IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERZ PHARMACEUTICALS, LLC. and MERZ NORTH AMERICA, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 20-cv-00848 (RGA)
GRANULES PHARMACEUTICALS, INC.	)	
Defendants.	)	

ANSWER TO PLAINTIFF'S COMPLAINT

Defendant Granules Pharmaceuticals, Inc. ("Granules"), by and through its undersigned counsel, respectfully submits its Answer to Plaintiff's Complaint, stating as follows:

RESPONSE TO ALLEGATIONS CONCERNING THE 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 Granules' filing of Abbreviated New Drug Application ("ANDA") No. 214735 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.

RESPONSE: Granules admits plaintiffs purport to assert an action for patent infringement under the patent laws of the United States, Title 35, United States Code. Granules admits plaintiffs purport to assert infringement of U.S. Patent Nos. 7,638,552 ("the '552 patent") and 7,816,396 ("the '396 patent"), which alleged infringement Granules denies, based on Granules' filing of ANDA No. 214735 pursuant to 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), as amended, seeking FDA approval for Granules' glycopyrrolate oral solution 1 mg/5 ml

strength. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

2. By letter dated May 14 2020, Defendant Granules notified Plaintiff Merz LLC that it had filed ANDA No. 214735, seeking FDA approval to manufacture and sell a generic version of Plaintiffs' CUVPOSA®.

RESPONSE: Granules admits it notified Merz Pharmaceuticals LLC that Granules had filed ANDA No. 214735 by letter dated May 14, 2020. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Granules is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

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.

RESPONSE: Granules is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

5. On information and belief, Defendant Granules is a company organized and existing under the laws of Delaware, having a principal place of business at 3701 Concorde Parkway, Chantilly, Virginia 20151.

RESPONSE: Admitted.

6. On information and belief, Granules, 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.

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

7. On information and belief, Granules has filed ANDA No. 214735 and will be involved in the manufacture, importation, marketing and sale of the drug that is subject to ANDA No. 214735 if it is approved.

RESPONSE: Admitted.

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Granules admits the Court has subject matter jurisdiction over this Action. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. This Court has personal jurisdiction over Granules for purposes of this civil action because, inter alia, Granules, on information and belief, is incorporated under the laws of the State of Delaware.

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

10. This Court has personal jurisdiction over Granules for purposes of this civil action because, inter alia, Granules has filed ANDA No. 214735 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. 214735 is approved. Such acts will lead to foreseeable harm to Plaintiffs in Delaware.

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

11. On information and belief, Granules 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., Genentech, Inc. et al. v. Granules Pharmaceuticals, Inc. et al., 1:19-cv-00164 (D. Del.); Takeda Pharmaceuticals USA, Inc. v. Granules Pharmaceuticals Inc., 1:17-01019 (D. Del.).

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

12. On information and belief, Granules 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 Genentech, Inc. et al. v. Granules Pharmaceuticals, Inc. et al., 1:19-cv-00164 (D. Del.).

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Granules does not object to the Court's exercise of personal jurisdiction over Granules or venue in this District. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Granules admits that Exhibit A appears to be a copy of the '552 patent, which is the best source of the contents therein. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

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.

RESPONSE: Granules admits that Exhibit B appears to be a copy of the '396 patent, which is the best source of the contents therein. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

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®.

RESPONSE: Admitted based upon information and belief.

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®.

RESPONSE: Based upon information and belief, Granules admits the patents-in-suit are listed in the Orange Book in connection with NDA No. 022571, the subject of which is marketed as Cuvposa®. Granules denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO DEFENDANT'S ANDA

18. On information and belief, Granules 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.

RESPONSE: Denied.

19. On information and belief, Granules submitted to the FDA ANDA No. 214735 seeking approval to engage in the commercial manufacture, use, and sale of glycopyrrolate oral solution, prior to the expiration of the patents-in-suit.

RESPONSE: Admitted.

20. On information and belief, Granules will manufacture, sell, market, and/or distribute a glycopyrrolate oral solution upon FDA approval of ANDA No. 214735.

RESPONSE: Given the uncertainty of future events, Granules is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

21. Plaintiff Merz LLC received a letter dated May 14, 2020 from Defendant Granules notifying Plaintiff Merz LLC that ANDA No. 214735 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Granules'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. 214735.

RESPONSE: Admitted based upon information and belief.

22. Plaintiffs commenced this action within 45 days of the date they received Granules's notice of ANDA No. 214735 containing the Paragraph IV certification.

RESPONSE: Admitted based upon information and belief.

RESPONSE TO FIRST CLAIM FOR RELIEF
(Alleged Infringement of the '552 Patent by Granules)

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

RESPONSE: Granules restates and incorporates its responses to paragraphs 1 through 22 as though full set forth herein.

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

RESPONSE: Denied.

25. By filing ANDA No. 214735 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, Granules has infringed the '552 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

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

RESPONSE: Admitted.

27. On information and belief, Granules 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. 214735, if approved.

RESPONSE: Denied.

28. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735.

RESPONSE: Denied.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 214735, Granules will, with knowledge of the ’552 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 214735 to patients to treat sialorrhea in a manner that infringes the ’552 Patent.

RESPONSE: Denied.

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735. On information and belief, Granules knows that the glycopyrrolate oral solution described in ANDA No. 214735 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.

RESPONSE: Denied.

31. Granules was aware of the existence of the ’552 Patent prior to filing ANDA No. 214735, 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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSE TO SECOND CLAIM FOR RELIEF
(Alleged Infringement of the '396 Patent by Granules)

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

RESPONSE: Granules restates and incorporates its responses to paragraphs 1 through 34 as though full set forth herein.

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

RESPONSE: Denied.

37. By filing ANDA No. 214735 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, Granules has infringed the '396 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

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

RESPONSE: Admitted.

39. On information and belief, Granules 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. 214735, if approved.

RESPONSE: Denied.

40. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735.

RESPONSE: Denied.

41. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735. On information and belief, through the product labeling for the glycopyrrolate oral solution described in ANDA No. 214735, Granules will, with knowledge of the '396 Patent, intentionally encourage medical care workers and individuals to administer the glycopyrrolate oral solution described in ANDA 214735 to patients to treat sialorrhea in a manner that infringes the '396 Patent.

RESPONSE: Denied.

42. Unless enjoined by this Court, upon FDA approval of ANDA No. 214735, Granules 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. 214735. On information and belief, Granules knows that the glycopyrrolate oral solution described in ANDA No. 214735 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.

RESPONSE: Denied.

43. Granules was aware of the existence of the '396 Patent prior to filing ANDA No. 214735, 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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegation in Plaintiffs' Complaint not expressly admitted by Granules are hereby denied. Having answered Plaintiffs' complaint, Granules denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Granules asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Granules' ANDA No. 214735 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example, for at least the reasons set forth in the Detailed Legal and Factual Basis for Granules' certification to the FDA that, to the best of Granules' knowledge, the claims of the patents-in-suit are invalid, unenforceable or would not be infringed by Granules' ANDA No. 214735, which accompanied Granules' notice to Plaintiff Merz Pharmaceuticals LLC dated May 14, 2020, informing Merz of the filing of Granules' ANDA.

THIRD SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in the Detailed Legal and Factual Basis for Granules' certification to the FDA that, to the best of Granules' knowledge, the claims of the patents-in-suit are invalid, unenforceable or would not be infringed by Granules' ANDA No. 214735, which accompanied Granules' notice to Plaintiff Merz Pharmaceuticals LLC dated May 14, 2020, informing Merz of the filing of Granules' ANDA.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. § 112, for example, indefiniteness, lack of enablement and/or written description, for example, for at least the reasons set forth in the Detailed Legal and Factual Basis for Granules' certification to the FDA that, to the best of Granules' knowledge, the claims of the patents-in-suit are invalid, unenforceable or would not be infringed by Granules' ANDA No. 214735, which accompanied Granules' notice to Plaintiff Merz Pharmaceuticals LLC dated May 14, 2020, informing Merz of the filing of Granules' ANDA.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of Granules' ANDA No. 214735.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Granules hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: September 14, 2020

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