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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG, *Plaintiffs*, v. AUROBINDO PHARMA LIMITED, AUROBINDO USA, INC., and AUROLIFE PHARMA LLC, *Defendants*.	C.A. No. 2:24-cv-11428-CCC **ANSWER TO COMPLAINT**

Defendants Aurobindo Pharma Limited ("APL"), Aurobindo Pharma USA, Inc. ("APUI"), and Aurolife Pharma LLC ("Aurolife") (collectively, "Defendants"), by and through their

undersigned counsel, respectfully submit their Answer to Plaintiffs' Complaint for alleged patent infringement, stating as follows:

RESPONSES TO ALLEGATIONS PERTAINING TO THE NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon Defendants' acts of infringement arising from the submission of Abbreviated New Drug Application ("ANDA") No. 214903 ("Defendants' ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' Neupro® transdermal system ("Defendants' ANDA Products"), prior to the expiration of United States Patent Nos. 8,246,979 ("the '979 Patent"), 9,925,150 ("the '150 Patent"), 10,130,589 ("the '589 Patent"), and 10,350,174 ("the '174 Patent"). Plaintiffs seek declaratory and injunctive relief precluding such infringement, damages (if any), attorneys' fees, costs, and any other relief the Court deems just and proper.

RESPONSE: Defendants admit Plaintiffs purport to bring a civil action for alleged patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendants admit Plaintiffs allege infringement allegedly arising from submission of Aurolife's ANDA No. 214903 ("Aurolife's ANDA") to FDA seeking regulatory approval for the drug product described therein ("Aurolife's ANDA Products") prior to expiration of the '979, '150, '589 and '174 patents (collectively, "Asserted Patents"). Defendants admit Plaintiffs purport to seek declaratory and injunctive relief as well as damages, attorneys' fees, costs and other relief but avers Plaintiffs are not entitled to any such relief. This paragraph contains legal conclusions requiring no response. To the extent a further response is required, Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE PARTIES

2. Plaintiff UCB, Inc. ("UCB, Inc.") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

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

3. Plaintiff UCB Pharma GmbH ("UCB Pharma," and collectively with UCB, Inc., "UCB") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Rolf-Schwarz-Schütte-Platz 1, 40789 Monheim am Rhein, Germany.

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

4. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

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

5. On information and belief, Defendant Aurobindo Pharma Limited ("Aurobindo Ltd.") is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India.

RESPONSE: Defendants admit APL is a company organized under the laws of the Republic of India with a place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA," and collectively with Aurobindo Ltd., "Aurobindo") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520.

RESPONSE: Defendants admit APUI is a corporation organized and existing under the laws of the State of Delaware with a place of business at 279 Princeton- Hightstown Road, East Windsor,

NJ 08520. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

7. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

RESPONSE: Admitted.

8. On information and belief, Aurobindo USA is the agent in the United States for Aurobindo Ltd. and acts at the direction, under the control, and for the benefit of Aurobindo Ltd.

RESPONSE: Defendants admit APUI has acted as the U.S. agent for API for the purpose of submitting ANDAs to FDA. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. On information and belief, Defendant Aurolife Pharma LLC ("Aurolife") is an LLC organized and existing under the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520.

RESPONSE: Defendants admit Aurolife is an LLC organized and existing under the laws of the State of Delaware with a place of business at 279 Princeton- Hightstown Road, East Windsor, NJ 08520. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

10. On information and belief, Aurolife is a wholly owned subsidiary of Aurobindo USA.

RESPONSE: Admitted.

11. On information and belief, Aurolife acts at the direction, and for the benefit, of Aurobindo Ltd. and Aurobindo USA, and is controlled by Aurobindo Ltd. and Aurobindo USA.

RESPONSE: Denied.

12. On information and belief, Aurobindo and Aurolife have cooperated and assisted in the preparation and filing of Defendants' ANDA, caused Defendants' ANDA to be submitted to FDA, continue to seek FDA approval of Defendants' ANDA, and will be involved in the manufacture, use, importation, marketing, offer for sale, and sale of Defendants' ANDA Products in the event FDA approves Defendants' ANDA.

RESPONSE: Defendants admit Aurolife submitted Aurolife's ANDA or caused Aurolife's ANDA to be submitted to FDA and continues to seek FDA approval of Aurolife's ANDA. Defendants object to the allegations regarding uncertain future events as calling for speculation and, on that ground, denies all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

13. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and alleges infringement of the '979, '150, '589, and '174 Patents. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and § 1400(b).

RESPONSE: Defendants admit Plaintiffs purport to bring a civil action alleging infringement under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendants admit Plaintiffs purport to allege infringement of the Asserted Patents. Defendants admit the Court has subject matter jurisdiction. This paragraph contains legal conclusions to which no response is required. To the extent a further response is required, Defendants deny all further allegations in this paragraph. Allegations not expressly admitted are denied.

14. This Court has personal jurisdiction over each of the Defendants because, *inter alia*, on information and belief, each Defendant has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell Defendants' ANDA Products in the State of New Jersey upon approval of Defendants' ANDA.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

15. On information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing drug products, including generic drug products, throughout the United States, including within the State of New Jersey, either directly or through the actions of their agents or subsidiaries, from which Defendants derive a substantial portion of their revenue.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

16. On information and belief, Defendants assist each other to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Defendants coordinated with each other to submit Defendants' ANDA to FDA, and will coordinate with each other to commercially manufacture, market, distribute, offer for sale, and/or sell Defendants' ANDA Products, in the event that FDA approves Defendants' ANDA.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

17. Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States and within the State of New Jersey, and by selling, directly or through their agents, pharmaceutical products in the State of New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

18. On information and belief, Defendants are licensed to sell pharmaceutical products in the State of New Jersey, either directly or through one or more of their agents or subsidiaries

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all allegations in this paragraph. Allegations not expressly admitted are denied.

19. Defendants filed Defendants' ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products in or into the United States, including in the State of New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all allegations in this paragraph. Allegations not expressly admitted are denied.

20. On information and belief, Defendants intend to market, manufacture, use, offer to sell, sell, or distribute Defendants' ANDA Products throughout the United States and within the State of New Jersey. On information and belief, Defendants know and intend that Defendants' ANDA Products will be marketed, manufactured, used, distributed, offered for sale, sold, or distributed in the United States and within the State of New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants object to allegations regarding uncertain future events as calling for speculation and, on that ground, denies all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

21. On information and belief, Defendants plan to sell Defendants' ANDA Products in the State of New Jersey, list Defendants' ANDA Products on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for the sales of Defendants' ANDA Products in the State of New Jersey, either directly or through one or more of their agents or subsidiaries.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants object to allegations regarding uncertain future events as calling for speculation and, on that ground, denies all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

22. On information and belief, if Defendants' ANDA is approved, Defendants' ANDA Products would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants object to allegations regarding uncertain future events as calling for

speculation and, on that ground, denies all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

23. This Court further has personal jurisdiction over Aurobindo Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) UCB's claims arise under federal law; (b) Aurobindo Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States including in this Judicial District, such that this Court's exercise of jurisdiction over Aurobindo Ltd. satisfies due process.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. This paragraph includes legal conclusions to which no response is required. To the extent a further response is required, Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

24. The Court further has personal jurisdiction over Aurobindo USA at least because Aurobindo USA has its principal place of business in New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

25. The Court further has personal jurisdiction over Aurolife at least because Aurolife has its principal place of business in New Jersey.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

26. Defendants have previously consented to personal jurisdiction and venue in this Judicial District in numerous recent actions arising out of their ANDA filings. *See, e.g.*, *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:21-cv-00624, D.I. 12, ¶¶ 15–17, 21, 27–30 (D.N.J. Mar. 11, 2021); *Teva Branded Pharma. Prods. R&D, Inc., et al. v. Aurobindo Pharma Ltd., et al.*, No. 2:20-cv-14833, D.I. 12, ¶¶ 15–22, 24–26 (D.N.J. Dec. 30, 2020); *Celgene Corp. v. Aurobindo*

Pharma Ltd., et al., No. 2:20-cv-00315, D.I. 14, ¶¶ 24–39 (D.N.J. Mar. 27, 2020); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:19-cv-05799, D.I. 15, ¶¶ 18–33 (D.N.J. July 1, 2019).

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

27. Defendants regularly invoke the jurisdiction of the courts of this Judicial District by filing counterclaims in other actions. *See, e.g.*, *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:21-cv-00624, D.I. 12, pp. 21–28 (D.N.J. Mar. 11, 2021); *Teva Branded Pharma. Prods. R&D, Inc., et al. v. Aurobindo Pharma Ltd., et al.*, No. 2:20-cv-14833, D.I. 12, pp. 74–88 (D.N.J. Dec. 30, 2020); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:20-cv-00315, D.I. 14, pp. 30–43 (D.N.J. Mar. 27, 2020); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:19-cv-05799, D.I. 15, pp. 22–30 (D.N.J. July 1, 2019).

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge personal jurisdiction. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

28. Venue is proper in this Judicial District as to Aurobindo Ltd. pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) at least because Aurobindo Ltd. is a foreign corporation organized under the laws of India and may be sued in any judicial district.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge venue in this Judicial District. This paragraph contains legal conclusions for which no response is required. To the extent a further response is required, Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

29. Venue is proper in this judicial district as to Aurobindo USA and Aurolife pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because Aurobindo USA and Aurolife are subject to personal jurisdiction and have their principal places of business within this Judicial District and, on information and belief, developed Defendants' ANDA Products within this Judicial District and submitted Defendants' ANDA to FDA from this Judicial District.

RESPONSE: Solely for the purpose of this litigation, Defendants do not challenge venue in this Judicial District. This paragraph contains legal conclusions for which no response is required. To

the extent a further response is required, Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO NEUPRO®

30. Plaintiffs make and sell the Neupro® transdermal system (Rotigotine Transdermal System), a treatment for the signs and symptoms of idiopathic Parkinson's disease ("PD") and moderate-to-severe Restless Legs Syndrome ("RLS"). PD affects movement, producing motor symptoms such as tremor, slowed movement, rigidity, and postural instability. PD can also cause neuropsychiatric disturbances, including disorders of speech, cognition, mood, behavior, and thought. RLS is characterized by uncomfortable or odd sensations in a person's limbs, which cause an irresistible urge to move the body for temporary relief.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

31. Neupro® is the first FDA-approved product containing rotigotine, a synthetic dopamine agonist. In PD, neurodegeneration results in the loss of dopamine-producing neurons and reduced activity within certain dopaminergic pathways, and restoring activity to these systems with a dopamine agonist such as rotigotine may improve the clinical signs of PD. Rotigotine is also called (6S)-6-{propyl[2-(2-thienyl)ethyl]amino}-5,6,7,8-tetrahydro-l-naphthalenol; or (-) 5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

32. Neupro® is also the first FDA-approved transdermal treatment for PD. Neupro® is a transdermal system that provides continuous delivery of rotigotine for 24 hours following application to intact skin. The product is a thin, matrix-type transdermal system composed of three layers: a backing film, drug matrix, and protective liner. The liner protects the drug matrix during storage and is removed just prior to application. Neupro® is approved and marketed in six different strengths: 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

33. Neupro®'s transdermal delivery of rotigotine has been shown to provide stable plasma levels of rotigotine over 24 hours, which may prevent or reduce long-term motor complications and motor fluctuations that are associated with unstable or fluctuating dopaminergic stimulation. Neupro® also offers other advantages. For example, by delivering the drug via transdermal application, Neupro® bypasses gastrointestinal complications that may be associated with PD. In addition, Neupro®'s once-daily formulation for 24 hours of treatment may improve early morning and nighttime symptoms of PD, as well as patient compliance.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

34. Plaintiff UCB, Inc. is the holder of New Drug Application ("NDA") No. 021829 for Neupro® (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours). FDA initially approved NDA No. 021829 in May 2007, for the treatment of signs and symptoms of early stage idiopathic PD. Following manufacturing and process changes to address product stability, and following additional clinical trials, in April 2012, FDA approved a new formulation of Neupro® for additional indications—for the treatment of the signs and symptoms of advanced stage idiopathic PD, and for the treatment of moderate-to-severe RLS. In its April 2012 approval of Neupro®, FDA granted Neupro® three years of regulatory exclusivity pursuant to 21 C.F.R. § 314.108.

RESPONSE: Upon information and belief, Defendants admit Plaintiff UCB, Inc., is the holder of NDA No. 021829. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO THE ASSERTED PATENTS

35. The '979 Patent, titled "Transdermal Delivery System for the Administration of Rotigotine," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on August 21, 2012. The '979 Patent is owned by Plaintiff UCB Pharma. A true and correct copy of the '979 Patent is attached as Exhibit A.

RESPONSE: Defendants admit Exhibit A to the Complaint appears to be a copy of the '979 patent, which is the best evidence of its contents. Defendants admit the '979 patent is titled "Transdermal Delivery System for the Administration of Rotigotine." Defendants admit the face of the '979 patent states the '979 patent issued August 21, 2012. Defendants deny the '979 patent

was duly or lawfully issued. Defendants deny all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

36. The '150 Patent, titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine," was duly and lawfully issued by the USPTO on March 27, 2018. The '150 Patent is co-owned by Plaintiffs UCB Pharma and LTS. A true and correct copy of the '150 Patent is attached as Exhibit B.

RESPONSE: Defendants admit Exhibit B to the Complaint appears to be a copy of the '150 patent, which is the best evidence of its contents. Defendants admit the '150 patent is titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine." Defendants admit the face of the '150 patent states the '150 patent issued March 27, 2018. Defendants deny the '150 patent was duly or lawfully issued. Defendants deny all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

37. The '589 Patent, titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine," was duly and lawfully issued by the USPTO on November 20, 2018. The '589 Patent is co-owned by Plaintiffs UCB Pharma and LTS. A true and correct copy of the '589 Patent is attached as Exhibit C.

RESPONSE: Defendants admit Exhibit C to the Complaint appears to be a copy of the '589 patent, which is the best evidence of its contents. Defendants admit the '589 patent is titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine." Defendants admit the face of the '589 patent states the '589 patent issued November 20, 2018. Defendants deny the '589 patent was duly or lawfully issued. Defendants deny all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

38. The '174 Patent, titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine," was duly and lawfully issued by the USPTO on July 16, 2019. The '174 Patent is co-owned by Plaintiffs UCB Pharma and LTS. A true and correct copy of the '174 Patent is attached as Exhibit D.

RESPONSE: Defendants admit Exhibit D to the Complaint appears to be a copy of the '174 patent, which is the best evidence of its contents. Defendants admit the '174 patent is titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine." Defendants admit the face of the '174 patent states the '174 patent issued July 16, 2019. Defendants deny the '174 patent was duly or lawfully issued. Defendants deny all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

39. The '979, '150, '589, and '174 Patents, among other patents (collectively, the "Neupro® Listed Patents"), are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for Neupro®

RESPONSE: Upon information and belief, Defendants admit the Asserted Patents are listed in the Orange Book in connection with the drug product sold as Neupro®. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO DEFENDANTS' ANDA

40. On information and belief, Defendants have submitted, or caused to be submitted, Defendants' ANDA to FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and importation of Defendants' ANDA Products, i.e., rotigotine extended-release transdermal film in 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours strengths, as purported generic versions of Neupro®, prior to the expiration of the Neupro® Listed Patents.

RESPONSE: Defendants admit Aurolife submitted, or caused to be submitted, Aurolife's ANDA seeking approval of Aurolife's ANDA Products prior to the expiration of the Asserted Patents. Defendants admit Aurolife's ANDA Products are rotigotine extended-release transdermal film in 1 mg/24 hours, 2mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours and 8 mg/24 hours strengths.

41. On information and belief, both Aurobindo Ltd. and Aurolife are owners or co-owners of Defendant's ANDA: each has claimed to be the owner of Defendants' ANDA. On

information and belief, Aurobindo USA assisted Aurobindo Ltd. and Aurolife with the preparation and submission of Defendants' ANDA to FDA.

RESPONSE: Defendants admit Aurolife owns Aurolife's ANDA. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

42. Aurobindo Ltd. sent Plaintiffs a letter dated November 14, 2024, titled "Notification of Paragraph IV Certification Regarding U.S. Patent Nos. 8,246,979; 9,925,150; 10,130,589 and 10,350,174 Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act" ("Aurobindo Notice Letter").

RESPONSE: Defendants admit a letter dated November 14, 2024, titled as alleged, was sent to Plaintiffs and aver the letter incorrectly identified API as the owner of Aurolife's ANDA. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

43. The Aurobindo Notice Letter represented that Aurobindo Ltd. is the owner of ANDA No. 214903, which it had submitted to FDA and amended with a purported Paragraph IV certification for the Neupro® Listed Patents pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

RESPONSE: Defendants admit the November 14, 2024, letter incorrectly identified API as the owner of Aurolife's ANDA No. 214903, which Aurolife submitted or caused to be submitted to FDA with Paragraph IV certifications directed to the Asserted Patents pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Defendants. deny all further allegations in this paragraph. Allegations not expressly admitted are denied.

44. Aurolife sent Plaintiffs a letter dated November 18, 2024, titled "Notification of Paragraph IV Certification Regarding U.S. Patent Nos. 8,246,979; 9,925,150; 10,130,589 and 10,350,174 Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act" ("Aurolife Notice Letter").

RESPONSE: Defendants admit Aurolife sent Plaintiffs a letter dated November 18, 2024, titled as alleged. Defendants deny all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

45. The Aurolife Notice Letter represented that Aurolife is the owner of ANDA No. 214903, which it had submitted to FDA and amended with a purported Paragraph IV certification for the Neupro® Listed Patents pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

RESPONSE: Defendants admits that the Aurolife Notice Letter accurately represented that Aurolife is the owner of Aurolife's ANDA No. 214903, which Aurolife had submitted to FDA with Paragraph IV certifications directed to the Asserted Patents pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Defendants deny all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

46. According to applicable regulations, Notice Letters like the Aurobindo and Aurolife Notice Letters must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." See 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

RESPONSE: This paragraph contains legal conclusions to which no response is required. To the extent a further response is required, Defendants deny all allegations in this paragraph. Allegations not expressly admitted are denied.

47. For at least one claim of the '979 Patent, Aurobindo's and Aurolife's Notice Letters failed to allege that any strength of Defendants' ANDA Products or the proposed administration of such Products would not meet the limitations of that claim.

RESPONSE: Denied.

48. Plaintiffs diligently sought to investigate Defendants' ANDA and Defendants' ANDA Products within the forty-five day window for bringing suit after receipt of a Paragraph IV notice letter, as set forth under 21 U.S.C. § 355(j)(5)(B)(iii). In both the Aurolife Notice Letter and the Aurobindo Notice Letter, Defendants purported to offer confidential access to portions of Defendants' ANDA on terms and conditions set forth in the letters. Defendants' purported offer sought to impose numerous unreasonable restrictions on Plaintiffs relating to, for example, who and how many individuals could view Defendants' ANDA. In particular, Defendants' offers did not permit any of Plaintiffs' in-house attorneys to access Defendants' ANDA. The offers further restricted access to a single scientific expert. The restrictions Defendants sought to impose far exceeded those that would apply under a protective order. Additionally, Defendants did not offer to produce Defendants' ANDA in its entirety, but only "relevant portions" of the ANDA as

determined by Defendants alone. Such limitations, and others contained in Defendants' offers, did not comport with 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information*" (emphasis added).

RESPONSE: Denied.

49. Beginning with correspondence on November 25, 2024, outside counsel for Plaintiffs sought to negotiate in good faith with counsel for Defendants in an attempt to reach agreement on reasonable terms of confidential access to Defendants' ANDA. In a November 25, 2024 correspondence, counsel for Plaintiffs explained the above issues to Defendants' counsel and proposed reasonable, alternative terms of access consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). Counsel for Defendants did not respond. On December 4, counsel for Plaintiffs followed up on their November 25 correspondence, and asked Defendants' counsel to provide Defendants' response as soon as possible. On December 5, counsel for Defendants replied that they were "looking at" Plaintiffs' proposed changes and "getting with" Defendants, and would provide a response the following week. No further response was received. Defendants' delay in responding to Plaintiffs and providing revisions to Plaintiffs' proposal was unreasonable and deprived Plaintiffs of an opportunity to review Defendants' ANDA, in contravention to the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III). To date, Plaintiffs have not received access to Defendants' ANDA.

RESPONSE: Denied.

50. On information and belief, FDA has not approved Defendants' ANDA.

RESPONSE: As of the date this Answer was submitted, Defendants admit Aurolife's ANDA has not yet received FDA approval. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

51. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, use, offer for sale, or sell Defendants' ANDA Products within the United States, or import Defendants' ANDA Products into the United States, including within the State of New Jersey.

RESPONSE: Defendants object to allegations regarding uncertain future events and, on that ground, deny all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

52. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products, including within the State of New Jersey.

RESPONSE: Defendants deny that anyone other than Aurolife owns Aurolife's ANDA. Defendants object to allegations regarding uncertain future events and, on that ground, deny all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

53. The commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products will directly infringe the Neupro® Listed Patents, either literally or under the doctrine of equivalents, and Defendants will actively induce and/or contribute to the infringement of those patents.

RESPONSE: Defendants deny that anyone other than Aurolife owns Aurolife's ANDA. Defendants object to allegations regarding uncertain future events and, on that ground, deny all such allegations. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

54. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Aurolife Notice Letter and Aurobindo Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

RESPONSE: This paragraph contains legal conclusions requiring no response. To the extent a further response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny the same. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS IN COUNT I:
ALLEGED INFRINGEMENT OF THE '979 PATENT

55. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1–54 as if fully set forth herein.

56. Plaintiffs own all rights, title, and interest in and to the '979 Patent.

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

57. On information and belief, Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '979 Patent.

RESPONSE: Denied.

58. On information and belief, Defendants have infringed one or more claims of the '979 Patent, including at least claim 1, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of Defendants' ANDA Products prior to the expiration of the '979 Patent.

RESPONSE: Denied.

59. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale in the United States and importation into the United States of Defendants' ANDA Products would directly infringe one or more claims of the '979 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g), and would actively induce and contribute to infringement of one or more claims of the '979 Patent, including at least claim 1, under 35 U.S.C. §§ 271(b) or (c). Accordingly, unless enjoined by this Court, upon FDA approval of Defendants' ANDA and amendments, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within, or import Defendants' ANDA Products into, the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '979 Patent.

RESPONSE: Denied.

60. On information and belief, Defendants had actual and constructive notice of the '979 Patent prior to submitting Defendants' ANDA to FDA. Defendants were aware that submitting Defendants' ANDA with the request for FDA approval prior to the expiration of the '979 Patent would constitute an act of infringement of the '979 Patent.

RESPONSE: Defendants admit Aurolife had notice of the '979 patent as of the date Aurolife submitted a Paragraph IV certification regarding the same. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

61. Defendants did not contest infringement of any claims of the '979 Patent in either the Aurobindo Notice Letter or the Aurolife Notice Letter. If Defendants had a factual or legal basis to contest infringement of the claims of the '979 Patent, they were required by applicable regulations to state such a basis in their respective Notice Letters. See 21 C.F.R. § 314.95(c)(7).

RESPONSE: Denied.

62. Defendants submitted Defendants' ANDA without adequate justification for asserting the '979 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '979 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

63. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for Defendants' ANDA to be a date that is not any earlier than the expiration date of the '979 Patent, including any extensions, adjustments, and exclusivities associated with the '979 Patent.

RESPONSE: Denied.

64. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '979 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

RESPONSE TO ALLEGATIONS IN COUNT II:
DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '979 PATENT

65. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

66. Plaintiffs own all rights, title, and interest in and to the '979 Patent.

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

67. Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '979 Patent.

RESPONSE: Denied.

68. On information and belief, if Defendants' ANDA is approved, Defendants' ANDA Products will be made, used, offered for sale, sold, distributed, or imported into the United States by or through Defendants and their affiliates and will therefore infringe one or more claims of the '979 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g).

RESPONSE: Denied.

69. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Products, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '979 Patent, including at least claim 1, under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

70. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '979 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '979 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

71. Defendants did not contest infringement of any claims of the '979 Patent in either the Aurobindo Notice Letter or the Aurolife Notice Letter. If Defendants had a factual or legal basis to contest infringement of the claims of the '979 Patent, they were required by applicable regulations to state such a basis in their respective Notice Letters. See 21 C.F.R. § 314.95(c)(7).

RESPONSE: Denied.

72. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants concerning liability for the infringement of the '979 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Defendants admit there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurolife concerning the '979 patent. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

73. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '979 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

74. Plaintiffs should be granted a declaratory judgment that the submission of Defendants' ANDA or commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products would infringe one or more claims of the '979 Patent.

RESPONSE: Denied.

75. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and Plaintiffs are entitled to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

RESPONSES TO ALLEGATONS IN COUNT III:
ALLEGED INFRINGEMENT OF THE '150 PATENT

76. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses paragraphs 1-54 as if fully set forth herein.

77. Plaintiffs own all rights, title, and interest in and to the '150 Patent.

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

78. On information and belief, Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '150 Patent.

RESPONSE: Denied.

79. On information and belief, Defendants have infringed one or more claims of the '150 Patent, including at least claim 1, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of Defendants' ANDA Products prior to the expiration of the '150 Patent.

RESPONSE: Denied.

80. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale in the United States and importation into the United States of Defendants' ANDA Products would directly infringe one or more claims of the '150 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g), and would actively induce and contribute to infringement of one or more claims of the '150 Patent, including at least claim 1, under 35 U.S.C. §§ 271(b) or (c). Accordingly, unless enjoined by this Court, upon FDA approval of Defendants' ANDA and amendments, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within, or import Defendants' ANDA Products into, the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '150 Patent.

RESPONSE: Denied.

81. On information and belief, Defendants had actual and constructive notice of the '150 Patent prior to submitting Defendants' ANDA to FDA. Defendants were aware that submitting Defendants' ANDA with the request for FDA approval prior to the expiration of the '150 Patent would constitute an act of infringement of the '150 Patent.

RESPONSE: Defendants admit Aurolife had notice of the '150 patent as of the date Aurolife submitted a Paragraph IV certification regarding the same. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

82. Defendants submitted Defendants' ANDA without adequate justification for asserting the '150 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '150 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

83. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for Defendants' ANDA to be a date that is not any earlier than the expiration date of the '150 Patent, including any extensions, adjustments, and exclusivities associated with the '150 Patent.

RESPONSE: Denied.

84. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '150 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS IN COUNT IV:
DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '150 PATENT

85. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

86. Plaintiffs own all rights, title, and interest in and to the '150 Patent.

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

87. Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '150 Patent.

RESPONSE: Denied.

88. On information and belief, if Defendants' ANDA is approved, Defendants' ANDA Products will be made, used, offered for sale, sold, distributed, or imported into the United States by or through Defendants and their affiliates and will therefore infringe one or more claims of the '150 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g).

RESPONSE: Denied.

89. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Products, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '150 Patent, including at least claim 1, under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

90. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '150 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '150 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

91. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants concerning liability for the infringement of the '150 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Defendants admit there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurolife concerning the '150 patent. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

92. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '150 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

93. Plaintiffs should be granted a declaratory judgment that the submission of Defendants' ANDA or commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products would infringe one or more claims of the '150 Patent.

RESPONSE: Denied.

94. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and Plaintiffs are entitled to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS IN COUNT V:
ALLEGED INFRINGEMENT OF THE '589 PATENT

95. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

96. Plaintiffs own all rights, title, and interest in and to the '589 Patent.

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

97. On information and belief, Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '589 Patent.

RESPONSE: Denied.

98. On information and belief, Defendants have infringed one or more claims of the '589 Patent, including at least claim 8, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of Defendants' ANDA Products prior to the expiration of the '589 Patent.

RESPONSE: Denied.

99. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale in the United States and importation into the United States of Defendants' ANDA Products would directly infringe one or more claims of the '589 Patent, including at least claim 8, under 35 U.S.C. §§ 271(a) or (g), and would actively induce and contribute to infringement of one or more claims of the '589 Patent, including at least claim 8, under 35 U.S.C. §§ 271(b) or (c). Accordingly, unless enjoined by this Court, upon FDA approval of Defendants' ANDA and amendments, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within or import Defendants' ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '589 Patent.

RESPONSE: Denied.

100. On information and belief, Defendants had actual and constructive notice of the '589 Patent prior to submitting Defendants' ANDA to FDA. Defendants were aware that submitting Defendants' ANDA with the request for FDA approval prior to the expiration of the '589 Patent would constitute an act of infringement of the '589 Patent.

RESPONSE: Defendants admit Aurolife had notice of the '589 patent as of the date Aurolife submitted a Paragraph IV certification regarding the same. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

101. Defendants submitted Defendants' ANDA without adequate justification for asserting the '589 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '589 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

102. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for Defendants' ANDA to be a date that is not any earlier than the expiration date of the '589 Patent, including any extensions, adjustments, and exclusivities associated with the '589 Patent.

RESPONSE: Denied.

103. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '589 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

RESPONSES TO ALLEGATONS IN COUNT VI:
DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '589 PATENT

104. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

105. Plaintiffs own all rights, title, and interest in and to the '589 Patent.

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

106. Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '589 Patent.

RESPONSE: Denied.

107. On information and belief, if Defendants' ANDA is approved, Defendants' ANDA Products will be made, used, offered for sale, sold, distributed, or imported into the United States by or through Defendants and their affiliates and will therefore infringe one or more claims of the '589 Patent, including at least claim 8, under 35 U.S.C. §§ 271(a) or (g).

RESPONSE: Denied.

108. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Products, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '589 Patent, including at least claim 8, under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

109. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '589 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '589 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

110. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants concerning liability for the infringement of the '589 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Defendants admit there is a real, substantial and continuing case or controversy between Plaintiffs and Aurolife regarding the '589 patent. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

111. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '589 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

112. Plaintiffs should be granted a declaratory judgment that the submission of Defendants' ANDA or commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products would infringe one or more claims of the '589 Patent.

RESPONSE: Denied.

113. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and Plaintiffs are entitled to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS IN COUNT VII:
ALLEGED INFRINGEMENT OF THE '174 PATENT

114. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

115. Plaintiffs own all rights, title, and interest in and to the '174 Patent.

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

116. On information and belief, Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '174 Patent.

RESPONSE: Denied.

117. On information and belief, Defendants have infringed one or more claims of the '174 Patent, including at least claim 1, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting Defendants' ANDA with a Paragraph IV certification and

thereby seeking FDA approval of Defendants' ANDA Products prior to the expiration of the '174 Patent.

RESPONSE: Denied.

118. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale in the United States and importation into the United States of Defendants' ANDA Products would directly infringe one or more claims of the '174 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g), and would actively induce and contribute to infringement of one or more claims of the '174 Patent, including at least claim 1, under 35 U.S.C. §§ 271(b) or (c). Accordingly, unless enjoined by this Court, upon FDA approval of Defendants' ANDA and amendments, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within or import Defendants' ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '174 Patent.

RESPONSE: Denied.

119. On information and belief, Defendants had actual and constructive notice of the '174 Patent prior to submitting Defendants' ANDA to FDA. Defendants were aware that submitting Defendants' ANDA with the request for FDA approval prior to the expiration of the '174 Patent would constitute an act of infringement of the '174 Patent.

RESPONSE: Defendants admit Aurolife had notice of the '174 patent as of the date Aurolife submitted a Paragraph IV certification regarding the same. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

120. Defendants submitted Defendants' ANDA without adequate justification for asserting the '174 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '174 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

121. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for Defendants' ANDA to be a date that is not any earlier than the expiration date of the '174 Patent, including any extensions, adjustments, and exclusivities associated with the '174 Patent.

RESPONSE: Denied.

122. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '174 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS IN COUNT VIII:
DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '174 PATENT

123. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

RESPONSE: Defendants restate and incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

124. Plaintiffs own all rights, title, and interest in and to the '174 Patent.

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

125. Defendants submitted Defendants' ANDA and thereby seek FDA approval of Defendants' ANDA and to manufacture, use, offer to sell, sell, and import Defendants' ANDA Products before the expiration of the '174 Patent.

RESPONSE: Denied.

126. On information and belief, if Defendants' ANDA is approved, Defendants' ANDA Products will be made, used, offered for sale, sold, distributed, or imported into the United States by or through Defendants and their affiliates and will therefore infringe one or more claims of the '174 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (g).

RESPONSE: Denied.

127. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Products, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '174 Patent, including at least claim 1, under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

128. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '174 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '174 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and (g).

RESPONSE: Denied.

129. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants concerning liability for the infringement of the '174 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Defendants admit there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurolife concerning the '174 patent. Defendants deny all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

130. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '174 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

RESPONSE: Denied.

131. Plaintiffs should be granted a declaratory judgment that the submission of Defendants' ANDA, commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products would infringe one or more claims of the '174 Patent.

RESPONSE: Denied.

132. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and Plaintiffs are entitled to recovery of their attorneys' fees and such other relief as this Court deems proper.

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegations in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' complaint, Defendants deny 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, Defendants assert 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 Aurolife's ANDA No. 214903 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 Asserted Patents.

SECOND SEPARATE DEFENSE

Each of the claims of each of the Asserted Patents 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.

THIRD SEPARATE DEFENSE

Each of the claims of each of the Asserted Patents is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in Aurolife's Notice Letter.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the Asserted Patents is invalid as anticipated or obvious, pursuant to 35 U.S.C. § 112, for example, indefiniteness, lack of enablement and/or written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the Asserted Patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of Defendants' ANDA No. 214903.

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, Defendants hereby demand 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.

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