

**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 Case No. 1:21-cv-00316-LPS

**MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.’S
ANSWER, AND AFFIRMATIVE DEFENSES**

Defendants Macleods Pharmaceuticals Ltd. (“Macleods Ltd.”) and Macleods Pharma USA, Inc. (“Macleods USA”) (collectively, “Defendants”), hereby provide their answer to the complaint of Plaintiffs Otsuka Pharmaceutical Co, Ltd. (“Otsuka”) and H. Lundbeck A/S (“Lundbeck”) (collectively, "Plaintiffs") as follows.

GENERAL DENIAL

Defendants deny each and every allegation of the Complaint that is not specifically admitted or qualified below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 (“the RE’059 patent”), 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 RE’059 patent.

ANSWER: Defendants admit that this action purports to be an action for patent infringement relating to an ANDA that Macleods Ltd., filed seeking FDA approval to market a

certain generic pharmaceutical product before expiration of the patent in suit. Defendants deny any infringement and deny the remaining allegations contained in Paragraph 1 of the Complaint.

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.

ANSWER: Defendants lack knowledge information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint and therefore deny them.

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 RE'059 patent.

ANSWER: Defendants lack knowledge information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint and therefore deny them.

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

ANSWER: Defendants lack knowledge information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the Complaint and therefore deny them.

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.

ANSWER: Defendants admit that Macleods Pharma is organized under the laws of India and has its corporate offices at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai - 400059, India. Defendants deny any infringement and deny the remaining allegations contained in Paragraph 5 of the Complaint.

6. Upon information and belief, Macleods Inc. is a corporation 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.

ANSWER: Defendants admit that Macleods USA is a corporation organized under the laws of Delaware with a principal place of business at 666 Plainsboro Rd, Ste 230, Plainsboro, NJ 08536.

JURISDICTION AND VENUE

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

ANSWER: Admitted.

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.

ANSWER: Defendants deny the allegations contained in Paragraph 8 of the Complaint. Nevertheless, Macleods Ltd., does not contest personal jurisdiction for the purpose of this action only.

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.*

ANSWER: Macleods Ltd., admits that statements made on its website were believed to be true at the time made. Macleods Ltd. does not contest personal jurisdiction for the purpose of this action only.

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

ANSWER: Admitted.

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.

ANSWER: Defendants admit that this Court has personal jurisdiction over Macleods Inc.

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.* Upon information and belief, Macleods Inc. states that "[s]upported ably by our parent company in India [Macleods Ltd.], we have now emerged as a vital player in the pharmaceutical market in USA." <https://www.macleodspharma.com/usa/> (accessed Mar. 1, 2021). Upon information and belief, Macleods Inc. "possess[es] close to 90 approvals with U.S. Food and Drug Administration." *Id.* Upon information and belief, Macleods Inc. states that "[it looks] forward to unveiling a brand- new manufacturing facility for finished dosages, exclusively for the US market." *Id.*

ANSWER: Defendants admit that the quoted language appears on the cited web pages.

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.

ANSWER: Defendants deny the allegations contained in Paragraph 13 of the Complaint. Nevertheless, Defendants do not dispute this Court's personal jurisdiction over them for the purpose of this case only.

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.*

ANSWER: Macleods Ltd. admits that statements made on its website were believed to be true at the time made. Macleods Ltd. does not contest personal jurisdiction for the purpose of this action only.

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 Mar. 1, 2021); <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.).

ANSWER: Defendants deny the allegations contained in Paragraph 15 of the Complaint. Nevertheless, Defendants do not contest personal jurisdiction for the purpose of this action only.

16. Macleods’ ANDA filing regarding the RE’059 patent 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.

ANSWER: Defendants deny the allegations contained in Paragraph 16 of the Complaint. Nevertheless, Defendants do not contest personal jurisdiction for the purpose of this action only.

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.

ANSWER: Defendants admit that Macleods Ltd. has applied for FDA approval to market certain generic drug products. Defendants aver that the other allegations contained in Paragraph 17 of the Complaint are directed to future events and can neither be admitted nor denied at the present. To the extent a response is required, they are denied. Nevertheless, Defendants do not contest personal jurisdiction for the purpose of this action only.

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.

ANSWER: Defendants admit that Macleods Ltd. has filed ANDA No. 213723. Defendants aver that the phrase “prime actor” is vague and ambiguous and prevents a response. To the extent a response is required, it is denied.

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.

ANSWER: Defendants deny the allegations contained in Paragraph 19 of the Complaint. Nevertheless Defendants do not dispute that venue is proper in this District for the purpose of this case only.

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.

ANSWER: Admitted.

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”).

ANSWER: Admitted on information and belief.

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

ANSWER: Admitted on information and belief.

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.

ANSWER: Defendants admit that Rexulti tablets are prescription drugs, and that the active ingredient is brexpiprazole. Defendants admit that Patent Use Code 1529 (“adjunctive treatment of major depressive disorder”) is listed in the FDA Orange Book with respect to certain patents listed against Rexulti.

The Patents In Suit

24. The United States Patent and Trademark Office (“the PTO”) issued the U.S. Patent No. 7,888,362 (“the ’362 patent”) on February 15, 2011, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.”

ANSWER: Admitted on information and belief.

25. The PTO reissued the ’362 patent as the RE’059 patent on June 23, 2020. A true and correct copy of the RE’059 patent is attached hereto as Exhibit A.

ANSWER: Admitted on information and belief.

26. As the reissue of the ’362 patent, Otsuka is the owner of the RE’059 patent through assignment as recorded by the PTO for the ’362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint and therefore deny them.

27. Pursuant to 35 U.S.C. § 251, the RE’059 patent issued for the unexpired term of the ’362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 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.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 of the Complaint and therefore deny them.

28. 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, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the ’362 patent. After the RE’059 patent issued,

Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059, which was granted on October 6, 2020. Thereafter, the Certificate Extending Patent Term Under 35 U.S.C. § 156(c) issued on January 14, 2021, which is attached as Exhibit C. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 of the Complaint and therefore deny them.

29. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: Admitted.

The ANDA

30. 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.

ANSWER: Defendants admit that Macleods Ltd. filed ANDA No. 213723 with the FDA seeking approval to sell generic brexpiprazole.

31. 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’ September 17, 2019, First 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’ September 17, 2019, First Notice Letter notified Otsuka that Macleods had filed ANDA No. 213723, seeking approval to engage in the commercial manufacture, use or sale of Macleods’ generic products before the expiration of the ’362 patent and brexpiprazole tablets, 0.25, 0.5, 1, 2, and 3 mg, before the expiration of U.S. Patent No. 10,307,419 (“the ’419 patent”).

ANSWER: Admitted on information and belief.

32. In response to Macleods’ September 17, 2019, First Notice Letter, Plaintiffs previously filed a separate action in this Court against Macleods for patent infringement, which included counts of infringement of the ’362 and ’419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Macleods Pharmaceuticals Ltd.*, C.A. No. 19-2065-LPS.

ANSWER: Admitted.

33. On June 23, 2020, the PTO reissued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

ANSWER: Plaintiffs lack information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint and therefore deny them.

34. Upon information and belief, ANDA No. 213723 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(VI) ("paragraph IV certification") alleging that the claims of the RE'059 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale of Macleods' generic products.

ANSWER: Admitted.

35. Otsuka received a second notice letter sent by Macleods, dated January 15, 2021, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213723 ("Macleods' January 15, 2021, Second 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' January 15, 2021, Second Notice Letter notified Otsuka that Macleods had filed ANDA No. 213723, seeking approval to engage in the commercial manufacture, use or sale of Macleods' generic products before the expiration of the RE'059 patent.

ANSWER: Admitted on information and belief.

36. Plaintiffs commenced this action within 45 days of receiving Macleods' January 15, 2021, Second Notice Letter.

ANSWER: Plaintiffs lack information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint and therefore deny them.

COUNT 1
(INFRINGEMENT OF THE RE'059 PATENT)

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

ANSWER: Defendants reallege and incorporate by this reference each preceding paragraph of this Answer.

38. Upon information and belief, Macleods filed ANDA No. 213723 seeking approval to manufacture, use, import, offer to sell and/or sell Macleods' generic products in the United States before the expiration of the RE'059 patent.

ANSWER: Defendants admit that Macleods Ltd. filed ANDA No. 213723 seeking the approvals described therein, and deny the remaining allegations contained in Paragraph 38 of the Complaint.

39. 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 RE'059 patent are invalid, unenforceable and/or not infringed.

ANSWER: Defendants admit that Macleods Ltd. filed a Paragraph IV certification in connection with ANDA No. 213723 and deny any remaining allegations in Paragraph 39 of the Complaint.

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

ANSWER: Defendants admit that Macleods Ltd. filed ANDA No. 213723 seeking the approvals and containing the statements described therein, aver that the ANDA speaks for itself, and deny any remaining allegations in Paragraph 40 of the Complaint.

41. Macleods has actual knowledge of Otsuka's RE'059 patent, as evidenced by Macleods' January 15, 2021, Second Notice Letter.

ANSWER: Admitted.

42. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed one or more claims of the RE'059 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' generic products before the expiration date of the RE'059 patent.

ANSWER: Denied.

43. 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' generic products.

ANSWER: Defendants cannot admit or deny the allegations in Paragraph 43 of the Complaint, are directed to future acts and events and cannot be admitted or denied at this time. To the extent a response is required the allegations are denied.

44. Upon information and belief, if ANDA No. 213723 is approved, Macleods will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Macleods' generic 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 RE'059 patent and any additional periods of exclusivity.

ANSWER: Denied.

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

ANSWER: Denied.

46. Plaintiffs will be irreparably harmed by Macleods' infringing activities unless this Court enjoins those activities.

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint or to any other relief whatsoever.

FIRST AFFIRMATIVE DEFENSE

Defendants have not, and will not, infringe directly, by contribution or by inducement, literally or under the doctrine of equivalents, any valid claim of the patent in suit.

SECOND AFFIRMATIVE DEFENSE

One or more claims of the patent in suit are invalid and/or unenforceable for failure to comply with one or more statutory or judicial requirements, including but not limited to the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

One or more count of the Complaint is subject for dismissal for failure to state a claim.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to injunctive relief, at least because any alleged injury to Plaintiffs is not immediate or irreparable, because Plaintiffs have an adequate remedy at law, and because public policy concerns weigh against any injunctive relief.

FIFTH AFFIRMATIVE DEFENSE

Defendants reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws, and any additional defenses that discovery may reveal, including that Plaintiffs have failed to aver any factors supporting the conclusion that this is an exceptional case or that an award of attorney's fees under 35 U.S.C. § 285 is warranted.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully prays for judgment as follows:

- a) Dismissing the Complaint with prejudice; denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;
- b) Awarding Defendants their reasonable attorney's fees under 35 U.S.C. § 285;
- c) Awarding Defendants their costs; and
- d) Awarding Defendants such other and further relief as the Court deems just and equitable.

Dated: June 1, 2021

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