IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Plaintiffs, v. GLAXOSMITHKLINE LLC and GLAXO GROUP LIMITED, Defendants.	Civil Action No. ____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. ("DRL"), by and through undersigned counsel, hereby bring their Complaint for Declaratory Judgment against GlaxoSmithKline LLC ("GSK") and Glaxo Group Limited ("GGL") (collectively, "Defendants"), and allege as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent Nos. 8,637,512 ("the '512 Patent") and 9,144,547 ("the '547 Patent") (collectively "the patents-in-suit") to enable DRL to bring its lamotrigine extended-release 250 mg tablets as described in DRL's Abbreviated New Drug Application ("ANDA") No. 202383 ("DRL's 250 mg ANDA Product'') to market at the earliest possible date under the applicable statutory and regulatory provisions and to allow the public to benefit from increased generic availability for this product.

THE PARTIES

2. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

3. Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

4. Upon information and belief, Defendant GlaxoSmithKline LLC is a Delaware limited liability company and is the United States subsidiary of GlaxoSmithKline plc. GlaxoSmithKline LLC is the successor of SmithKline Beecham Corporation, which was the successor of SmithKline Beckman Corporation. GlaxoSmithKline LLC has headquarters in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina.

5. Upon information and belief, Defendant Glaxo Group Limited is a corporation organized under the laws of Great Britain, having a principal place of business at Glaxo Welcome House, Berkeley Avenue, Greenford, Middlesex, UB06 0NN, Great Britain.

JURISDICTION AND VENUE

6. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.,* as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355), and by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) ("the MMA") (collectively herein the "Hatch-Waxman Act"), based upon an actual controversy between the parties for a final judgment declaring that DRL is free, upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, use, market, sell, offer to sell, and/or

import DRL's 250 mg ANDA Product.

7. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over GSK because GSK is incorporated under the laws of Delaware. On information and belief, this Court also has personal jurisdiction over GSK and GGL because of their continuous and systematic contacts with the State of Delaware, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware.

9. Further, both GSK and GGL have frequently subjected themselves to the jurisdiction of this Court, including, but not limited to: *Glaxo Group Ltd. v. Teva Pharmaceuticals USA, Inc.*, No. 07-713-JJF (D. Del.); *Glaxo Group Limited v. Teva Pharmaceuticals USA, Inc.*, No. 02-219-GMS (D. Del.); *GlaxoSmithKline LLC v. Roche Holding Ltd.*, No. 10-cv-799-GMS (D. Del.); *GlaxoSmithKline LLC v. Anchen Pharmaceuticals, Inc.*, No. 11-cv-00046-RGA (D. Del.).

10. This Court has also exercised jurisdiction in other actions seeking declaratory judgment which involved lamotrigine extended-release tablet products and the patents-in-suit, including, but not limited to: *Lotus Pharmaceutical Co., Ltd. v. GlaxoSmithKline LLC, et al.*, No. 16-cv-00377-GMS (D. Del) and *Amneal Pharmaceuticals LLC v. GlaxoSmithKline LLC, et al.*, No. 16-cv-0300-SLR (D. Del.).

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b). Venue is also proper in the District under 28 U.S.C. § 1391 because GGL is an alien corporation subject to personal jurisdiction in the District.

PATENTS-IN-SUIT

12. On its face, the '512 Patent entitled "Formulations and Method of Treatment" indicates it was issued by the United States Patent and Trademark Office on January 28, 2014. A copy of the '512 Patent is attached hereto as **Exhibit A.**

13. According to the records at the United States Patent and Trademark Office, GGL is the assignee of the '512 Patent. Upon information and belief, GSK is the exclusive licensee of the '512 Patent with respect to commercializing pharmaceutical products containing lamotrigine in the United States.

14. On its face, the '547 Patent entitled "Oral Dosage Form for Controlled Drug Release" indicates it was issued by the United States Patent and Trademark Office on September 29, 2015. A copy of the '547 Patent is attached hereto as **Exhibit B.**

15. According to the records at the United States Patent and Trademark Office, GGL is the assignee of the '547 Patent. Upon information and belief, GSK is the exclusive licensee of the '547 Patent with respect to commercializing pharmaceutical products containing lamotrigine in the United States.

BACKGROUND

16. Before marketing a new drug in the United States, a manufacturer must submit a New Drug Application ("NDA") to the FDA, and the FDA must approve it. Once approved, new drugs generally are referred to as brand name drugs because they are marketed under a trade name or trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

17. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to the FDA information on each patent that claims the drug

or a method of using the drug that is the subject of the NDA with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, sale or importation of the drug product. A brand name drug manufacturer should submit patent information – the patent's number and its expiration date – in connection with its NDA if the patent claims a drug or claims a method of using the drug covered by the NDA. 21 U.S.C. §355(b)(1); 21 C.F.R. §314.53.

18. Once the FDA approves an NDA, the FDA lists the patent information submitted by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. §355(b)(1).

19. With respect to generic drug products, the Hatch-Waxman Act authorizes the submission of an ANDA to seek approval of a generic version of any Reference Listed Drug ("RLD") in the Orange Book. The Hatch-Waxman Act further authorizes the inclusion within an ANDA of a so-called "Paragraph IV" certification, in which the applicant certifies to the FDA that the proposed ANDA product will not infringe any valid and enforceable claim of one or more patents in the Orange Book for the RLD. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. With respect to any such Paragraph IV certification, the ANDA applicant must provide notice of the certification to the patent holder and the holder of the New Drug Application for the RLD ("the NDA holder"), along with a statement of the factual and legal basis for its certification ("Notice Letter"). The filing of an ANDA with a Paragraph IV certification creates jurisdiction so that the patent and NDA holder may commence a patent infringement action within 45 days of receiving that notice ("the 45-day statutory period"). *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa) and 35 U.S.C. § 271(e)(2).

21. The Hatch-Waxman Act expressly authorizes the bringing of a declaratory judgment action under 28 U.S.C. § 2201 where the following conditions are met: (1) the 45-day statutory period for the patent and NDA holder to bring suits has passed, without either entity having brought suit, and (2) the ANDA applicant included with its Paragraph IV certification notice a statutory offer of confidential access to review the ANDA to the patent and NDA holders. *See* 21 U.S.C. § 355(j)(5)(C)(i).

22. In order to encourage generic market entry, the first ANDA applicant to file a substantially complete ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period.

23. In December 2003, Congress passed the MMA. Title XI of that Act is entitled "Access to Affordable Pharmaceuticals" and includes a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the patent owner or NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. §355(j)(5)(C).

24. In order to prevent a First Filer from unduly delaying generic market competition, the MMA also added provisions whereby the First Filer will forfeit the 180-day exclusivity period. 21 U.S.C. §355 (j)(5)(D). One such forfeiture provision provides that the First Filer forfeits the 180-day exclusivity period if it does not market its product within 75 days after "a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent [which entitled the first applicant to exclusivity] is invalid or not infringed." Once the exclusivity period has run or been forfeited, the FDA may grant final approval to subsequently filed ANDAs.

25. Thus, removal of a blocking exclusivity period may be obtained by a final judgment that all patents which are the subject of the Paragraph IV certification giving rise to exclusivity are not infringed or are invalid. *See* 21 U.S.C. *§* 355(j)(5)(D)(i)(I). The Hatch-Waxman Act expressly provides that such a final judgment may come from a declaratory judgment action brought by a generic challenger. *Id.* Upon such a forfeiture, the FDA may grant final approval to the generic challenger's ANDA.

FACTS

26. On information and belief, GSK is the holder of approved NDA No. 22-115 for Lamictal XR® containing 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg lamotrigine.

27. GSK caused the '512 and '547 Patents to be listed in the Orange Book with respect to the RLD Lamictal XR® shortly after these patents' respective dates of issuance on January 28, 2014 (the '512 Patent), and September 29, 2015 (the '547 Patent).

28. By listing the '512 and '547 Patents in the Orange Book, GSK represented to the FDA that such patents are those 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." 21 U.S.C. §355(b)(1).

29. As a consequence of listing the '512 and '547 Patents in the Orange Book, GSK maintains, and has affirmatively represented to the FDA and the public, that the '512 and '547 Patents claim the product approved in NDA No. 22-115, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant, including DRL, seeking FDA approval to market a generic version of the drug prior to the expiration of the '512 and '547 Patents.

30. On November 1, 2010, DRL submitted ANDA No. 202383 to the FDA for

proposed extended release drug products containing 25 mg, 50 mg, 100, mg, and 200 mg lamotrigine.

31. While DRL's original ANDA No. 202383 did not include the product containing 250 mg lamotrigine, DRL filed a Supplement to ANDA No. 202383 to add the 250 mg lamotrigine dosage on June 30, 2014. The RLD for DRL's 250 mg ANDA product is GSK's Lamictal XR® tablets containing 250 mg of lamotrigine.

32. All other dosages of DRL's proposed ANDA Product have been approved by the FDA except for DRL's 250 mg ANDA Product which was added in the Supplement to the original ANDA No. 202383.

33. With respect to ANDA No. 202383 for DRL's 250 mg lamotrigine extended release tablets, DRL amended its ANDA to include a Paragraph IV Certification for the '512 Patent on November 21, 2014. DRL served GSK and GGL with a Notice Letter dated November 21, 2014 informing them of DRL's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of DRL's 250 mg ANDA Product before the expiration of the '512 Patent. DRL's Notice Letter complied fully with 35 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95. In addition, DRL's Notice Letter included an offer of access to confidential information within the meaning of 271 U.S.C. § 355(j)(5)(C)(i)(III). Neither GSK nor GGL brought an action for infringement of the '512 Patent against DRL within the 45-day statutory period.

34. Shortly after the '547 Patent issued on September 28, 2015, GSK caused it to be listed in the Orange book for Lamictal XR®. DRL thereafter amended its ANDA to include a Paragraph IV certification for the '547 Patent. DRL served GSK and GGL with a Notice Letter dated May 24, 2016 informing them of DRL's ANDA seeking approval to engage in the

commercial manufacture, use, importation, offer for sale, or sale of DRL's 250 mg ANDA Product before the expiration of the '547 Patent. DRL's Notice Letter dated May 24, 2016 complied fully with 35 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95. Neither GSK nor GGL brought suit against DRL for infringement of the '547 Patent within the 45-day statutory period.

35. Accordingly, both requirements are met for the declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) the 45-day statutory period has passed without either GSK or GGL bringing an action for infringement, and (2) DRL made the statutory offer of confidential access in connection with both the '512 and '547 Patents. *See* 21 U.S.C. § 355(j)(5)(C)(i).

36. Moreover, notwithstanding GSK's and GGL's decision not to bring suit, DRL's ability to obtain final FDA approval of its 250 mg ANDA Product depends on DRL's ability to obtain a final judgment that its proposed 250 mg ANDA Product does not infringe the '512 and '547 Patents. Publicly available FDA records reflect that a generic challenger filed an ANDA with a Paragraph IV certification as to the '512 Patent on February 12, 2014-shortly after GSK listed the '512 Patent in the Orange Book. This first ANDA filer on Lamictal XR® is presumptively entitled to a period of exclusivity, during which the FDA is statutorily barred from finally approving DRL's 250 mg ANDA Product. It is uncertain, however, when or even if that exclusivity period will begin. Accordingly, DRL may be blocked indefinitely from competing with GSK.

37. To prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides DRL the right to attempt to trigger a forfeiture of the first filer's exclusivity period by obtaining a judgment that the '512 and '547 Patents are not infringed or are invalid. *See* 21

U.S.C. § 355(j)(5)(D)(i)(l).

38. A final judgment of noninfringement in favor of the '512 and '547 Patents in favor of DRL is thus necessary to trigger the forfeiture of the blocking first filer's 180-day exclusivity period, and will thus allow DRL to obtain FDA approval to market DRL's 250 mg ANDA Product. Absent such final judgment, FDA approval of DRL's 250 mg ANDA Product may be indefinitely delayed.

39. Accordingly, actual and justiciable controversies exist between DRL and Defendants relating to the '512 and '547 Patents.

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '512 AND '547 PATENTS

40. DRL repeats and realleges each of the allegations in paragraphs 1-39, as if fully set forth herein.

41. There is a substantial and continuing controversy between Defendants and DRL, and a declaration of rights is both necessary and appropriate to establish that DRL's 250 mg ANDA Product does not infringe any valid or enforceable claim of the '512 and '547 Patents.

42. But for GSK's decision to list the '512 and '547 Patents in the Orange Book, FDA approval of DRL's 250 mg ANDA Product would not have been independently delayed by those patents. DRL is being injured by GSK's actions of requesting the FDA to list the '512 and '547 Patents in the FDA Orange Book and continuing said listings in the FDA Orange Book.

43. DRL's injury can be redressed by the requested relief: a declaratory judgment of noninfringement of DRL's 250 mg ANDA Product would trigger the first applicant's

exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of DRL's 250 mg ANDA Product. If DRL is blocked by the first filer's exclusivity, DRL will be monetarily harmed, as it will lose sales of its 250 mg ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete with GSK and others in the market for extended release lamotrigine tablets containing 250 mg lamotrigine.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests the Court enter judgment as follows:

A. Declaring that the claims of the '512 and '547 Patents have not been infringed by the filing of DRL's ANDA 202383 with respect to DRL's 250 mg ANDA Product;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the 250 mg ANDA Product that is the subject of DRL's ANDA No. 202383 have not infringed, do not infringe, and would not, if marketed, infringe, or induce or contribute to the infringement by others of, any claims of the '512 and '547 Patents;

C. Declaring that the United States Food & Drug Administration may approve DRL's 250 mg ANDA Product of ANDA No. 202383 whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patents-in-suit are not infringed pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa); and any other marketing exclusivity periods to which GSK might otherwise be entitled (including any pediatric exclusivity) with respect to the '512 and '547 Patents is shortened to expire upon the date of entry of judgment in this case;

D. Awarding DRL its costs and such other and further relief that the Court deems just and proper under the circumstances.

Dated: April 12, 2018

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Eve H. Ormerod

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