IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

GLENMARK GENERICS LTD., *et. al.*,	)	
	)	
Plaintiffs,	)	
v.	)	Civil Action No. 3:14CV422–HEH
	)	
FERRING B.V.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION
(Denying Defendant's Motion to Dismiss)

This is an action seeking a declaratory judgment pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301-399, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch–Waxman Act" or the "Act"), arising from the listing of a patent in an FDA promulgated document called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

The case is presently before the Court on Defendant Ferring B. V.'s ("Ferring") Motion to Dismiss ("Motion", ECF No. 15) challenging subject matter jurisdiction, filed on July 30, 2014. The parties have fully briefed the issue, and the Court heard oral argument on the motion on September 19, 2014. For the reasons stated herein, the Court finds that it has subject matter jurisdiction in this matter, as the case presents a justiciable Article III controversy. Moreover, the Court finds no persuasive reason to exercise its discretion pursuant to the Declaratory Judgment Act and decline jurisdiction in this

matter. Accordingly, the Court denies Ferring's Motion to Dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

I. BACKGROUND

A. Statutory Framework

The approval of prescription drugs is governed by the Hatch–Waxman and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA Amendments"). The Hatch–Waxman Act was created to "'strike a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (internal citations omitted).

The Act requires pharmaceutical companies seeking to market new, previously unapproved drugs, to file a New Drug Application ("NDA") with the FDA. 21 U.S.C. § 355(a), (b). The innovating pharmaceutical company must provide the FDA with information including "all patents covering its drug or the methods of using the drug with respect to 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." *Caraco*, 527 F.3d at 1282 (citing 21 U.S.C. § 355(b)(1), (c)(2)). The FDA then promulgates the patents in the Orange Book. 21 U.S.C. § 355(j)(7)(A). Drugs approved by the FDA are known as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i).

The Hatch–Waxman Act also provides a less arduous approval process for companies seeking to market generic versions of these patented drugs, known as the

"Abbreviated New Drug Application" ("ANDA"). *Caraco*, 527 F.3d at 1282. To successfully file an ANDA, generic drug makers are not required to conduct their own independent clinical trials to prove the safety and efficacy of their drugs. 21 U.S.C. § 355(j)(2)(A)(iv). Instead, generic drug companies can, and usually do, utilize the research of the innovating pharmaceutical company so long as the generic drug company establishes that its generic drug product is the "bioequivalent" to a NDA listed drug. *Id.*

Each ANDA applicant must submit one of four certifications addressing each of the patents it seeks to take advantage of for the relevant drug listed in the Orange Book. 21 U.S.C. § 355(j)(2)(A)(vii). In particular, the ANDA filer must certify that either: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

The last certification option, that an Orange–Book–listed patent is invalid or not infringed, is commonly known as a "Paragraph IV" certification.

Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: (i) whether the holder of the listed patent brings an infringement suit within forty-five days of receiving notice of the ANDA filing, and (ii) whether the company seeking approval was the first to file an ANDA with a Paragraph IV certification to the listed patent. *See* 21 U.S.C. § 355(j)(5)(B)(iii). To encourage the filing of ANDAs, the Act grants the first company to file an ANDA Paragraph IV

certification, a 180–day period of generic marketing exclusivity from the date of its "first commercial marketing" before other generic companies will be approved by the FDA to enter the market. 21 U.S.C. § 355(j)(5)(B)(iv).

Pursuant to the MMA amendments, the exclusivity period is triggered only by the first-filing generic's first commercial marketing, but can be forfeited under certain conditions, including failure to launch after a final court judgment of noninfringement or invalidity. *See Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012) (citing Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108–173, § 1102, 117 Stat. 2066, 2457–60)). The MMA was enacted "to prevent NDA holders from 'gaming' the Hatch–Waxman Act by forestalling the resolution of patent disputes with ANDA filers." *Caraco*, 527 F.3d at 1285. Put another way, if a subsequent ANDA filer obtained a final judgment that the patents were invalid or not infringed, then the first ANDA filer would forfeit its 180-day exclusivity period if it did not market the drug within 75 days. *See id.* (citing 21 U.S.C. § 355(j)(5)(D)).

B. Factual Background

This case involves Glenmark's efforts to obtain the Food and Drug Administration's ("FDA") approval to market a generic version of Ferring's U.S. Patent No. 7,002,340 ("'340 patent") for desmopressin acetate.[1] Sanofi holds the approved NDA for DDAVP Tablets, which contain the active ingredient desmopressin acetate. (Compl. ¶ 20, ECF No. 1). DDAVP is the reference-listed drug upon which Glenmark's ANDA relies. (*Id.*) Although Ferring does not hold the NDA, it owned the '340 patent

[1] Desmopressin acetate acts on the kidneys to reduce the amount of urine produced at night. WEBMD, http://www.webmd.com/drugs/2/drug-12128/desmopressin-oral/details (last visited September 19, 2014).

thus causing the patent to be listed. (*Id.*) Another unidentified ANDA applicant filed the first substantially complete ANDA that included a Paragraph IV certification with respect to the '340 patent and, thus, holds eligibility for the 180-day market exclusivity for the '340 patent. (*Id.* ¶ 23.) Before Glenmark filed this suit, Ferring disclaimed the '340 patent and requested that the FDA delist the '340 patent from the Orange Book. (*Id.* ¶ 34.) The FDA, however, has yet to delist the patent from the Orange Book. (*Id.* ¶ 23.) Consequently, the FDA has not given final approval for Glenmark's ANDA. (*Id.* ¶ 28.) To enable such approval, Glenmark seeks a declaratory judgment that Ferring's disclaimed patent is unenforceable.

II. STANDARD OF REVIEW[2]

A motion made pursuant to Fed. R. Civ. P. 12(b)(1) challenges the court's jurisdiction over the subject matter of the complaint. If a defendant contends that the complaint fails to allege facts upon which subject matter jurisdiction can be based, all facts in the complaint are presumed true. *See Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982); *see also King v. Riverside Reg'l Med. Ctr.*, 211 F.Supp.2d 779, 780–81 (E.D. Va. 2002). Alternatively, if the defendant argues that the jurisdictional facts in the complaint are untrue, "the Court may 'look beyond the jurisdictional allegations of the complaint and view whatever evidence has been submitted on the issue to determine whether in fact subject matter jurisdiction exists.'" *Virginia v. U.S.*, 926 F.Supp. 537,

[2] Although Defendant's Motion to Dismiss comes to the Court pursuant to 12(b)(1) and 12(b)(6), jurisdiction is a threshold matter. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994) (citations omitted) ("Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute"). That is, the Court must first determine whether it has jurisdiction. As the Court does have subject matter jurisdiction in this matter, Ferring's motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim is similarly denied, as it is premised upon the '340 being viewed as never having existed, a contention that, as explained *infra*, does not affect the FDA's approval process.

540 (E.D. Va. 1995) (quoting *Capitol Leasing Co. v. FDIC*, 999 F.2d 188, 191 (7th Cir. 1993)); *see also Adams*, 697 F.2d at 1219. In either case, the plaintiff bears the burden of proving the court has the constitutional authority to act. *Richmond, Fredericksburg & Potomac R.R. Co. v. U.S.*, 945 F.2d 765, 768 (4th Cir. 1991).

In the Hatch–Waxman context, Congress extended subject matter jurisdiction to ANDA Paragraph IV disputes, 21 U.S.C. § 355(j)(5)(C), and has directed federal courts to exercise jurisdiction over these disputes "'to the extent consistent with the Constitution,' 35 U.S.C. § 271(e)(5)." *Dey Pharma*, 677 F.3d at 1162. Thus, federal courts have subject matter jurisdiction over declaratory judgment actions "to the extent that they present an Article III case or controversy." *Caraco*, 527 F.3d at 1285.

The Supreme Court has stated that the requirement of a case or controversy is met where "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." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007) (internal citation omitted).

A declaratory judgment action is "justiciable under Article III only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." *Caraco*, 527 F.3d at 1291 (internal citations omitted). "The declaratory judgment plaintiff bears the burden of showing the existence of an 'actual controversy.'" *Organic Seed Growers and Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1358 (Fed. Cir. 2013) (internal citation omitted).

III. ANALYSIS[3]

Ferring moves to dismiss Glenmark's complaint arguing that there can be no justiciable dispute as to the statutorily disclaimed '340 patent. Glenmark argues, however, that an Article III case or controversy exists because a judgment as to the '340 patent's validity has not been entered and the '340 patent, despite Ferring's request to delist, remains listed in the Orange Book, preventing Glenmark from selling its tentatively approved competing generic version of desmopressin acetate. (*Id.* ¶ 40.)

A. Standing

To have standing, a party must demonstrate: (1) an alleged injury in fact – a harm suffered by the plaintiff that is concrete and actual or imminent; (2) causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant; and (3) redressability – a likelihood that the requested relief will redress the alleged injury. *Caraco*, 527 F.3d at 1291 (internal citations omitted).

i. Glenmark Alleges a Judicially Cognizable Injury–in–Fact that is Fairly Traceable to Ferring

In this case, the alleged injury-in-fact stems from Glenmark's inability to market its competing generic version of desmopressin acetate, as it lacks final approval from the FDA. The FDA's final approval of the ANDA, Glenmark explains, is delayed because the '340 patent that Ferring owned remains listed in the Orange Book and the exclusivity

[3] *Teva Pharms., USA, Inc. v. Eisai Co. Ltd.*, taken together with other Federal Circuit precedent, guides this Court's analysis. Although *Teva* was dismissed on procedural grounds, the Court finds its unaffected, reasoned analysis of the Federal Circuit's Hatch-Waxman precedence persuasive. *Teva Pharms., USA, Inc. v. Esai Co. Ltd.*, 620 F.3d 1341, 1345 (Fed. Cir. 2010), *vacated on procedural grounds* by *Teva Pharms. Usa, Inc. v. Eisa Co., Ltd.*, —— U.S. – ——, 131 S.Ct. 2991, 180 L.Ed.2d 818 (2011).

period of the unknown first-filer has not been triggered. At bottom, Glenmark is alleging a deprivation of the opportunity to market and sell a noninfringing generic version of desmopressin acetate. It is well-settled in the Hatch-Waxman context that the inability of a generic drug company to market a non-infringing drug is sufficient to establish Article III's injury-in-fact requirement.[4] *See Caraco*, 527 F.3d at 1292 (internal citations omitted). Of equal importance is that Glenmark's injury is fairly traceable to Ferring's actions.

Ferring held an exclusive license to the '340 patent that is listed in connection with Sanofi's NDA for DDAVP Tablets. The Federal Circuit has consistently held that "the alleged action taken (giving rise to the injury-in-fact) [is] [the] listing [of] particular patents in the Orange Book." *Teva Pharms., USA, Inc. v. Eisai Co. Ltd.*, 620 F.3d 1341, 1346–47 (citing *Caraco*, 527 F.3d at 1292; and *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359–60 (Fed. Cir. 2008). The same logic applies here. That is, "'but-for' the [] list[ing] [of the '340] patent in the Orange Book, FDA approval of [Glenmark's] drug would not have been independently delayed by the patent." *Id.* The statutory disclaimer and request to delist the patent from the Orange Book does not obscure the traceability of Glenmark's injury to Ferring. In other words, the statutory disclaimer of the '340 patent, that Glenmark admits renders the patent legally nonexistent, does not eliminate the patent from obstructing the FDA's approval of

[4] The only case holding otherwise, *Janssen*, is entirely distinguishable. The subsequent ANDA filer there "[could not] claim [] it was being excluded from selling a noninfringing product by an invalid patent [because] it stipulated to the validity [infringement, and enforceability] of the '663 patent." *Janssen*, 540 F.3d at 1360–61.

Glenmark's ANDA.[5] The '340 patent remains the critical factor in the FDA's approval process.

ii. Glenmark's Injury is Redressible by a Favorable Judgment

As explained earlier, although the exclusivity period is only triggered by the first-filing generic's first commercial marketing, a second ANDA filer can obtain a final judgment that the underlying patent is invalid or not infringed thus creating a situation where the initial ANDA would forfeit its 180–day exclusivity period if it did not market the drug within 75 days. 21 U.S.C. § 355(j)(5)(D); *see also Dey Pharma*, 677 F.3d at 1160.[6] Thus, a declaratory judgment from this Court could redress Glenmark's alleged injury, as it could remove the '340 patent's effect of excluding the generic drug from the market. *See Caraco*, 527 F.3d at 1293.

B. Ripeness

In conducting a ripeness review, the Court must determine "'the fitness of the issues for judicial decision' and 'the hardship to the parties of with-holding court consideration.'" *Retail Indus. Leaders Assoc. v. Fielder*, 475 F.3d 180, 188 (4th Cir. 2007). An issue is fit for judicial review where further factual development would not

[5] The FDA has not followed up on Ferring's request to delist the disclaimed '340 patent from the Orange Book because such removal is prohibited by the workings of the Hatch-Waxman act. *Ranbaxy Labs Ltd. v. Leavitt* and *Teva Pharms., USA, Inc. v. Sebelius* hold that the FDA's decision to delist a patent from the Orange Book at the request of an NDA or patentee before the initiation of a first filer's 180-day exclusivity period is not a result envisioned by the Hatch-Waxman Act. *See Ranbaxy Labs Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) (explaining that the "FDA's [de-listing] policy allows an NDA holder [or patentee], by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity."); *Teva Pharms., USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (holding that "nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act [] changes the structure of the statute such that brand companies should be newly able to delist challenged patents [ ] that deprives generic companies of the period of marketing exclusivity they otherwise deserve."). The Fourth Circuit, albeit in an older, unpublished decision, similarly champions the importance of the 180-day exclusivity to the framework of the Hatch-Waxman Act. *See Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998)

[6] This change in the statutory trigger makes no substantive difference as to the effect of a final judgment. *Dey Pharma*, 677 F.3d at 1160.

"significantly advance [a court's] ability to deal with the legal issues presented." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 812, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003). "In assessing hardship, [the Court should] examine the immediacy and degree of hardship the party seeking relief will suffer if adjudication is delayed." *Newport News Shipbuilding & Drydock Co. v. Dir., Office of Workers' Comp. Programs*, 474 F.3d 109, 112 (4th Cir. 2006)

The circumstances at hand satisfy the ripeness requirements in *Caraco*. *See Caraco*, 527 F.3d at 1295–96. Glenmark has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts are required to determine whether the product infringes the '340 patent. Additionally, "if [Glenmark's] drug does not infringe [the '340 patent], withholding this Court's consideration of the declaratory judgment action has the 'immediate and substantial impact' of forestalling [Glenmark's] ability to [essentially] activate [the unknown first-filer's] exclusivity period." *Id.* In essence, if Glenmark's drug does not infringe the '340 patent, then delaying court consideration of Glenmark's declaratory judgment action on the '340 patent delays the date the FDA may approve Glenmark's ANDA. *Id.* Accordingly, this action is ripe for judicial review.

C. Mootness

An action is moot where the personal stake required for a party to have standing at its outset does not continue to exist throughout all stages of the action. *Caraco*, 527 F.3d at 1296 (citing *United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 397, 100 S.Ct.

1202, 63 L.Ed.2d 479 (1980)). "Simply stated, a case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Id.*

The court's analysis in *Caraco* is instructive as to the issue of mootness as well. There, the court determined that a covenant not-to-sue on the Orange Book listed patents did not moot the issue because it "[did] not allow [the subsequent ANDA filer] to enter the generic drug market." *Id.* at 1297. In other words, the covenant not to sue "[did] not affect the FDA's authority to approve the ANDA" because "a generic drug manufacturer['s] [inability to] enter the market" is directly attributable to a patent being listed in the Orange Book not an NDA holder or patentee's affiliation with the patent. *Id.* at 1296.[7]

Likewise, Ferring's statutory disclaimer does not affect the FDA's authority to approve the ANDA because Glenmark's inability to enter the market is directly attributable to the '340 patent being listed in the Orange Book. Most critically, the statutory disclaimer does not obviate the necessity of a final judgment to trigger the 75–day countdown to forfeiture of the exclusivity period "thus allow[ing] the FDA to approve the subsequent Paragraph IV ANDA [thereafter]." *Id.* Because the '340 patent remains listed in the Orange Book, this action presents a live Article III case and controversy.

IV. DECLARATORY JUDGMENT ACT

While the Court finds that it may exercise jurisdiction in this matter, the Court must still address whether exercising its discretion under the Declaratory Judgment Act is

[7] "Neither the statutory disclaimers nor [] covenant-not-to-sue render [a] declaratory judgment action moot because the DJ patents remain listed in the Orange Book." *Eisai*, 620 F.3d at n.3 (citing *Caraco*, 527 F.3d at 1296–97).

prudent. *See* 28 U.S.C. § 2201(a) § 2201; *see also Eisai*, 620 F.3d at 1348–49.[8] Unlike some other jurisdictional grants, which may be mandatory, "[a] federal court has the discretion to entertain a declaratory judgment action when it finds that the declaratory relief sought (i) will serve a useful purpose in clarifying and settling the legal relations in issue; and (ii) will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." *Cont'l Cas. Co. v. Fuscardo*, 35 F.3d 963, 966 (4th Cir. 1994) (citation and internal quotation marks omitted). Although discretionary, "a district court must have 'good reason' for declining to exercise its declaratory judgment jurisdiction." *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581, 594 (4th Cir.2004) (quoting *Cont'l Cas. Co.*, 35 F.3d at 965).

Finding that it may appropriately exercise jurisdiction over the matter, the Court now finds no persuasive reason to decline to do so. Exercising jurisdiction in this matter will not merely serve a useful purpose in settling the legal relations at issue and affording relief from the underlying controversy, but is essential to doing so. There exists a legitimate dispute over the continued listing of the '340 patent in the Orange Book that the Court may resolve through "specific relief ... of a conclusive character." *MedImmune*, 549 U.S. at 127 (citations and internal quotation marks omitted). Such relief is appropriately sought under the Declaratory Judgment Act.

[8] The court in *Eisai* persuasively explains that "§ 271(e)(5) speaks only to the power of a court to decide a case, not the prudence[,]" [and] [t]hus [] while § 271(e)(5) clarifies the maximum extent of a court's jurisdiction, it does not govern how the district court may exercise its discretion under § 2201 in deciding whether to declare the rights of the litigants." *Eisai*, 620 F.3d at 1348–49

V. CONCLUSION

For the foregoing reasons, Ferring's Motion to Dismiss will be denied. An appropriate Order will accompany this Memorandum Opinion.

/s/
Henry E. Hudson
United States District Judge

Date: Oct. 14, 2014
Richmond, Virginia