

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

OTSUKA PHARMACEUTICAL CO., LTD.)
AND H. LUNDBECK A/S,)
Plaintiffs,)
v.) Case No. 1:20-cv-01581 (LPS)
AUROBINDO PHARMA LTD. AND)
AUROBINDO PHARMA USA, INC.,)
Defendants.)

ANSWER TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendants Aurobindo Pharma Ltd. (“APL”) and Aurobindo Pharma USA, Inc. (“APUI”) (collectively for identification purposes only, “Aurobindo”), by and through their undersigned counsel, respectfully submit their Answer to Plaintiff’s Complaint, stating as follows:

RESPONSE TO ALLEGATIONS CONCERNING THE 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 Aurobindo’s 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.

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action to assert infringement of the patent identified in this paragraph under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and, therefore, denies the same.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

5. Upon information and belief, Aurobindo Pharma Ltd. is a corporation organized under the laws of India and its principal place of business is located at Plot No. 2, Maitrivihaar, Ameerpet, Hyderabad - 500038, Telangana, India.

RESPONSE: Aurobindo admits that APL is an Indian company organized under the laws of India with a place of business located at Plot No. 2, Maitrivihaar, Ameerpet, Hyderabad – 500038, Telangana, India. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

6. Upon information and belief, Aurobindo Pharma USA, Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 279 Princeton Hightstown Road, East Windsor, NJ 08520-1401. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

RESPONSE: Aurobindo admits APUI is a corporation organized under the laws of Delaware

with a place of business located at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

Aurobindo admits APUI is a wholly owned subsidiary of APL. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

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

RESPONSE: Aurobindo admits the Court has subject matter jurisdiction over claims arising under the Patent Laws of the United States, Title 35 of the United States Code. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction over APL. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. Upon information and belief, Aurobindo Pharma Ltd. admits that it is "a fully integrated pharma company," is "ranked 5th prescription supplier" in the United States and "caters to the [United States]" through its subsidiaries, including Aurobindo Pharma USA, Inc. <https://www.aurobindo.com> (accessed Nov. 20, 2020); Aurobindo Pharma Ltd. 2017-2018 Annual Report to the National Stock Exchange of India Limited (<https://www.bseindia.com/bseplus/annualreport/524804/5248040318.pdf>, accessed Nov. 20, 2020).

RESPONSE: Denied.

10. Upon information and belief, Aurobindo Pharma Ltd. admits it has filed 500+ ANDAs with 360+ final approvals. <https://www.aurobindo.com> (accessed Nov. 20, 2020).

RESPONSE: Denied.

11. Upon information and belief, Aurobindo Pharma Ltd. is the holder of FDA Drug Master File No. 33572 for brexpiprazole.

RESPONSE: Admitted.

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction over APUI. Aurobindo denies all remaining allegations in this paragraph.
Allegations not expressly admitted are denied.

13. Upon information and belief, Aurobindo Pharma USA, Inc. admits that its mission is to “[a]dd value through superior customer service in the distribution of a broad line of generic pharmaceuticals, leveraging vertical integration and efficient controlled processes.” <https://www.aurobindousa.com/company/our-story> (accessed Nov. 20, 2020). Upon information and belief, Aurobindo Pharma USA, Inc. admits that “[s]ince its first US ANDA approval in 2004, Aurobindo has expanded its portfolio to include more than 150 product families, representing a wide range of therapeutic categories.” <https://www.linkedin.com/company/aurobindo-pharma-us-a-about> (Aurobindo USA LinkedIn Profile, accessed Nov. 20, 2020).

RESPONSE: Denied.

14. Upon information and belief, Aurobindo Pharma USA, Inc. has an active pharmacy wholesale license in the state of Delaware with the license number A4-0001270 and an active controlled substances distributor/manufacturer license in the state of Delaware with the license number DM-0006550.

RESPONSE: Admitted.

15. Upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, 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.

RESPONSE: Denied.

16. Upon information and belief, Aurobindo Pharma Ltd. reported in 2018 that Aurobindo Pharma USA, Inc. had 256 approved ANDAs and accounted for 74% of Aurobindo's overall US business. <https://www.aurobindo.com/wp-content/uploads/2018/10/Investor-Presentation-May-2018.pdf> (accessed Nov. 20, 2020).

RESPONSE: Denied.

17. Aurobindo's 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 Aurobindo's intent to market and sell Aurobindo's generic products in this judicial district.

RESPONSE: Denied.

18. Aurobindo 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, Aurobindo intends to direct sales of its generic drugs in this judicial district, among other places, once Aurobindo receives the requested FDA approval to market its generic products. Upon information and belief, Aurobindo will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

RESPONSE: Denied.

19. Upon information and belief, Aurobindo has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213659.

RESPONSE: Denied.

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge venue in this District. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge venue in this District. Aurobindo admits APUI is incorporated in Delaware. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO THE FACTUAL BACKGROUND

RESPONSE TO ALLEGATIONS PERTAINING TO THE NDA

22. 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”).

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

24. 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

RESPONSE TO ALLEGATIONS PERTAINING TO THE PATENTS-IN-SUIT

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, on that basis, denies them. Allegations not expressly admitted are denied.

26. 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.

RESPONSE: Aurobindo admits Exhibit A appears to be a copy of the RE’059 patent. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, on that basis, denies them.

27. 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

28. 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

29. 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. 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).

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

30. 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.

RESPONSE: Admitted.

RESPONSE TO ALLEGATIONS PERTAINING TO DEFENDANT'S ANDA

31. Upon information and belief, Aurobindo filed ANDA No. 213659 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 (“Aurobindo’s generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets..

RESPONSE: Aurobindo admits APL filed an ANDA, which FDA assigned number 213659, seeking FDA approval of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied. Allegations not expressly admitted are denied.

32. Otsuka received a letter sent by Aurobindo, dated September 4, 2019, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 213659 (“Aurobindo’s September 4, 2019, First Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B)(i)-(iv), § 505(j)(2)(B)(i)-(ii) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Aurobindo’s September 4, 2019, First Notice Letter notified Otsuka that Aurobindo had filed ANDA No. 213659, seeking approval to engage in the commercial manufacture, use or sale of Aurobindo’s generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 (“the ‘840 patent”), 8,618,109 (“the ‘109 patent”), 9,839,637 (“the ‘637 patent”) and 10,307,419 (“the ‘419 patent”).

RESPONSE: Aurobindo admits having sent Otsuka a letter dated September 4, 2019, pursuant to 21 U.S.C. § 355(j), notifying Otsuka of APL's filing of ANDA No. 213659 with Paragraph IV Certifications. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

33. In response to Aurobindo's September 4, 2019, First Notice Letter, Plaintiffs previously filed a separate action in this Court against Aurobindo for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Aurobindo Pharma Ltd.*, C.A. No. 19-1965-LPS.

RESPONSE: Aurobindo admits to being a party in a separate action in this Court against Plaintiffs. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

34. On June 23, 2020, the PTO issued 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®.

RESPONSE: Admitted based upon information and belief.

35. Upon information and belief, ANDA No. 213659 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("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, sale, offer for sale and/or importation Aurobindo's generic products.

RESPONSE: Admitted.

36. Otsuka received a second notice letter sent by Aurobindo, dated October 9, 2020, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213659 ("Aurobindo's October 9, 2020, Second Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B)(i)-(iv), § 505(j)(2)(B)(i)-(ii) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Aurobindo's October 9, 2020, Second Notice Letter notified Otsuka that Aurobindo had filed ANDA No. 213659, seeking approval to engage in the commercial manufacture, use or sale of Aurobindo's generic products in the United States before the expiration of the RE'059 patent.

RESPONSE: Aurobindo admits having sent Otsuka a second notice letter dated October 9, 2020

pursuant to 21 U.S.C. § 355(j), notifying Otsuka of APL's filing of ANDA No. 213659 with Paragraph IV Certifications. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

37. Plaintiffs commenced this action within 45 days of receiving Aurobindo's October 9, 2020, Second Notice Letter.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

RESPONSE TO FIRST CLAIM FOR RELIEF
(Alleged Infringement of the RE'059 Patent by Aurobindo)

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

RESPONSE: Aurobindo restates and incorporates each response to each preceding paragraph as though fully set forth herein.

39. Upon information and belief, Aurobindo filed ANDA No. 213659 seeking approval to manufacture, use, import, offer to sell and/or sell Aurobindo's generic products in the United States before the expiration of the RE'059 patent.

RESPONSE: Admitted.

40. Upon information and belief, Aurobindo 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.

RESPONSE: Admitted.

41. Upon information and belief, in its ANDA No. 213659, Aurobindo has represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Aurobindo avers it has complied with the legal requirements for submitting its ANDA No. 213659. Aurobindo denies the remaining allegations in this paragraph. Matters

not expressly admitted are denied.

42. Aurobindo has actual knowledge of Otsuka's RE'059 patent, as evidenced by Aurobindo's October 9, 2020, Second Notice Letter.

RESPONSE: Aurobindo admits it had knowledge of Otsuka's RE'059 patent at the time Aurobindo served its October 9, 2020, Notice Letter. Aurobindo denies all remaining allegations in this paragraph. Matters not expressly admitted are denied.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213659, seeking approval to commercially manufacture, use, import, offer to sell or sell Aurobindo's generic products before the expiration date of the RE'059 patent.

RESPONSE: Denied.

44. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo intends to and will offer to sell, sell and/or import in the United States Aurobindo's generic products.

RESPONSE: Denied.

45. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo 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 Aurobindo's 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. 213659 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

RESPONSE: Denied.

46. Upon information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 213659 complained of herein were done by and for the benefit of Aurobindo.

RESPONSE: Denied.

47. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless this Court enjoins those activities.

RESPONSE: Denied.

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

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegation in Plaintiffs' Complaint not expressly admitted by Aurobindo are hereby denied. Having answered Plaintiffs' complaint, Aurobindo denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of APL's ANDA No. 213659 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patent-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of each of the patent-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example,

for at least the reasons set forth in APL's October 9, 2020, Notice Letter.

THIRD SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in APL's Notice Letter dated October 9, 2020.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. § 112, for example, indefiniteness, lack of enablement and/or written description, for example, for at least the reasons set forth in APL's Notice Letter dated October 9, 2020.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of Aurobindo's ANDA No. 213659.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Aurobindo hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: February 10, 2021

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