IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERZ PHARMACEUTICALS, LLC and MERZ NORTH AMERICA, INC., Plaintiffs, v. AUROBINDO PHARMA LTD, and AUROBINDO PHARMA USA INC., Defendants.	C.A. No. 1:20-cv-1760 (RGA-JLH)

ANSWER TO COMPLAINT

Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. (together, "Aurobindo" or "Defendants"), through their undersigned counsel, hereby answers the complaint filed by Plaintiffs Merz Pharmaceuticals, LLC ("Merz LLC") and Merz North America, Inc. ("Merz N.A.") (together, "Merz" or "Plaintiffs") and alleges in response to the numerous allegations set forth in the complaint of December 23, 2020 involving generic glycopyrrolate (CUVPOSA®) as follows:

NATURE OF THE ACTION

1. **This is an action for patent infringement of United States Patent Nos. 7,638,552 ("the '552 Patent") and 7,816,396 ("the '396 Patent," collectively, the "patents-in-suit"), arising under the United States patent laws, Title 35, United States Code. This action relates to Aurobindo's filing of Abbreviated New Drug Application ("ANDA") No. 214847 under section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to**

manufacture and sell a generic version of Plaintiffs' CUVPOSA® (glycopyrrolate), 1mg/5mL oral solution ("CUVPOSA®") prior to the expiration of the '552 and the '396 Patents.

ANSWER: Aurobindo admits that Plaintiffs have brought an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100 et seq., and a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 and that Plaintiffs have asserted that it arises from Aurobindo's Abbreviated New Drug Application ("ANDA") No. 214847 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CUVPOSA® (glycopyrrolate) 1mg/5mL oral solution ("CUVPOSA") ("Aurobindo's ANDA Product"), but denies any remaining allegations of Paragraph 1.

2. **By letter dated November 16, 2020, Defendant Aurobindo notified Plaintiff Merz LLC that it had filed ANDA No. 214847, seeking FDA approval to manufacture and sell a generic version of Plaintiffs' CUVPOSA®.**

ANSWER: Aurobindo admits that it notified Merz that Aurobindo submitted ANDA No. 214847 ("Aurobindo's ANDA") to the FDA by letter dated November 16, 2020 ("Aurobindo's Notice Letter"). Aurobindo directs Merz to Aurobindo's Notice Letter for the best description of what Aurobindo has sought to do under Aurobindo's ANDA.

THE PARTIES

3. **Plaintiff Merz LLC is a limited liability company organized and existing under the laws of North Carolina, with a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Plaintiff Merz LLC is in the business of, inter alia,**

holding intellectual property and regulatory approval rights to innovative pharmaceutical products.

ANSWER: Upon information and belief, Aurobindo admits that Plaintiff Merz LLC is a limited liability company organized and existing under the laws of North Carolina, with a place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Upon information and belief, Aurobindo admits that Plaintiff Merz LLC is in the business of, inter alia, developing and/or marketing pharmaceutical products throughout the United States. Aurobindo denies the remaining allegations of Paragraph 3.

4. **Plaintiff Merz N.A. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Plaintiff Merz N.A. is in the business of, inter alia, researching, developing, manufacturing, marketing, promoting, selling, distributing, and/or obtaining regulatory approval for innovative pharmaceutical products throughout the United States, including in this judicial district.**

ANSWER: Upon information and belief, Aurobindo admits that Plaintiff Merz N.A. is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Upon information and belief, Aurobindo admits that Plaintiff Merz N.A. is in the business of, inter alia, developing and/or marketing pharmaceutical products throughout the United States. Aurobindo denies the remaining allegations of Paragraph 4.

5. **On information and belief, Defendant APL is a corporation that is incorporated in India, having a principal place of business at Plot No 2, Maitrivihar, Behind Maitrivanam, Ameerpet, Hyderabad, Telangana TS 500038 IN.**

ANSWER: Aurobindo admits that Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, with a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Aurobindo denies the remaining allegations of Paragraph 5.

6. **On information and belief, Defendant APUI is a corporation that is incorporated in Delaware, having a principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520-1401.**

ANSWER: Aurobindo admits that Aurobindo Pharma USA, Inc. 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, New Jersey 08520. Aurobindo denies the remaining allegations of Paragraph 6.

7. **On information and belief, Defendant APUI is a wholly owned subsidiary of APL.**

ANSWER: Aurobindo admits that Aurobindo Pharma USA Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd.

8. **On information and belief, Aurobindo, by itself and/or through its affiliates and agents, is in the business of, inter alia, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within the State of Delaware.**

ANSWER: Aurobindo admits that Aurobindo is in the business of, among other things, developing, manufacturing, and marketing generic pharmaceutical products in the United States, including in the State of Delaware. Aurobindo denies the remaining allegations of Paragraph 8.

9. **On information and belief, Aurobindo has filed ANDA No. 214847 and will be involved in the manufacture, importation, marketing and sale of the drug that is subject to ANDA No. 214847 if it is approved.**

ANSWER: Paragraph 9 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer is required, Aurobindo admits that Aurobindo has submitted ANDA No. 214847 to the FDA for approval of a generic glycopyrrolate product, but cannot speak one way or another as to the ultimate intentions of this submission due to the variability of market conditions over time. Aurobindo denies the remaining allegations of Paragraph 9.

10. **On information and belief, and consistent with their past practices, APL and APUI acted collaboratively in the preparation and submission of ANDA No. 214847.**

ANSWER: Paragraph 10 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer is required, Aurobindo admits that Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. often collaborate on submissions of material to the FDA. Aurobindo denies the remaining allegations of Paragraph 10.

11. **On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 214847, APL and APUI will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 214847 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.**

ANSWER: Paragraph 11 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer is required, Aurobindo admits that Aurobindo has submitted ANDA No. 214847 to the FDA for approval of a generic

glycopyrrolate product, but cannot speak one way or another as to the ultimate intentions of this submission due to the variability of market conditions over time. Aurobindo denies the remaining allegations of Paragraph 11.

JURISDICTION AND VENUE

12. **This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.**

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent that a response is required, Aurobindo admits for purposes of this case only that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. With respect to any remaining allegations of Paragraph 12, Aurobindo denies the same.

13. **This Court has personal jurisdiction over APL because APL, through its wholly- owned subsidiary APUI, has purposely availed itself of the benefits and protections of Delaware's laws, as it develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware. Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of Delaware.**

ANSWER: Paragraph 13 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits Aurobindo Pharma Ltd. has done and is doing business in Delaware, and sells drug products in various states of the United States, including Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 13, Aurobindo denies the same.

14. **Alternatively, to the extent the above facts do not establish personal jurisdiction over APL, this Court may exercise jurisdiction over APL pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) APL is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) APL has sufficient contacts within the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.**

ANSWER: Paragraph 14 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma Ltd. is qualified to do business in Delaware, has appointed a registered person for service of process in Delaware, and sells some of its generic products in Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 14, Aurobindo denies the same.

15. **This Court has personal jurisdiction over APUI for purposes of this civil action because, inter alia, APUI, on information and belief, is incorporated in the State of Delaware.**

ANSWER: Paragraph 15 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the State of Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 15, Aurobindo denies the same.

16. **This Court also has personal jurisdiction over APUI for purposes of this civil action because, inter alia, APUI has purposely availed itself of the benefits and protections of Delaware's laws, as it develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware. Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of Delaware.**

ANSWER: Paragraph 16 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits Aurobindo Pharma USA Inc. has done and is doing business in Delaware, and sells drug products in various states of the United States, including Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 16, Aurobindo denies the same.

17. **This Court has personal jurisdiction over Aurobindo for purposes of this civil action because, inter alia, Aurobindo has filed ANDA No. 214847 and intends to make, use, offer for sale, sell and/or import its proposed ANDA product in the United States, including Delaware, prior to the expiration of the patents-in-suit if ANDA No. 214847 is approved. Such acts will lead to foreseeable harm to Plaintiffs in Delaware.**

ANSWER: Paragraph 17 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits it has submitted ANDA No. 214847 to the FDA for approval of Aurobindo's generic glycopyrrolate product. Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States including in the State of Delaware even upon receiving FDA

approval to market. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 17, Aurobindo denies the same.

18. **On information and belief, Aurobindo has not challenged personal jurisdiction in this Court in one or more prior cases arising out of the filing of its ANDAs. *See, e.g., Merck Sharp & Dohme Corp. v. Aurobindo Pharma Ltd et al., C.A. No. 20-1099 (D. Del.); Novartis Pharmaceuticals Corp. v. Aurobindo Pharma Ltd. et al., C.A. No. 20-1426 (D. Del.); Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-1528 (D. Del.).**

ANSWER: Paragraph 18 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it has been involved in litigation in the District of Delaware as indicated in Paragraph 18, where Aurobindo did not challenge personal jurisdiction for the narrow purposes of specific actions. Although Aurobindo does not admit that personal jurisdiction is proper, it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 18.

19. **On information and belief, Aurobindo has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction. *See, e.g., Merck Sharp & Dohme Corp. v. Aurobindo Pharma Ltd et al., C.A. No. 20-1099 (D. Del.); Novartis Pharmaceuticals Corp. v. Aurobindo Pharma Ltd. et al., C.A. No. 20-1426 (D. Del.); Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.,* C.A. No. 20-1528 (D. Del.).**

ANSWER: Paragraph 19 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it has been

involved in litigation in the District of Delaware as indicated in Paragraph 19, where Aurobindo filed counterclaims within the District of Delaware. Although Aurobindo does not admit that personal jurisdiction is proper, it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 19.

20. **Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).**

ANSWER: Paragraph 20 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits only that it will not contest venue or personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 20, Aurobindo denies the same.

THE PATENTS-IN-SUIT AND CUVPOSA®

21. **On December 29, 2009, the United States Patent and Trademark Office ("PTO") issued the '552 Patent, entitled "Method for Increasing The Bioavailability of Glycopyrrolate," to Sciele Pharma, Inc., the initial assignee of the named inventors, Alan Roberts and Balaji Venkataraman. The '552 Patent was subsequently assigned to Shiongi Pharma, Inc. on January 11, 2010; to Shionogi Inc. on March 31, 2011; and then to Plaintiff Merz LLC on August 24, 2012. Plaintiff Merz LLC is the current record owner of the '552 Patent. A copy of the '552 Patent is attached hereto as Exhibit A.**

ANSWER: Paragraph 21 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. 7,638,552 ("the '552 patent") as set forth at Exhibit A to the Complaint, the '552 patent was issued on December 29, 2009 with such title to such initial assignees. Upon information and belief, based on the assignment record at the United States

Patent and Trademark Office ("USPTO"), plaintiff Merz Pharmaceuticals LLC is the current record owner of the '552 Patent. With respect to any remaining allegations of Paragraph 21, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

22. **On October 19, 2010, the PTO issued the '396 Patent, entitled "Method for Increasing The Bioavailability of Glycopyrrolate," to Sciele Pharma, Inc., the initial assignee of the named inventors, Alan Roberts and Balaji Venkataraman. The '396 Patent was subsequently assigned to Shionogi Pharma, Inc. on January 11, 2010; to Shionogi Inc. on March 31, 2011; and then to Plaintiff Merz LLC on August 24, 2012. Plaintiff Merz LLC is the current record owner of the '396 Patent. A copy of the '396 Patent is attached hereto as Exhibit B.**

ANSWER: Paragraph 22 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. 7,816,396 ("the '396 patent") as set forth at Exhibit B to the Complaint, the '396 patent was issued on March 31, 2011 with such title to such initial assignee. Upon information and belief based on the assignment record at the USPTO, plaintiff Merz Pharmaceuticals LLC is the current record owner of the '396 Patent. With respect to any remaining allegations of Paragraph 22, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

23. **On July 28, 2010, the FDA approved New Drug Application ("NDA") No. 022571 for CUVPOSA®. Plaintiff Merz LLC is the holder of NDA No. 022571 for CUVPOSA®.**

ANSWER: Upon information and belief, Aurobindo admits that the FDA approved NDA No. 022571 for CUVPOSA® on July 28, 2010. Upon information and belief, Plaintiff Merz Pharmaceuticals LLC is the holder of NDA No. 022571, which pertains to the product CUVPOSA®. Aurobindo denies the remaining allegations of Paragraph 23.

24. **In the publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book"), the patents-in-suit are listed as covering CUVPOSA®.**

ANSWER: Upon information and belief, the '552 patent and the '396 patent (together, the "Patents-in-Suit") are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with CUVPOSA®. Aurobindo denies the remaining allegations of Paragraph 24.

DEFENDANTS' ANDA

25. **On information and belief, Aurobindo reviewed the patents-in-suit and certain commercial and economic information relating to CUVPOSA®, including estimates of the revenues generated by the sale of CUVPOSA®, and decided to file an ANDA, seeking approval to market a glycopyrrolate oral solution.**

ANSWER: Paragraph 25 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it submitted an ANDA to the FDA for approval to market a generic glycopyrrolate oral solution product. Aurobindo denies the remaining allegations in Paragraph 25.

26. **On information and belief, Aurobindo submitted to the FDA ANDA No. 214847 seeking approval to engage in the commercial manufacture, use, and sale of glycopyrrolate oral solution, prior to the expiration of the patents-in-suit.**

ANSWER: Paragraph 26 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it has submitted ANDA No. 214847 to the FDA for approval of a generic glycopyrrolate oral solution product. Aurobindo directs Plaintiffs to Aurobindo's Notice Letter for the best description of what Aurobindo has sought to do under Aurobindo's ANDA. Aurobindo denies the remaining allegations in Paragraph 26.

27. **On information and belief, Aurobindo will manufacture, sell, market, and/or distribute a glycopyrrolate oral solution upon FDA approval of ANDA No. 214847.**

ANSWER: Paragraph 27 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits it has submitted ANDA No. 214847 to the FDA for approval of a generic glycopyrrolate oral solution prior to the expiration of the Patents-in-Suit. Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States including in the State of Delaware even upon receiving FDA approval to market. Aurobindo denies the remaining allegations in Paragraph 27.

28. **Merz LLC received a letter dated November 16, 2020 from Aurobindo notifying Merz LLC that ANDA No. 214847 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Aurobindo's opinion, the patents-in-suit are invalid, unenforceable, or will not be infringed by the commercial**

manufacture, use, or sale of the glycopyrrolate oral solution described in ANDA No. 214847.

ANSWER: Aurobindo admits it sent Plaintiff Merz Pharmaceuticals LLC a letter dated November 16, 2020 stating that Aurobindo's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") certifying that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's ANDA Product. Aurobindo denies the remaining allegations in Paragraph 28.

29. **Plaintiffs commenced this action within 45 days of the date they received Aurobindo's notice of ANDA No. 214847 containing the Paragraph IV certification.**

ANSWER: Upon information and belief, Aurobindo admits that Plaintiffs commenced this action within 45 days of the date they received Aurobindo's Notice Letter. Aurobindo denies the remaining allegations in Paragraph 29.

FIRST CLAIM FOR RELIEF
(Infringement of the '552 Patent by Aurobindo)

30. **Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 29 hereof, as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 29 of the Answer to the Complaint with the same force and effect as if hereinafter set forth at length.

31. **Through the conduct alleged above, Aurobindo has infringed, and continues to infringe, one or more claims of the '552 Patent.**

ANSWER: Denied.

32. **By filing ANDA No. 214847 and seeking FDA approval to engage in the commercial manufacture, use, sale, marketing, distribution, and/or importation of the**

glycopyrrolate oral solution disclosed therein prior to the expiration of the '552 Patent, Aurobindo has infringed the '552 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

33. **There is a justiciable controversy between the parties hereto as to the infringement of the '552 Patent.**

ANSWER: Admitted.

34. **On information and belief, Aurobindo will be actively involved in the infringement of the '552 Patent through the manufacture, use, sale, marketing, distribution, and/or importation of glycopyrrolate oral solution described in ANDA No. 214847, if approved.**

ANSWER: Paragraph 34 contains allegations to which no response is required. To the extent that an answer is required, due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 34, Aurobindo denies the same.

35. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will infringe the '552 Patent under 35 U.S.C § 271(a) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847.**

ANSWER: Paragraph 35 contains allegations to which no response is required. To the extent that an answer is required, due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to

engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 35, Aurobindo denies the same.

36. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will induce infringement of the '552 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 214847, Aurobindo will, with knowledge of the '552 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 214847 to patients to treat sialorrhea in a manner that infringes the '552 Patent.**

ANSWER: Denied.

37. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will contributorily infringe the '552 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847. On information and belief, Aurobindo knows that the glycopyrrolate oral solution described in ANDA No. 214847 and the product labeling for that product, are especially made or adapted for use in infringing the '552 Patent and are not suitable for substantial noninfringing use.**

ANSWER: Denied.

38. **Aurobindo was aware of the existence of the '552 Patent prior to filing ANDA No. 214847, but took such action knowing that by doing so, they would infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit.**

ANSWER: Paragraph 38 contains allegations to which no response is required. To the extent that an answer is required, Aurobindo admits that it was aware of the existence of the '552 Patent prior to filing Aurobindo's ANDA. Aurobindo also notes that it submitted a Paragraph IV certification certifying that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's ANDA Product. Aurobindo denies the remaining allegations in Paragraph 38.

39. **On information and belief, Aurobindo acted without reasonable basis for a good faith belief that they would not be liable for infringing the '552 Patent.**

ANSWER: Denied.

40. **Aurobindo's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.**

ANSWER: Denied.

41. **Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing the '552 Patent.**

ANSWER: Denied.

SECOND CLAIM FOR RELIEF
(Infringement of the '396 Patent by Aurobindo)

42. **Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 41 hereof, as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 41 of the Answer to the Complaint with the same force and effect as if hereinafter set forth at length.

43. **Through the conduct alleged above, Aurobindo has infringed, and continues to infringe, one or more claims of the '396 Patent.**

ANSWER: Denied.

44. **By filing ANDA No. 214847 and seeking FDA approval to engage in the commercial manufacture, use, sale, marketing, distribution, and/or importation of the glycopyrrolate oral solution disclosed therein prior to the expiration of the '396 Patent, Aurobindo has infringed the '396 Patent under 35 U.S.C. § 271(e)(2)(A).**

ANSWER: Denied.

45. **There is a justiciable controversy between the parties hereto as to the infringement of the '396 Patent.**

ANSWER: Admitted.

46. **On information and belief, Aurobindo will be actively involved in the infringement of the '396 Patent through the manufacture, use, sale, marketing, distribution, and/or importation of glycopyrrolate oral solution described in ANDA No. 214847, if approved.**

ANSWER: Denied.

47. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will infringe the '396 Patent under 35 U.S.C § 271(a) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847.**

ANSWER: Paragraph 47 contains allegations to which no response is required. To the extent that an answer is required, due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon

receiving FDA approval to market. With respect to any remaining allegations of Paragraph 47, Aurobindo denies the same.

48. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will induce infringement of the '396 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 214847, Aurobindo will, with knowledge of the '396 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 214847 to patients to treat sialorrhea in a manner that infringes the '396 Patent.**

ANSWER: Paragraph 48 contains allegations to which no response is required. To the extent that an answer is required, due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 48, Aurobindo denies the same.

49. **Unless enjoined by this Court, upon FDA approval of ANDA No. 214847, Aurobindo will contributorily infringe the '396 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling the glycopyrrolate oral solution described in ANDA No. 214847. On information and belief, Aurobindo knows that the glycopyrrolate oral solution described in ANDA No. 214847 and the product labeling for that product, are especially made or adapted for use in infringing the '396 Patent and are not suitable for substantial noninfringing use.**

ANSWER: Denied.

50. **Aurobindo was aware of the existence of the '396 Patent prior to filing ANDA No. 214847, but took such action knowing that by doing so, they would infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit.**

ANSWER: Paragraph 50 contains allegations to which no response is required. To the extent that an answer is required, Aurobindo admits that it was aware of the existence of the '396 Patent prior to filing Aurobindo's ANDA. Aurobindo also notes that it submitted a Paragraph IV certification certifying that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's ANDA Product. Aurobindo denies the remaining allegations in Paragraph 50.

51. **On information and belief, Aurobindo acted without reasonable basis for a good faith belief that they would not be liable for infringing the '396 Patent.**

ANSWER: Denied.

52. **Aurobindo's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.**

ANSWER: Denied.

53. **Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing the '396 Patent.**

ANSWER: Denied.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. **An order adjudging and decreeing that Aurobindo has infringed one or more claims of the patents-in-suit by submitting ANDA No. 214847, and that the**

making, using, offering to sell, or selling in the United States, or importing into the United States, of the glycopyrrolate oral solution described in ANDA No. 214847 by Aurobindo will infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit;

B. **An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 214847 be no earlier than the expiration date of the patents- in-suit, including any extensions and/or exclusivities;**

C. **A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Aurobindo, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the glycopyrrolate oral solution described in ANDA No. 214847 until the expiration date of the patents-in-suit, including any extensions and/or exclusivities;**

D. **A declaration that the commercial manufacture, use, sale, marketing, distribution, and/or importation of the glycopyrrolate oral solution described in ANDA No. 214847 will directly infringe, induce, or contribute to the infringement of the patents-in-suit;**

E. **A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and**

F. **Such other and further relief as the Court may deem just and proper.**

ANSWER TO PRAYER FOR RELIEF: The "WHEREFORE" paragraphs following Paragraph 53 states Plaintiffs' prayer for relief for which no response is required. To the extent a response is required, Defendants deny the allegations contained in the "WHEREFORE"

paragraphs following Paragraph 53 of the Complaint and deny that Plaintiffs are entitled to any of the relief required, or to any relief whatsoever. Aurobindo specifically denies that Plaintiffs are entitled to the general or specific relief requested against Aurobindo, or to any relief whatsoever, and pray for judgment in favor of Aurobindo dismissing this action with prejudice, and awarding Aurobindo its reasonable attorneys' fees.

ADDITIONAL DEFENSES

Aurobindo asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

FIRST ADDITIONAL DEFENSE (FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND ADDITIONAL DEFENSE (INVALIDITY AND UNENFORCEABILITY)

U.S. Patent No. 7,638,552 ("the '552 patent") and U.S. Patent No. 7,816,396 ("the '396 patent") (collectively, the "Patents-In-Suit") and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, including as particularly set forth in the November 16, 2020 Notice Letter ("Aurobindo's Notice Letter") sent in respect Aurobindo's Paragraph IV Certifications ("Aurobindo's Paragraph IV Certification").

THIRD ADDITIONAL DEFENSE
(NO DIRECT INFRINGEMENT)

As set forth in the Detailed Statement of Aurobindo's Notice Letter, Aurobindo does not infringe literally any valid and enforceable claim of the Patents-In-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in Aurobindo's proposed product for the missing elements of any of the claims of the Patents-In-Suit, there can be no infringement under the doctrine of equivalents.

FOURTH ADDITIONAL DEFENSE
(NO INDIRECT INFRINGEMENT)

Aurobindo has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Aurobindo ANDA product does not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit.

FIFTH ADDITIONAL DEFENSE
(NO COSTS)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH ADDITIONAL DEFENSE
(FAILURE TO STATE CLAIM OF WILFULNESS)

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH ADDITIONAL DEFENSE
(RESERVATION OF RIGHTS)

Aurobindo reserves the right to assert additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS OF AUROBINDO

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. ("Aurobindo" or "Counterclaim-Plaintiffs"), through their undersigned attorneys, for their Counterclaims against Merz Pharmaceuticals, LLC and Merz North America, Inc. (together, "Merz" or "Counterclaim-Defendants"), hereby state the following:

1. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of Aurobindo's (Defendants') Answer and Additional Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of U.S. Patent No. 7,638,552 ("the '552 patent") and U.S. Patent No. 7,816,396 ("the '396 patent") (collectively, the "Patents-In-Suit"). Upon information and belief, a true and correct copy of the '552 patent is attached to the Answer to the Complaint as Exhibit A. Upon information and belief, a true and correct copy of the '396 patent is attached to the Answer to the Complaint as Exhibit B.

THE PARTIES

3. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

4. Counterclaim-Plaintiff Aurobindo Pharma Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andra Pradesh, India.

5. On information and belief, based on the complaint filed by Plaintiff/Counterclaim-Defendant in this case, Plaintiff Merz LLC is a limited liability company organized and existing

under the laws of North Carolina, with a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615.

6. On information and belief, based on the complaint filed by Plaintiff/Counterclaim-Defendant in this case, Plaintiff Merz N.A. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615.

JURISDICTION

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Counterclaim-Plaintiffs, on the one hand, and the Counterclaim-Defendants on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has personal jurisdiction over Counterclaim-Defendants based, *inter alia,* on the filing by Counterclaim-Defendants of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ORANGE BOOK LISTING OF THE PATENTS

10. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

11. On information and belief, on December 29, 2009, the U.S. Patent and Trademark Office ("PTO") issued the '552 Patent. On information and belief, a true and

correct copy of the '552 Patent is attached to the complaint as Exhibit A.

12. On information and belief, on October 19, 2010, the U.S. Patent and Trademark Office ("PTO") issued the '396 Patent. On information and belief, a true and correct copy of the '396 Patent is attached to the complaint as Exhibit B.

13. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendants caused the FDA to list the Patents-In-Suit in the Orange Book in connection with NDA No. 022571 in respect of the brand name product CUVPOSA® (generic name glycopyrrolate) ("CUVPOSA NDA").

14. By maintaining the listings of the Patents-In-Suit in the Orange Book, Counterclaim-Defendants represent to the world that the Patents-In-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product before the expiration of the Patents-in-Suit.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION

15. Aurobindo filed ANDA No. 214847 ("Aurobindo's ANDA") with the FDA seeking approval to market a glycopyrrolate oral solution, intended to be a generic version of CUVPOSA®. Aurobindo's ANDA included a Paragraph IV Certification to the Patents-In-Suit, certifying that to the best of its knowledge that all of the claims of the Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Aurobindo's ANDA.

THE PRESENCE OF A CASE OR CONTROVERSY

16. By maintaining the Orange Book listings of the Patents-In-Suit in connection with the CUVPOSA®, Counterclaim-Defendants represent that the Patents-In-Suit could reasonably be asserted against anyone making, using or selling a glycopyrrolate oral solution,

intended to be generic version of CUVPOSA®, without a license from the Counterclaim-Defendant prior to the expiration of the Patents-In-Suit.

17. Counterclaim-Defendants have filed an infringement action under Title 35, United States Code, Sections 100 et seq., asserting the Patents-In-Suit against Counterclaim-Plaintiffs and seeking a declaration of infringement regarding the Patents-In-Suit. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiffs on the one hand, and Counterclaim-Defendants, on the other hand, as to whether the products disclosed in Aurobindo's ANDA infringe the Patents-In-Suit, and whether any valid, enforceable claim in the Patents-In-Suit exists.

18. Aurobindo seeks to market a generic glycopyrrolate oral solution that is the subject of Aurobindo's ANDA in the United States prior to the expiration of the Patents-In-Suit.

19. If Counterclaim-Plaintiffs succeed in proving that their generic glycopyrrolate oral solution that is the subject of Aurobindo's ANDA does not infringe the Patents-In-Suit or all asserted claims are invalid or unenforceable, and thus non-infringing, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendants' maintenance of the Patents-In-Suit in the Orange Book in connection with the CUVPOSA® NDA.

20. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendants and Counterclaim-Plaintiffs as to whether the claims of the Patents-In-Suit are invalid and/or not infringed by Counterclaim-Plaintiffs.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE PATENTS-IN-SUIT)

21. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-20 of their Counterclaims, above, as if fully set forth herein.

22. This counterclaim arises 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. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning the Patents-In-Suit and the claims of the Patents-In-Suit.

23. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA infringes one or more claims of the Patents-In-Suit.

24. Counterclaim-Plaintiffs assert that no valid claim of the Patents-In-Suit are infringed by the manufacture, use, offer for sale, sale, and/or importation of the generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA.

25. Counterclaim-Plaintiffs are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's' generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA does not infringe any valid claim of the Patents-In-Suit.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE PATENTS-IN-SUIT)

26. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-25 of Counterclaim-Plaintiffs' Counterclaims, above, as if fully set forth herein.

27. This counterclaim arises 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. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning the claims of the Patents-In-Suit.

28. Counterclaim-Defendants allege that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA infringes one or more claims of the Patents-In-Suit.

29. Counterclaim-Plaintiffs assert that the manufacture, use, offer-for-sale, sale, and/or importation of Counterclaim-Plaintiffs' generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA do not infringe any valid claim of the Patents-In-Suit, and that the claims of the Patents-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation in particular for all the reasons set forth in Aurobindo's November 16, 2020 Notice Letter (which Counterclaim-Plaintiffs can resupply if needed).

30. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the Patents-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other

judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that the Court enter judgment in their favor and against Counterclaim-Defendants as follows:

a. Denying Counterclaim-Defendants' claims and dismissing Plaintiff's Complaint with prejudice;

b. Declaring that the claims of the Patents-In-Suit are invalid;

c. Declaring that the claims of the Patents-In-Suit are not, and will not be, infringed by Counterclaim-Plaintiffs' manufacture, use, sale, offer for sale, or importation of the generic glycopyrrolate oral solution product that is the subject of Aurobindo's ANDA;

d. Preliminarily and permanently enjoining Counterclaim-Defendants, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendants, from utilizing the Patents-In-Suit to block, hamper, hinder or obstruct FDA approval of Counterclaim-Plaintiffs' proposed product;

e. Permanently enjoining Counterclaim-Defendants, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patents-In-Suit against Counterclaim-Plaintiffs or anyone in privity with Counterclaim-Plaintiffs;

f. Declaring this case exceptional and awarding Counterclaim-Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;

g. Awarding costs to Counterclaim-Plaintiffs; and

h. Awarding to Counterclaim-Plaintiffs any other such and further relief as is just and proper

Dated: March 8, 2021

/s/ Kenneth L. Dorsney
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