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MSN PHARMACEUTICALS INC.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 21-10057 (SRC) (JSA)
(CONSOLIDATED)

DEFENDANTS MSN LABORATORIES PRIVATE LTD. AND MSN PHARMACEUTICALS INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, "MSN" or "Defendants") through their undersigned counsel, hereby respond to the separately numbered paragraphs of the Complaint filed by Bausch Health Ireland Limited ("Bausch") and Salix Pharmaceuticals, Inc. ("Salix") (collectively "Plaintiffs") against MSN as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

ANSWER: Defendants, upon information and belief, admit the allegations in this paragraph.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principal place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 208745, which covers Trulance®.

ANSWER: Defendants, upon information and belief, admit the allegations in this paragraph.

3. Upon information and belief, MSN Laboratories Private Ltd. ("MSN Labs") is a corporation organized and existing under the laws of India, having a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018 India.

ANSWER: Admitted.

4. Upon information and belief, MSN Pharmaceuticals Inc. ("MSN Pharms") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08854.

ANSWER: Admitted.

5. Upon information and belief, MSN Pharms is a wholly-owned subsidiary of MSN Labs.

ANSWER: Admitted.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent No. 12,146,003 ("the '003 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to MSN's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic plecanatide oral tablets, 3 mg ("MSN's generic plecanatide oral tablets").

ANSWER: Defendants admit that this action purports to be an action for patent infringement arising under the laws of the United States of America relating to the '003 patent. Defendants deny any patent infringement as alleged by Plaintiffs.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Defendants do not contest subject matter jurisdiction in this Court solely for purposes of the claims asserted against Defendants in this case.

8. Upon information and belief, this court has jurisdiction over MSN Labs. Upon information and belief, MSN Labs is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Labs directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Labs purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Labs has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit MSN Labs is in the business of, *inter alia*, developing, manufacturing, and selling pharmaceutical products, including generic drug products. Defendants also do not contest jurisdiction in this Court solely for purposes of the claims asserted against Defendants in this case. Defendants deny the remaining allegations of paragraph 8.

9. Upon information and belief, this court has jurisdiction over MSN Pharms. Upon information and belief, MSN Pharms is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Pharms directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Pharms purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Pharms has its principal place of business at

20 Duke Rd., Piscataway, New Jersey 08854. Upon information and belief, MSN Pharms has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit MSN Pharms is in the business of developing, marketing, importing and selling pharmaceutical products, including generic drug products. Defendants admit MSN Pharms has conducted and continues to conduct business in New Jersey, and that MSN Pharms has its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08854. Defendants do not contest jurisdiction in this Court solely for purposes of the claims asserted against Defendants in this case. Defendants deny the remaining allegations of paragraph 9.

10. MSN Labs has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. MSN Labs' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, MSN Labs intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, MSN Labs will engage in marketing of its generic Plecanatide oral tablets in New Jersey upon approval of its ANDA.

ANSWER: Defendants do not contest jurisdiction in this Court solely for purposes of the claims asserted against Defendants in this case. Defendants admit that MSN Labs has applied to the FDA for approval of plecanatide oral tablets. Defendants deny the remaining allegations of paragraph 10.

11. Upon information and belief, MSN Labs and MSN Pharms operate as a single integrated business. Upon information and belief, MSN Labs and MSN Pharms each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Defendants do not contest jurisdiction in this Court solely for purposes of the claims asserted against Defendants in this case. Defendants admit that MSN Pharms acts as an agent of MSN Labs to obtain regulatory approval for the generic plecanatide tablets that are the subject of its ANDA No. 215780. Defendants deny the remaining allegations of paragraph 11.

12. MSN Labs and MSN Pharms know or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

ANSWER: Defendants admit, upon information and belief, that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, NJ 08807 USA, otherwise, denied.

13. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants do not contest the venue in this Court solely for the purposes of the claims asserted against Defendants in this case. Defendants deny any remaining allegations of paragraph 13.

14. Venue is proper against MSN Labs, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants do not contest the venue in this Court solely for the purposes of the claims asserted against Defendants in this case. Defendants deny any remaining allegations of paragraph 14.

15. Venue is proper against MSN Pharms because it operates a principal place of business in this judicial district.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants do not contest the venue in this Court solely for the purposes of the claims asserted against Defendants in this case. Defendants admit that MSN Pharms operates a place of business in this judicial district. Defendants deny any remaining allegations of paragraph 15.

THE PATENT IN SUIT

16. The U.S. Patent and Trademark Office ("PTO") issued the '003 patent on November 19, 2024. The '003 patent claims, *inter alia*, oral formulations of a purified peptide. Plaintiffs hold all substantial rights in the '003 patent and have the right to sue for infringement thereof. A copy of the '003 patent is attached hereto as Exhibit A.

ANSWER: Defendants admit that a copy of the '003 patent is attached as Exhibit A. Defendants admit that, according to the first page of Exhibit A, the '003 patent issued on November 19, 2024, and it purports to claim *inter alia*, oral formulations of a purified peptide. Defendants lack sufficient information to admit or deny that Plaintiffs hold all substantial rights to the '003 patent, but do not (at present) dispute said assertion. Defendants deny any remaining allegations of paragraph 16.

17. Salix is the holder of NDA No. 208745 for Trulance®, which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the '003 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

ANSWER: Admitted.

18. Plecanatide oral tablets, 3mg, are sold in the United States under the trademark Trulance®.

ANSWER: Admitted.

MSN'S INFRINGING ANDA SUBMISSION

19. Upon information and belief, MSN Labs filed or caused to be filed with the FDA ANDA No. 215780, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Admitted.

20. Upon information and belief, MSN's ANDA No. 215780 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

ANSWER: Defendants admit that they submitted ANDA No. 215780 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products within the United States. Defendants deny the remaining allegations of this paragraph as phrased, and affirmatively state that they will decide whether to market their product in the United States only upon FDA approval.

21. Plaintiffs received a letter from MSN Labs dated March 15, 2021, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certifications ("MSN's First Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's First Notice Letter was addressed to Salix and Bausch.

ANSWER: Admitted.

22. MSN's First Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

ANSWER: Defendants admit that they submitted ANDA No. 215780 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products within the United States. Defendants deny the remaining allegations of this paragraph as phrased, and affirmatively state that they will decide whether to market their product in the United States upon FDA approval.

23. MSN's First Notice Letter states that MSN's ANDA No. 215780 "contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product," for MSN's generic plecanatide oral tablets.

ANSWER: Admitted.

24. Plaintiffs received a second letter from MSN Labs dated May 2, 2023, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certifications ("MSN's Second Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's Second Notice Letter was addressed to Salix and Bausch.

ANSWER: Admitted.

25. MSN's Second Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

ANSWER: Defendants admit that they submitted ANDA No. 215780 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of plecanatide oral tablets, 3 mg, within the United States. Defendants deny the remaining allegations

of this paragraph as phrased, and affirmatively state that they will decide whether to market their product in the United States upon FDA approval.

26. MSN's Second Notice Letter states that MSN's ANDA No. 215780 "contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product," for MSN's generic plecanatide oral tablets.

ANSWER: Admitted.

27. Plaintiffs received a third letter from MSN Labs dated May 7, 2024, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certification ("MSN's Third Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's Third Notice Letter was addressed to Salix and Bausch.

ANSWER: Admitted.

28. MSN's Third Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

ANSWER: Defendants admit that they submitted ANDA No. 215780 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of plecanatide oral tablets, 3 mg, within the United States. Defendants deny the remaining allegations of this paragraph as phrased, and affirmatively state that they will decide whether to market their product in the United States upon FDA approval.

29. MSN's Third Notice Letter states that MSN's ANDA No. 215780 "contain[s] any required bioavailability or bioequivalence data or information," for MSN's generic plecanatide oral tablets.

ANSWER: Admitted.

30. Upon information and belief, ANDA No. 215780 seeks approval of MSN's generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

ANSWER: Defendants admit that they submitted ANDA No. 215780 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products within the United States. Defendants deny the remaining allegations of this paragraph as phrased.

31. Upon information and belief, MSN Labs' actions related to ANDA No. 215780 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of MSN Pharms.

ANSWER: Defendants deny the allegations of paragraph 31.

32. As a result of MSN's Notice Letters, Plaintiffs filed related Complaints against MSN in this District. *See Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al*., Civil Action No. 21-10057 (SRC)(JSA) (CONSOLIDATED); *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al*., Civil Action No. 23-3333 (SRC)(JSA), consolidated into *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al*., Civil Action No. 21-10057 (SRC)(JSA) (CONSOLIDATED); and *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 24-7182 (SRC)(JSA).

ANSWER: MSN admits that Plaintiffs filed Complaints against MSN in this District in the matters of *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 21-10057 (SRC)(JSA) (consolidated); *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 23-3333 (SRC)(JSA), consolidated into the21-10057; and *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action

No. 24-7182 (SRC)(JSA). To the extent paragraph 32 contains any additional allegations, MSN denies them.

33. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding ANDA No. 215780 for the '003 patent ("'003 Patent Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95.

ANSWER: Admitted.

34. Despite that Defendants have not yet sent a '003 Patent Notice Letter, Defendants' prior Notice Letters and the information contained therein, coupled with regulatory requirements, demonstrate Defendants' infringement of the '003 patent.

ANSWER: Defendants admit that they have not yet sent a '003 Patent Notice Letter. Defendants deny the remaining allegations of Paragraph 34.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '003 Patent Under § 271(e)(2)

35. Paragraphs 1-34 are incorporated herein as set forth above.

ANSWER: Defendants incorporate their responses to paragraphs 1-34 as if fully set forth herein.

36. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '003 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '003 patent.

ANSWER: Defendants recognize that filing an ANDA with a Paragraph IV certification provides a basis for jurisdiction under 35 U.S.C. § 271(e). Defendants deny the remaining allegations of this paragraph.

37. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '003 patent.

ANSWER: Defendants deny the allegations of paragraph 37.

38. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '003 patent.

ANSWER: Defendants deny the allegations of paragraph 38.

39. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '003 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Defendants deny the allegations of paragraph 39.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '003 Patent

40. Paragraphs 1-39 are incorporated herein as set forth above.

ANSWER: Defendants incorporate their responses to paragraphs 1-39 as if fully set forth herein.

41. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 41 calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that this action purports to be an action for patent infringement and that it purports to arise under the Declaratory Judgment Act. Defendants deny the remaining allegations of paragraph 41.

42. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Admitted.

43. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '003 patent, including MSN's filing of ANDA No. 215780.

ANSWER: Defendants admit that they filed its ANDA to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products in the United States before expiration of the '003 patent. Defendants deny the remaining allegations of this paragraph, and affirmatively state that Defendants will decide whether to market their product only upon FDA approval.

44. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '003 patent.

ANSWER: Defendants deny the allegations of paragraph 44.

45. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '003 patent.

ANSWER: Defendants deny the allegations of paragraph 45.

RESPONSE PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested by the Complaint, or any other relief whatsoever.

DEFENDANT'S SEPARATE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Defendants do not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Defendants reserve the right to assert other defenses and/or to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale, or importation of MSN's ANDA Products have not, do not, and will not infringe any valid and enforceable claim of the '003 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND DEFENSE
(Invalidity)

One or more claims of the '003 patent are invalid for failure to comply with one or more of the provisions of the United States Code, 35 U.S.C. § 101 *et seq.*, including but not limited to, 35 U.S.C. § 103.

THIRD DEFENSE
(Lack of Irreparable Harm)

Plaintiffs have planned for, and in fact anticipated, the filing of ANDA applications with the FDA for the approval of generic forms of its TRULANCE® product for many years. Accordingly, should MSN's ANDA Products be approved and should they further be sold in the United States market, Plaintiffs would not be irreparably harmed as a result of such anticipated competition. Should such sales occur, there are adequate remedies at law available, assuming such sales are found to infringe the patent-in-suit. Moreover, considering the balance of hardships

between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

FOURTH DEFENSE
(Failure to State a Claim)

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FIFTH DEFENSE
(Additional Defenses or Counterclaims)

Defendants reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiffs have failed to aver any facts supporting that this is an exceptional case and an award of attorneys' fees under 35 U.S.C. § 285.

COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendants Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. ("Counterclaim-Defendants"), Counterclaim-Plaintiff MSN Laboratories Private Ltd and MSN Pharmaceuticals, Inc. (hereafter "MSN" or "Counterclaim-Plaintiffs"), states as follows:

PARTIES

1. MSN Laboratories Private Ltd. is an Indian corporation having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018 India.

2. MSN Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08854.

3. Upon information and belief, Counterclaim-Defendant Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

4. Upon information and belief, Counterclaim-Defendant Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principal place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1, 271(e)(5), 1331, 1338(a), *et seq.*, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 35 U.S.C. § 271(e)(5); and 21 U.S.C. § 355(j)(5)(C)(i).

7. This Court has personal jurisdiction over Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by bringing this civil action in this Judicial District and because, upon information and belief, Counterclaim-Defendants conduct substantial business in, and have regular and systematic contact with, this Judicial District.

8. Venue for these counterclaims is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) based on the fact that Counterclaim-Defendants have asserted the patent-in-suit against MSN in this Judicial District.

COUNTERCLAIM PATENT-IN-SUIT

9. Salix holds New Drug Application ("NDA") No. 208745 for which the United States Food and Drug Administration ("FDA") granted approval for the manufacture and sale of the active ingredient plecanatide oral tablets, 3 mg, which is prescribed and sold in the United States under the brand name TRULANCE®.

10. MSN filed Abbreviated New Drug Application ("ANDA") No. 215780 seeking approval from the FDA to commercially manufacture, use, market, or sell generic plecanatide oral tablets.

11. Counterclaim-Defendants purport to own, and to have the right to enforce, United States Patent No. 12,146,003 ("the '003 patent") (the "Counterclaim Patent").

12. The Counterclaim Patent is listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in association with the TRULANCE® drug product. As a consequence of such listing, Counterclaim-Defendants maintain, and have affirmatively represented to the world, that a claim for patent infringement could be asserted against any generic ANDA applicant attempting to market a generic product before patent expiration, including MSN.

13. Counterclaim-Defendants have already created a substantial controversy by suing MSN for alleged infringement of the Counterclaim Patent. There is an actual, substantial, and continuing justiciable case and controversy between MSN and Counterclaim-Defendants regarding infringement of the Counterclaim Patent as well, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

14. MSN is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of MSN's ANDA products do not and will not infringe the Counterclaim Patent, and/or that such patent is invalid. Absent the exercise of jurisdiction by this Court and such

declaratory relief, MSN and the American public will be irreparably harmed by the indefinite delay in the market entry and availability of lower-priced generic products.

U.S. PATENT NO. 12,146,003

15. United States Patent No. 12,146,003 (the "'003 patent") is listed in the Orange Book in association with the TRULANCE® drug product.

16. On November 19, 2024, the United States Patent and Trademark Office ("USPTO") issued the '003 patent, entitled, "Ultra-Pure Agonists of Guanylate Cyclase C, Method of Making and Using Same."

17. Upon information and belief, Plaintiffs hold all substantial rights in the '003 patent.

18. MSN submitted Abbreviated New Drug Application ("ANDA") No. 215780 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval for the commercial manufacture, use, and sale of plecanatide oral tablets, in the United States before the '003 patent expires. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) indicating that the '003 patent is invalid, unenforceable and/or will not be infringed.

19. On December 16, 2024, Counterclaim-Defendants initiated this civil action, 24-cv-11179, against MSN in this Judicial District alleging infringement of the '003 patent.

20. MSN seeks a declaratory judgment that the '003 patent is not valid and/or is not infringed.

COUNT I
(Declaratory Judgment of Invalidity of the '003 Patent)

21. MSN restates and re-alleges each of the foregoing Paragraphs 1-23 of the counterclaims as if fully set forth herein.

22. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in

this action, there is an actual substantial, and continuing justiciable case or controversy between MSN and Counterclaim-Defendants having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '003 patent.

23. The claims of the '003 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, 35 U.S.C. § 101 et seq., including § 102, § 103, and § 112. For example, the claims of the '003 patent are invalid because they fail to recite essential limitations of the purported invention disclosed in the '003 patent and the provisional application to which it claims priority, e.g., that the purified peptide is characterized by having a bulk density of less than 0.1 g/ml, less than 0.25% alpha-Asp^{9} plecanatide and less than 50 ppm acetamide. As such, the claims are either invalid under 35 U.S.C. § 112 for lacking written description and failure to claim what the inventor or joint inventors regarded as their invention. Alternately, each claim is invalid under 35 U.S.C. § 102(a)(1) or 35 U.S.C. § 103 in view of WO 2012/118972 ("WO '972").

24. MSN is entitled to a judicial determination that the claims of the '003 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, 35 U.S.C. § 101 et seq., including § 102, § 103 and § 112.

COUNT II
(Declaratory Judgment of Non-Infringement of the '003 Patent)

25. MSN restates and re-alleges each of the foregoing Paragraphs 1-27 of the counterclaims as if fully set forth herein.

26. Counterclaim-Defendants have alleged that MSN's filing of ANDA No. 215780 infringes the '003 patent.

27. As evidenced by Counterclaim-Defendants Complaint and MSN's Answers in this

action, there is an actual substantial, and continuing justiciable case or controversy between the parties having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’003 patent.

28. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN’s ANDA Products will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’003 patent.

29. MSN is entitled to a judicial determination that MSN’s ANDA Product which is the subject of ANDA No. 215780 has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the ’003 patent.

PRAYER FOR RELIEF

WHEREFORE, Defendants/Counterclaim-Plaintiffs respectfully requests that this Court enter a judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Defendants/Counterclaim-Plaintiffs;

(b) Declaring that no valid claim of the ’003 patent would be infringed, either directly or indirectly, literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of MSN’s ANDA Products;

(c) Declaring that the asserted claims of the ’003 patent are invalid;

(d) Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs from threatening to assert or otherwise attempting to enforce the ’003 patent against Defendants/Counterclaim-Plaintiffs, its customers, suppliers, or anyone in privity with Defendants/Counterclaim-Plaintiffs;

(e) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Defendants/Counterclaim-Plaintiffs its reasonable attorneys’ fees and costs incurred in this action;

(f) Awarding Defendants/Counterclaim-Plaintiffs its costs and expenses incurred in this action; and

(g) Awarding Defendants/Counterclaim-Plaintiffs such other and further relief as this Court may deem proper.

DATED: December 30, 2024

Respectfully submitted,

s/ Peter C. Urmston

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