

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

MERZ PHARMACEUTICALS, LLC and
MERZ NORTH AMERICA, INC.,

Plaintiffs,

v.

MSN PHARMACEUTICALS INC.

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 MSN Pharmaceuticals Inc. (“MSN”), and alleges 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 MSN’s filing of Abbreviated New Drug Application (“ANDA”) No. 216084 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 June 9, 2021, MSN notified Merz that MSN had filed ANDA No. 216084, seeking FDA approval to manufacture and sell a generic version of Merz's CUVPOSA®.

THE PARTIES

3. 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. Merz LLC 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.

4. 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. 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, MSN is a corporation that is incorporated in Delaware, having a principal place of business at 20 Duke Rd, Piscataway, NJ 08854.

6. On information and belief, MSN, 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.

7. On information and belief, MSN has filed ANDA No. 216084 and will be involved in the manufacture, importation, marketing and sale of the drug that is subject to ANDA No. 216084 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 MSN for purposes of this civil action because, *inter alia*, MSN, on information and belief, has its principal place of business in New Jersey.

10. This Court also has personal jurisdiction over MSN for purposes of this civil action because, *inter alia*, MSN has filed ANDA No. 216084 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. 216084 is approved. Such acts will lead to foreseeable harm to Plaintiffs in New Jersey.

11. On information and belief, MSN 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., Actelion Pharmaceuticals Ltd et al. v. MSN Pharmaceuticals Inc. et al.*, C.A. No. 20-cv-3859 (D. N.J.) D.I. 16; *Merck Sharp & Dohme B.V. et al. v. MSN Laboratories Private Limited et al.*, C.A. No. 20-cv-3314 (D. N.J.) D.I. 19.

12. On information and belief, MSN 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., Merck Sharp & Dohme B.V. et al. v. MSN Laboratories Private Limited et al.*, C.A. No. 20-cv-3314 (D. N.J.) D.I. 19.

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 Shionogi Pharma, Inc. on January 11, 2010; to Shionogi Inc. on March 31, 2011; and then to Merz LLC on August 24, 2012. 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 Merz LLC on August 24, 2012. 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®. Merz LLC is the holder of NDA No. 022571 for CUVPOSA®.

17. In FDA’s 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, MSN 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, MSN submitted to the FDA ANDA No. 216084 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, MSN will manufacture, sell, market, and/or distribute a glycopyrrolate oral solution upon FDA approval of ANDA No. 216084.

21. Merz LLC received a letter dated June 9, 2021 from MSN notifying Merz LLC that ANDA No. 216084 includes “a certification pursuant to 21 U.S.C. § 355(j)(2)(B)(vii)(IV) [sic] that the ’552 and ’396 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product” described in ANDA No. 216084 (the “Paragraph IV certification”).

22. Plaintiffs commenced this action within 45 days of the date it received MSN’s notice of ANDA No. 216084 containing the Paragraph IV certification.

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

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, MSN has infringed, and continues to infringe, one or more claims of the ’552 Patent.

25. By filing ANDA No. 216084 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, MSN 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, MSN 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. 216084, if approved.

28. Unless enjoined by this Court, upon FDA approval of ANDA No. 216084, MSN 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. 216084.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 216084, MSN 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. 216084. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 216084, MSN will, with knowledge of the '552 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 216084 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. 216084, MSN 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. 216084. On information and belief, MSN knows that the glycopyrrolate oral solution described in ANDA No. 216084 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. MSN was aware of the existence of the '552 Patent prior to filing ANDA No. 216084, 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, MSN acted without reasonable basis for a good faith belief that they would not be liable for infringing the '552 Patent.

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

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

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

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, MSN has infringed, and continues to infringe, one or more claims of the '396 Patent.

37. By filing ANDA No. 216084 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, MSN 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, MSN 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. 216084, if approved.

40. Unless enjoined by this Court, upon FDA approval of ANDA No. 216084, MSN 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. 216084.

41. Unless enjoined by this Court, upon FDA approval of ANDA No. 216084, MSN 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. 216084. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 216084, MSN will, with knowledge of the '396 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 216084 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. 216084, MSN 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. 216084. On information and belief, MSN knows that the glycopyrrolate oral solution described in ANDA No. 216084 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. MSN was aware of the existence of the '396 Patent prior to filing ANDA No. 216084, 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, MSN acted without reasonable basis for a good faith belief that they would not be liable for infringing the '396 Patent.

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

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

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. An order adjudging and decreeing that MSN has infringed one or more claims of the patents-in-suit by submitting ANDA No. 216084, 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. 216084 by MSN 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. 216084 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 MSN, 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. 216084 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. 216084 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.

Dated: July 16, 2021

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