

**IN THE UNITED STATES DISTRICT
COURT FOR THE DISTRICT OF DELAWARE**

HARMONY BIOSCIENCES, LLC, BIOPROJET
SOCIÉTÉ CIVILE DE RECHERCHE and
BIOPROJET PHARMA SAS,

Plaintiffs,

v.

MSN PHARMACEUTICALS INC., MSN
LABORATORIES PRIVATE LIMITED,

Defendants

C.A. No. 1:23-cv-01420-JLH

**DEFENDANTS MSN PHARMACEUTICALS INC. AND
MSN LABORATORIES PRIVATE LIMITED’S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively “MSN” or “Defendants”), by and through their undersigned attorneys, respond to the Complaint for Patent Infringement filed by Plaintiffs Harmony Biosciences, LLC, Bioprojet Société Civile De Recherche, and Bioprojet Pharma SAS (collectively “Plaintiffs”) as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), MSN denies all allegations in Plaintiffs’ Complaint, except those expressly admitted below.

NATURE OF THE ACTION

1. MSN admits that Plaintiffs brought this action for alleged infringement of United States Patent Nos. 8,486,947 (the “’947 patent”), 8,207,197 (the “’197 patent”), and 8,354,430 (the “’430 patent”) (collectively, “the patents-in-suit”) arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. MSN admits that it filed Abbreviated New Drug

Application (“ANDA”) No. 218873. MSN denies the remaining allegations contained in this paragraph.

WAKIX® AND THE PATENTS-IN-SUIT

2. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

3. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

4. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

5. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

6. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

7. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

8. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

9. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph, and, therefore, denies the allegations of the paragraph on this basis.

10. MSN admits that Exhibit A purports to be the '947 patent, which is entitled "Treatment of Parkinson's Disease, Obstructive Sleep Apnea, Dementia with Lewy Bodies, Vascular Dementia with Non-Imidazole Alkylamines Histamine H3-Receptor Ligands." MSN denies that the '947 patent is valid and lawfully issued by the USPTO. MSN denies the remainder of the allegations in this paragraph.

11. MSN admits that Exhibit B purports to be the '197 patent which is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine." MSN denies that the '197 patent is valid and lawfully issued by the USPTO. MSN denies the remainder of the allegations in this paragraph.

12. MSN admits that Exhibit C purports to be the '430 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine." MSN denies the remainder of the allegations in this paragraph. MSN denies that the '430 patent is valid and lawfully issued by the USPTO. MSN denies the remainder of the allegations in this paragraph.

13. MSN admits that the Orange Book lists the patents-in-suit. MSN denies the remainder of the allegations in this paragraph.

THE PARTIES

14. On information and belief, MSN admits Plaintiff Harmony Biosciences, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 630 W Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, USA. MSN is without sufficient information or knowledge to admit or deny the allegations

contained in the remainder of this paragraph.

15. MSN is without sufficient information or knowledge to admit or deny the allegations contained in the remainder of this paragraph, and denies the remainder of this paragraph for this reason.

16. MSN is without sufficient information or knowledge to admit or deny the allegations contained in the remainder of this paragraph, and denies the remainder of this paragraph for this reason.

17. MSN Pharmaceuticals Inc. (“MSN Pharma”) admits that it is a Delaware corporation and does business at 20 Duke Road, Piscataway, New Jersey 08854.

18. MSN Laboratories Private Limited (“MSN Labs”) admits that it 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 – 18 Telangana, India.

19. MSN Pharma admits that it is the U.S. Agent for MSN Labs for the purposes of ANDA No. 218873. MSN denies the remaining allegations contained in this paragraph.

20. MSN Pharma admits it is a wholly owned subsidiary of MSN Labs.

21. MSN admits MSN Labs owns Drug Master File No. 38131 for pitolisant.

22. MSN Pharma admits that it is the U.S. Agent for MSN Labs for the purposes of ANDA No. 218873. MSN denies the remaining allegations contained in this paragraph.

23. MSN admits that ANDA No. 218873 has been submitted to FDA. The MSN ANDA speaks for itself. MSN denies the remaining allegations contained in this paragraph.

24. MSN Pharma admits that it is the U.S. Agent for MSN Labs for the purposes of ANDA No. 218873. MSN denies the remaining allegations of Paragraph 24.

25. Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 25 are wholly speculative. MSN denies the remaining allegations of Paragraph 25.

26. MSN Pharma admits that it is the U.S. Agent for MSN Labs for the purposes of ANDA No. 218873. Further, Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 26 are wholly speculative. MSN denies the remaining allegations of Paragraph 26.

JURISDICTION AND VENUE

27. This paragraph contains legal conclusions to which no answer is required. For the purposes of this action only, MSN does not assert that this Court lacks subject matter jurisdiction in this action.

28. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest that personal jurisdiction is proper as to MSN Pharma.

29. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest that personal jurisdiction is proper as to MSN Pharma and MSN Labs.

30. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest that personal jurisdiction is proper as to MSN Pharma and MSN Labs.

31. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest that personal jurisdiction is proper as to MSN

Pharma and MSN Labs.

32. Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 32 are wholly speculative. MSN denies the remaining allegations of Paragraph 32.

33. Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 33 are wholly speculative. MSN denies the remaining allegations of Paragraph 33.

34. Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 34 are wholly speculative. MSN denies the remaining allegations of Paragraph 34.

35. For the purposes of this litigation only, MSN does not contest that personal jurisdiction is proper as to MSN. To the extent that a response is required, MSN admits that it previously has engaged in patent litigations in this District.

36. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest that personal jurisdiction is proper as to MSN.

37. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, MSN does not contest venue. To the extent that a response is required, MSN denies the allegations in this paragraph.

38. This paragraph contains legal conclusions to which no answer is required. For

purposes of this action only, MSN does not contest venue. To the extent that a response is required, MSN denies the allegations in this paragraph.

MSN'S ANDA NO. 218873

39. MSN admits that they submitted to the FDA ANDA No. 218873. The ANDA speaks for itself. MSN denies the remaining allegations contained in this paragraph.

40. MSN admits that they submitted to the FDA ANDA No. 218873. The ANDA speaks for itself. MSN denies the remaining allegations contained in this paragraph. Further, Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 40 are wholly speculative. MSN denies the remaining allegations of Paragraph 40.

41. MSN admits the allegations in this paragraph.

42. MSN admits that MSN sent the October 13, 2023 Correspondence. The October 13, 2023 Correspondence speaks for itself. MSN denies the remaining allegations contained in this paragraph.

43. MSN states that MSN has been prepared to provide its ANDA to Plaintiffs or their counsel, but Plaintiffs never sought to obtain MSN's ANDA. MSN denies the remaining allegations contained in this paragraph.

44. MSN admits that they submitted to the FDA ANDA No. 218873. MSN denies the remaining allegations contained in this paragraph.

45. Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 45 are wholly speculative. MSN denies the remaining allegations of Paragraph 45.

46. Paragraph 46 contains legal conclusions and allegations to which no answer is

required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 46 are wholly speculative. MSN denies the remaining allegations of Paragraph 46.

47. MSN denies the allegations in this paragraph.

48. MSN denies the allegations in this paragraph.

* * *

49. This paragraph contains information regarding a third party, so MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph. Thus, MSN denies the allegations of this paragraph on this basis.

50. This paragraph contains information regarding a third party, so MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph. Thus, MSN denies the allegations of this paragraph on this basis.

51. MSN admits that it filed a declaratory judgment action against Bioprojet Société Civile de Recherche on the '197, '947, and '430 patents in the Alexandria Division of the United States District Court for the Eastern District of Virginia. MSN denies the remainder of this paragraph.

COUNT 1
INFRINGEMENT OF THE '947 PATENT

52. MSN incorporates by reference the foregoing paragraphs as if fully set forth here.

53. MSN admits the allegations contained in this paragraph of the Complaint.

54. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph.

55. MSN denies the allegations contained in this paragraph of the Complaint.

56. MSN admits the allegations contained in this paragraph of the Complaint.

57. MSN denies the allegations contained in this paragraph of the Complaint.

58. MSN denies the allegations contained in this paragraph of the Complaint.

59. MSN denies the allegations contained in this paragraph of the Complaint.

60. MSN denies the allegations contained in this paragraph of the Complaint.

61. Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 61 are wholly speculative. MSN denies the remaining allegations of Paragraph 61.

62. Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 62 are wholly speculative. MSN denies the remaining allegations of Paragraph 62.

63. MSN denies the allegations contained in this paragraph of the Complaint.

64. MSN denies the allegations contained in this paragraph of the Complaint.

65. MSN denies the allegations contained in this paragraph of the Complaint.

COUNT II
INFRINGEMENT OF THE '197 PATENT

66. MSN incorporates by reference the foregoing paragraphs as if fully set forth here.

67. MSN admits the allegations contained in this paragraph of the Complaint.

68. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph.

69. MSN denies the allegations contained in this paragraph of the Complaint.

70. MSN denies the allegations contained in this paragraph of the Complaint.

71. MSN denies the allegations contained in this paragraph of the Complaint.

72. Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 72 are wholly speculative. MSN denies the remaining allegations of Paragraph 72.

73. Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 73 are wholly speculative. MSN denies the remaining allegations of Paragraph 73.

74. Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 74 are wholly speculative. MSN denies the remaining allegations of Paragraph 74.

75. MSN denies the allegations contained in this paragraph of the Complaint.

76. MSN denies the allegations contained in this paragraph of the Complaint.

77. MSN denies the allegations contained in this paragraph of the Complaint.

COUNT III
INFRINGEMENT OF THE '430 PATENT

78. MSN incorporates by reference the foregoing paragraphs as if fully set forth here.

79. MSN admits the allegations contained in this paragraph of the Complaint.

80. MSN is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph.

81. MSN denies the allegations contained in this paragraph of the Complaint.

82. MSN denies the allegations contained in this paragraph of the Complaint.

83. MSN denies the allegations contained in this paragraph of the Complaint.

84. MSN denies the allegations contained in this paragraph of the Complaint.

85. Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 85 are wholly speculative. MSN denies the remaining allegations of Paragraph 85.

86. Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MSN's ANDA is not yet approved by FDA and the allegations of Paragraph 86 are wholly speculative. MSN denies the remaining allegations of Paragraph 86.

87. MSN denies the allegations contained in this paragraph of the Complaint.

88. MSN denies the allegations contained in this paragraph of the Complaint.

89. MSN denies the allegations contained in this paragraph of the Complaint.

PRAYER FOR RELIEF

MSN denies that Plaintiffs are entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever.

DEFENDANTS' AFFIRMATIVE DEFENSES

MSN asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. MSN does not assume the burden of proof on any such defenses, except as required by the applicable law with

respect to the particular defense asserted. MSN reserves the right to assert other defenses and/or to supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(No Direct Infringement)

MSN does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit, and if the products that are the subject of ANDA No. 218873 were marketed, MSN would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit.

SECOND AFFIRMATIVE DEFENSE
(No Indirect Infringement)

MSN has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the patents-in-suit and if the products that are the subject of ANDA No. 218873 were marketed, MSN would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the patents-in-suit.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the patents-in-suit are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

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 claims of the patents-in-suit are infringed by the product that is the subject of MSN's ANDA No. 218873.

FIFTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

SIXTH AFFIRMATIVE DEFENSE
(Costs)

Upon information and belief, Plaintiffs are barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

SEVENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

MSN's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

DEFENDANTS' COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively “MSN”), for their Counterclaims against Plaintiffs Harmony Biosciences, LLC, Bioprojet Société Civile De Recherche and Bioprojet Pharma SAS (collectively “Plaintiffs”) allege as follows:

1. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN’s Answer and Affirmative Defenses to the Complaint.

THE PARTIES

2. MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 20 Duke Road, Piscataway, NJ 08854.

3. MSN Laboratories Private Limited 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 - 18, Telangana, India.

4. On information and belief, Harmony Biosciences, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 630 W Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, USA.

5. On information and belief, Bioprojet SCR is an independent, privately owned company organized and existing under the laws of France, having places of business at 7, rue Rameau, 75002, Paris, France and 9, rue Rameau, 75002, Paris, France.

6. On information and belief, Bioprojet Pharma is a wholly owned subsidiary of Bioprojet SCR, existing under the laws of France, having a place of business at 9, rue Rameau, 75002, Paris, France.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for

declaratory judgment pursuant to 35 U.S.C. § 271(3)(5); 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited and Plaintiffs arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

8. This Court has personal jurisdiction over Plaintiffs based, *inter alia*, on the filing by Plaintiffs of this lawsuit in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), and 21 U.S.C. § 355(j)(5)(c)(i)(II).

NATURE OF THE ACTION AND STATUTORY BACKGROUND

10. Under the “Drug Price Competition and Patent Term Restoration Act of 1984,” also known as the Hatch-Waxman Act, which governs the U.S. Food and Drug Administration’s (“FDA’s”) approval of both new and generic drugs, when a company files a New Drug Application (“NDA”), it must, *inter alia*, identify those patents “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1).

11. Then, as required by statute, after an NDA is approved, FDA publishes the enumerated patents in a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (colloquially, “Orange Book”). *Id.*

12. Under the Hatch-Waxman Act, a company filing an Abbreviated New Drug Application (“ANDA”) must, *inter alia*, submit a patent certification with respect to each patent in the Orange Book listed for that particular product at the time the ANDA is filed. 21 U.S.C. § 355(j)(2)(A)(vii).

13. Though there are four patent certification options, the only certification relevant to this action is a so-called “Paragraph IV Certification,” which states that an Orange Book-listed

patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

14. If an ANDA applicant elects to file a Paragraph IV Certification to one or more of the Orange Book-listed patents, it is required by statute to provide written notice of the certification to (1) the owner of each patent that is the subject of the certification, and (2) the holder of the approved NDA—a so-called “Paragraph IV Notice Letter.” 21 U.S.C. § 355(j)(2)(B).

15. After both the patent owner and NDA holder have received the Paragraph IV Notice Letter, they have forty-five days to file suit asserting infringement of one or more Orange Book listed patents, 21 U.S.C. § 355(j)(5)(B)(iii), in order to trigger a mandatory regulatory stay of FDA approval of the ANDA. If no suit is filed, there is no stay.

16. An ANDA applicant, who has not been sued within forty-five days of the NDA holder and patent holder’s receipt of a Paragraph IV Notice Letter, may file a declaratory-judgment complaint against the NDA holder and/or the patent owner seeking a ruling of non-infringement, invalidity and/or unenforceability of any Orange Book-listed patent for which the ANDA applicant submitted a Paragraph IV Certification. 21 U.S.C. § 355 (j)(5)(C).

PATENTS AT ISSUE
U.S. Patent Nos. 8,486,947, 8,207,197 and 8,354,430

17. The ’947 patent is entitled “Treatment of Parkinson’s Disease, Obstructive Sleep Apnea, Dementia with Lewy Bodies, Vascular Dementia with Non-Imidazole Alkylamines 3 Histamine H3-Receptor Ligands,” and issued by the USPTO on July 16, 2013. Upon information and belief, Bioprojet is the sole owner and assignee of the ’947 patent.

18. The ’197 patent is entitled “Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine,” and issued by the USPTO on June 26, 2012. Upon information

and belief, Bioprojet is the sole owner and assignee of the '197 patent.

19. The '430 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and issued by the USPTO on January 15, 2013. Upon information and belief Bioprojet is the sole owner and assignee of the '430 patent.

FACTS GIVING RISE TO THIS ACTION

20. The FDA Orange Book includes an entry for pitolisant hydrochloride tablet, offered under the trade name WAKIX[®], with an NDA number 211150.

21. Upon information and belief, WAKIX[®] is available in film-coated tablets containing 5 mg or 20 mg of pitolisant hydrochloride (equivalent to 4.45 mg or 17.8 mg of pitolisant free base, respectively).

22. On information and belief, the '947 patent was submitted to the FDA for listing in the Orange Book for NDA Number 211150 on September 11, 2019.

23. On information and belief, the '197 patent was submitted to the FDA for listing in the Orange Book for NDA Number 211150 on September 11, 2019.

24. On information and belief, the '430 patent was submitted to the FDA for listing in the Orange Book for NDA Number 211150 on September 11, 2019.

25. By maintaining the listing of the '947, '197 and '430 patents in the Orange Book, the NDA holder represents that a claim of infringement of the '947, '197 and '430 patents "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of" a generic pitolisant tablet. 21 U.S.C. § 355(b)(1)(A)(viii).

26. On August 14, 2023, MSN filed ANDA No. 218873 with the FDA seeking approval to manufacture, distribute, market and sell a generic pitolisant tablet ("MSN's ANDA Product") in the United States, including in this District and the Commonwealth of Virginia.

27. In that ANDA, MSN submitted Paragraph IV certifications for U.S. Patent Nos. 8,207,197; 8,354,430; and 8,486,947, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

28. On September 26, 2023, MSN received an FDA Paragraph IV Acknowledgement Letter, and on October 13, 2023—within the 20-day period—MSN sent its notice letter to Harmony Biosciences LLC (the NDA Holder) and Bioprojet (the Patent Owner) via Federal Express in accordance with FDA regulations. *See* 21 C.F.R. §§ 314.95(a), (b), and (d).

29. Plaintiffs received MSN's notice no later than October 18, 2023 (*See* D.I. 9-6, 9-7) making December 4, 2023 the forty-five day deadline for it to file suit of infringement on the noticed Paragraph IV certified patents. 21 C.F.R. § 314.95(f).

30. On December 4, 2023, no action for infringement was brought within forty-five days of the notice MSN provided to Plaintiffs regarding MSN's Paragraph IV certifications.

31. Because Plaintiffs did not assert the patents-in-suit in a lawsuit within the forty-five day period, MSN's ANDA is not subject to a thirty-month regulatory stay.

32. Additionally, under 21 U.S.C. § 355(j)(5)(C)(i), MSN may seek a declaratory judgment.

THE PRESENCE OF A CASE OF ACTUAL CONTROVERSY

33. In addition to the foregoing circumstances, Plaintiffs' Complaint gives rise to an actual controversy with respect to the patents-in-suit for ANDA No. 218873.

34. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have made, and will continue to make, substantial preparations in connection with their request for FDA approval of their ANDA Product.

35. To avoid legal uncertainty and to protect MSN's substantial investment (and anticipated future investment) in MSN's ANDA Product, MSN Pharmaceuticals Inc. and MSN

Laboratories Private Limited seek declaratory relief with respect to the patents-in-suit.

36. MSN has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the patents-in-suit.

37. Upon FDA approval of MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited's ANDA, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited will be able to market and sell their ANDA Product in the United States.

38. A judgment declaring that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of MSN's ANDA Product will remove any independent barriers to competition.

39. The totality of circumstances support that a case or controversy exists with respect to the infringement, invalidity, and/or unenforceability of the claims of the patents-in-suit.

FIRST COUNT
(Declaratory Judgment of Non-Infringement of the '947 Patent)

40. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Declaratory Judgment Complaint.

41. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C)(i). An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Bioprojet and MSN concerning the infringement of the '947 patent.

42. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product pursuant to ANDA No. 218873 do not infringe any valid and enforceable claim of the of the '947 patent.

43. Thus, MSN is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product do not infringe any valid and enforceable claim of the '947 patent.

SECOND COUNT
(Declaratory Judgment of Invalidity of the '947 Patent)

44. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Declaratory Judgment Complaint.

45. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C)(i). An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Bioprojet and MSN concerning the invalidity of the claims of the '947 patent.

46. The claims of the '947 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

47. Thus, MSN is entitled to a declaration that the claims of the '947 patent are invalid.

THIRD COUNT
(Declaratory Judgment of Non-Infringement of the '197 Patent)

48. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Declaratory Judgment Complaint.

49. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C.

§ 355(j)(5)(C)(i). An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Bioprojet and MSN concerning the infringement of the claims of the '197 patent.

50. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product pursuant to ANDA No. 218873 do not infringe any valid and enforceable claim of the '197 patent.

51. Thus, MSN is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product do not infringe any valid and enforceable claim of the '197 patent.

FOURTH COUNT
(Declaratory Judgment of Non-Infringement of the '430 Patent)

52. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Declaratory Judgment Complaint.

53. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C.

§ 355(j)(5)(C)(i). An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Bioprojet and MSN concerning the infringement of the claims of the '430 patent.

54. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product pursuant to ANDA No. 218873 do not infringe any valid and enforceable claim of the '430 patent.

55. Thus, MSN is entitled to a declaration that the manufacture, use, offer for sale,

sale, and/or importation into the United States of MSN's ANDA Product do not infringe any valid and enforceable claim of the '430 patent.

EXCEPTIONAL CASE

This case is an exceptional one, and MSN is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYERS FOR RELIEF

WHEREFORE, Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited pray that the Court enter judgment in their favor and against Plaintiffs as follows:

- A. Declaring that the making, using, selling, offering for sale, marketing, or importation of MSN's ANDA Product described in ANDA No. 218873 do not infringe any valid or enforceable claim of the patents-in-suit;
- B. Declaring that the patents-in-suit and all of their claims are invalid;
- C. Granting MSN judgment in its favor on Plaintiffs' claims;
- D. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against MSN or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of MSN, or charging it either orally or in writing with infringement of any patent asserted herein against MSN;
- E. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from interfering with FDA's approval of ANDA No. 218873;
- F. Denying Plaintiffs' claims with prejudice;

G. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding MSN its costs and reasonable attorneys' fees; and

H. Awarding any other such relief as is just and proper.

Dated: February 29, 2024

Respectfully submitted,

By: /s/ Richard C. Weinblatt
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