IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERZ PHARMACEUTICALS, LLC and MERZ NORTH AMERICA, INC., Plaintiffs, v. ANNORA PHARMA PRIVATE LTD. Defendant.	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 Annora Pharma Private Ltd ("Annora" or "Defendant"), 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"), arising under the United States patent laws, Title 35, United States Code. This action relates to Annora's filing of Abbreviated New Drug Application ("ANDA") No. 213698 under section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 335(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 October 8, 2019, Defendant Annora notified Plaintiff Merz LLC that it had filed ANDA No. 213698, 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, among other things, 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, among other things, 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 Annora is a company organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State, 502313, India.

6. On information and belief, Annora, 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.

7. On information and belief, Annora has filed ANDA No. 213698 and will be involved in the manufacture, importation, marketing and sale of the drug that is subject to ANDA No. 213698 if it is approved.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Annora for purposes of this civil action because, *inter alia*, Annora has filed ANDA No. 213698 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. 213698 is approved. Such acts will lead to foreseeable harm to Plaintiffs in Delaware.

10. Alternatively, to the extent the above facts do not establish personal jurisdiction over Annora, this Court may exercise jurisdiction over Annora pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Annora is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Annora 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 Annora satisfies due process.

11. On information and belief, Annora 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. Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Annora Pharma Private Ltd. et al.*, 1:18-cv-01786 (D.

Del.); *Vifor Fresenius Medical Care Renal Pharma Ltd. et al. v. Annora Pharma Private Ltd. et al.*, 1:18-01996 (D. Del.).

12. On information and belief, Annora 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, including in the matter of *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Annora Pharma Private Ltd. et al.*, 1:18-cv-01786 (D. Del.).

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

THE PATENTS-IN-SUIT AND CUVPOSA®

14. 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.

15. 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.

16. 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®.

17. 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®.

DEFENDANT'S ANDA

18. On information and belief, Annora 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.

19. On information and belief, Annora submitted to the FDA ANDA No. 213698 seeking approval to engage in the commercial manufacture, use, and sale of glycopyrrolate oral solution, prior to the expiration of the patents-in-suit.

20. On information and belief, Annora will manufacture, sell, market, and/or distribute a glycopyrrolate oral solution upon FDA approval of ANDA No. 213698.

21. Plaintiff Merz LLC received a letter dated October 8, 2019 from Defendant Annora notifying Plaintif Merz LLC that ANDA No. 213698 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Annora'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. 213698.

22. Plaintiffs commenced this action within 45 days of the date they received Annora's notice of ANDA No. 213698 containing the Paragraph IV certification.

FIRST CLAIM FOR RELIEF
(Infringement of the ’552 Patent by Annora)

23. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 22 hereof, as if fully set forth herein.

24. Through the conduct alleged above, Annora has infringed, and continues to infringe, one or more claims of the ’552 Patent.

25. By filing ANDA No. 213698 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, Annora has infringed the ’552 Patent under 35 U.S.C. § 271(e)(2)(A).

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

27. On information and belief, Annora 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. 213698, if approved.

28. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 213698, Annora will, with knowledge of the ’552 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate

oral solution described in ANDA 213698 to patients to treat sialorrhea in a manner that infringes the ’552 Patent.

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698. On information and belief, Annora knows that the glycopyrrolate oral solution described in ANDA No. 213698 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.

31. Annora was aware of the existence of the ’552 Patent prior to filing ANDA No. 213698, 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.

32. On information and belief, Annora acted without reasonable basis for a good faith belief that they would not be liable for infringing the ’552 Patent.

33. Annora’s conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

34. Plaintiffs will be irreparably harmed if Annora is not enjoined from infringing the ’552 Patent.

SECOND CLAIM FOR RELIEF
(Infringement of the ’396 Patent by Annora)

35. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 34 hereof, as if fully set forth herein.

36. Through the conduct alleged above, Annora has infringed, and continues to infringe, one or more claims of the ’396 Patent.

37. By filing ANDA No. 213698 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, Annora has infringed the '396 Patent under 35 U.S.C. § 271(e)(2)(A).

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

39. On information and belief, Annora 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. 213698, if approved.

40. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698.

41. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 213698, Annora will, with knowledge of the '396 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 213698 to patients to treat sialorrhea in a manner that infringes the '396 Patent.

42. Unless enjoined by this Court, upon FDA approval of ANDA No. 213698, Annora 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. 213698. On information and belief, Annora knows that the glycopyrrolate oral solution described in ANDA No. 213698 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.

43. Annora was aware of the existence of the '396 Patent prior to filing ANDA No. 213698, 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.

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

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

46. Plaintiffs will be irreparably harmed if Annora 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 Annora has infringed one or more claims of the patents-in-suit by submitting ANDA No. 213698, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of the glycopyrrolate solution described in ANDA No. 213698 by Annora 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. 213698 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 Annora, 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. 213698 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. 213698 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;

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

Dated: November 20, 2019

MCCARTER & ENGLISH, LLP

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