IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
Western Division
No. 5:18-CV-00584

MERZ PHARMACEUTICALS, LLC and MERZ NORTH AMERICA, INC., Plaintiffs, v. SUVEN LIFE SCIENCES, LTD., TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS U.S.A., INC., Defendants.	**COMPLAINT**

Plaintiffs Merz Pharmaceuticals, LLC ("Merz LLC") and Merz North America, Inc. ("Merz N.A.") (together, "Merz" or "Plaintiffs"), for their Complaint against Defendants Suven Life Sciences, Ltd. ("Suven"), Taro Pharmaceutical Industries Ltd. ("Taro Ltd."), and Taro Pharmaceuticals U.S.A., Inc. ("Taro U.S.A.") (collectively, "Defendants"), allege as follows:

NATURE OF THE CASE

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United Stated Food and Drug Administration ("FDA"), in which Defendants seek FDA approval to manufacture and sell a generic version of Plaintiffs' CUVPOSA® (glycopyrrolate), 1mg/5mL oral solution ("CUVPOSA®") prior to the expiration of U.S. Patent Nos. 7,638,552 ("the '552 Patent") and 7,816,396 ("the '396 Patent") (together, "patents-in-suit").

2. By letter dated November 1, 2018, Defendants Suven and Taro Ltd. notified Plaintiff Merz LLC that they had filed ANDA No. 212467, 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 the State of North Carolina, having 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 District.

5. On information and belief, Defendant Suven is an Indian company, having a principal place of business at 6th Floor, SDE Serene Chambers, Avenue – 7, Road No. 5, Banjara Hills, Hyderabad 500 034, Telangana, India. On information and belief, Suven is in the business of, among other things, supporting the development and manufacturing of generic copies of branded pharmaceutical products throughout the United States, including in this District.

6. On information and belief, Defendant Taro Ltd. is an Israeli company, having a principal place of business at 14 Hakitor Street, P.O. Box 10347, Haifa Bay, 2624761, Israel. On

information and belief, Taro Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

7. On information and belief, Defendant Taro U.S.A., is a corporation organized and existing under the laws of the State of New York having a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532. On information and belief, Taro U.S.A. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

8. On information and belief, following any approval of ANDA No. 212467, Defendants will operate in concert to manufacture, sell, market, and/or distribute the glycopyrrolate oral solution product described in ANDA No. 212467 throughout the United States, including in this District.

9. On information and belief, Defendants regularly transact business and will continue to transact business within North Carolina, including but not limited to, through Suven's potential shipping of generic drugs to Taro Ltd. and/or Taro U.S.A. from locations outside the United States for marketing, sale and distribution by Taro Ltd. and/or Taro U.S.A. within the United States generally, and North Carolina specifically.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Defendants are subject to personal jurisdiction in this District, because, *inter alia*, on information and belief, they regularly transact business in this District and have engaged in

systematic and continuous business contacts within the State of North Carolina, and their suit-related conduct, *i.e.*, the submission of ANDA No. 212467 seeking FDA approval to manufacture and sell a glycopyrrolate oral solution product in the United States, including in North Carolina, creates a substantial connection with North Carolina, and also demonstrates Defendants' plans to direct sales of their generic drugs into North Carolina.

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

THE PATENTS-IN-SUIT AND CUVPOSA®

13. 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 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.

14. 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.

15. 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®.

16. 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

17. On information and belief, Defendants seek to constantly expand the range of generic products they manufacture and sell.

18. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

19. On information and belief, Defendants 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.

20. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 212467.

21. On information and belief, Defendants submitted to the FDA ANDA No. 212467 seeking approval to engage in the commercial manufacture, use, and sale of a glycopyrrolate oral solution, prior to the expiration of the patents-in-suit.

22. On information and belief, Taro Ltd. and/or Taro U.S.A. will manufacture, sell, market, and/or distribute a glycopyrrolate oral solution upon FDA approval of ANDA No. 212467.

23. Plaintiff Merz LLC received a letter dated November 1, 2018 from Defendants Suven and Taro Ltd. notifying Plaintiff Merz LLC that ANDA No. 212467 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in

Suven's and Taro Ltd.'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. 212467.

24. Plaintiffs commenced this action within 45 days of the date they received Defendants Suven's and Taro Ltd.'s notice of ANDA No. 212467 containing the Paragraph IV certification.

25. On information and belief, Defendants continue to collaborate in seeking FDA approval of ANDA No. 212467 and intend to collaborate in the commercial manufacture, marketing, sale and/or distribution of a glycopyrrolate oral solution (including in the State of North Carolina) in the event that the FDA approves ANDA No. 212467.

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

26. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 25 hereof, as if fully set forth herein.

27. Through the conduct alleged above, Defendants have infringed, and continue to infringe, one or more claims of the '552 Patent.

28. By filing ANDA No. 212467 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, Defendants have infringed the '552 Patent under 35 U.S.C. § 271(e)(2)(A).

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

30. On information and belief, Defendants will be actively involved in the infringement of the ’552 Patent through the manufacture, use, sale, marketing, distribution, and/or importation of the glycopyrrolate oral solution described in ANDA No. 212467, if approved.

31. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467.

32. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 212467, Defendants will, with knowledge of the ’552 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA No. 212467 to patients to treat sialorrhea in a manner that infringes the ’552 Patent.

33. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467. On information and belief, Defendants know that the glycopyrrolate oral solution described in ANDA No. 212467, 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.

34. Defendants were aware of the existence of the ’552 Patent prior to filing ANDA No. 212467, 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.

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

36. Defendants’ conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

37. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’552 Patent.

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

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

39. Through the conduct alleged above, Defendants have infringed, and continue to infringe, one or more claims of the ’396 Patent.

40. By filing ANDA No. 212467 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, Defendants have infringed the ’396 Patent under 35 U.S.C. § 271(e)(2)(A).

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

42. On information and belief, Defendants will be actively involved in the infringement of the ’396 Patent through the manufacture, use, sale, marketing, distribution,

and/or importation of the glycopyrrolate oral solution described in ANDA No. 212467, if approved.

43. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467.

44. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 212467, Defendants will, with knowledge of the ’396 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA No. 212467 to patients to treat sialorrhea in a manner that infringes the ’396 Patent.

45. Unless enjoined by this Court, upon FDA approval of ANDA No. 212467, Defendants 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. 212467. On information and belief, Defendants know that the glycopyrrolate oral solution described in ANDA No. 212467, 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.

46. Defendants were aware of the existence of the ’396 Patent prior to filing ANDA No. 212467, 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.

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

48. Defendants’ conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

49. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’396 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Defendants have infringed one or more claims of the patents-in-suit by submitting ANDA No. 212467, 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. 212467 by Defendants 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. 212467 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 Defendants, their 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. 212467 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. 212467 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.

This the 12th day of December, 2018.

/s/ Robert J. Morris
Robert J. Morris
N.C. State Bar No. 15981
SMITH ANDERSON BLOUNT DORSETT MITCHELL & JERNIGAN, LLP
2300 Wells Fargo Capitol Center
150 Fayetteville Street
Raleigh, North Carolina 27601
Telephone: (919) 821-1220
Facsimile: (919) 821-6800
jmorris@smithlaw.com

Attorneys for Plaintiffs

Of Counsel:

Arlene L. Chow
Ernest Yakob
Takashi Okuda
HOGAN LOVELLS US LLP
875 Third Avenue
New York, New York 10022
Telephone: (212) 918-3000
Facsimile: (212) 918-3100
arlene.chow@hoganlovells.com
ernest.yakob@hoganlovells.com
takashi.okuda@hoganlovells.com

Attorneys for Plaintiffs