IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC PHARMACEUTICALS, INC., Plaintiffs, v. GLAXOSMITHKLINE LLC AND GLAXO GROUP LIMITED, Defendants.	C.A. No.

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY

Plaintiffs Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively, "Alembic" or "Plaintiffs"), by its attorneys, brings this Complaint for a declaratory judgment of patent invalidity against GlaxoSmithKline LLC ("GSK") and Glaxo Group Limited ("GGL") (collectively, "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. Alembic seeks a declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., seeking a declaration of non-infringement of United States Patent Nos. 8,637,512 ("the '512 Patent") and 9,144,547 ("the '547 Patent"), to enable Alembic to bring its lamotrigine extended-release 100 mg, 200 mg, 250 mg, and 300 mg tablets as described in Alembic's Abbreviated New Drug Application ("ANDA") No. 211821 ("Alembic's. 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 Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having its corporate office at Alembic Road, Vadodara 390 003, Gujarat, India.

3. Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate office at 750 Highway 202, Bridgewater, NJ 08807. Alembic Pharmaceuticals, Inc. is a wholly-owned subsidiary of Alembic Global Holding SA which is a wholly owned subsidiary of Alembic Pharmaceuticals Limited.

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 claim arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*., and 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 Alembic is free, upon approval by the United States Food and Drug Administation ("FDA"), to manufacture, use, market, sell, offer to sell, and/or import Alembic's 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), *Amneal Pharmaceuticals LLC v. GlaxoSmithKline LLC, et al.*, No. 16-cv-0300-SLR (D. Del.), and *Dr. Reddy's Laboratories, Inc. v. GlaxoSmithKline LLC, et al.*, No. 18-cv-00548-UNA (D. Del.).

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400. 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.

FACTUAL BACKGROUND

THE 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.

STATUTORY FRAMEWORK GIVING RISE TO CASE OR CONTROVERSY

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. Each strength of a drug product is afforded its own separate exclusivity that may run concurrently with the exclusivity of other strengths.

24. 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).

25. 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 ("the 75 day period") 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.

26. The generic filer that receives a final decision from which no appeal has been or can be taken must receive tentative approval before this forfeiture provision to becomes effective.

27. That said, tentative approval is "not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1366 (Fed. Cir. 2015).

28. Even if a generic filer receives tentative approval after the entry of a final decision of invalidity or non-infringement, the FDA will retroactively begin the 75 day period starting on the date of that final decision, once tentative approval has been granted.

29. 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).

30. 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.

ALEMBIC'S ANDA IS "PARKED" BEHIND AN UNKNOWN FIRST APPLICANT

31. On information and belief, GSK holds the approved NDA No. 22-115 for Lamictal XR® containing 25, 50, 100 200, 250, and 300 mg lamotrigine under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

32. 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).

33. 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).

34. 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 Alembic, seeking FDA approval to market a generic version of the drug prior to the expiration of the '512 and '547 Patents.

35. Publicly available FDA records reflect that a generic challenger filed an ANDA with a Paragraph IV certification as to the '512 Patent for the 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg tablets, on February 12, 2014, shortly after GSK listed the '512 Patent in the Orange Book.

36. This first ANDA applicant on Lamictal XR® with a Paragraph IV certification is presumptively entitled to a period of exclusivity, during which the FDA is statutorily barred from finally approving Alembic's ANDA Product.

37. The identity of this presumptive first applicant is unknown.

38. Upon information and belief, this presumptive first applicant has not received approval of its ANDA from the FDA, tentative or otherwise.

39. Upon information and belief, with the exception of the 250 mg strength, no forfeiture event has occurred that would divest first applicant exclusivity for the presumptive first applicant's ANDA under 21 U.S.C. §§ 355(j)(5)(D), nor has the FDA determined that any such forfeiture has occurred.

40. Three generic filers have sought and received final declaratory judgments of noninfringement of the '512 and '547 Patents. *Lotus Pharmaceutical Co., Ltd. v. GlaxoSmithKline LLC, et al.*, No. 16-cv-00377-GMS (D. Del), *Amneal Pharmaceuticals LLC v. GlaxoSmithKline LLC, et al.*, No. 16-cv-0300-SLR (D. Del.), and *Dr. Reddy's Laboratories, Inc. v. GlaxoSmithKline LLC, et al.*, No. 18-cv-00548-UNA (D. Del.).

41. Of those three generic filers, publicly available FDA records indicate that only Dr. Reddy's has received tentative approval.

42. Dr. Reddy's only sought judgment of non-infringement as to the 250 mg strength.

43. Therefore, a triggering event sufficient to start the First Filer's 75 day period to market or otherwise forfeit its exclusivity has occurred with respect to the 250 mg strength only.

44. On March 27, 2018, Alembic submitted ANDA No. 211821 to the FDA for proposed extended release drug products containing 100, mg, 200 mg, 250 mg, and 300 mg lamotrigine.

45. Alembic is not a first ANDA applicant with a Paragraph IV certification seeking to market a generic version Lamictal XR®.

46. Alembic's ANDA No. 211821 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '512 and '547 Patents are unenforceable, invalid and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in ANDA No. 211821.

47. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on May 21, 2018, Alembic sent GSK and GGL notice of Alembic's Paragraph IV certification with ANDA No. 211821 ("Alembic's Notice Letter").

48. Alembic's Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 211821 to each Defendant so that each could determine whether Alembic's generic products would infringe any valid claim of the Orange Book-listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

49. Alembic's Notice Letter initiated a 45-day statutory period during which Defendants had the opportunity to file an action for patent infringement.

50. Neither GSK nor GGL brought an action for infringement of the '512 or '547 Patents against Alembic within the 45-day statutory period.

51. 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) Alembic 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).

52. Moreover, notwithstanding GSK's and GGL's decision not to bring suit, Alembic's ability to obtain final FDA approval of its ANDA Product depends on Alembic's ability to obtain a final judgment that its proposed ANDA Product does not infringe the '512 and '547 Patents. Accordingly, Alembic may be blocked indefinitely from competing with GSK.

53. Publicly available FDA records reflect that at least one first applicant filed an ANDA with a Paragraph IV certification as to the '512 Patent, and is presumptively entitled to a period of exclusivity during which the FDA is statutorily barred from finally approving Alembic's ANDA.

54. It is uncertain, however, when or even if that exclusivity period will begin. Accordingly, Alembic may be blocked indefinitely from competing with GSK.

55. To prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides Alembic 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).

56. "[T]he dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs.,* 527 F.3d 1278, 1296-97 (Fed. Cir. 2008) (citation omitted).

COUNT I
(Declaratory Judgment of Noninfringement of the '512 Patent)

57. Plaintiffs repeat and reallege Paragraphs 1-56 as though fully set forth herein.

58. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

59. For at least these reasons, Alembic's ANDA Product does not infringe the claims of the '512 Patent either literally or under the Doctrine of Equivalents.

60. There is a real, immediate, substantial, and justiciable controversy between the Plaintiffs and Defendants, and a declaration of rights is both necessary and appropriate to establish that Alembic's ANDA Product does not infringe any valid or enforceable claim of the '512 Patent.

61. But for GSK's decision to list the '512 Patent in the Orange Book, FDA approval of Alembic's ANDA Product would not be delayed by those patents. Alembic is being injured by GSK's actions of requesting the FDA to list the '512 Patent in the FDA Orange Book and continuing said listings in the FDA Orange Book.

62. Alembic's injury can be redressed by the requested relief: a declaratory judgment of noninfringement of Alembic's ANDA Product would trigger the first applicant's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Alembic's ANDA Product. If Alembic is blocked by the first filer's exclusivity, Alembic will be monetarily harmed, as it will lose sales of its 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.

COUNT II
(Declaratory Judgment of Noninfringement of the '547 Patent)

63. Plaintiffs repeat and reallege Paragraphs 1-62 as though fully set forth herein.

64. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. Alembic's ANDA Product does not infringe the claims of the '547 Patent either literally or under the Doctrine of Equivalents.

66. There is a real, immediate, substantial, and justiciable controversy between the Plaintiffs and Defendants, and a declaration of rights is both necessary and appropriate to establish that Alembic's ANDA Product does not infringe any valid or enforceable claim of the '547 Patent.

67. But for GSK's decision to list the '547 Patent in the Orange Book, FDA approval of Alembic's ANDA Product would not be delayed by those patents. Alembic is being injured by GSK's actions of requesting the FDA to list the '547 Patent in the FDA Orange Book and continuing said listings in the FDA Orange Book.

68. Alembic's injury can be redressed by the requested relief: a declaratory judgment of noninfringement of Alembic's ANDA Product would trigger the first applicant's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Alembic's ANDA Product. If Alembic is blocked by the first filer's exclusivity, Alembic will be monetarily harmed, as it will lose sales of its 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask this Court to enter judgment in its favor and against Defendants and against Defendants' respective subsidiaries, successors, parents, affiliates, officers, directors, agents, servants and employees, and all persons in active concert or participation with Defendants, granting the following relief:

A. Declaring that the claims of the '512 and '547 Patents have not been infringed by the filing of Alembic's ANDA 211821 with respect to Alembic's ANDA Product;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the ANDA Product that is the subject of Alembic's ANDA No. 211821 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 Alembic's ANDA Product of ANDA No. 211821 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. For a judgment declaring that this case is exceptional and awarding Alembic its expenses, costs, and attorneys' fees in accordance with 35 U.S.C. § 285 and Rule 54(d) of the Federal Rules of Civil Procedure; and

E. For such other relief to which Alembic is entitled under law, and any other and further relief that this Court or a jury may deem just and proper.

/s/ Kelly E. Farnan

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