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

FERRING B.V.'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Ferring respectfully submits this reply in support of its motion to dismiss Glenmark's declaratory judgment complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the reasons discussed below and in Ferring's opening brief, no case or controversy exists between the parties, and Glenmark has failed to state a claim upon which relief may be granted. Ferring therefore respectfully requests that this Court dismiss Glenmark's complaint.

I. INTRODUCTION

On May 14, 2014, Ferring statutorily disclaimed all claims of U.S. Patent 7,022,340 ("the '340 patent") pursuant to 35 U.S.C. § 253, and thus the '340 patent is viewed as never having existed. Further, at Ferring's request, the U.S. Food and Drug Administration ("FDA") delisted the '340 patent from the Orange Book in connection with Ferring's New Drug Application ("NDA") No. 021795 for desmopressin acetate tablets. Because there is no longer a patent to adjudicate, Glenmark cannot meet its burden of establishing that a real and substantial

controversy now exists between Glenmark and Ferring as to whether the non-existent patent is allegedly "unenforceable." Moreover, Glenmark fails to plead any legal or factual basis for an "unenforceability" claim and improperly conflates "not enforceable" with "unenforceable" as that term is used under the patent laws. Glenmark's complaint thus amounts to no more than a request for an advisory opinion concerning the '340 patent, which Glenmark admits does not exist.

Furthermore, because the claims in Glenmark's complaint relate only to a disclaimed, non-existent patent, Glenmark also fails to state a legally cognizable claim. As Glenmark concedes in its opposition brief, any purported injury does not result from either the '340 patent itself or from Ferring's NDA. Instead, Glenmark contends its injury stems from the FDA's continued listing of the '340 patent in the Orange Book in connection with ***another*** company's NDA. That company, Sanofi, also asked the FDA to delist the non-existent patent from its own NDA, but the FDA has not yet delisted the patent. Glenmark's dispute thus lies not with Ferring, but with the FDA, if anywhere. Accordingly, as discussed below and in Ferring's opening brief, the Court should dismiss Glenmark's complaint.

II. ARGUMENT

A. No Case or Controversy Exists Between Glenmark and Ferring

As the declaratory judgment plaintiff, Glenmark bears the burden of establishing the existence of an actual case or controversy between Glenmark and Ferring. Glenmark must establish 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 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Glenmark cannot meet its burden because

no dispute exists between Glenmark and Ferring as to the "unenforceability" of a patent that does not exist, and thus the parties do not have adverse legal interests subject to adjudication.

As Glenmark recognizes in both its complaint and in its opposition brief, "[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." *See, e.g.*, *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996); *see also* Dkt. 1, ¶ 38; Opposition Brief, Dkt. 23 at 11. Glenmark thus concedes, as it must, that the '340 patent is viewed as never having existed. (Dkt. 1, ¶ 38.) The non-existent, disclaimed patent can no longer be the source of any dispute over validity, enforceability or infringement.

As discussed in Ferring's opening brief, other courts have analyzed this issue and concluded that a disclaimed patent for which a delisting request has been filed cannot give rise to an Article III case or controversy. *See, e.g.*, *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 2014 WL 114127, at *1-2 (N.D. Ill. 2014); *Merck & Co. v. Apotex, Inc.*, 2007 WL 4082616, at *5 (D.N.J. 2007), *aff'd on other grounds*, 292 Fed. App'x 38 (Fed. Cir. 2008) (unpublished). For example, in *Apotex v. Daiichi*, which was decided earlier this year, Daiichi disclaimed the patent at issue and requested that the FDA delist the disclaimed patent from the Orange Book. Although the disclaimed patent in fact remained listed in the Orange Book, the court granted Daiichi's motion to dismiss Apotex's declaratory judgment claim for lack of subject matter jurisdiction. *See, e.g.*, *Daiichi*, 2014 WL 114127, at *1-2. The *Daiichi* court reasoned that a disclaimed patent "does not create an independent barrier that deprives [an ANDA filer] of an economic opportunity to compete" and that the NDA holder was not "preventing the FDA from approving [the] ANDA through any delay tactics or strategies[.]" *Id.* at *4. Moreover, the *Daiichi* court noted 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 by which Apotex may seek a declaratory judgment regarding a nonexistent patent."[1] *Id.*

Glenmark fails to address the *Daiichi* court's rationale in its opposition brief, however, and instead simply disparages that court, stating 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." (Dkt. 23 at 11.) Instead of addressing the merits of *Daiichi*, Glenmark recklessly speculates that some unknown ANDA filer somehow possesses a 180-day regulatory exclusivity period that allegedly "'bottlenecks' FDA approval of Glenmark's application." (*Id.* at 5.) At least three generic manufactures, however, have approved ANDAs for desmopressin acetate tablets and have long been selling their generic products on the market, and the FDA recently approved a fourth ANDA on June 27, 2014.[2] Accordingly, Glenmark's speculative remarks about "180-day exclusivity" and "bottlenecks" wholly lack merit, and Glenmark's baseless criticism of the *Daiichi* court should not be entertained.

B. Glenmark's Arguments and the Cases on Which It Relies in Its Opposition Brief Are Inapposite

Glenmark's reliance on the *Caraco*, *Dey Pharma* and *Teva v. Eisai* cases fails to address important factual differences that render these cases inapposite to the present matter. Neither *Caraco* nor *Dey Pharma*, for example, involved a statutory disclaimer of a patent that was the subject of a declaratory judgment suit by an ANDA filer. Instead, in both cases the NDA holder attempted to avoid adjudicating at least one of multiple Orange Book-listed patents associated

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[1] As discussed in Ferring's opening brief, the *Merck* case involved similar facts, and the court reached the same outcome, dismissing the declaratory judgment complaint for lack of jurisdiction. (Dkt. 16 at 7.) As with *Daiichi*, Glenmark fails to address the *Merck* court's rationale in its opposition brief.

[2] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/excelTempai.cfm (last accessed on August 19, 2014).

with the NDA. In both *Caraco* and *Dey Pharma*, the NDA holders sued ANDA filers on only *some* of the Orange Book-listed patents and declined to sue on at least one other listed patent. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1286, 1288 (Fed. Cir. 2008); *Dey Pharma, LP v. Sunovion Pharm., Inc.*, 677 F.3d 1158, 1161 (Fed. Cir. 2012). Here, by contrast, Ferring has disclaimed the ***only*** Orange Book-listed patent at issue.

Similarly, in *Teva Pharmaceuticals USA, Inc. v. Eisai Co.*, the ANDA filer's declaratory judgment suit involved Orange Book-listed patents that the NDA holder did *not* disclaim. The patentee (who was also the NDA holder) disclaimed only two of the four patents for which the ANDA filer sought a declaration of non-infringement, and the parties negotiated a covenant not to sue as to the other two patents. 620 F.3d 1341, 1345 (Fed. Cir. 2010), *vacated*, 426 Fed. App'x 904 (Fed. Cir. 2011). Ferring, however, has disclaimed the ***only*** Orange Book-listed patent and thus *Teva v. Eisai* is not "on all fours with this case," as Glenmark wrongly claims in its opposition brief. (Dkt. 23 at 8-9.)

In other words, in every case on which Glenmark relies, the NDA holder retained at least one Orange Book-listed patent that it did not disclaim, which theoretically could be the subject of a substantive adjudication as to validity, enforceability, or infringement. Moreover, the remaining patents that were not disclaimed remained listed in the FDA's Orange Book. Here, by contrast, Ferring disclaimed the ***only*** Orange Book-listed patent, and this patent cannot be substantively adjudicated because it is viewed as never having existed. Furthermore, the FDA has delisted the '340 patent from the Orange Book in connection with Ferring's NDA, and the other NDA holder, Sanofi, also has requested delisting in connection with its NDA. None of the

cases on which Glenmark relies addresses this scenario.[3] And, contrary to Glenmark's arguments, courts that have addressed this scenario have concluded that no declaratory judgment subject matter jurisdiction exists when a patentee statutorily disclaims a patent and requests that the FDA delist it from the Orange Book. *See, e.g.*, *Merck*, 2007 WL 4082616, at *5; *Daiichi*, 2014 WL 114127, at *4.

Furthermore, none of the cases Glenmark cites analyzes a scenario in which a patentee disclaims its patent and the FDA delists it from the Orange Book as to the *patentee's* NDA but the patent remains listed in the Orange Book in connection with a *different company's* NDA. *Caraco*, *Dey Pharma* and *Teva v. Eisai* address only the issue of whether subject matter jurisdiction exists as to the holder of an NDA for which the Orange Book still lists the patent. As discussed, however, Ferring's NDA no longer lists the non-existent patent at issue. Rather, this patent remains in the Orange Book *only* in connection with another company's NDA.

Nor has Glenmark established that Ferring is responsible for any alleged "bottleneck" of Glenmark's ANDA or that Ferring has engaged in any "gamesmanship." Unlike in *Caraco*, *Dey Pharma* or *Teva v. Eisai*, at least three generic manufactures have approved ANDAs for desmopressin acetate tablets and have long been selling their generic products on the market. Under these circumstances, Glenmark cannot establish that Ferring's actions have resulted in any delay of approval of Glenmark's ANDA or otherwise subjugated Glenmark to any 180-day exclusivity period.

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[3] Similarly, *Shire LLC v. Teva Pharmaceuticals USA Inc.*, which Glenmark cites in its opposition brief, involved not only a disclaimed patent but also two other patents that were listed in the Orange Book in connection with Shire's NDA and that the patentee did not disclaim.

C. Glenmark's Dispute, if Any, Is with the FDA

Glenmark does not allege that its purported injury stems from Ferring's acquisition or use of the now non-existent '340 patent, and Glenmark concedes in its opposition brief that it was not injured by the listing of the '340 patent in the Orange Book in connection with Ferring's NDA. (*E.g.*, Dkt. 23 at 6.) Indeed, Glenmark argues in its opposition brief that Ferring's delisting of the '340 patent from its NDA "had no practical effect on the issues presented here" and "is not relevant whatsoever." (Dkt. 23 at 6, 12.) Glenmark's contention that Ferring's actions are irrelevant only underscores that Glenmark's dispute properly lies, if anywhere, with the FDA.[4]

Glenmark contends that its dispute cannot lie with the FDA because there is purportedly a legal prohibition against delisting a patent when another ANDA applicant may be entitled to 180-day exclusivity as to that patent. (Dkt. 23 at 6, 12.) As an initial matter, Glenmark's ability or inability to succeed in obtaining relief from the FDA has no bearing on whether subject matter jurisdiction exists over Glenmark's declaratory judgment suit against Ferring. Moreover, Glenmark's argument that it has no conceivable way to challenge the FDA's delisting rules is unpersuasive. The very case Glenmark cites as barring it from pursuing any action with the FDA, *Ranbaxy Laboratories Ltd. v. Leavitt*, stemmed from citizens petitions filed by ANDA applicants seeking to have the FDA correct an Orange Book listing issue. 469 F.3d 120, 121 (D.C. Cir. 2006). (Dkt. 23 at 6, 12.) Glenmark has made no showing that it has attempted to pursue such action here.

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[4] Glenmark admits that "*Sanofi's* New Drug Application is the only relevant Application in this suit." (Dkt. 23 at 7 n.2.) Glenmark has not filed suit against Sanofi in this Court, however, even though it did in its first declaratory judgment suit in the District of New Jersey. Glenmark has never explained this inconsistency.

Additionally, in *Ranbaxy*, the FDA complied with an NDA holder's request to delist two patents that the NDA holder had not disclaimed. 469 F.3d at 123. The ANDA applicants then filed citizen petitions seeking to have the FDA *relist* the patents. *Id.* The other case on which Glenmark relies, *Teva Pharmaceuticals USA, Inc. v. Sebelius*, assessed whether an Orange Book delisting request triggered a statutory "forfeiture event" under the 2003 Medicare Modernization Act amendments to the Hatch-Waxman Act resulting in the loss of a first ANDA filer's 180-day exclusivity period. 595 F.3d 1303, 1315-18 (D.C. Cir. 2010). *Ranbaxy* and *Teva v. Sebelius* thus present altogether different factual scenarios than here. Moreover, as discussed, at least three generic manufactures have approved ANDAs for desmopressin acetate tablets and have long been selling their generic products on the market, and the FDA recently approved a fourth ANDA on June 27, 2014. It therefore is not surprising that Glenmark has made no showing that approval of its ANDA is somehow being blocked by another ANDA filer's exclusivity period.

Furthermore, although Glenmark points to the FDA's continued Orange Book listing of the '340 patent as to Sanofi's NDA, Sanofi is not a party to this case and Glenmark has not indicated that it has pursued any action against the FDA. Glenmark's dispute plainly lies, if at all, with the FDA, not with Ferring.

D. Glenmark's Complaint Fails to State a Claim Upon Which Relief May Be Granted

Glenmark's complaint asks this Court to render a substantive adjudication that a patent that Glenmark admits does not exist is nonetheless "unenforceable" under the patent laws. Because the '340 patent never existed, Glenmark cannot plead any facts that would justify a declaration that the non-existent patent is "unenforceable." Accordingly, Glenmark's complaint fails to state a claim upon which relief may be granted.

The patent act states that unenforceability is a defense that may be pleaded in an action involving the validity or infringement of a patent. *See* 35 U.S.C. § 282(b) (listing unenforceability among "defenses in any action involving the validity or infringement of a patent"). The existence of a patent is thus a necessary predicate for Glenmark's declaratory judgment of unenforceability. The listing of unenforceability in § 282 was meant to cover several equitable defenses, including equitable estoppel, laches and unclean hands. *See, e.g.*, P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 215 (1993). Unenforceability may also result from inequitable conduct. *See, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285-91 (Fed. Cir. 2011) (en banc).

In its complaint, Glenmark alleges no facts to support an inference that Ferring committed any act that would justify holding the '340 patent to be "unenforceable" under any of the above-mentioned equitable theories. Instead, Glenmark's opposition brief simply asserts that a disclaimed patent is *per se* "unenforceable." (Dkt. 23 at 13.) Glenmark cites no case law or other support for its contention that disclaiming a patent automatically renders it "unenforceable" as that term is used under the patent laws. Glenmark's complaint is therefore inadequate to state a plausible claim for relief based on unenforceability. Accordingly, Ferring respectfully requests that the Court dismiss Glenmark's complaint for failing to state a claim.

III. CONCLUSION

For at least the reasons discussed above and in Ferring's opening brief, Ferring respectfully requests that the Court dismiss Glenmark's complaint under Rules 12(b)(1) and/or 12(b)(6) of the Federal Rules of Civil Procedure.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 19, 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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