IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. MACLEODS PHARMACEUTICALS LTD. AND MACLEODS PHARMA USA, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Macleods Pharmaceuticals Ltd. ("Macleod Ltd.") and Macleods Pharma USA, Inc. ("Macleods Inc.") (collectively, "Macleods"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent") and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Macleods' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the patents in suit.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the ’362 and ’419 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Macleods Ltd. is a corporation organized under the laws of India and its principal place of business is located at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai - 400059, India.

6. Upon information and belief, Macleods Inc. is a coproration organized under the laws of Delaware and its principal place of business is located at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Macleods Ltd. Upon information and belief, Macleods Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Macleods Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Macleods’ generic products.

9. Upon information and belief, Macleods Ltd. admits it has "expand[ed] and file[d] products for approval in the . . . U.S. market[]." https://www.macleodspharma.com/UnitedStates.asp (accessed Oct. 29, 2019). Upon information and belief, Macleods Ltd. has filed "more than 150 Abbreviated New Drug Applications (ANDAs) and has received FDA approval on 62." *Id.*; *see also* https://www.macleodspharma.com/products_US_Appr.asp. Upon information and belief, Macleods Ltd. has facilities to manufacture tablets, hard gelatin capsules, soft gelatin capsules, dry powder injections, dry syrups, granules and liquid orals in "facilities approved by international regulatory agencies including USFDA[.]" https://www.macleodspharma.com/manufacturing.asp (accessed Oct. 29, 2019). Upon information and belief, Macleods Ltd. admits it "has [the] ability to manufacture a wide range of finished drug products and Active Pharmaceutical ingredients in GMP facilities thus ensuring product quality and packaging to meet with international standards." *Id*.

10. Upon information and belief, Macleods Ltd. is the holder of FDA Drug Master File No. 33482 for brexpiprazole.

11. This Court has personal jurisdiction over Macleods Inc. Upon information and belief, Macleods Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Macleods Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Macleods' generic products.

12. Upon information and belief, Macleods Inc. is "the U.S. division" of Macleods Ltd. https://www.macleodspharma.com/UnitedStates.asp (accessed Oct. 29, 2019). Upon information

and belief, Macleods Inc. admits it is "staffed by an experienced management team with years of experience in the . . . U.S. Generics market." *Id.*

13. Upon information and belief, Macleods Ltd. and Macleods Inc. hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

14. Upon information and belief, Macleods Ltd. admits it is "A Vertically Integrated Global Pharmaceutical Company." https://www.macleodspharma.com/default.asp (accessed Oct. 29, 2019). Upon information and belief, Macleods Ltd. admits its mission is "[t]o be a strong vertically integrated global generic manufacturer." https://www.macleodspharma.com/mission_vision.asp (accessed Oct. 29, 2019). Upon information and belief, Macleods Ltd. and Macleods Inc. admit "Macleods Pharma USA is the U.S. division of Macleods Pharmaceuticals, LTD, a developer and manufacturer of Generic Active Pharmaceutical Ingredients (API) and Finished Dosage Forms." https://www.macleodspharma.com/UnitedStates.asp (accessed Oct. 29, 2019). Upon information and belief, Macleods Ltd. and Macleods Inc. admit that "[t]he U.S. division is based in Plainsboro, NJ and ships its products from its FDA inspected, VAWD certified warehouse in Indianapolis." *Id.*

15. Upon information and belief, Macleods Ltd. manufactures its generic products for marketing and/or distribution by Macleods Inc. in the United States. *See, e.g.*, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/macleods-pharmaceutical-limited-issues-voluntary-nationwide-consumer-level-recall-losartan-potassium (Macleod's losartan potassium label stating "Manufactured by: [Macleods Ltd.] . . . Manufactured for: [Macleods Inc.]") (accessed Oct. 30, 2019); https://www.accessdata.fda.gov/scripts/ires/index.

cfm?Product=175131 (accessed Oct. 30, 2019) (Macleods Inc. recalls from U.S. market Tamsulosin Hydrochloride Capsules manufactured by Macleods Ltd.).

16. Macleods' ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Macleods' intent to market and sell Macleods' generic products in this judicial district.

17. Macleods has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Macleods intends to direct sales of its generic drugs in this judicial district, among other places, once Macleods receives the requested FDA approval to market its generic products. Upon information and belief, Macleods will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

18. Upon information and belief, Macleods has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213723.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Macleods Ltd. is incorporated in India and may be sued in any judicial district.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Macleods Inc. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

21. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

22. The FDA approved NDA No. 205422 on July 10, 2015.

23. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patents In Suit

24. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as Exhibit A.

25. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

26. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

27. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986 days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

28. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

29. The PTO issued the ’419 patent on June 4, 2019, entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” A true and correct copy of the ’419 patent is attached as Exhibit D.

30. Otsuka owns the ’419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

31. The ’419 patent expires on October 12, 2032.

32. The ’419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

33. Upon information and belief, Macleods filed ANDA No. 213723 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg (“Macleods’ generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets.

34. Upon information and belief, ANDA No. 213723 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the ’362 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use or sale of the 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg dosage strengths of Macleods’ generic products (“Macleods’ Group I products”).

35. Upon information and belief, ANDA No. 213723 contains paragraph IV certifications, alleging that the claims of the ’419 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use or sale of the 0.25 mg, 0.5 mg, 1 mg, 2 mg and 3 mg dosage strengths of Macleods’ generic products (“Macleods’ Group II products”).

36. Otsuka received a letter sent by Macleods, dated September 17, 2019, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213723 ("Macleods' Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c). Macleods' Notice Letter notified Otsuka that Macleods had filed ANDA No. 213723, seeking approval to engage in the commercial manufacture, use or sale of Macleods' Group I products and Macleods' Group II products before the expiration of the '362 patent and the '419 patent, respectively.

37. Plaintiffs commenced this action within 45 days of receiving Macleods' Notice Letter.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

38. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

39. Upon information and belief, Macleods filed ANDA No. 213723 seeking approval to manufacture, use, import, offer to sell and/or sell Macleods' Group I products in the United States before the expiration of the '362 patent.

40. Upon information and belief, Macleods filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

41. Upon information and belief, in its ANDA No. 213723, Macleods has represented to the FDA that Macleods' Group I products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

42. Macleods has actual knowledge of Otsuka's '362 patent, as evidenced by Macleods' Notice Letter.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed one or more claims of the ’362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213723, seeking approval to commercially manufacture, use, import, offer to sell or sell Macleods’ Group I products before the expiration date of the ’362 patent.

44. Upon information and belief, if ANDA No. 213723 is approved, Macleods intends to and will offer to sell, sell and/or import in the United States Macleods’ Group I products.

45. Upon information and belief, if ANDA No. 213723 is approved, Macleods will infringe one or more claims of the ’362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Macleods’ Group I products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213723 shall be no earlier than the expiration of the ’362 patent and any additional periods of exclusivity.

46. Upon information and belief, Macleods’ actions relating to Macleods’ ANDA No. 213723 complained of herein were done by and for the benefit of Macleods.

47. Plaintiffs will be irreparably harmed by Macleods’ infringing activities unless this Court enjoins those activities.

48. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE ’419 PATENT)

49. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

50. Upon information and belief, Macleods filed ANDA No. 213723 seeking approval to manufacture, use, import, offer to sell and/or sell Macleods’ Group II products in the United

States before the expiration of the ’419 patent.

51. Upon information and belief, Macleods filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’419 patent are invalid, unenforceable and/or not infringed.

52. Upon information and belief, in its ANDA No. 213723, Macleods has represented to the FDA that Macleods’ Group II products are pharmaceutically and therapeutically equivalent to Otsuka’s REXULTI® Tablets.

53. Macleods has actual knowledge of Otsuka’s ’419 patent, as evidenced by Macleods’ Notice Letter.

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed one or more claims of the ’419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213723, seeking approval to commercially manufacture, use, import, offer to sell or sell Macleods’ Group II products before the expiration date of the ’419 patent.

55. Upon information and belief, if ANDA No. 213723 is approved, Macleods will infringe one or more claims of the ’419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Macleods’ Group II products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213723 shall be no earlier than the expiration of the ’419 patent and any additional periods of exclusivity.

56. Upon information and belief, Macleods’ actions relating to Macleods’ ANDA No. 213723 complained of herein were done by and for the benefit of Macleods.

57. Plaintiffs will be irreparably harmed by Macleods’ infringing activities unless this

Court enjoins those activities.

58. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Macleods has infringed at least one claim of the ’362 patent through Macleods’ submission of ANDA No. 213723 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Macleods’ Group I products in the United States before the expiration of the ’362 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Macleods’ making, using, offering to sell, selling or importing of Macleods’ Group I products before the expiration of the ’362 patent will infringe, actively induce infringement and/or contribute to the infringement of the ’362 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Macleods’ Group I products shall be no earlier than the expiration date of the ’362 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Macleods and all persons acting in concert with Macleods from commercially manufacturing, using, offering for sale or selling Macleods’ Group I products within the United States, or importing Macleods’ Group I products into the United States, until the expiration of the ’362 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Macleods has infringed at least one claim of the ’419 patent through Macleods’ submission of ANDA No. 213723 to the

FDA seeking approval to manufacture, use, import, offer to sell and/or sell Macleods' Group II products in the United States before the expiration of the '419 patent;

F. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Macleods' making, using, offering to sell, selling or importing of Macleods' Group II products before the expiration of the '419 patent will infringe, actively induce infringement and/or contribute to the infringement of the '419 patent under 35 U.S.C. § 271(a), (b) and/or (c);

G. The issuance of an order that the effective date of any FDA approval of Macleods' Group II products shall be no earlier than the expiration date of the '419 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

H. The entry of a preliminary and/or permanent injunction, enjoining Macleods and all persons acting in concert with Macleods from commercially manufacturing, using, offering for sale or selling Macleods' Group II products within the United States, or importing Macleods' Group II products into the United States, until the expiration of the '419 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

I. The entry of a preliminary and/or permanent injunction, enjoining Macleods and all persons acting in concert with Macleods from seeking, obtaining or maintaining approval of the ANDA until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

K. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

L. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S

Of Counsel:

James B. Monroe
Denise Main
Erin M. Sommers
Tyler B. Latcham
C. Collette Corser
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Dated: October 30, 2019