In the United States District Court
for the Eastern District of Virginia
Alexandria Division

Glenmark Generics Ltd.
Glenmark House,
HDO-Corporate Building, Wing-A,
B D Sawant Marg, Chakala, Off Western
Express Highway,
Mumbai 400099,
Maharashtra, India

And

Glenmark Generics Inc., USA
750 Corporate Drive,
Mahwah,
New Jersey 07430

Plaintiffs,

v.

Ferring, B.V.
Polaris Avenue 144,
2132 JX Hoofddorp,
Netherlands

Defendant.

Civil Action No. 3:14CV422 HEH

Complaint for Declaratory Judgment of Patent Unenforceability

Plaintiffs Glenmark Generics Ltd. ("Glenmark Ltd.") and Glenmark Generics Inc., USA ("Glenmark USA") (collectively, "Glenmark") bring this suit to end Defendant Ferring's gaming tactics that have prevented Glenmark from obtaining final FDA approval to market its low-cost, generic desmopressin acetate drug product.[1] In this suit, Glenmark seeks a declaratory judgment

[1] Desmopressin acetate is an important antidiuretic hormone affecting renal water conservation.

that Ferring's U.S. Patent No. 7,022,340 ("the '340 patent") is unenforceable that, if granted, would free the FDA to approve Glenmark's generic-drug application, thereby allowing Glenmark to market its low-cost, generic desmopressin acetate product.

This case arises under the Hatch–Waxman Act, which governs the FDA's approval of both new and generic drugs. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 217(e). A critical feature of the Act, relevant here, is its provision of a "civil action to obtain patent certainty" ("CAPC"). *See* 21 U.S.C. § 355(j)(5)(C). The CAPC is intended to stop brand-name drug companies from gaming the Hatch–Waxman Act scheme by using tactics that forestall the resolution of patent disputes with generic drug makers, thereby keeping competing generic drug makers from entering the market. *See Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

Here, Ferring, whose '340 patent covers the brand-name desmopressin acetate, has gamed the Hatch–Waxman Act framework to block Glenmark's entry into the market. The FDA cannot approve Glenmark's application for generic desmopressin acetate unless and until a court enters a judgment that Ferring's '340 patent is not infringed, is invalid, or is unenforceable. Ferring has studiously avoided putting these issues to the test. First, it chose not to sue Glenmark for patent infringement, even though Ferring had a statutory right to sue. Second, when Glenmark sued Ferring for declaratory judgments[2] of invalidity and non-infringement, Ferring responded by refusing to accept service of process and instead disclaimed the '340 patent, apparently believing there would no longer be any case or controversy as a result of the statutory

[2] That case is styled *Glenmark Generics Ltd. v. Sanofi-Aventis U.S. LLC*, No. 2:14-cv-02374-SRC-CLW, (D.N.J. 2014). In conjunction with filing this suit, Glenmark is dismissing the other suit. This Court has jurisdiction over Ferring under 35 U.S.C. § 293.

disclaimer. But that is not correct—Ferring's actions continue to prevent the FDA from approving Glenmark's generic desmopressin acetate, so a significant Article III case or controversy remains over whether Ferring's patent is enforceable. *Id.*

I. The Parties

1. Glenmark Ltd. is an Indian company with its principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Glenmark Ltd. develops and manufactures prescription pharmaceutical drugs, including affordable, high-quality generic medicines.

2. Glenmark USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark USA markets and distributes prescription pharmaceutical drugs, including affordable, high-quality generic medicines. Glenmark USA is the North American division of Glenmark Ltd.

3. Based on publicly available information, Ferring is a corporation organized and existing under the laws of the Netherlands with its corporate headquarters at Polaris Avenue 144, 2132 JX Hoofddorp, Netherlands. Ferring is engaged in the research, development, manufacture, and sale of pharmaceutical products. Consistent with USPTO records, Ferring's attorney has told Glenmark that Ferring owns the '340 patent, which lies at the heart of this suit.

II. Jurisdiction and Venue

4. This is a Complaint for Declaratory Judgment that Ferring's '340 patent is unenforceable, which arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch–Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202), 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

6. This Court has personal jurisdiction over Ferring under 35 U.S.C. § 293, which provides that in cases involving a patentee not residing in the United States, the United States District Court for the Eastern District of Virginia "shall have the same jurisdiction to take any action respecting the patent or rights thereunder that it would have if the patentee were personally within the jurisdiction of the court," assuming that "no person" has been designated "within the Patent and Trademark Office … on whom may be served process or notice of proceedings affecting the patent or rights thereunder." Ferring does not reside in the United States and has not designated an agent to accept service of process as provided by 35 U.S.C. § 293.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(3) and 35 U.S.C. § 293.

III. Legal Framework and Factual Background of the Parties' Controversies

A. Hatch–Waxman Act Overview

8. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch–Waxman Act. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch–Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

9. To accomplish this goal, the Hatch–Waxman Act established a framework with five elements that are pertinent here.

10. First, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *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). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in a document colloquially referred to as the Orange Book. *See* 21 U.S.C. § 355(b)(1)(G). The new FDA-approved drug is known as the "reference-listed drug" or "RLD."

11. Second, the Hatch–Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an Abbreviated New Drug Application ("ANDA") to the FDA. An ANDA is "abbreviated" because it is generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA can rely on the NDA's preclinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

12. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *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."

13. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and the NDA holder of its Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i). It is common for the patent owner and NDA applicant to be separate companies.

14. Third, the Hatch–Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a Paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45-days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

15. Fourth, to encourage prompt generic-market entry, the Hatch–Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a Paragraph IV certification to an Orange-Book-listed patent a 180-day period of marketing exclusivity that begins on the earliest of the date it begins commercial marketing of its generic-drug product or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1).

16. Either of these two events—commercial marketing by the first-filer or a court decision finding the patent invalid, unenforceable, or not infringed—triggers the first-filer's 180-day exclusivity. Conversely, if the first-filer does not commercially market the generic drug and there is no court decision on the relevant Orange-Book-listed patent, the first applicant's 180-day

exclusivity period will be delayed indefinitely, ultimately blocking final FDA approval of all subsequent ANDAs. This block is colloquially referred to as "bottlenecking" or the "statutory block" of a subsequent ANDA.

17. Fifth, to alleviate the potential for bottlenecking and to avoid gamesmanship by the NDA holder or patent owner, the Hatch–Waxman Act allows ANDA applicants to bring CAPC suits against an NDA-holder or an owner of an Orange-Book-listed patent if (1) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and (2) the ANDA applicant's notice of Paragraph IV certification included an offer of confidential access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

18. By authorizing declaratory-judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely, or blocked, by the first ANDA filer's 180-day exclusivity. A declaratory-judgment action by a subsequent ANDA applicant could result in a court decision that triggers the first-filer's 180-day exclusivity, thereby clearing the way for approval of the subsequent-filers' bottlenecked ANDAs.

19. Congress explained the need for CAPC suits:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could … force the first generic to market. In … these … circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon expiration of the 45-day period.

Caraco, 527 F.3d at 1285 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions)).

B. Ferring Lists the '340 Patent in the FDA's Orange Book

20. Sanofi holds the approved NDA for DDAVP Tablets, which contain the active ingredient desmopressin acetate. DDAVP is the reference-listed drug upon which Glenmark's ANDA relies.

21. Although Ferring does not hold the NDA, it owns the '340 patent. Ferring caused or authorized the '340 patent to be listed in the Orange Book in conjunction with DDAVP.

22. The '340 patent issued on April 4, 2006, and is entitled "Pharmaceutical Composition as Solid Dosage Form and Method for Manufacturing Thereof." The patent will expire on April 20, 2023.

C. An Unknown Applicant Is the First ANDA Filer for the '340 Patent

23. Although not known to Glenmark at the time, 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 180-day market exclusivity for desmopressin acetate. A copy of the '340 patent, as it issued, is attached to this Complaint as Exhibit 1.

24. Glenmark does not know who the blocking ANDA applicant is or when (or if) that ANDA applicant will ever get FDA approval for or will market generic desmopressin acetate.

D. Glenmark Applies for FDA Approval of its Generic Desmopressin Product

25. In 2010, Glenmark filed ANDA No. 201-831 seeking approval to market generic versions of the referenced-listed desmopressin acetate products marketed by Sanofi and allegedly covered by Ferring's Orange-Book-listed '340 patent. In its ANDA, Glenmark made a Paragraph IV certification that the claims of the '340 patent were not infringed, were invalid, or were unenforceable.

26. On June 8, 2010, Glenmark sent Ferring the required notice of its Paragraph IV certification and offered Ferring confidential access to its ANDA. This gave Ferring a statutory 45-day right to sue Glenmark for infringement of the '340 patent, but Ferring chose not to sue Glenmark.

27. On December 13, 2013, after several years of review, the FDA tentatively approved Glenmark's ANDA, meaning that Glenmark had satisfied all substantive requirements for approval of its ANDA.

E. Glenmark's Approval Is Blocked

28. Glenmark is prepared to begin immediate commercial marketing of its desmopressin acetate products. Glenmark, however, is blocked from receiving final approval and prevented from actually entering the market because an earlier, yet unknown ANDA applicant holds eligibility to 180-day generic exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).

29. Were Glenmark free to market its generic desmopressin acetate product, it would earn millions of dollars in annual profits.

30. Because the unknown ANDA applicant's ANDA has not received approval, it is unclear when, if ever, that applicant will launch its desmopressin product and clear the block on Glenmark's ANDA.

31. Glenmark therefore could only remove the statutory bottleneck by a judgment that the claims of Ferring's '340 patent are invalid, unenforceable, or not infringed by the product described in Glenmark's ANDA.

F. Glenmark Seeks to Remove the Block, But Ferring Attempts to Stymie this Effort

32. In response to Ferring's choice not to sue and to leave the bottleneck in place, Glenmark filed a declaratory-judgment suit for non-infringement and invalidity of the '340

patent, and Glenmark asked Ferring to enter into a consent decree of non-infringement, which would have lifted the statutory block to final approval of Glenmark's ANDA.

33. Ferring refused, thereby maintaining the block to final FDA approval of Glenmark's ANDA.

34. In the middle of negotiations to resolve their disputes, Ferring abruptly (i) filed a statutory disclaimer under 35 U.S.C. § 253 with the USPTO, disclaiming all claims of the '340 patent, dedicating them to the public and rendering the '340 patent unenforceable, and (ii) requested that FDA delist (*i.e.*, remove) the '340 patent from the Orange Book.

35. In so doing, Ferring was attempting to game the Hatch–Waxman framework in an, ultimately fruitless, effort to eliminate any case or controversy between Glenmark and Ferring as to the '340 patent.

36. Ferring, a sophisticated brand-name drug company, knew that its request to delist the '340 patent was futile. The '340 patent must remain listed in the Orange Book notwithstanding Ferring's disclaimer and delisting request because a first-filed ANDA applicant has 180-day exclusivity that hinges on Orange-Book-listing of the '340 patent. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006); *Teva Pharm., USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010).

37. And Ferring knew that its patent disclaimer would also not clear the bottleneck, because the FDA only recognizes judgments of non-infringement, invalidity, and unenforceability as triggering the 180-day exclusivity period. It does not recognize a patent disclaimer as a triggering event. *See Teva Pharm. 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 April 18, 2007 Letter from G. Buehler (Office of Generic Drugs, FDA) to ANDA Applicants for Amlodipine Besylate Tablets, 2007N-0123 (Let 2).

G. The '340 Patent Is Unenforceable Due to Ferring's Statutory Disclaimer

38. A patent owner may disclaim any claim in its patent under 35 U.S.C. § 253, which provides, "[a] patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent." A statutory disclaimer has the effect of cancelling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the first place. See Guinn v. Kopf, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Any claim that has been statutorily disclaimed can no longer be enforced, rendering them unenforceable. See Teva Pharm. 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).

39. The '340 patent is unenforceable due to Ferring's statutory disclaimer filed under 37 C.F.R. § 1.321(a), which states that "[a] patentee owning the whole or any sectional interest in a patent may disclaim any complete claim or claims in a patent. In like manner any patentee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted." Such a disclaimer is "binding" and Ferring's May 14, 2014, USPTO filing states that "all claims" have been disclaimed and thus dedicated to the public. A true and correct copy of Ferring's statutory disclaimer as filed is attached to this Complaint as Exhibit 2.

IV. An Article III Case or Controversy Exists for this Court to Decide

40. Though Ferring's patent disclaimer has rendered the '340 patent unenforceable, the '340 patent continues to harm Glenmark in its business by blocking approval of Glenmark's ANDA and continues to benefit Ferring in its business because the '340 patent's blocking effect

limits the number of generic manufacturers against whom Ferring must compete. Only a judgment from this Court can alleviate the harm to Glenmark.

41. There is an actual and ongoing controversy between Glenmark and Ferring, B.V. with respect to the enforceability of the '340 patent that can be resolved by a declaratory judgment from this Court. A judgment of unenforceability from this Court will trigger the 180-day exclusivity block to Glenmark's pending ANDA, allowing Glenmark to bring its generic desmopressin acetate tablets to market.

42. The present dispute between Glenmark and Ferring satisfies the three-part framework for determining whether an action presents a justiciable Article III controversy: (i) the plaintiffs have standing; (2) the issues are ripe for adjudication; and (3) the case is not rendered moot. *Caraco*, 527 F.3d at 1278.

A. Glenmark Has Standing

43. "Standing" requires the following three elements: (1) an alleged injury in fact—"a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical'"; (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.

44. First, Glenmark has been injured in fact by Ferring's actions that have restrained Glenmark's ability to freely exploit its non-infringing generic desmopressin product. Ferring's actions were intended to, and did, delay the FDA from approving Glenmark's ANDA. *See id.* ("ANDA filer suffers the requisite injury-in-fact where its ability to secure approval of its ANDA has been prevented by an NDA holder."). And Glenmark's injury is unique in the Hatch–Waxman context as compared to ordinary infringement action: "Ordinarily, a potential

competitor in other fields is legally free to market its product in the fact of an adversely-held patent. In contrast, under the Hatch–Waxman Act an ANDA filer is not legally free to enter the market without FDA approval." *Id.* Ferring created the bottleneck to Glenmark's ANDA causing injury-in-fact to Glenmark. *Id.*

45. Second, Glenmark's injury—the block on its ANDA from receiving approval—is directly traceable to Ferring's actions, not the Hatch–Waxman Act or the FDA regulations. For example, the following facts, each traceable to Ferring, are the reason for Glenmark's injury: (1) Ferring caused the '340 patent to list in the Orange Book; (2) Ferring chose not to sue Glenmark after receiving a Notice of Glenmark's Paragraph IV certification, so as to avoid an adverse judgment on the '340 patent; (3) when confronted with Glenmark's invitation to enter into a consent decree of non-infringement, Ferring refused; (4) when sued for a declaratory judgment of non-infringement and invalidity, Ferring disclaimed its patent and requested that the FDA delist the '340 patent, knowing that neither act would lift the block on Glenmark's ANDA. Ferring's actions are precisely the sort of "gaming" the system that "[t]he CAPC is designed to prevent." *Id.* at 1285.

46. But for Ferring's choice to cause the '340 patent to be listed in the Orange Book and to avoid litigating the validity and infringement of the '340 patent, Glenmark would not be harmed. Therefore Glenmark's injuries are traceable to Ferring. *Id.* Ferring's listing of the '340 patent in the Orange Book effectively denied Glenmark an economic opportunity to enter the marketplace unless Glenmark obtains a judgment that the '340 patent is unenforceable.

47. Third, Glenmark's injury-in-fact is redressible by a declaratory judgment of unenforceability. There can be no legitimate factual dispute that the '340 patent is unenforceable because of Ferring's disclaimer. A judgment from this Court to that effect in this case would

clear the path to FDA approval for Glenmark's ANDA. Such judgment would activate the unknown ANDA filer's 180-day exclusivity period and would provide Glenmark final approval as swiftly as possible. A favorable judgment from this court in this action would eliminate the continued exclusion of Glenmark from the marketplace by the '340 patent.

B. The Issues Presented Are Ripe for Judicial Review

48. Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 1294. Glenmark satisfies both prongs for ripeness. First, additional factual development would not advance the district court's ability to decide Glenmark's action for a declaratory judgment of unenforceability. Glenmark has a complete generic product that has received tentative FDA approval, *i.e.*, has met all substantive requirements and is ready to be shipped into commerce. And, Glenmark is ready, willing, and able to launch its generic product once it obtains approval. Second, no additional facts are required to determine that the '340 patent is unenforceable. The patent is disclaimed "upon entry of a disclaimer under § 253." *See Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011); *Altoona Publix Theaters v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935) ("Upon the filing of the disclaimers, the original claims were withdrawn from the protection of the patent laws."). Withholding court consideration of Glenmark's declaratory complaint has the "immediate and substantial impact of forestalling [Glenmark's] ability to activate the [first filer's] exclusivity period through the court-judgment trigger of 21 U.S.C.§ 355(j)(5)(B)(iv)(II)." *Caraco.* at 1295.

49. Because Glenmark cannot market its generic drug without FDA approval, being delayed from resolving the blocking issues attendant with the '340 patent creates a potential for substantial lost profits to Glenmark; therefore, Glenmark's action is ripe for judicial review.

C. The Case Has Not Been Rendered Moot

50. The mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action. Ferring's patent disclaimer and delisting request does not render Glenmark's declaratory complaint moot. Just the opposite. The continued listing of the '340 patent in the Orange Book effectively prevents Glenmark from entering the relevant desmopressin drug market, thus harming Glenmark. Ferring's patent disclaimer has no effect on the FDA and Ferring's delisting request is a futile act. *See Ranbaxy*, 469 F.3d 120.

51. The only way to alleviate the harm to Glenmark is a favorable judgment of patent unenforceability from this Court to warrant the issuance of a declaratory judgment.

V. Claim for Relief: The Court Should Enter a Declaratory Judgment of Unenforceability of the '340 Patent

52. Glenmark realleges and incorporates by reference paragraphs 1 through 51, inclusive, as though fully set forth in this paragraph.

53. There is an actual, substantial, and continuing justiciable case or controversy between Ferring and Glenmark regarding the unenforceability of the '340 patent.

54. The claims of the '340 patent are unenforceable because Ferring filed a statutory disclaimer disclaiming all claims of the '340 patent.

VI. Prayer for Relief

WHEREFORE, Glenmark respectfully requests this Court enter judgment as follows:

A. Declaring that all claims of the '340 patent are unenforceable;

B. Awarding Glenmark its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

C. Awarding Glenmark such other relief as this Court deems just and proper.

Dated: June 9, 2014

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

By: _____

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