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

MERZ PHARMACEUTICALS, LLC and MERZ NORTH AMERICA, INC., Plaintiffs, v. AUROBINDO PHARMA LTD, and AUROBINDO PHARMA USA INC. Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merz Pharmaceuticals, LLC ("Merz LLC") and Merz North America, Inc. ("Merz N.A.") (together, "Merz" or "Plaintiffs") bring this action against Defendant Aurobindo Pharma Ltd., ("APL") and Aurobindo Pharma USA Inc. ("APUI," collectively, "Aurobindo" or "Defendants"), and allege 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.

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®.

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.

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.

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.

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.

7. On information and belief, Defendant APUI operates a distribution center at 6 Wheeling Road, Dayton, NJ 08810.

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

9. 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 New Jersey.

10. 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.

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

12. 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.

JURISDICTION AND VENUE

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

14. 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 New Jersey'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 New Jersey.

Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

15. 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.

16. This Court has personal jurisdiction over APUI for purposes of this civil action because, *inter alia*, APUI, on information and belief, has a principal place of business and at least one other regular and established place of business in New Jersey.

17. 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 New Jersey'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 New Jersey. Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

18. 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 New

Jersey, 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 New Jersey.

19. 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., Bausch Health US, LLC f/k/a Valeant Pharmaceuticals North America LLC et al., v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 20-02738 (D. N.J.); *Merck Sharp & Dohme Corp. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 20-10444 (D. N.J.); *Merck Sharp & Dohme B.V. et al., v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 20-02576 (D. N.J.).

20. 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 New Jersey, having asserted counterclaims in this jurisdiction, *See, e.g., Bausch Health US, LLC f/k/a Valeant Pharmaceuticals North America LLC et al., v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 20-02738 (D. N.J.); *Merck Sharp & Dohme Corp. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 20-10444 (D. N.J.).

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

THE PATENTS-IN-SUIT AND CUVPOSA®

22. 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.

23. 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.

24. 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®.

25. 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®.

DEFENDANTS' ANDA

26. 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.

27. 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.

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

29. 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.

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

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

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

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

33. 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).

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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

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

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

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

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

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

45. 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).

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

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

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

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

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.

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Dated: December 28, 2020

HOGAN LOVELLS US LLP

s/ Jason A. Leonard

Jason A. Leonard
390 Madison Avenue
New York, NY 10017
(212) 918-3000
jason.leonard@hoganlovells.com

Attorneys for Plaintiffs Merz Pharmaceuticals, LLC and Merz North America, Inc.