

In this case, Glenmark cannot establish that an actual controversy exists between it and Ferring concerning a patent that Ferring disclaimed. "A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). By filing a statutory disclaimer, Ferring withdrew the '340 patent claims from the protection of the patent laws and relinquished any right to exclude others from the subject matter of the claims. *Id.* (citing *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935)); *see also W.L. Gore & Assoc., Inc. v. Oak Materials Grp., Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) (holding that the "patentee has no further right either to enforce the claims which have been disclaimed, or to obtain a reissue of any of those claims"). As a result, there can be no dispute over the validity, enforceability or infringement of the '340 patent because the effect of the disclaimer is that the patent is viewed as having never existed.

Several district courts have considered this issue and concluded that a disclaimed patent cannot give rise to an Article III case or controversy. In *Apotex, Inc. v. Daiichi Sankyo, Inc.*, for example, Apotex sought a declaratory judgment of non-infringement of a patent that Daiichi had already disclaimed. 2014 WL 114127, at *1-2 (N.D. Ill. 2014). Daiichi requested that the FDA delist the patent from the Orange Book but, unlike the situation with Ferring's NDA, the FDA did not delist Daiichi's patent. *Id.* at *4. Despite the fact that Daiichi's patent remained listed in the Orange Book, the district court granted Daiichi's motion to dismiss for lack of subject matter jurisdiction. *Id.* The court explained that the disclaimed patent "does not create an independent barrier that deprives Apotex of an economic opportunity to compete." *Id.* The court noted that Daiichi was not "preventing the FDA from approving Apotex's ANDA through any delay tactics

or strategies." *Id.* The *Daiichi* court also stated that "[t]he mere fact that the FDA has failed for some reason to delist the [patent], despite Daiichi's request, does not create a case or controversy" because Daiichi properly requested delisting. *Id.*

Similarly, in *Merck & Co v. Apotex, Inc.*, Apotex sought a declaratory judgment of non-infringement and invalidity of two patents that Merck had statutorily disclaimed. 2007 WL 4082616, at *5 (D.N.J. 2007), *aff'd on other grounds*, 292 Fed. App'x 38 (Fed. Cir. 2008) (unpublished). Merck had also asked the FDA to delist the patents. *Id.*, at *2. The district court dismissed the declaratory judgment claims for lack of any actual case or controversy because the result of Merck's statutory disclaimer was that Merck "has no further right to enforce the claims that have been disclaimed, or to obtain a reissue of any of these claims." *Id.*, at *5.

The court noted that Merck's disclaimer distinguished the case from *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, in which the NDA holder sued on only one of five Orange Book-listed patents and did not disclaim the other four patents. *Id.* (citing 482 F.3d 1330, 1340-46 (Fed. Cir. 2007)). The court in *Merck* explained that, unlike the NDA holder in *Teva v. Novartis*, Merck could not enforce any claims as to the challenged patents because of its statutory disclaimer. *Id.* This same distinction also differentiates both this case and *Merck* from *Teva Pharm. USA, Inc. v. Eisai Co.*, on which Glenmark relies in its complaint. 620 F.3d 1341 (Fed. Cir. 2010), *vacated*, 426 Fed. App'x 904 (Fed. Cir. 2011). Unlike here, the NDA holder in *Teva v. Eisai* sued the ANDA applicant for infringement of one of five patents listed in the Orange Book and only disclaimed two of the other patents. *Id.* at 1343-45.

Where, as here, a patentee disclaims its patent, the patent is dedicated to the public and can no longer be the source of any dispute over validity, enforceability, or infringement. *Guinn v. Kopf*, 96 F.3d at 1422. In its complaint, Glenmark admits that the '340 patent effectively

never existed as a result of the disclaimer. (*E.g.*, Dkt. 1, ¶ 38.) Throughout the complaint, however, Glenmark refers to the patent as if it could still somehow be the source of a substantial and continuing dispute with Ferring. For example, Glenmark states that Ferring "owns the '340 patent" (Dkt. 1, ¶ 21.) and that the patent "will expire on April 20, 2023" (Dkt. 1, ¶ 22.). Both of these assertions are incorrect. Ferring cannot now own a patent that never existed, nor can such a patent have a term or an expiration date. Ferring cannot assert the patent against Glenmark, now or ever.

Nor does the fact that Ferring listed the '340 patent in the Orange Book, as it was statutorily required to do, give rise to jurisdiction here. As the courts found in both *Daiichi* and *Merck*, no case or controversy exists where a patentee disclaims a patent and requests that the FDA delist the patent from the Orange Book. *Daiichi*, 2014 WL 114127, at *4; *Merck*, 2007 WL 4082616, at *5. Under such circumstances, it is the FDA and the statutory scheme of the Hatch-Waxman Act that give rise to the ANDA applicant's alleged injury, if any, and not any action by the NDA holder. *Daiichi*, 2014 WL 114127, at *4. Moreover, unlike in *Daiichi* or *Merck*, in this case the FDA did, in fact, delist the disclaimed '340 patent from Ferring's NDA. Glenmark is thus wrong when it states in its complaint that "Ferring, a sophisticated brand-name drug company, knew that its request to delist the '340 patent was futile." (Dkt. 1, ¶ 36.)

Throughout its complaint, Glenmark asserts that Ferring's disclaimer of the '340 patent renders the patent unenforceable. (*See, e.g.*, Dkt. 1, ¶¶ 34, 38-41, 47.) This argument misstates and misconstrues the law. The word "unenforceable" has a specific meaning under the patent laws and does not apply to this case. Unenforceability is an equitable doctrine meant to address, for example, a patentee's inequitable conduct in procuring a patent from the USPTO. *See, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285-91 (Fed. Cir. 2011) (en banc).

Ferring has committed no misconduct, nor has Glenmark alleged any facts that would support a holding of unenforceability. A patent that cannot be asserted because it was statutorily disclaimed is not "unenforceable" within the meaning of the patent laws. Accordingly, there is no actual controversy between the parties as to the unenforceability of the '340 patent.

The facts of this case demonstrate that the parties do not have adverse legal interests sufficient to establish an actual case or controversy. Ferring owns no patent that could be substantively adjudicated in this case, and the FDA already delisted the '340 patent from Ferring's NDA at Ferring's request. Glenmark's complaint asks this Court to make an impermissible determination of whether the non-existent '340 patent is allegedly "unenforceable." This is precisely the sort of advisory opinion that the U.S. Supreme Court has prohibited. *See, e.g.*, *Coffman v. Breeze Corps.*, 323 U.S. 316 (1945) (holding that "[t]he declaratory judgment procedure . . . may not be made the medium for securing an advisory opinion in a controversy which has not arisen" (citations omitted)). Accordingly, Glenmark's complaint should be dismissed.

C. Glenmark's Dispute Is with the FDA, Not Ferring

Glenmark incorrectly asserts that, even though Ferring disclaimed the '340 patent, the patent "continues to harm Glenmark in its business by blocking approval of Glenmark's ANDA and continues to benefit Ferring" by blocking generic competition for desmopressin acetate tablets. (Dkt. 1, ¶ 40.) Ferring has no knowledge as to what the FDA is or is not doing vis-à-vis Glenmark's ANDA. To the extent that the FDA is not approving Glenmark's ANDA for some reason, it is the FDA, not the '340 patent, that is preventing Glenmark from receiving approval for its ANDA. Moreover, as Glenmark undoubtedly knows, Ferring is already subject to generic

competition from at least three generic manufacturers that have approved ANDAs for desmopressin acetate tablets and have long been selling their generic products on the market.[5]

Although Glenmark refers to Sanofi's NDA throughout its complaint, and originally filed suit against both Ferring *and* Sanofi, Glenmark filed the present suit against Ferring only. Sanofi is thus not a party to this case, and any issue that Glenmark has with Sanofi or the FDA involving Sanofi does not implicate Ferring.

D. Glenmark's Complaint Fails to State a Claim

Because Glenmark's complaint seeks a substantive adjudication of the unenforceability of a non-existent patent, its complaint fails to state a claim upon which relief can be granted. Accordingly, its complaint should be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

A complaint should be dismissed under Rule 12(b)(6) where it appears that the facts alleged, accepted as true, fail to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "To survive a Rule 12(b)(6) motion to dismiss, a complaint must establish 'facial plausibility' by pleading 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 554 (4th Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678).

As discussed above, Glenmark admits in its complaint that the effect of dedicating the '340 patent to the public is that the patent is viewed as never having existed. (*E.g.*, Dkt. 1, ¶ 38.) Because the '340 patent never existed, Glenmark cannot allege any facts that state a plausible

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[5] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm (last accessed on July 30, 2014).

claim for entitlement to a declaration that the '340 patent is now unenforceable. Accordingly, Ferring respectfully requests that the Court dismiss Glenmark's complaint under Rule 12(b)(6) for failing to state a claim.

IV. CONCLUSION

For the foregoing reasons, this Court lacks subject matter jurisdiction over Glenmark's complaint, which seeks a substantive ruling of unenforceability of a non-existent patent. Ferring has relinquished all rights in the '340 patent, which is no longer listed in the Orange Book with respect to Ferring's NDA for desmopressin acetate tablets. For the same reasons, Glenmark's complaint fails to state a claim upon which relief can be granted. Accordingly, Ferring respectfully requests that this Court dismiss Glenmark's complaint under Rules 12(b)(1) and/or 12(b)(6) of the Federal Rules of Civil Procedure.

Dated: July 30, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 30, 2014, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send notification of such filing (NEF) to the following:

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