IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., GLOBAL BLOOD THERAPEUTICS, INC. and PF PRISM IMB B.V., *Plaintiffs,* v. MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS INC., *Defendants.*	C.A. No. 24-315 (JPM)(JLH)

MSN LABORATORIES PRIVATE LTD. AND MSN PHARMACEUTICALS INC.'S ANSWER TO AMENDED COMPLAINT, SEPARATE DEFENSES, AND COUNTERCLAIMS

MSN Laboratories Private Ltd. ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") (collectively, "MSN" or "Defendants"), hereby answer the First Amended Complaint of Pfizer Inc. ("Pfizer"), Global Blood Therapeutics, Inc. ("GBT"), and PF PRISM IMB B.V. ("PF PRISM") (collectively, "Plaintiffs"), as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), MSN denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from MSN's submission of Abbreviated New Drug Application ("ANDA") No. 219094 to the United States Food and Drug Administration ("FDA"), seeking approval to market generic versions of Plaintiffs' OXBRYTA® (voxelotor) tablets before the expiration of U.S. Patent Nos. 9,447,071 ("the '071 patent") and 11,020,382 ("the '382 patent") (collectively, "the patents-in-suit").

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Complaint purports to state a claim for alleged patent infringement. MSN further admits that MSN Laboratories submitted Abbreviated New Drug Application No. 219094 ("MSN Laboratories' ANDA") to the United States Food and Drug Administration ("FDA") seeking approval for voxelotor tablets before the expiration of U.S. Patent No. 9,447,071 ("the '071 patent") and U.S. Patent No. 11,020,382 ("the '382 patent") (collectively, "Patents-in-Suit"). MSN denies any and all remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Pfizer is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent MSN is required to answer, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies any and all allegations of Paragraph 2.

3. Plaintiff GBT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 181 Oyster Point Blvd, South San Francisco, CA 94080. GBT is a wholly owned subsidiary of Pfizer.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent MSN is required to answer, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies any and all allegations of Paragraph 3.

4. Plaintiff PF PRISM is a private limited liability company (*besloten venootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands. Pfizer is the ultimate parent of PF PRISM.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent MSN is required to answer, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies any and all allegations of Paragraph 4.

5. Upon information and belief, Defendant MSN Laboratories is a company organized and existing under the laws of India, having a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad – 500018 Telangana, India.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Laboratories is a Private Limited company organized and existing under the laws of India, with a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad – 500018 Telangana, India. MSN denies any and all remaining allegations of Paragraph 5.

6. Upon information and belief, Defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Pharmaceuticals is a Delaware corporation with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies any and all remaining allegations of Paragraph 6.

7. Upon information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories. MSN denies any and all remaining allegations of Paragraph 7.

8. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals are generic pharmaceutical companies that, in coordination with each other or at the direction of MSN Laboratories, develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Group is the fastest growing research-based pharmaceutical company based out of India. Founded in 2003 with a mission to make health care affordable, this Hyderabad-based venture has fifteen API and six finished dosage facilities established across India & USA. MSN denies any and all remaining allegations of Paragraph 8.

THE PATENTS-IN-SUIT

9. On September 20, 2016, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '071 patent, entitled "Crystalline Polymorphs of the Free Base of 2-Hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '071 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '071 patent. A copy of the '071 patent is attached to this First Amended Complaint as Exhibit A.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '071 patent is titled "Crystalline Polymorphs of the Free Base of 2-Hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde" and that the face of the patent includes an issue date of September 20, 2016. MSN further admits that the face of the patent lists Global Blood Therapeutics, Inc. as the assignee of the '071 patent. MSN further admits that what purports to be a copy of the '071 patent is attached to the Complaint as Exhibit A. Further answering, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegation that PF PRISM is the exclusive licensee of the '071 patent, and therefore denies this allegation. MSN denies that the '071 patent was duly or lawfully issued. MSN denies any and all remaining allegations of Paragraph 9.

10. On June 1, 2021, the USPTO duly and legally issued the '382 patent, entitled "Dosing Regimens for 2-Hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '382 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '382 patent. A copy of the '382 patent is attached to this First Amended Complaint as Exhibit B.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '382 patent is titled "Dosing Regimens for 2-Hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde" and that the face of the patent includes an issue date of June 1, 2021. MSN further admits that the face of the patent lists Global Blood Therapeutics, Inc. as the assignee of the '382 patent. MSN further admits that what purports to be a copy of the '382 patent is attached to the Complaint as Exhibit B. Further answering, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegation that PF PRISM is the exclusive licensee of the '382 patent, and therefore denies this allegation. MSN denies that the '382 patent was duly or lawfully issued. MSN denies any and all remaining allegations of Paragraph 10.

OXBRYTA®

11. GBT holds approved New Drug Application No. 213137 for voxelotor tablets (trade name OXBRYTA®) for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that according to the electronic version of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), "GLOBAL BLOOD THERAPEUTICS INC" is listed as the holder of the NDA No. 213137 for voxelotor tablets. MSN denies any and all remaining allegations of Paragraph 11.

12. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to OXBRYTA®.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that according to the electronic version of

the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), the Patents-in-Suit are listed with respect to voxelotor tablets. MSN denies any and all remaining allegations of Paragraph 12.

THE MSN ANDA

13. Upon information and belief, MSN Laboratories prepared and submitted, through MSN Pharmaceuticals, ANDA No. 219094 (the "MSN ANDA") to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of voxelotor tablets ("MSN's ANDA Product") before the expiration of the patents-in-suit.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Laboratories submitted ANDA No. 219094 to the FDA. MSN further admits that MSN Laboratories' Notice Letter states "The ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of Voxelotor Tablets, 300 mg and 500 mg, before the expiration of the '071, … '382 … patents." MSN denies any and all remaining allegations of Paragraph 13.

14. Upon information and belief, MSN Laboratories acted in concert with or directed MSN Pharmaceuticals to prepare and submit the MSN ANDA.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

15. Upon information and belief, MSN's ANDA Product is a generic copy of OXBRYTA®.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Reference Listed Drug in MSN Laboratories' ANDA is OXBRYTA ® (voxelotor) tablets, NDA N213137. MSN denies any and all remaining allegations of Paragraph 15.

16. Upon information and belief, the MSN ANDA refers to and relies upon GBT's New Drug Application No. 213137 and purports to contain data on the bioequivalence of MSN's ANDA Product to OXBRYTA®.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Reference Listed Drug in MSN Laboratories' ANDA is OXBRYTA ® (voxelotor) tablets, NDA N213137. Further answering, MSN admits that MSN Laboratories' Notice Letter states as follows: "The ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver." MSN denies any and all remaining allegations of Paragraph 16.

17. By a letter to GBT and its parent company Pfizer dated January 24, 2024 ("MSN's Paragraph IV Notice Letter"), MSN stated that the MSN ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patents-in-suit will be infringed by the manufacture, use, or sale of MSN's ANDA Product (the "Paragraph IV Certifications"). MSN's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certifications.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Laboratories, by a letter dated January 24, 2024 ("MSN Laboratories' Notice Letter"), properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Plaintiffs that MSN Laboratories submitted MSN Laboratories' ANDA to FDA seeking approval to market MSN Laboratories' ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 17.

18. Upon information and belief, if the FDA approves the MSN ANDA, MSN will manufacture, distribute, import, offer for sale and/or sell MSN's ANDA Product throughout the United States, including within the State of Delaware.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

19. This action was filed within 45 days of GBT and Pfizer's receipt of MSN's Paragraph IV Notice Letter.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that Plaintiffs filed the Complaint on March 8, 2024. MSN denies any and all remaining allegations of Paragraph 19.

JURISDICTION AND VENUE

20. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN states that for the limited purposes of this action only, it does not contest subject matter jurisdiction solely for the claims directed against MSN under 35 U.S.C. § 271(e)(2)(A) in this matter. MSN denies any and all remaining allegations of Paragraph 20.

21. This Court has personal jurisdiction over MSN Laboratories because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, MSN Laboratories is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Laboratories directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, MSN Laboratories's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of MSN's ANDA Product.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN Laboratories does not contest personal jurisdiction solely for the limited purposes of this action only.

22. Upon information and belief, MSN Laboratories is the holder of the MSN ANDA.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN states that MSN Laboratories' Notice Letter states that "FDA has received an Abbreviated New Drug Application ("ANDA") from [MSN

Laboratories Private Ltd.] for Voxelotor Tablets, 300 mg and 500 mg." MSN denies any and all remaining allegations of Paragraph 22.

23. Upon information and belief, MSN Laboratories acted in concert with or directed MSN Pharmaceuticals to prepare and submit the MSN ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the MSN ANDA. *See, e.g.*, https://msnpi.com/ (last accessed June 5, 2024) ("[MSN Pharmaceuticals] was established in the year 2014. Finished Dosage form facility was built in 2018. . . . [MSN Pharmaceuticals] is a fully owned subsidiary of the MSN group of companies. [MSN Pharmaceuticals] develops and manufacture products for MSN group. . . .").

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the website "https://msnpi.com/" states as follows:

> MSNPI was established in the year 2014. Finished Dosage form facility was built in 2018. It is a state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey. MSN PI is a fully owned subsidiary of the **MSN group of companies** .MSNPI develops and manufacture products for MSN group as well as specialized in contract development and manufacturing of high-quality generic pharmaceutical products.

(https://msnpi.com/ (last accessed September 4, 2024)). MSN denies any and all remaining allegations of Paragraph 23. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only.

24. This Court has personal jurisdiction over MSN Pharmaceuticals because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic that MSN Pharmaceuticals resides in Delaware.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN Pharmaceuticals does not contest personal jurisdiction solely for the limited purposes of this action only.

25. This Court also has personal jurisdiction over MSN Pharmaceuticals because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, MSN Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its

products into the stream of commerce for distribution and consumption in Delaware, MSN Pharmaceuticals's [sic] contacts with the State of Delaware have been systematic and continuous, and this judicial district is a likely destination of MSN's ANDA Product.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN Pharmaceuticals does not contest personal jurisdiction solely for the limited purposes of this action only.

26. Upon information and belief, MSN Pharmaceuticals acted in concert with or at the direction of MSN Laboratories to prepare and submit the MSN ANDA, with the intention of receiving a significant financial benefit from marketing and distribution of MSN's ANDA Product throughout the United States, including in Delaware. *See, e.g.*, https://msnpi.com/ (last accessed June 5, 2024) ("[MSN Pharmaceuticals] was established in the year 2014. Finished Dosage form facility was built in 2018. . . . [MSN Pharmaceuticals] is a fully owned subsidiary of the MSN group of companies. [MSN Pharmaceuticals] develops and manufacture products for MSN group. . . .").

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the website "https://msnpi.com/" states as follows:

> MSNPI was established in the year 2014. Finished Dosage form facility was built in 2018. It is a state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey. MSN PI is a fully owned subsidiary of the **MSN group of companies** .MSNPI develops and manufacture products for MSN group as well as specialized in contract development and manufacturing of high-quality generic pharmaceutical products.

(https://msnpi.com/ (last accessed September 4, 2024)). MSN denies any and all remaining allegations of Paragraph 26. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only.

27. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals have thus been, and continue to be, agents of each other and/or operate in concert with respect to the drafting, submission, approval, and maintenance of the MSN ANDA.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only.

28. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to MSN's ANDA Product.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only.

29. This Court also has personal jurisdiction over MSN Laboratories and MSN Pharmaceuticals because they have availed themselves of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district and by asserting counterclaims against plaintiffs. *See, e.g.*, *Allergan Holdings Unlimited Co. v. MSN Lab'ys Priv. Ltd.*, C.A. No. 23-794 (D. Del.); *Actelion Pharms. US, Inc. v. MSN Lab'ys Priv. Ltd.*, C.A. No. 23-731 (D. Del.); *Celgene Corp. v. MSN Lab'ys Priv. Ltd.*, C.A. No. 23-699 (D. Del.); *Astellas Pharma Inc. v. MSN Pharms. Inc.*, C.A. No. 23-689 (D. Del.); *Abbvie Inc. v. Alkem Lab'ys Ltd.*, C.A. No. 22-1423 (D. Del.).

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN further admits that the records of any previous litigations involving MSN Laboratories and MSN Pharmaceuticals speak for themselves. MSN denies any and all remaining allegations of Paragraph 29.

30. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 30.

31. Venue is proper in this Court for MSN Laboratories under 28 U.S.C. § 1391 because, upon information and belief, MSN Laboratories is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN Laboratories does not contest venue solely for

the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 31.

32. Venue is proper in this Court for MSN Pharmaceuticals under 28 U.S.C. §§ 1391 and 1400(b) because MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN Pharmaceuticals does not contest venue solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 32.

COUNT I
(Infringement of the '071 Patent)

33. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

34. Defendants have infringed one or more claims of the '071 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '071 patent.

ANSWER: Denied.

35. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would infringe one or more claims of the '071 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

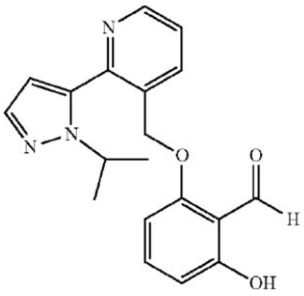
36. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would induce and/or contribute to the infringement of one or more claims of the '071 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

37. For example, claim 1 of the ’071 patent recites:

A crystalline ansolvate of Compound 1:

Compound 1

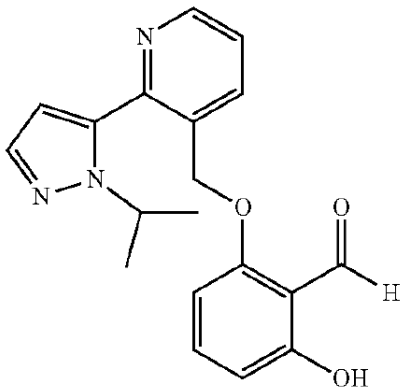


wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the ’071 patent reads as follows:

1. A crystalline ansolvate of Compound 1:

Compound 1



wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

(The ’071 patent at claim 1). MSN denies any and all remaining allegations of Paragraph 37.

38. Upon information and belief, MSN's ANDA Product will contain a crystalline ansolvate of Compound 1 wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ).

ANSWER: Denied.

39. Upon information and belief, Defendants have acted with full knowledge of the '071 patent and without a reasonable basis for believing that they would not be liable for infringement of the '071 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '071 patent.

ANSWER: Denied.

40. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

41. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '071 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '071 patent immediately and imminently upon approval of the MSN ANDA.

ANSWER: Denied.

42. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '071 patent.

ANSWER: Denied.

43. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

44. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT II
(Declaratory Judgment of Infringement of the '071 Patent)

45. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

46. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '071 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent upon approval of the MSN ANDA.

ANSWER: MSN admits that there is a substantial and immediate controversy between Plaintiffs and MSN concerning the '071 patent. MSN denies any and all remaining allegations of Paragraph 46.

47. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would infringe one or more claims of the '071 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

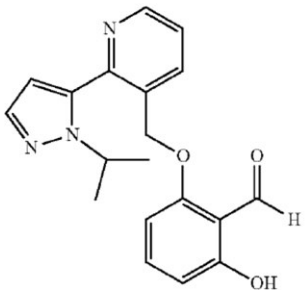
48. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would induce and/or contribute to the infringement of one or more claims of the '071 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

49. For example, claim 1 of the '071 patent recites:

A crystalline ansolvate of Compound 1:

Compound 1

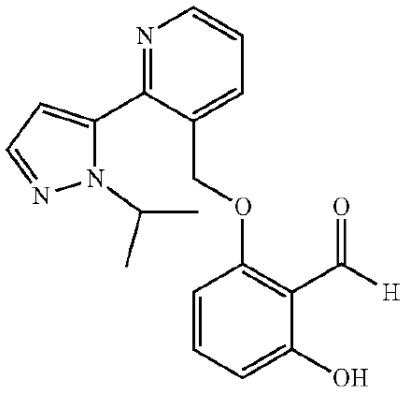


wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '071 patent reads as follows:

1. A crystalline ansolvate of Compound 1:

Compound 1



wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

(The '071 patent at claim 1). MSN denies any and all remaining allegations of Paragraph 49.

50. Upon information and belief, MSN's ANDA Product will contain a crystalline ansolvate of Compound 1 wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ).

ANSWER: Denied.

51. Upon information and belief, Defendants have acted with full knowledge of the '071 patent and without a reasonable basis for believing that they would not be liable for infringement of the '071 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '071 patent.

ANSWER: Denied.

52. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

53. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '071 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '071 patent immediately and imminently upon approval of the MSN ANDA.

ANSWER: Denied.

54. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '071 patent.

ANSWER: Denied.

55. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

56. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

COUNT III
(Infringement of the '382 Patent)

58. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

59. Defendants have infringed one or more claims of the '382 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '382 patent.

ANSWER: Denied.

60. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would infringe one or more claims of the '382 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

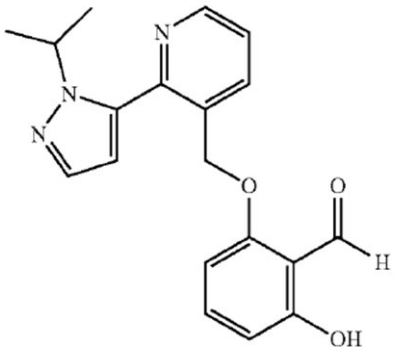
ANSWER: Denied.

61. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would induce and/or contribute to the infringement of one or more claims of the '382 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

62. For example, claim 1 of the '382 patent recites:

> A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1:



1

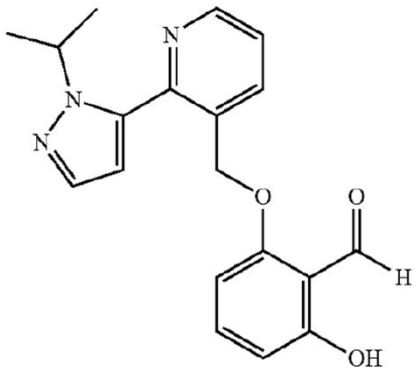
wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and Compound 1 is in a crystalline ansolvate form characterized by X- ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ± 0.2° 2θ.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the ’382 patent reads as follows:

1. A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient

Compound 1:

1



wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and

Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ±0.2° 2θ.

(The '382 patent at claim 1). MSN denies any and all remaining allegations of Paragraph 62.

63. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1. Upon further information and belief, Compound 1 of MSN's ANDA Product will be administered orally in a dose of about 1500 mg once daily, and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ, each peak is ± 0.2° 2θ.

ANSWER: Denied.

64. Upon information and belief, Defendants have acted with full knowledge of the '382 patent and without a reasonable basis for believing that they would not be liable for infringement of the '382 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '382 patent.

ANSWER: Denied.

65. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

66. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '382 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '382 patent immediately and imminently upon approval of the MSN ANDA.

ANSWER: Denied.

67. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '382 patent.

ANSWER: Denied.

68. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

69. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT IV
(Declaratory Judgment of Infringement of the '382 Patent)

70. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

71. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '382 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent upon approval of the MSN ANDA.

ANSWER: MSN admits that there is a substantial and immediate controversy between Plaintiffs and MSN concerning the '382 patent. MSN denies any and all remaining allegations of Paragraph 71.

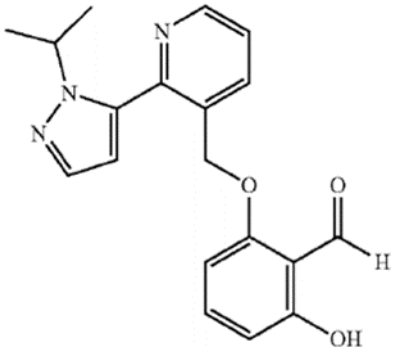
72. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would infringe one or more claims of the '382 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

73. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would induce and/or contribute to the infringement of one or more claims of the '382 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

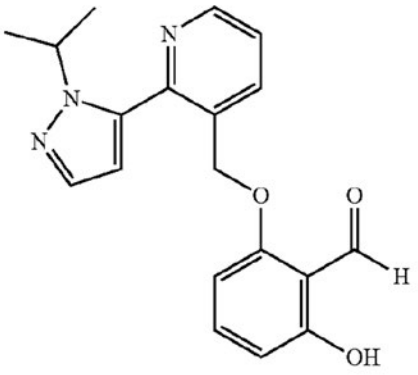
74. For example, claim 1 of the '382 patent recites:

> A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1:
>
> 1
>
> 
>
>
> wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and Compound 1 is in a crystalline ansolvate form characterized by X- ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ± 0.2° 2θ.

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '382 patent reads as follows:

1. A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient

Compound 1:



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wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and

Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ±0.2° 2θ.

(The '382 patent at claim 1). MSN denies any and all remaining allegations of Paragraph 74.

75. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1. Upon further information and belief, Compound 1 of MSN's ANDA Product will be administered orally in a dose of about 1500 mg once daily, and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ, each peak is ± 0.2° 2θ.

ANSWER: Denied.

76. Upon information and belief, Defendants have acted with full knowledge of the '382 patent and without a reasonable basis for believing that they would not be liable for infringement of the '382 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '382 patent.

ANSWER: Denied.

77. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

78. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '382 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '382 patent immediately and imminently upon approval of the MSN ANDA.

ANSWER: Denied.

79. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '382 patent.

ANSWER: Denied.

80. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

81. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

82. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '382 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

83. The factual contentions in the preceding paragraphs have evidentiary support, or likely will have evidentiary support after a reasonable opportunity for further investigation or discovery.

ANSWER: Denied.

PRAYER FOR RELIEF

MSN denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief, or to any relief whatsoever, and further requests that judgment be entered in favor of MSN, dismissing Plaintiffs' First Amended Complaint with prejudice, awarding MSN attorneys' fees

and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiff, MSN avers and asserts the following defenses to the Complaint.

FIRST DEFENSE
(Invalidity)

The claims of U.S. Patent No. 9,447,071 ("the '071 patent") and U.S. Patent No. 11,020,382 ("the '382 patent"), (collectively, "Asserted Patents") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

SECOND DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale or importation of the proposed voxelotor tablets, 300 mg and 500 mg, that are the subject of MSN Laboratories' ANDA No. 219094, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(No Inducement)

MSN has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the Asserted Patents.

FOURTH DEFENSE
(No Contributory Infringement)

MSN has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the Asserted Patents.

FIFTH DEFENSE
(No Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over this action solely for the claims against MSN including for any and all claims asserted under 35 U.S.C. § 271 (a), (b) or (c).

SIXTH DEFENSE
(Safe Harbor)

MSN is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

SEVENTH DEFENSE
(No Exceptional Case)

The Complaint fails to state a claim for exceptional case.

EIGHTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

NINTH DEFENSE
(Additional Defenses)

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs MSN Laboratories Private Ltd. ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") (collectively, "MSN" or "Defendants/Counterclaim-Plaintiffs"), for MSN's Counterclaims against Plaintiff/Counterclaim-Defendants Pfizer Inc. ("Pfizer"), Global Blood Therapeutics, Inc. ("GBT"), and PF PRISM IMB B.V. ("PF PRISM") (collectively "Plaintiffs/Counterclaim-Defendants"), allege as follows:

The Parties

1. MSN Laboratories is a Private Limited company organized and existing under the laws of India, having a principal place of business at MSN House Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad – 500018, Telangana, India.

2. MSN Pharmaceuticals is a is a Delaware corporation with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

3. On information and belief and according to the Complaint (D.I. 7 ¶ 2), Pfizer is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

4. On information and belief and according to the Complaint (D.I. 7 ¶ 3), GBT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 181 Oyster Point Blvd, South San Francisco, CA 94080. GBT is a wholly owned subsidiary of Pfizer.

5. On information and belief and according to the Complaint (D.I. 7 ¶ 4), PF PRISM is a private limited liability company (*besloten venootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business

address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands. Pfizer is the ultimate parent of PF PRISM.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction of this forum by suing MSN in this District, and, on information and belief, Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Background

10. On or about September 20, 2016, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 9,447,071 ("the '071 patent").

11. On or about June 1, 2021, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 11,020,382 ("the '382 patent").

COUNT I
(Declaratory Judgment of Non-Infringement of the '071 Patent)

12. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

13. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN Laboratories' ANDA Product would infringe any valid and/or enforceable claim of the '071 patent.

14. MSN Laboratories' ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '071 patent.

15. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN Laboratories' ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '071 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '071 Patent)

16. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

17. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '071 patent.

18. One or more claims of the '071 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

19. MSN is entitled to a judicial declaration that the claims of the '071 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '382 Patent)

20. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

21. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN Laboratories' ANDA Product would infringe any valid and/or enforceable claim of the '382 patent.

22. MSN Laboratories' ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '382 patent.

23. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN Laboratories' ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '382 patent.

COUNT I
(Declaratory Judgment of Invalidity of the '382 Patent)

24. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

25. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '382 patent.

26. One or more claims of the '382 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

27. MSN is entitled to a judicial declaration that the claims of the '382 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of MSN Laboratories' ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any and/or enforceable claim of the Asserted Patents;

(b) Declaring that the claims of the Asserted Patents are invalid;

(c) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Defendants/Counterclaim-Plaintiffs MSN;

(d) Declaring this case exceptional and awarding MSN its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding MSN such other and further relief as the Court may deem just and proper.

Dated: September 4, 2024

Respectfully submitted,

/s/ *Stamatios Stamoulis*
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