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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

VIFOR (INTERNATIONAL) AG AND
AMERICAN REGENT, INC.,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE LIMITED
AND MSN PHARMACEUTICALS INC.,

Defendants.

Civil Action No.: 3:25-03286-GC-JBD

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

Defendants MSN Laboratories Private Limited and MSN Pharmaceuticals Inc.

(collectively "MSN" or "Defendants"), by and through their undersigned attorneys, respond to the Complaint filed by Plaintiffs Vifor (International) AG and American Regent, Inc (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' complaint appears to raise a patent infringement action arising under Title 35 of the United States Code and concerning the above-named defendants filing of ANDA No. 219580 with the FDA for approval of Plaintiff's Injectafer®, ferriccarboxymaltose injection prior to the expiration of United States Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); 8,895,612 ("the '612 patent"); 11,364,260 ("the '260 patent"); 11,433,091 ("the '091 patent"); and 11,478,502 ("the '502 patent"), MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 1 and, therefore, denies them on this basis.

THE PARTIES

2. On information and belief, MSN admits Plaintiff Vifor (International) AG ("Vifor") has a principal place of business at Rechenstraße 37, CH-9001, St. Gallen, Switzerland. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

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

4. On information and belief, MSN admits Plaintiff American Regent Inc.'s, ("ARI") principal place of business is at 5 Ramsey Road, Shirley, New York 11967. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

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

6. MSN Laboratories Private Limited 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.

7. MSN Laboratories Private Limited admits the allegations in this paragraph.

8. MSN Pharmaceuticals Inc. admits that it is a Delaware corporation and does business at 20 Duke Road, Piscataway, New Jersey 08854.

9. MSN Pharmaceuticals Inc. admits it is a wholly owned subsidiary of MSN Laboratories Private Limited. MSN denies the remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

10. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, MSN does not assert that this Court lacks subject matter jurisdiction in this action.

11. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

12. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

13. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

14. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

15. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

16. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

17. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

18. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

19. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

20. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

21. 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. To the extent that a response is required, MSN denies the allegations in this paragraph.

22. MSN denies the allegations of this paragraph.

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

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

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

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

PATENTS-IN-SUIT

27. MSN admits that the '109 patent is entitled "Water-Soluble Iron-Carbohydrate Complexes, Production Thereof, and Medicaments Containing Said Complexes," and that on its face, the '109 patent has an issue date of November 3, 2009. MSN denies that the '109 patent was duly and legally issued. MSN admits that a copy of the '109 patent appears to be attached as Exhibit A to the Complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

28. MSN admits that the '702 patent is entitled "Methods of treatment and pharmaceutical composition," and that on its face, the '702 patent has an issue date of July 13, 2010. MSN denies that the '702 patent was duly and legally issued. MSN admits that a copy of the '702 patent appears to be attached as Exhibit B to the Complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

29. MSN admits that the '612 patent is entitled Methods and Compositions For Administration of Iron," and that on its face, the '612 patent has an issue date of November 25, 2014. MSN denies that the '612 patent was duly and legally issued. MSN admits that a copy of the '612 patent appears to be attached as Exhibit C to the Complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

30. MSN admits that the '260 patent is entitled "Methods and Compositions For Administration of Iron," and that on its face, the '260 patent has an issue date of June 21, 2022. MSN denies that the '260 patent was duly and legally issued. MSN admits that a copy of the '260 patent appears to be attached as Exhibit D to the Complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

31. MSN admits that the '091 patent is entitled "Methods and Compositions For Administration of Iron," and that on its face, the '091 patent has an issue date of September 6, 2022. MSN denies that the '091 patent was duly and legally issued. MSN admits that a copy of the '091 patent appears to be attached as Exhibit E to the Complaint. MSN is without sufficient

information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

32. MSN admits that the '502 patent is entitled "Methods and Compositions For Administration of Iron," and that on its face, the '502 patent has an issue date of October 25, 2022. MSN denies that the '502 patent was duly and legally issued. MSN admits that a copy of the '502 patent appears to be attached as Exhibit F to the Complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

NDA NO. 203565 AND INJECTAFER

33. MSN admits that the FDA approved New Drug Application ("NDA") No. 203565 for Injectafer® (ferric carboxymaltose) on July 25, 2013. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

34. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis. MSN further states that patents—the '109, '702, '612, '260, '091, and '502 patents are not properly listed in the Orange Book and should be delisted.

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

36. MSN admits that a copy of a label for Injectafer® is attached as exhibit G to the complaint. MSN is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

THE MSN DEFENDANTS' ALLEGED INFRINGING ANDA SUBMISSION

37. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

38. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

39. MSN denies the allegations in this paragraph.

40. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

41. MSN denies the allegations in this paragraph.

42. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

43. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

44. MSN admits that it sent a letter to Plaintiffs dated March 12, 2025. MSN further states that the document speaks for itself. To the extent that any further response is required, MSN denies the allegations in this paragraph.

45. MSN admits that it sent a letter to Plaintiffs dated October 11, 2024. MSN further states that the document speaks for itself. MSN further admits to the existent of a separate action

related to that letter. To the extent that any further response is required, MSN denies the allegations in this paragraph.

COUNT I (INFRINGEMENT OF THE '109 PATENT)

46. MSN incorporates their responses to paragraphs 1 – 45 as if fully set forth herein.

47. This paragraph contains legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations contained in this paragraph.

48. MSN denies the allegations contained in this paragraph.

49. MSN denies the allegations contained in this paragraph.

50. MSN denies the allegations contained in this paragraph.

51. MSN denies the allegations contained in this paragraph.

52. MSN denies the allegations contained in this paragraph.

53. MSN denies the allegations contained in this paragraph.

54. MSN denies the allegations contained in this paragraph.

55. MSN denies the allegations contained in this paragraph.

56. MSN denies the allegations contained in this paragraph.

57. MSN denies the allegations contained in this paragraph.

58. MSN denies the allegations contained in this paragraph.

COUNT II (INFRINGEMENT OF THE '702 PATENT)

59. MSN incorporates their responses to paragraphs 1 – 58 as if fully set forth herein.

60. MSN denies the allegations contained in this paragraph.

61. MSN denies the allegations contained in this paragraph.

62. MSN denies the allegations contained in this paragraph.

63. MSN denies the allegations contained in this paragraph.

64. MSN denies the allegations contained in this paragraph.

65. MSN denies the allegations contained in this paragraph.

66. MSN denies the allegations contained in this paragraph.

67. MSN denies the allegations contained in this paragraph.

68. MSN denies the allegations contained in this paragraph.

69. MSN denies the allegations contained in this paragraph.

70. MSN denies the allegations contained in this paragraph.

COUNT III (INFRINGEMENT OF THE '612 PATENT)

71. MSN incorporates their responses to paragraphs 1 – 71 as if fully set forth herein.

72. MSN denies the allegations contained in this paragraph.

73. MSN denies the allegations contained in this paragraph.

74. MSN denies the allegations contained in this paragraph.

75. MSN denies the allegations contained in this paragraph.

76. MSN denies the allegations contained in this paragraph.

77. MSN denies the allegations contained in this paragraph.

78. MSN denies the allegations contained in this paragraph.

79. MSN denies the allegations contained in this paragraph.

80. MSN denies the allegations contained in this paragraph.

81. MSN denies the allegations contained in this paragraph.

82. MSN denies the allegations contained in this paragraph.

COUNT IV (INFRINGEMENT OF THE '260 PATENT)

83. MSN incorporates their responses to paragraphs 1 – 83 as if fully set forth herein.

84. MSN denies the allegations contained in this paragraph.

85. MSN denies the allegations contained in this paragraph.

86. MSN denies the allegations contained in this paragraph.

- 87. MSN denies the allegations contained in this paragraph.
- 88. MSN denies the allegations contained in this paragraph.
- 89. MSN denies the allegations contained in this paragraph.
- 90. MSN denies the allegations contained in this paragraph.
- 91. MSN denies the allegations contained in this paragraph.
- 92. MSN denies the allegations contained in this paragraph.
- 93. MSN denies the allegations contained in this paragraph.
- 94. MSN denies the allegations contained in this paragraph.

COUNT V (INFRINGEMENT OF THE '091 PATENT)

- 95. MSN incorporates their responses to paragraphs 1 – 95 as if fully set forth herein.
- 96. MSN denies the allegations contained in this paragraph.
- 97. MSN denies the allegations contained in this paragraph.
- 98. MSN denies the allegations contained in this paragraph.
- 99. MSN denies the allegations contained in this paragraph.
- 100. MSN denies the allegations contained in this paragraph.
- 101. MSN denies the allegations contained in this paragraph.
- 102. MSN denies the allegations contained in this paragraph.
- 103. MSN denies the allegations contained in this paragraph.
- 104. MSN denies the allegations contained in this paragraph.
- 105. MSN denies the allegations contained in this paragraph.
- 106. MSN denies the allegations contained in this paragraph.

COUNT VI (INFRINGEMENT OF THE '502 PATENT)

- 107. MSN incorporates their responses to paragraphs 1 – 107 as if fully set forth herein.

108. MSN denies the allegations contained in this paragraph.

109. MSN denies the allegations contained in this paragraph.

110. MSN denies the allegations contained in this paragraph.

111. MSN denies the allegations contained in this paragraph.

112. MSN denies the allegations contained in this paragraph.

113. MSN denies the allegations contained in this paragraph.

114. MSN denies the allegations contained in this paragraph.

115. MSN denies the allegations contained in this paragraph.

116. MSN denies the allegations contained in this paragraph.

117. MSN denies the allegations contained in this paragraph.

118. MSN denies the allegations contained in this paragraph.

PLAINTIFFS' PRAYER FOR RELIEF

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

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

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

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

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

5. MSN denies that Plaintiffs are entitled to any of the relief requested in this paragraph of 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 '109, '702, '612, '260, '091, and '502 patents, and if the products that are the subject of ANDA No. 219580 were marketed, MSN would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '109, '702, '612, '260, '091, and '502 patents.

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 '109, '702, '612, '260, '091, and '502 patents, and if the products that are the subject of ANDA No. 219580 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 '109, '702, '612, '260, '091, and '502 patents.

THIRD AFFIRMATIVE DEFENSE (Invalidity)

The claims of the '109, '702, '612, '260, '091, and '502 patents 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. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

DEFENDANT'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc., for their Counterclaims against Plaintiffs allege as follows:

MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint.

THE PARTIES

6. 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.

7. 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.

8. Upon information and belief, American Regent Inc. is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

9. Upon information and belief, Vifor (International) AG ("Vifor") is a foreign corporation with a principal place of business at Rechenstraße 37, CH-9001, St. Gallen, Switzerland.

JURISDICTION AND VENUE

10. 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

Laboratories Private Limited and MSN Pharmaceuticals, Inc. and Plaintiffs arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

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

12. 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).

The '109 Patent

13. On information and belief, on November 3, 2009, the Patent and Trademark Office (“PTO”) issued the '109 patent. The '109 patent lists, on its face, Peter Geisser, Erik Philipp, and Walter Richle as inventors of the patent. On information and belief, Plaintiffs Vifor (International) AG is the assignee of the '109 patent.

14. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the '109 patent will expire on February 5, 2026.

The '702 Patent

15. On information and belief, on July 13, 2010, the Patent and Trademark Office (“PTO”) issued the '702 patent. The '702 patent lists, on its face, Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as inventors of the patent. On information and belief, Plaintiff American Regent Inc. is the assignee of the '702 patent.

16. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the '702 patent will expire on February 15, 2028.

The '612 Patent

17. On information and belief, on November 25, 2014, the Patent and Trademark Office (“PTO”) issued the ’612 patent. The ’612 patent lists, on its face, Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as inventors of the patent. On information and belief, Plaintiff American Regent Inc. is the assignee of the ’612 patent.

18. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ’612 patent will expire on January 8, 2027.

The ’260 Patent

19. On information and belief, on June 21, 2022, the Patent and Trademark Office (“PTO”) issued the ’260 patent. The ’260 patent lists, on its face, Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as inventors of the patent. On information and belief, Plaintiff American Regent Inc. is the assignee of the ’260 patent.

20. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ’260 patent will expire on January 8, 2027.

The ’091 Patent

21. On information and belief, on September 6, 2022, the Patent and Trademark Office (“PTO”) issued the ’091 patent. The ’091 patent lists, on its face, Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as inventors of the patent. On information and belief, Plaintiff American Regent Inc. is the assignee of the ’091 patent.

22. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ’091 patent will expire on January 8, 2027.

The ’502 Patent

23. On information and belief, on October 25, 2022, the Patent and Trademark Office (“PTO”) issued the ’502 patent. The ’502 patent lists, on its face, Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as inventors of the patent. On information and belief, Plaintiff American Regent Inc. is the assignee of the ’502 patent.

24. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ’502 patent will expire on January 8, 2027.

THE APPLICATIONS AT ISSUE

The NDA

25. On information and belief, ARI is the current holder of NDA No. 203565 for ferric carboxymaltose (“Injectafer NDA”), which ARI markets and sells, directly or indirectly, under the trade name Injectafer® in the United States, including this judicial district.

26. On information and belief, the FDA approved NDA No. 203565 on July 25, 2013., which permitted ARI to market and sell its ferric carboxymaltose in this judicial district and throughout the United States.

27. Upon information and belief, ARI, as the NDA holder for Injectafer® (NDA No. 203565), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the ’702 patent in the Orange Book for Injectafer®.

28. On information and belief, ARI represented to the FDA that the claims of the ’702 patent read on Plaintiff’s Injectafer® product.

29. Plaintiff’s maintenance of the ’109, ’702, ’612, ’260, ’091, and ’502 patents in the Orange Book means that it believes these patents “claims the drug for which the application was submitted [i.e., Injectafer®] and with respect to which a claim or patent infringement could

reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” See 21 U.S.C. § 355(b)(1).

APPROVAL OF GENERIC DRUGS

30. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a “Paragraph I Certification.”

31. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a “Paragraph II Certification”), (b) when the patent will expire (a “Paragraph III Certification”), or (c) that the patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a “Paragraph IV Certification” or “PIV Certification”). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

32. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

33. If the ANDA contains Paragraph III Certifications and no PIV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. §355 (j)(5)(B)(ii).

34. If an ANDA contains one or more PIV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a “detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed.” 21 U.S.C. §355 (j)(2)(B)(iv)(II).

35. If an ANDA containing a PIV Certification is the first such ANDA submitted, then, subject to other requirements, it can qualify for 180 days of generic exclusivity, during which the FDA will not make effective its approval of another ANDA product that is a generic version of the same NDA product as the first-to-file ANDA. 21 U.S.C. §355 (j)(5)(B)(iv).

36. The filing of a PIV Certification is treated under the patent law as an act of technical infringement that provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement suit within 45 days after it receives the notice of the PIV filing, the FDA's approval of the corresponding ANDA will automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. §355 (j)(5)(B)(iii).

37. If an infringement action is brought against an ANDA applicant in response to receiving notice of a PIV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

ANDA NO. 219580

38. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. have filed an ANDA with the FDA seeking approval to market ferric carboxymaltose, ("ANDA Products"). As part of the application, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. certified that their ANDA Products described in ANDA No. 219580 did not infringe the '109, '702, '612, '260, '091, and '502 patents, and/or that the '109, '702, '612, '260, '091, and '502 patents are invalid and/or unenforceable.

39. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. provided notice of their certification with respect to the '109, '702, '612, '260, '091, and '502 patents to

Plaintiffs, which Plaintiffs received on or about March 12, 2025. The notice provided the factual and legal bases as to why, in MSN's opinion, the '109, '702, '612, '260, '091, and '502 patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products before the expiration of the '109, '702, '612, '260, '091, and '502 patents. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. also enclosed an Offer of Confidential Access to MSN's ANDA in accordance with 21 U.S.C. § 505(j)(5)(C)(i)(III).

40. Plaintiffs conduct impairs MSN's ability to market MSN's ANDA Products. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. thus seek a declaratory judgment that their ANDA Products do not infringe the '109, '702, '612, '260, '091, and '502 patents and/or that these patents are invalid and/or unenforceable.

THE PRESENCE OF A CASE OF ACTUAL CONTROVERSY

41. By maintaining the Orange Book listing of the '109, '702, '612, '260, '091, and '502 patents in connection with Injectafer®, ARI continues to represent that the '109, '702, '612, '260, '091, and '502 patents could reasonably be asserted against anyone making, using, or selling a generic product without a license from Plaintiff.

42. MSN Laboratories Private Limited's and MSN Pharmaceuticals, Inc.'s Paragraph IV certification states that the '109, '702, '612, '260, '091, and '502 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of the ANDA Products.

43. Plaintiff's Complaint gives rise to an actual controversy with respect to the '109, '702, '612, '260, '091, and '502 patents with respect to ANDA No. 219580.

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

45. To avoid legal uncertainty and to protect MSN's anticipated future investment in MSN's ANDA Products, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. seek declaratory relief with respect to the '109, '702, '612, '260, '091, and '502 patents.

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

47. A judgment declaring that the '109, '702, '612, '260, '091, and '502 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of MSN's ANDA Products will remove any independent barriers to competition that may exist by virtue of Plaintiff's maintenance of the listing of the '109, '702, '612, '260, '091, and '502 patents in the Orange Book in connection with NDA No. 203565.

48. The totality of circumstances support that a case or controversy exists with respect to the infringement, invalidity, and/or unenforceability of the '109, '702, '612, '260, '091, and '502 patents.

FIRST COUNT

(Declaratory Judgment of Non-Infringement of the '109 Patent)

49. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

50. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '109 patent.

51. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '109 patent.

52. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '109 patent.

(Declaratory Judgment of Non-Infringement of the '702 Patent)

53. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

54. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '702 patent.

55. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '702 patent.

56. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the

United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '702 patent.

(Declaratory Judgment of Non-Infringement of the '612 Patent)

57. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

58. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '612 patent.

59. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '612 patent.

60. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '612 patent.

(Declaratory Judgment of Non-Infringement of the '260 Patent)

61. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

62. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '260 patent.

63. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '260 patent.

64. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '260 patent.

(Declaratory Judgment of Non-Infringement of the '091 Patent)

65. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

66. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '091 patent.

67. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '091 patent.

68. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the

United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '091 patent.

(Declaratory Judgment of Non-Infringement of the '502 Patent)

69. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

70. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the infringement of the '502 patent.

71. The manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products pursuant to ANDA No. 219580 does not infringe any valid and enforceable claim of the '502 patent.

72. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Products do not infringe any valid and enforceable claim of the '502 patent.

SECOND COUNT

(Declaratory Judgment of Invalidity of the '109 Patent)

73. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

74. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '109 patent.

75. The claims of the '109 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

76. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '109 patent are invalid.

(Declaratory Judgment of Invalidity of the '702 Patent)

77. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

78. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '702 patent.

79. The claims of the '702 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

80. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '702 patent are invalid.

(Declaratory Judgment of Invalidity of the '612 Patent)

81. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

82. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '612 patent.

83. The claims of the '612 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

84. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '612 patent are invalid.

(Declaratory Judgment of Invalidity of the '260 Patent)

85. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

86. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '260 patent.

87. The claims of the '260 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

88. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '260 patent are invalid.

(Declaratory Judgment of Invalidity of the '091 Patent)

89. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

90. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '091 patent.

91. The claims of the '091 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

92. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '091 patent are invalid.

(Declaratory Judgment of Invalidity of the '502 Patent)

93. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. repeat and incorporate by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

94. This Counterclaim arises 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. 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 Plaintiffs and MSN concerning the invalidity of claims of the '502 patent.

95. The claims of the '502 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. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

96. Thus, MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. are entitled to a declaration that the claims of the '502 patent are invalid.

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 Laboratories Private Limited and MSN Pharmaceuticals Inc. 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 Products described in ANDA No. 219580 do not infringe any valid or enforceable claim of the '109, '702, '612, '260, '091, and '502 patents;

B. Declaring that the '109, '702, '612, '260, '091, and '502 patents and all of its claims are invalid;

C. Declare that Plaintiffs are not entitled to any relief under 35 U.S.C. §271(e)(4)(A) resetting MSN's FDA approval date.

D. Declare that the '109, '702, '612, '260, '091, and '502 patents are not properly listed in the Orange Book for Injectafer®.

E. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with it 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;

F. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice hereof, from interfering with FDA's approval of ANDA No. 219580;

G. Granting MSN judgment in its favor on Plaintiffs' claims;

H. Denying Plaintiffs' claims with prejudice;

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

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

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants, by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, other than the following pending cases:

- *American Regent, Inc. v. MSN Laboratories Private Limited et al.*, Civil Action No. 24-10674 (D.N.J.);
- *Vifor (International) AG et al v. Dr. Reddy's Laboratories, Ltd.*, Civil Action No. 24-06833 (D.N.J.);
- *Vifor (International) AG et al v. Apotex Inc. et al.* Civil Action No. 1-25-cv-00211 (DDE); and
- *Vifor (International) AG et al v. Orbicular Pharmaceutical Technologies Private Limited.*, Civil Action No. 1-25-cv-00540 (DDE)

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: May 8, 2025

Respectfully submitted,

/s/ Rebekah Conroy
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