**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| Lotus Pharmaceutical Co., Ltd.<br><br>Plaintiff,<br><br>v.<br><br>Glaxosmithkline LLC and Glaxo Group Limited<br><br>Defendants. | Civil Action No. _____ |

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Lotus Pharmaceutical Co., Ltd. ("Lotus"), through counsel, hereby brings this Complaint for Declaratory Judgment against Glaxosmithkline LLC and Glaxo Group Limited (collectively, "Defendants"), and alleges as follows:

**INTRODUCTION**

1. This is a declaratory judgment action seeking a declaration of noninfringement of U.S. Patent Nos. 8,637,512 ("the '512 Patent") and 9,144,547 ("the '547 Patent") to enable Lotus to bring its generic extended release lamotrigine tablets to market at the earliest possible date under the applicable statutory and regulatory provisions and to allow the public to enjoy the benefits of increased generic competition for these products.

**THE PARTIES**

2. Lotus Pharmaceutical Co., Ltd. is a Taiwanese corporation having offices located at No. 30 Chenggong 1st Road, Nantou City, Nantou County 540, Taiwan.

3. Upon information and belief, Defendant GlaxoSmithKline LLC ("GSK") 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

4. Upon information and belief, Defendant Glaxo Group Limited ("GGL") 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 ONN, Great Britain.

## JURISDICTION AND VENUE

5. 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) (the "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) (the "MMA"), based upon an actual controversy between the parties to declare that Lotus is free, upon approval by the Food and Drug Administration's ("FDA"), to manufacture, use, market, sell, offer to sell and/or import its Lamotrigine Extended Release product as described in Lotus's abbreviated new drug application ("ANDA") No. 204501 ("Lotus's ANDA Product").

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

7. 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 substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware.

8. On information and belief, Defendants regularly conduct or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware, including through their own actions and/or the actions of their affiliates and agents, demonstrating that Defendants have continuous and systematic contacts with 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 Limitedv. Teva Pharmaceuticals USA, Inc.,* No. 02-219-GMS (D. Del.); *GlaxoSmithKline LLC v. Roche Holding Ltd.,* No. 1 0-cv-799-GMS (D. Del.); *GlaxoSmithKline LLC v. Anchen Pharmaceuticals, Inc.,* No. 11-cv-00046-RGA (D. Del.).

10. 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**

11. 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.**

12. 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.

13. 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.**

14. 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

New Drugs and Patent Listing Requirements

15. Before marketing a new drug in the United States, a manufacturer must submit a New Drug Application (“NDA”) to FDA, and 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.

16. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to 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.

17. Once FDA approves an NDA, 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).

18. Generic Drug Applications and Patent Certification Requirements

19. A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product.

20. Before marketing a generic drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it. An ANDA applicant must show that its generic drug is bioequivalent to the previously approved brand name drug.

21. Generic drugs typically enjoy a significant price advantage over their brand name counterparts. Consequently, generic drugs are frequently prescribed in an effort to control healthcare costs. Generic drugs represent a substantial and increasing portion of the medicines used in the United States.

22. A generic drug manufacturer seeking FDA approval for a generic version of a brand name drug product must file one of four certifications with FDA: (i) that the brand name drug manufacturer has not filed patent information with FDA; or, for each patent listed in the Orange Book as claiming the brand name drug or a method of use for which the ANDA applicant is seeking approval; (ii) that the patent has expired; (iii) that the patent expires on a date before which the generic manufacturer is seeking to market its generic product; or (iv) that the patent claiming the brand name drug is invalid, unenforceable, or will not be infringed by the manufacturer, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. §355(j)(2)(A)(vii); 21 C.F.R. §314.94(a)(12)(i)(a)(4). The final certification is commonly referred to as a Paragraph IV certification.

23. If an ANDA applicant submits an ANDA with a Paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA. The filing of an ANDA with a Paragraph IV certification creates jurisdiction so that a brand name drug

manufacturer may commence an action for patent infringement against the ANDA applicant. See 35 U.S.C. §271(e)(2).

Generic Marketing Exclusivity

24. 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.

25. 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 NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. §355(j)(5)(C).

26. In order to prevent a First Filer from unduly delaying generic market competition, the MMA also added provisions whereby the First Filer forfeits 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." 21 U.S.C. §355(j)(5)(D)(i)(I)(bb).

27. GSK's NDA and Patent Certifications by ANDA Filers

28. On information and belief, GSK is the current holder of approved NDA No. 22-115 for Lamictal XR®.

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

30. By listing the ’512 and ’547 Patents in the Orange Book, GSK represented to 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).

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

32. On June 15, 2012, Lotus submitted ANDA No. 204501 (“Lotus’s ANDA”) to the FDA for proposed extended release drug products containing 25mg, 50mg and 100 mg of lamotrigine ("Lotus’s ANDA product"). The RLD for Lotus’s ANDA is GSK's Lamictal XR® tablets.

33. On October 22, 2014, Alvogen Pine Brook, Inc. (now Alvogen Pine Brook LLC) as U.S. agent for Lotus, sent a Notice Letter to Defendants notifying them that Lotus’s ANDA was amended to include a Paragraph IV certification to the ’512 Patent. The October 22, 2014, Notice Letter included a detailed statement of the factual and legal bases for Lotus’s Paragraph IV certification and an Offer of Confidential Access to Lotus’s ANDA pursuant to 21 U.S.C. §355(j)(5)(C)(i)(III).

34. On December 4, 2015, Alvogen Pine Brook LLC as U.S. agent for Lotus, sent a Notice Letter to Defendants notifying them that Lotus's ANDA was amended to include a Paragraph IV certification to the '547 Patent. The December 4, 2015, Notice Letter included a detailed statement of the factual and legal bases for Lotus's Paragraph IV certification and an Offer of Confidential Access to Lotus's ANDA pursuant to 21 U.S.C. §355(j)(5)(C)(i)(III).

35. Lotus's submission of the Lotus ANDA to FDA containing a Paragraph IV certification to the '512 and '547 Patents creates the necessary case or controversy and subject matter jurisdiction for Lotus to obtain declaratory judgment against Defendants regarding infringement of the '512 and '547 Patents.

36. As of today's date, Defendants did not bring an action for infringement of the '512 and '547 Patents against Lotus.

37. Pursuant to 21 U.S.C. §355(j)(5)(C), an ANDA applicant may bring a declaratory judgment action for invalidity or noninfringement of an Orange Book listed patent if neither the NDA holder nor patent owner files suit within 45 days of receiving the notice letter, provided that an offer of confidential access accompanied the notice letter in an instance where the notice letter asserts noninfringement.

38. Defendants did not file suit against Lotus within 45 days of receiving Lotus's Notice Letters.

39. Lotus remains under threat of an infringement suit relating to the '512 and '547 Patents because the 45-day window under 21 U.S.C. §355(j)(5)(B)(iii) does not preclude Defendants from pursuing subsequent patent infringement suits relating to Lotus's ANDA against Lotus under 35 U.S.C. §271(e)(2)(A) or, upon FDA approval of Lotus's ANDA under 35 U.S.C. §§271(a), (b) and/or (c).

40. Moreover, notwithstanding GSK's and GGL's decision not to bring suit, Lotus's ability to obtain final FDA approval of its ANDA depends on Lotus's ability to obtain a final judgment that its proposed product does not infringe the '512 and '547 Patents. Publicly available FDA records reflect that an unknown 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 unknown first ANDA filer on Lamictal XR® is presumptively entitled to a period of exclusivity, during which the FDA is statutorily barred from finally approving Lotus's ANDA. It is uncertain, however, when or even if that exclusivity period will begin. Accordingly, Lotus may be blocked indefinitely from competing with GSK.

41. To prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides Lotus 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)(I).

42. Among other things, a final and nonappealable judgment of noninfringement of the '512 and '547 Patents would trigger the forfeiture of the first filer's presumptive 180-day exclusivity period, allowing Lotus to obtain FDA approval to market its ANDA Product. Absent such judgment, FDA approval of Lotus's ANDA may be indefinitely delayed.

43. Actual and justiciable controversies exist between Lotus and Defendants relating to the '512 and '547 Patents.

**COUNT 1: DECLARATION OF NONINFRINGEMENT OF THE '512 AND '547 PATENTS**

44. Lotus repeats and realleges Paragraphs 1-41 as if fully set forth therein.

45. An actual and justiciable controversy between Defendants and Lotus regarding the noninfringement of the '512 and '547 Patents, and a declaration of rights is both necessary and

appropriate to establish that Lotus does not infringe any valid or enforceable claim of the ’512 and ’547 Patents.

46. But for GSK's decision to list the ’512 and ’547 Patents in the Orange Book, FDA approval of Lotus’s ANDA would not have been independently delayed by those patents. Lotus 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.

47. Lotus's injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger a forfeiture of the unknown first applicant's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Lotus’s ANDA. If Lotus is blocked by the first filer's exclusivity, Lotus 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, Lotus respectfully requests that the Court enter judgment as follows:

A. that Lotus does not infringe the claims of the ’512 and ’547 Patents;

B. that the submission of Lotus’s ANDA does not constitute infringement of the claims of the ’512 or ’547 Patents;

C. that the commercial manufacture, use, sale, offer for sale or importation of Lotus’s ANDA Product does not and will not infringe the ’512 and ’547 Patents;

D. that Defendants, their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with Defendants be preliminarily and permanently enjoined from using the ’512 and ’547 Patents to block, hamper, hinder or obstruct

FDA approval and/or the commercial manufacture, use, sale, offer for sale or importation of the products described in Lotus's ANDA; and

E. that Lotus be awarded such other and further relief as the Court deems just and proper.

PROCTOR HEYMAN ENERIO LLP

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