IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S,	)	
Plaintiff,	)	
v.	)	C.A. No. 19-cv-01965-LPS
AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

ANSWER AND DEFENSES TO PLAINTIFFS' COMPLAINT AGAINST AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.

Defendants Aurobindo Pharma Ltd. ("APL") and Aurobindo Pharma USA, Inc. ("APUI") (collectively for identification purposes only, "Aurobindo"), by and through their undersigned counsel, answer the Complaint of Plaintiffs Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("H. Lundbeck") (collectively, "Plaintiffs") as follows:

RESPONSE TO ALLEGATIONS PERTAINING TO THE NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 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") (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 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 patents in suit.

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action to assert infringement

of the patents 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 '362, '840, '109, '637 and '419 patents.

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.

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, on that basis, denies them.

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, Maitrivihar, 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, Maitrivihar, 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

October 12, 2019); 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 Oct. 12, 2019).

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 Oct. 12, 2019).

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 admits the Court has 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 Oct. 12, 2019). 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-u- s-a-/about (Aurobindo USA LinkedIn Profile, accessed Oct. 12, 2019).

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 October 12, 2019).

RESPONSE: Denied.

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

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

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 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 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.

RESPONSE: Aurobindo admits Exhibit A appears to be a copy of the '362 patent, which is the best evidence of its contents. 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. 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.

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.

27. 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.

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. 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).

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. 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.

RESPONSE: Admitted.

30. The PTO issued the '840 patent on January 8, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '840 patent is attached as Exhibit D.

RESPONSE: Aurobindo admits Exhibit D appears to be a copy of the '849 patent, which is the best evidence of its contents. 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. Allegations not expressly admitted are denied.

31. Otsuka owns the '840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

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.

32. The '840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

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.

33. The '840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Admitted.

34. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine- Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as Exhibit E.

RESPONSE: Aurobindo admits Exhibit E appears to be a copy of the '109 patent, which is the best evidence of its contents. Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same. Allegations not expressly admitted are denied.

35. Otsuka owns the '109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

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.

36. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

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.

37. The '109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.\

RESPONSE: Admitted.

38. The PTO issued the '637 patent on December 12, 2017, entitled "Piperazine- Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '637 patent is attached as Exhibit F.

RESPONSE: Aurobindo admits Exhibit F appears to be a copy of the '637 patent, which is the best evidence of its contents. 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. Allegations not expressly admitted are denied.

39. Otsuka owns the '637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

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.

40. The '637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

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.

41. The '637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Admitted.

42. 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 G.

RESPONSE: Aurobindo admits Exhibit G appears to be a copy of the '419 patent, which is the best evidence of its contents. 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. Allegations not expressly admitted are denied.

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

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.

44. The '419 patent expires on October 12, 2032.

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.

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

RESPONSE: Admitted.

RESPONSE TO ALLEGATIONS PERTAINING TO THE ANDA

46. 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 the 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.

47. Upon information and belief, ANDA No. 213659 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Aurobindo's generic products.

RESPONSE: Admitted.

48. 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 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 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 patents in suit.

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.

49. Plaintiffs commenced this action within 45 days of receiving Aurobindo's September 4, 2019, 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 ALLEGATIONS PERTAINING TO COUNT I
(Alleged Infringement of the '362 Patent)

50. 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.

51. 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 '362 patent.

RESPONSE: Denied.

52. 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 '362 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Denied.

53. 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: Denied.

54. Aurobindo has actual knowledge of Otsuka's '362 patent, as evidenced by Aurobindo's September 4, 2019, Notice Letter.

RESPONSE: Denied.

55. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '362 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 '362 patent.

RESPONSE: Denied.

56. 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.

57. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo 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 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 '362 patent and any additional periods of exclusivity.

RESPONSE: Denied.

58. 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.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSE TO ALLEGATIONS PERTAINING TO COUNT II
(Alleged Infringement of the '840 PATENT)

61. 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.

62. 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 '840 patent.

RESPONSE: Denied.

63. 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 '840 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Denied.

64. 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: Denied.

65. Aurobindo has actual knowledge of Otsuka's '840 patent, as evidenced by Aurobindo's September 4, 2019, Notice Letter.

RESPONSE: Denied.

66. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '840 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 '840 patent.

RESPONSE: Denied.

67. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo will infringe one or more claims of the '840 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 '840 patent and any additional periods of exclusivity.

RESPONSE: Denied.

68. Upon information and belief, Aurobindo knows, should know and intends that physicians will prescribe and patients will take Aurobindo's generic products for which approval is sought in ANDA No. 213659, and therefore will infringe at least one claim of the '840 patent.

RESPONSE: Denied.

69. Upon information and belief, Aurobindo has knowledge of the '840 patent and, by its proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

RESPONSE: Denied.

70. Upon information and belief, Aurobindo is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

RESPONSE: Denied.

71. 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.

72. 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.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSE TO ALLEGATIONS PERTAINING TO COUNT III

(Alleged Infringement of the '109 Patent)

75. 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.

76. 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 '109 patent.

RESPONSE: Denied.

77. 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 '109 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Denied.

78. 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: Denied.

79. Aurobindo has actual knowledge of Otsuka's '109 patent, as evidenced by Aurobindo's September 4, 2019, Notice Letter.

RESPONSE: Denied.

80. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '109 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 '109 patent.

RESPONSE: Denied.

81. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo will infringe one or more claims of the '109 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 '109 patent and any additional periods of exclusivity.

RESPONSE: Denied.

82. Upon information and belief, Aurobindo knows, should know and intends that physicians will prescribe and patients will take Aurobindo's generic products for which approval is sought in ANDA No. 213659, and therefore will infringe at least one claim of the '109 patent.

RESPONSE: Denied.

83. Upon information and belief, Aurobindo has knowledge of the '109 patent and, by its proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

RESPONSE: Denied.

84. Upon information and belief, Aurobindo is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.

RESPONSE: Denied.

85. 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.

86. 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.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSE TO ALLEGATIONS PERTAINING TO COUNT IV
(Alleged Infringement of the '637 Patent)

89. 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.

90. 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 '637 patent.

RESPONSE: Denied.

91. 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 '637 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Denied.

92. 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: Denied.

93. Aurobindo has actual knowledge of Otsuka's '637 patent, as evidenced by Aurobindo's September 4, 2019, Notice Letter.

RESPONSE: Denied.

94. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '637 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 '637 patent.

RESPONSE: Denied.

95. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo will infringe one or more claims of the '637 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 '637 patent and any additional periods of exclusivity.

RESPONSE: Denied.

96. Upon information and belief, Aurobindo knows, should know and intends that physicians will prescribe and patients will take Aurobindo's generic products for which approval is sought in ANDA No. 213659, and therefore will infringe at least one claim of the '637 patent.

RESPONSE: Denied.

97. Upon information and belief, Aurobindo has knowledge of the '637 patent and, by its proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

RESPONSE: Denied.

98. Upon information and belief, Aurobindo is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.

RESPONSE: Denied.

99. 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.

100. 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.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSE TO ALLEGATIONS PERTAINING TO COUNT V
(Alleged Infringement of the '419 Patent)

103. 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.

104. 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 '419 patent.

RESPONSE: Denied.

105. 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 '419 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Denied.

106. 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: Denied.

107. Aurobindo has actual knowledge of Otsuka's '419 patent, as evidenced by Aurobindo's September 4, 2019, Notice Letter.

RESPONSE: Denied.

108. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '419 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 '419 patent.

RESPONSE: Denied.

109. Upon information and belief, if ANDA No. 213659 is approved, Aurobindo 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 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 '419 patent and any additional periods of exclusivity.

RESPONSE: Denied.

110. 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.

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

RESPONSE: Denied.

112. 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 patents-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of each of the patents-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 Notice Letter dated September 4, 2019.

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 September 4, 2019.

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 least the reasons set forth in APL's Notice Letter dated September 4, 2019.

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: March 16, 2020

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