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

GLENMARK GENERICS LTD., et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
FERRING, B.V.	)	
	)	Civil Action No. 3:14-cv-00422-HEH
Defendant.	)	
	)	U.S. District Judge Henry E. Hudson

Glenmark's Opposition To Ferring's Motion To Dismiss

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I. Introduction

Ferring's motion to dismiss has no merit either on the facts or the law.

First, the facts establish that Glenmark is ready, willing, and able to immediately launch its generic desmopressin product, but it cannot do so because FDA approval of Glenmark's drug is blocked by the Orange Book listing of Ferring's U.S. Patent No. 7,022,340 ("the '340 patent"). (D.I. 1, ¶¶ 25-31.) And Ferring is responsible for the Orange Book listing of the '340 patent. (D.I. 1, ¶ 21.) Glenmark's suit seeks a declaration that Ferring's patent is unenforceable, which, if obtained, would clear the block to FDA approval of Glenmark's generic drug application. Secondly, as a matter of law, Glenmark's complaint alleged the three elements needed for a justiciable Article III controversy: (i) Glenmark has *standing* (D.I. 1, ¶¶ 43-47.); (ii) the issues are *ripe* for adjudication (D.I. 1, ¶¶ 48-49.); and (iii) the case is *not rendered moot*. (D.I. 1, ¶¶ 50-51.) *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

The law addresses but rejects the arguments Ferring advances for why the Court lacks subject matter jurisdiction. The Federal Circuit has addressed and rejected Ferring's argument that its patent disclaimer moots this controversy. *See Teva Pharms., USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1345 (Fed. Cir. 2010), *vacated on procedural grounds*, 426 F. App'x 904 (Fed. Cir. 2011); *see also Shire LLC v. Teva Pharms. USA, Inc.*, 1:10-cv-00329-RGA (Order [D.I. 395] ¶ 1) (D. Del. July 23, 2012) (**Exhibit A**). And, Ferring's argument that its request for the FDA to delist the patent means Glenmark's dispute lies with FDA is contrary to the law. The FDA is legally prohibited from delisting the '340 patent in the circumstances of this case. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006); *Teva Pharms, USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010).

The Court should deny Ferring's motion to dismiss and put this case on a path to end Ferring's legal gaming tactics that have kept Glenmark's generic drug from the market. To delay Glenmark's market entry, Ferring opted to not to sue Glenmark, even though it had a statutory right to do so. (D.I. 1, ¶ 26.) When Glenmark filed a prior declaratory-judgment suit to remove the barrier caused by the listing of the '340 patent, Ferring responded by first avoiding service of process, then by disclaiming its patent. (D.I. 1, ¶¶ 32-33.) Those actions flew in the face of Glenmark's offer to simply enter a consent decree in the prior suit, which would have resolved the dispute, and forced Glenmark to file this suit. (D.I. 1, ¶ 32-33.) Now Ferring files this costly motion to dismiss, attempting to again evade adjudicating the merits of the '340 patent and alleviating the ongoing harm to Glenmark. The Court should not allow Ferring to continue in its gamesmanship tactics.

II. Factual Background

To demonstrate that the requisite case or controversy exists, Glenmark provides facts necessary to explain the legal context in which this case arises. The Hatch–Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 156 and 217(e), established a framework that regulates the approval of brand and generic drugs. The act provides five elements that are pertinent here.

A. Ferring caused the '340 patent to list in the FDA's Orange Book

All pharmaceutical companies must obtain FDA approval to market a drug in the United States. Companies seeking to market a new drug (so-called "brand-name companies") must submit a New Drug Application to the FDA requesting permission to market that new drug. *See* 21 U.S.C. § 355. That Application must identify every patent that claims the drug composition or methods for using the drug. *See* 21 U.S.C. § 355(b)(1); *see also* 21 U.S.C. § 355(c)(2); 21 C.F.R. §§ 314.53(b) and 314.53(c)(2). When the FDA approves the application, it will list all such

patents for the approved drug in an electronic database known as the Orange Book. *See* 21 U.S.C. § 355(b)(1)(G).

For our purposes, Sanofi-Aventis followed this procedure and obtained approval to market desmopressin acetate, under the brand name DDAVP. (D.I. 1, ¶ 20.) Because Ferring owns the ’340 patent that covers Sanofi’s desmopressin product, Ferring caused the ’340 patent to be listed in the Orange Book for Sanofi’s desmopressin product. (D.I. 1, ¶ 21.)

B. Glenmark filed an Abbreviated New Drug Application (“ANDA”), certifying that the ’340 patent was not infringed, invalid, or unenforceable

Generic-drug companies can use a streamlined process for seeking FDA approval for generic versions of brand-name drugs by filing an ANDA. These ANDAs are “abbreviated” in the sense that they may omit the extensive preclinical and clinical data necessary for a New Drug Application if the generic-drug applicant shows that its generic drug is bioequivalent to the corresponding brand-name drug. *See* 21 U.S.C. § 355(j)(4)(F).The corresponding brand-name drug is known as the “reference-listed drug.” As part of the ANDA submission, the generic applicant must also certify for all patents listed in the Orange Book for the reference-listed drug:

(I) that there are no patents listed in the Orange Book;

(II) that any listed patent has expired;

(III) that the listed patent will expire before the generic manufacturer will market its generic product; or

(IV) that the listed patent is invalid, is unenforceable, or will not be infringed by the manufacture, use or sale of the generic drug described in the ANDA.

See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a “Paragraph IV certification.”

In 2010, Glenmark filed an ANDA with the FDA seeking approval to market generic versions of Sanofi’s desmopressin acetate drug product covered by Ferring’s ’340 patent. (D.I. 1,

¶ 25.) Thus, Sanofi's desmopressin (DDAVP) is the reference-listed drug upon which Glenmark's ANDA relies. Because the '340 patent was listed in the Orange Book as covering Sanofi's desmopressin drug product, Glenmark certified that the claims of the '340 patent were not infringed, invalid, or were unenforceable. *Id.* As required by statute, Glenmark immediately notified Ferring of its Paragraph IV certification, which gave rise to Ferring's right to sue Glenmark for patent infringement. (*Id.*, ¶ 26.)

C. Ferring elects not to sue Glenmark

The Hatch-Waxman Act allows brand-name drug companies and generic-drug companies to promptly resolve patent disputes by authorizing patent owners to sue generic-drug applicants for patent infringement if the generic-drug applicant has made a Paragraph IV certification (as Glenmark certified here). *See* 35 U.S.C. § 271(e)(2). These suits generally proceed before FDA approval of the ANDA so that patent issues are resolved before the generic drug is marketed.

Ferring received Glenmark's notice of its Paragraph IV certification for the '340 patent, but chose not to sue Glenmark for patent infringement. (D.I. 1, ¶ 26.)

D. FDA approval of Glenmark's application is bottlenecked

To encourage early generic-market entry, the Hatch–Waxman Act grants a 180-day period of marketing exclusivity to the first generic applicant that files a substantially complete ANDA with a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1). For that 180-day period the first-filed generic is the only competitor with the brand-name drug maker. Importantly, until the first-filer's 180-day exclusivity period is triggered and runs its course, no other subsequent generic applicant can receive approval from the FDA. *Eisai*, 620 F.3d at 1343.

Only two events can trigger this exclusivity: (i) the first-filed generic company's marketing of its generic-drug product or (ii) entry of a judgment that the Orange Book listed

patent is invalid, unenforceable, or not infringed.[1] *Eisai*, 620 F.3d at 1343. In the absence of a triggering event, the 180-day exclusivity period will be delayed indefinitely, which blocks FDA approval of all later-filed ANDAs. *Id.* This situation is commonly called a "bottleneck" or "blocking injury."

Glenmark filed its ANDA more than three years ago. (D.I. 1, ¶ 25.) The FDA *tentatively, but not finally,* approved Glenmark's ANDA. Glenmark has not received FDA approval because an (unknown) generic applicant holds 180-day exclusivity for the same reference-listed drug, Sanofi's desmopressin acetate. (D.I. 1, ¶ 23.) That exclusivity "bottlenecks" FDA approval of Glenmark's application. Glenmark is blocked from entering the market until that applicant markets its generic product or a court enters judgment that the '340 patent is not infringed, invalid, or unenforceable.

Glenmark is indefinitely excluded from competing in the market because Ferring caused the '340 patent to be Orange Book listed for Sanofi's desmopressin product, causing significant economic harm to Glenmark. (D.I. 1, ¶¶ 21, 28-31.) Glenmark is ready, willing, and able to market its generic desmopressin products, and stands to earn millions of dollars in annual profit, but for the bottleneck. (*Id.*, ¶¶ 28-31.) Glenmark's only recourse to remove the bottleneck and enter the market is to secure a court judgment that the claims of the '340 patent are not infringed, invalid, or unenforceable. (*Id.*, ¶¶ 40-42.)

E. Glenmark files a declaratory-judgment suit to clear the bottleneck, but Ferring seeks to avoid judgment by disclaiming the '340 patent

The Hatch–Waxman Act addresses "bottlenecking" to combat gamesmanship by brand-name drug companies by authorizing generic-drug applicants to file a "civil action to obtain

[1] A patent disclaimer is not a triggering event. *See Eisai*, 620 F.3d at 1345.

patent certainty" against the owner of an Orange Book listed patent if neither the patent owner nor the NDA-holder sues the generic-drug company for patent infringement within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc); s*ee Caraco*, 527 F.3d at 1285.

Based on the bottleneck issue, and in view of Ferring's decision not to sue, which left the bottleneck in place, Glenmark filed an earlier declaratory-judgment suit for non-infringement and invalidity of the '340 patent. Glenmark asked Ferring to enter into a consent decree of non-infringement, which would have lifted the statutory block to FDA approval of Glenmark's ANDA. (D.I. 1, ¶ 32.) Ferring refused. Instead, Ferring abruptly (i) filed a statutory disclaimer with the Patent Office disclaiming and dedicating to the public all claims of the '340 patent, and (ii) requested that the FDA delist (*i.e.*, remove) the '340 patent from the Orange Book. (*Id.*, ¶ 34.)

Ferring's action had no practical effect on the issues presented here. The '340 patent remains—indeed must remain—listed in the Orange Book because the undisclosed ANDA filer's 180-day exclusivity hinges on the Orange Book listing of the '340 patent. *See Ranbaxy Labs. Ltd.*, 469 F.3d 120; *Sebelius*, 595 F.3d 1303 (D.I. 1, ¶¶ 36-37.) Thus, factually, Ferring's disclaimer and its delisting requests do not moot Glenmark's issue.

III. Argument

A. Overview

In deciding a motion under Fed. R. Civ. P. 12(b), the Court must accept as true all material allegations of the complaint. *Com. of Puerto Rico ex rel. Quiros v. Alfred L. Snapp & Sons, Inc.*, 632 F.2d 365, 367 (4th Cir. 1980) *aff'd sub nom., Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592 (1982).

Ferring moved to dismiss based on Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), basing its motion to dismiss on three arguments: (i) that Ferring's statutory disclaimer renders this case moot; (ii) that Ferring's delisting request means that Glenmark's dispute is with the FDA, not with Ferring; and (iii) that Ferring's delisting of the '340 patent from its own New Drug Application for desmopressin (as opposed to with respect to Sanofi's New Drug Application for DDAVP) removes any case or controversy.[2] Ferring's arguments, whether based on Rule 12(b)(1) or 12(b)(6), fail for the reasons discussed below.

First, Ferring's argument that its disclaimer of the '340 patent means there is no case or controversy in the Hatch-Waxman context has no merit. (Br. at 6-7.) The Federal Circuit has rejected that precise argument. See *Teva Pharms., USA, Inc. v. Eisai Co., Ltd*., 620 F.3d 1341, 1345 (Fed. Cir. 2010), *vacated on procedural grounds*, 426 F. App'x 904 (Fed. Cir. 2011); *see also Shire LLC v. Teva Pharms. USA, Inc*., 1:10-cv-00329-RGA (Order [D.I. 395] ¶ 1) (D. Del. July 23, 2012).

Second, Ferring's argument that Glenmark's grievance lies with the FDA, which has not delisted the patent as requested, also has no merit. (Br. at 9-10.) This argument fails because the FDA is legally prohibited from delisting the '340 patent based on the factual situation here. (*See* D.I. 1, ¶¶ 35-37; Section II.E, *supra.*); *see also Ranbaxy Labs. Ltd.*, 469 F.3d 120; *Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010).

Ferring's last argument—that Glenmark's complaint fails to state a claim upon which relief may be granted—simply repackages its patent-disclaimer argument (the first argument).

[2] Ferring's motion misstates this fact. (Br. at 3-4.) Ferring holds a separate New Drug Application for a desmopressin drug that is not the reference-listed drug for Glenmark's ANDA. The Orange Book listing (and later delisting) of the '340 patent for *Ferring's application* has no bearing on the approval of Glenmark's ANDA. *Sanofi's* New Drug Application is the only relevant Application in this suit. *See* Section III.D, *infra*.

Based on the facts presented here, the disclaimed '340 patent is not unenforceable. This argument fails for the same reason that the subject-matter jurisdiction argument fails to show this Court lacks subject-matter jurisdiction—courts have already addressed and rejected the notion that a disclaimed patent cannot be the subject of a declaratory-judgment suit.

B. This Court has subject matter jurisdiction

Ferring's statutory disclaimer does not remove the case and controversy between the parties because Glenmark still suffers a blocking injury from the '340 patent that remains listed in the Orange Book. The Federal Circuit has addressed this specific issue in multiple cases and consistently held that voluntarily removing the right to enforce a patent listed in the Orange Book does not moot a case or controversy in this situation. *See, e.g., Caraco*, 527 F.3d at 1296 (holding that an irrevocable covenant not to sue does not extinguish a case or controversy "where the first Paragraph IV ANDA filer fails to trigger its own exclusivity period, a subsequent Paragraph IV ANDA filer can only obtain FDA approval before the relevant Orange–Book–listed patents expire by obtaining a judgment that those patents are invalid[, unenforceable], or not infringed."); *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158 (Fed. Cir. 2012) (same); *Eisai*, 620 F.3d at 1341 (holding that patent statutory disclaimer does not extinguish case or controversy where subsequent ANDA filer is bottlenecked).[3]

Indeed, the Federal Circuit and sister district courts have addressed and rejected Ferring's argument that a patent disclaimer eliminates a case or controversy. *See Eisai*, 620 F.3d at 1345; *Shire*, 1:10-cv-00329-RGA (Order [D.I. 395] ¶ 1) (D. Del. July 23, 2012). The Federal Circuit's

[3] The Federal Circuit's decision in *Eisai* was later vacated by the Supreme Court on procedural grounds, because the case was mooted while pending appeal because the first filer ANDA applicant launched its product, thereby triggering its exclusivity. However, neither the Federal Circuit nor the Supreme Court has ever questioned the reasoning or analysis in *Eisai*.

Eisai decision is on all fours with this case and, for that reason, will be treated in detail. In *Eisai*, the bottlenecked ANDA filer brought a declaratory judgment action over four Orange Book listed patents. Two of the patents had been statutorily disclaimed, exactly as Ferring has done here with the '340 patent. The patent owner then moved to dismiss for lack of subject matter jurisdiction in view of the disclaimers, again exactly as Ferring has done. The district court dismissed the declaratory-judgment suit pursuant to Rule 12(b)(1) based on the disclaimer. The Federal Circuit reversed, applying the common-sense approach that "[w]hat matters for our purposes is that [the] patents remain listed in the Orange Book." *Eisai*, 620 F.3d at 1345. In rejecting the patent owner's argument concerning the statutory disclaimer and dedication to the public, the Federal Circuit explained:

> Neither the statutory disclaimers [of the patent] nor [patent owner's] covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book. Thus, regardless of whether [patent owner] could bring an infringement action with respect to the DJ patents, under the Hatch–Waxman Act [the subsequent ANDA filer] still needs a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market.

Id. at 1348 (internal citations omitted). The *Eisai* decision specifically reaffirmed the central holding in *Caraco*: "*Caraco* holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact." *Id*. at 1346. The *Eisai* decision applies to the instant case.[4]

The District of Delaware recently denied a motion to dismiss brought for the same reason: the patent had been statutorily disclaimed and dedicated to the public. In denying the motion to dismiss, that court expressly cited *Eisai*:

[4] Notably, the Federal Circuit also found that the District Court below abused its discretion by declining to exercise its "broad discretion under the Declaratory Judgment Act" because "no sound basis for refusing to adjudicate the case had been shown." *Eisai*, 620 F.3d at 1350.

> The Court retains jurisdiction over a patent dedicated to the public where, as here, it remains listed on the Orange Book and therefore has the potential to create a triggering event for the first-filer's exclusivity. The Court adopts the reasoning set forth in *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1347-48 (Fed. Cir. 2010), *vacated as moot*, 131 S.Ct. 2991 (2011).

Shire, 1:10-cv-00329-RGA (D. Del. July 23, 2012) (Order [D.I. 395] ¶ 1) (D. Del. July 23, 2012). The court then proceeded to enter a judgment of invalidity as a matter of law on the patent *even though it had been disclaimed and dedicated to the public*. *Id.* at ¶ 2. Once past this procedural motion, Glenmark believes this Court will find the '340 patent unenforceable as a matter of law.

Ferring half-heartedly attempts to distinguish the *Eisai* case, observing that other non-disclaimed patents were also involved in the suit. But Ferring never explains why this minor distinction makes any difference. To be sure, there is no difference. The *Eisai* Court did not rely on the existence of other non-disclaimed patents that were also disputed by the parties, which is not surprising because subject matter jurisdiction does not focus on whether there is a general dispute between the parties, but whether the parties have a specific dispute over a specific patent.

Ferring's other arguments also miss the point. For example, Ferring argues that "[b]y 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" and that it "has no further right … to enforce the claims which have been disclaimed." (Br. at 6.) Ferring mischaracterizes the controlling law. The Federal Circuit consistently has held that eliminating the right to enforce a patent, *i.e.*, removing the threat of asserting infringement, does not eliminate the right of a subsequent ANDA filer to bring a declaratory judgment action. *See, e.g., Caraco*, 527 F.3d at 1296; *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158 (Fed. Cir. 2012) (same); *Eisai*, 620 F.3d at 1341. The touchstone of subject matter jurisdiction in this context is whether the subsequent ANDA filer is suffering a blocking injury. Glenmark

unquestionably suffers such harm, a fact that Ferring's brief ignores. "The Federal Circuit has recognized, in the context of the Hatch–Waxman Act, that the creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *Seattle Children's Hosp. v. Akorn, Inc.*, U.S. Dist. LEXIS 145998, at *15 (N.D. Ill. Dec. 20, 2011) (citations omitted); *see also Eisai*, 620 F.3d 1341.

Finally, the cases Ferring cites in support of its position are inapposite. *Guinn v. Kopf*, 96 F.3d 1419 (Fed. Cir. 1996) did not address whether a disclaimer can remove Article III case or controversy. *Guinn* involved an appeal from the Patent Office, not an Article III court, and merely addressed whether the Patent Office had *statutory* jurisdiction. *Guinn* held that "[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*, 96 F.3d at 1422. *Guinn* simply does not state, as Ferring asserts, that a disclaimed patent can no longer be the subject of a dispute over "validity, enforceability, or infringement." (Br. at 7.)

Likewise, *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 2014 WL 114127 (N.D. Ill. 2014), is inapposite. In *Apotex*, it was uncertain whether the Orange Book listed patent would ever present a block to final FDA approval because the ANDA filer had not received tentative FDA approval as Glenmark has received here.[5] The *Apotex* opinion further shows that the court was misinformed and did not appreciate that the FDA *cannot* grant a delisting request when an applicant's 180-day exclusivity rests on its Orange Book listing. *Apotex*, 2014 WL 114127 at, *4 ("It is unclear why the FDA has yet to actually remove the patent from the Orange Book.") The

[5] http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=OLMESARTAN%20MEDOXOMIL (last accessed August 12, 2014)

reason is that FDA is prohibited by law from doing so under these circumstances. *See Ranbaxy Labs. Ltd.*, 469 F.3d 120; *Sebelius*, 595 F.3d 1303. Only a judgment of the court can remove the blocking effect of that patent. *Eisai*, 620 F.3d 1341.

Finally, Ferring's reliance on *Merck & Co. v. Apotex, Inc.*, 2007 WL 4082616 (D.N.J. 2007), *aff'd on other grounds*, 292 Fed. App'x 38 (Fed. Cir. 2008) (unpublished) is also misplaced because it conflicts with the Federal Circuit's *Caraco* and *Eisai* decisions, which the Federal Circuit decided after *Merck*.

C. The remedy for Glenmark's harm lies with defendant Ferring, not the FDA

Ferring incorrectly argues that "Glenmark's dispute is with the FDA, not Ferring" because a request for delisting of the '340 patent has been made with respect to Sanofi's New Drug Application for desmopressin, the reference-listed drug for Glenmark's ANDA. (Br. at 9.) This is wrong. Ferring has to know that Glenmark cannot seek relief from the FDA. The FDA is prohibited by law from delisting a patent from the Orange Book when an ANDA applicant's 180-day exclusivity hangs on that patent. *See Ranbaxy Labs. Ltd.*, 469 F.3d 120; *Sebelius*, 595 F.3d 1303. The same law that binds the FDA allows Glenmark to clear the block by obtaining entry of judgment of unenforceability from this Court. *Eisai*, 620 F.3d at 1343.

D. The delisting of the '340 patent from Ferring's own *separate* new drug application for desmopressin—as opposed to Sanofi's new drug application for DDAVP—is irrelevant to this case

Ferring's brief argues that the '340 patent has been delisted from the Orange Book with respect to Ferring's *own* NDA (No. 21795) for desmopressin. Ferring would have this Court believe that this point is somehow relevant. It is not relevant whatsoever, and is nothing more than a red herring. Ferring's New Drug Application does not correspond to the reference-listed drug in Glenmark's ANDA. Nor is it mentioned in Glenmark's complaint. The relevant New Drug Application is Sanofi's (NDA No. 19955), for which Ferring caused the '340 patent to be

listed. In plain terms, the delisting that Ferring sought and obtained was a for a different drug product than is the subject of Glenmark's ANDA.

E. Glenmark's complaint states a proper claim for relief

Ferring's Rule 12(b)(6) challenge collapses into its Rule 12(b)(1) challenge and rests on the same arguments. Glenmark already has shown those arguments are without merit. For the same reasons, Ferring's motion to dismiss under Rule 12(b)(6) also should be denied.

The law is clear: "A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently *enforced*." *Eisai*, 620 F.3d at 1345 (citing *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996), (emphasis added)). And the *Eisai* court specifically held that despite the disclaimer, an Orange Book listed patent is nevertheless subject to adjudication and judgment in a district court if there is a blocking injury.

In this case, Glenmark and Ferring both agree that the claims of the '340 patent have been disclaimed and dedicated to the public. The parties also agree that this means that no claim of the '340 patent can be enforced. Indeed, a case that Ferring cites confirms this point. (Br. at 6 (citing *W.L. Gore & Assoc., Inc. v. Oak Materials Grp., Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) ("patentee has *no further right* … to *enforce* the claims which have been disclaimed…") (emphasis added).)

Inexplicably, Ferring argues that "[t]he 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." (Br. at 8.) Ferring is wrong. Ferring wants this Court to limit the meaning of the phrases "not enforceable" or "unenforceability" only to cases of inequitable conduct. While it is true that inequitable conduct can be *one* of the reasons a patent is rendered unenforceable,

Ferring advances no authority to support such a limited reading of a word that is clear on its face. The Court should reject Ferring's unsupported arguments.

IV. Conclusion

For the foregoing reasons, this Court retains subject matter jurisdiction over this dispute between the parties. Glenmark's complaint properly alleged an Article III case and controversy. Ferring's motion to dismiss has no merit. Ferring's statutory disclaimer of the '340 patent does not remove the bottleneck, and Glenmark continues to suffer ongoing harm directly traceable to Ferring and the '340 patent. Similarly, Ferring's request to delist the '340 patent from the FDA's Orange Book for Sanofi's desmopressin (DDAVP) also has not mooted the parties' dispute for the simple reason that the FDA *has not* (and cannot under law) delist the '340 patent. Accordingly, Glenmark respectfully requests that the Court deny Ferring's motion to dismiss.

Dated: August 13, 2014

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