

Cynthia S. Betz  
Mark M. Makhail  
**McCARTER & ENGLISH, LLP**  
100 Mulberry Street  
4 Gateway Center  
Newark, NJ 07102  
973-622-4444  
cbetz@mccarter.com  
mmakhail@mccarter.com

*Attorneys for Plaintiff  
American Regent, Inc.*

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

AMERICAN REGENT, INC.,

Plaintiff,

v.

MSN LABORATORIES PRIVATE LIMITED  
and MSN PHARMACEUTICALS INC.,

Defendants.

Civil Action No.

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff American Regent, Inc. (“American Regent”), by their attorneys, through this Complaint hereby alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against MSN Laboratories Private Limited (“MSN Pvt. Ltd.”) and MSN Pharmaceuticals Inc. (“MSN Inc.”) (MSN Pvt. Ltd. and MSN Inc., collectively, “the MSN Defendants”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 219580, filed by the MSN Defendants with the U.S. Food and Drug

Administration (“FDA”) for approval to market a generic version of Plaintiff’s Injectafer<sup>®</sup>, ferric carboxymaltose injection (100 mg Iron/2 mL; 500 mg Iron /10 mL; 750 mg Iron/15 mL; 1 g Iron /20 mL) (“MSN’s ANDA Products”) prior to the expiration of United States Patent No. 7,754,702 (“the ’702 patent”). The ’702 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for Injectafer<sup>®</sup>.

### **THE PARTIES**

2. Plaintiff American Regent 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. American Regent was formerly known as “Luitpold Pharmaceuticals, Inc.,” until January 2, 2019, when its New York Certificate of Incorporation was amended to change the name of the corporation to “American Regent, Inc.”

3. American Regent was involved in the design and development of Injectafer<sup>®</sup>. American Regent markets, distributes, and sells injectable pharmaceutical drug products, including Injectafer<sup>®</sup>, in this judicial district and throughout the United States.

4. On information and belief, Defendant MSN Pvt. Ltd. is a company organized and existing under the laws of the Republic of India and has a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018, India.

5. On information and belief, MSN Pvt. Ltd. itself, and through its subsidiary and agent MSN Inc., develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

6. On information and belief, Defendant MSN Inc. is a corporation organized and existing under the laws of the State of Delaware and is registered to conduct business in the State of New Jersey, with a principal place of business at 20 Duke Rd, Piscataway, New Jersey, 08854-3714.

7. On information and belief, MSN Inc. is a wholly owned subsidiary of MSN Pvt. Ltd. and is controlled and/or dominated by MSN Pvt. Ltd. On information and belief, MSN Pvt. Ltd. established MSN Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district. On information and belief, MSN Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

### **JURISDICTION AND VENUE**

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

9. On information and belief, this Court has personal jurisdiction over MSN Inc., under the New Jersey state long arm statute and consistent with due process of law, because MSN Inc. maintains its principal place of business in New Jersey.

10. On information and belief, this Court has personal jurisdiction over MSN Pvt. Ltd., under the New Jersey state long arm statute and consistent with due process of law because MSN Pvt. Ltd. has extensive contacts with the State of New Jersey, including through its subsidiary MSN Inc., and regularly does business in this judicial district, including through its subsidiary MSN Inc. Further, the MSN Defendants plan to sell their ANDA product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

11. MSN Pvt. Ltd. has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the principal place of business for MSN Inc., admitting to jurisdiction in this judicial district, and/or pursuing counterclaims in this judicial district. *See, e.g., Esperion Therapeutics, Inc. v. MSN*

*Pharmaceuticals Inc. et al.*, Civil Action No. 24-06386 (D.N.J.) (MSN Pvt. Ltd. and MSN Inc. did not contest personal jurisdiction and asserted counterclaims); *AbbVie Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 24-04662 (D.N.J.) (same); *BeiGene USA, Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 24-01971 (D.N.J.) (same); *Jazz Pharmaceuticals Research UK Limited f/k/a GW Research Limited v. Apotex Inc. et al.*, Civil Action No. 23-23141 (D.N.J.) (same); *Jazz Pharmaceuticals Research UK Limited f/k/a GW Research Limited v. Teva Pharmaceuticals, Inc. et al.*, Civil Action No. 23-03914 (D.N.J.) (same); *GW Research Limited v. Teva Pharmaceuticals, Inc. et al.*, Civil Action No. 23-00018 (D.N.J.) (same); *Chiesi USA, Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 19-18564 (D.N.J.) (same); *Mitsubishi Tanabe Pharma Corporation et al. v. MSN Laboratories Private Limited et al.*, Civil Action No. 19-18958 (D.N.J.) (same); *Bausch Health Ireland Limited et al. v. MSN Laboratories Private Limited et al.*, Civil Action No. 23-03333 (D.N.J.) (MSN Pvt. Ltd. and MSN Inc. did not contest personal jurisdiction and MSN Pvt. Ltd. asserted counterclaims); *Bausch Health Ireland Ltd. f/k/a Valeant Pharmaceuticals Ireland Ltd. et al. v. MSN Laboratories Private Limited et al.*, Civil Action No. 21-10057 (D.N.J.) (MSN Pvt. Ltd. and MSN Inc. did not contest personal jurisdiction and MSN Pvt. Ltd. asserted counterclaims).

12. On information and belief, MSN Pvt. Ltd. and MSN Inc. are subject to personal jurisdiction in New Jersey because they regularly do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, demonstrating that MSN Pvt. Ltd. and MSN Inc. have systematic and continuous contacts with this judicial district.

13. On information and belief, MSN Pvt. Ltd. and MSN Inc. purposefully have conducted and continue to conduct business in this judicial district by manufacturing, importing,

marketing, and distributing pharmaceutical products, including generic drug products, either alone or through their parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in this judicial district. The MSN Defendants further intend to sell their generic ANDA products in the State of New Jersey.

14. On information and belief, MSN Inc. is registered to do business in the State of New Jersey under Entity Identification Number 0400627791, and MSN Inc. is also licensed to do business with the New Jersey Department of Health as a “Manufacturer and Wholesale[r]” of pharmaceuticals in the State of New Jersey (Registration Number 5006107). Moreover, on information and belief, MSN Inc. has appointed a registered agent in New Jersey for the receipt of service of process.

15. On information and belief, MSN Pvt. Ltd. and MSN Inc. are subject to personal jurisdiction in this judicial district through their pursuit of regulatory approval for MSN’s ANDA Products for the commercial manufacture, use, and/or sale of MSN’s ANDA Products, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, MSN Pvt. Ltd. and MSN Inc. have purposely availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district.

16. On information and belief, consistent with their past practices, MSN Pvt. Ltd. and MSN Inc. acted collaboratively in the preparation and submission of ANDA No. 219580.

17. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 219580, MSN Pvt. Ltd. and MSN Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 219580 throughout the United States and/or import such generic drug products

into the United States, including in this judicial district.

18. On information and belief, if ANDA No. 219580 is approved, MSN's ANDA Products will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; administered by healthcare professionals located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

19. On information and belief, if ANDA No. 219580 is approved, MSN Pvt. Ltd. and MSN Inc. will import, market, distribute, offer for sale, and/or sell MSN's ANDA Products, alone or through their parent corporation, subsidiaries, and/or affiliates in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of MSN's ANDA Products in the state of New Jersey.

20. If ANDA No. 219580 is approved, American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of MSN's ANDA Products, including in New Jersey.

21. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because MSN Inc. has its principal place of business in the State of New Jersey, and has committed acts of infringement in New Jersey. MSN Pvt. Ltd. is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3). Moreover, MSN Pvt. Ltd. and MSN Inc. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey.

22. On information and belief, MSN Inc. has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting ANDA No. 219580 to the FDA, by taking steps indicating its intent to market MSN's ANDA Products in New Jersey, and by the acts that it

non-speculatively intends to take in New Jersey if MSN's ANDA receives final FDA approval.

23. On information and belief, MSN Inc. has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, MSN Inc. maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 20 Duke Rd, Piscataway, New Jersey, 08854-3714.

24. On information and belief, MSN Pvt. Ltd. and MSN Inc. have taken steps in New Jersey, including preparing ANDA No. 219580 and communicating with the FDA regarding ANDA No. 219580, that indicate their intent to market MSN's ANDA Products. As set forth above, on information and belief, if ANDA No. 219580 is approved, the MSN Defendants intend to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling MSN's ANDA Products.

#### **PATENT-IN-SUIT**

25. The U.S. Patent and Trademark Office ("PTO") issued the '702 patent entitled "Methods and Compositions For Administration of Iron," on July 13, 2010 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. At the time of its issuance, the '702 patent was assigned to Luitpold Pharmaceuticals, Inc., and on January 11, 2019, the assignment records for the '702 patent were amended to reflect that Luitpold Pharmaceuticals, Inc. had changed its name to "American Regent, Inc." The Change of Name of the assignee for the '702 patent is recorded by the PTO at Reel 048067, Frame 0271. American Regent is the current assignee of the '702 patent and has the right to enforce it. The '702 patent expires on February 15, 2028. The '702 patent claims, *inter alia*, methods of treating iron deficiency anemia by administering an iron carbohydrate complex. A true and correct copy of the '702 patent is

attached hereto as **Exhibit A**.

**NDA NO. 203565 AND INJECTAFER®**

26. American Regent is the owner of New Drug Application (“NDA”) No. 203565 for Injectafer® (ferric carboxymaltose), which the FDA approved on July 25, 2013. The Orange Book lists the NDA holder as “American Regent, Inc.,” in accordance with the name change from “Luitpold Pharmaceuticals, Inc.” to “American Regent, Inc.,” effective January 2, 2019.

27. In conjunction with NDA No. 203565, American Regent listed with the FDA, *inter alia*, the ’702 patent.

28. Injectafer® is covered by one or more claims of the ’702 patent.

29. Injectafer® is currently approved to treat iron deficiency anemia in certain patients and iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity. A true and correct copy of the current Injectafer® label is attached as **Exhibit B**.

**THE MSN DEFENDANTS’ INFRINGING ANDA SUBMISSION**

30. Plaintiff received a letter from the MSN Defendants dated October 11, 2024, purporting to be a “Notice of Paragraph IV Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(f)(2)(B)) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95 of U.S. Patent No. 7,754,702 in ANDA No. 219580 for generic Ferric Carboxymaltose Injection, 750mg iron/15ml (50mg iron/ml); 100mg iron/2ml (50mg iron/ml); 500mg iron/10ml (50mg iron/ml); and 1gm iron/20ml (50mg iron/ml) doses” (“MSN’s Notice Letter”).

31. MSN’s Notice Letter states that the MSN Defendants are seeking approval to engage in the commercial manufacture, use, and/or sale of MSN’s ANDA Products before the expiration of the ’702 patent.

32. On information and belief, the MSN Defendants submitted ANDA No. 219580 to



FDA under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to, and intending to, manufacture, use, import, offer to sell, and/or sell MSN's ANDA Products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States before the expiration of the '702 patent.

33. On information and belief, each of MSN's ANDA Products contains ferric carboxymaltose.

34. On information and belief, each of the MSN Defendants has made, and continues to make, substantial preparation in the United States to manufacture, use, import, offer to sell, and/or sell MSN's ANDA Products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, before the expiration of '702 patent.

35. By filing ANDA No. 219580, and as indicated in MSN's Notice Letter, the MSN Defendants have represented to the FDA that MSN's ANDA Products have the same active ingredient as Injectafer®, have the same dosage forms and strengths as Injectafer®, and are bioequivalent to Injectafer®.

36. On information and belief, the MSN Defendants are seeking approval to market MSN's ANDA Products for the same approved indications as Injectafer®.

37. MSN's Notice Letter states that it has attached a “[d]etailed statement of the legal and factual bases of MSN's position for the paragraph IV certification for U.S. Patent No. 7,745,702” and “MSN has submitted a paragraph IV certification to the FDA, stating that in MSN's opinion and to the best of their knowledge, U.S. Patent No. 7,754,702, is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in MSN's ANDA.”

#### **COUNT I (INFRINGEMENT OF THE '702 PATENT)**

38. Plaintiff alleges, and incorporates in full herein, each of the preceding paragraphs

1–37.

39. The claims of the '702 patent, including claims 4–9, 16–22, 24, 31–40, and 44–57, are presumed valid under 35 U.S.C. § 282.

40. Under 35 U.S.C. § 271(e)(2)(A), the MSN Defendants have infringed at least one claim of the '702 patent by submitting, or causing to be submitted to the FDA, ANDA No. 219580 seeking approval to engage in the commercial manufacture, use, or sale of MSN's ANDA Products before the expiration date of the '702 patent. On information and belief, the product described in ANDA No. 219580 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '702 patent under 35 U.S.C. § 271(e)(2)(A).

41. In MSN's Notice Letter, the MSN Defendants did not provide any allegation that MSN's ANDA Products do not fall within the scope of certain claims of the '702 patent, including claims 4, 21–22, 24, 31–40, and 44–57, and therefore admit infringement of the '702 patent.

42. On information and belief, based on MSN's Notice Letter, the absence of any allegation that MSN's ANDA Products do not fall within the scope of claims of the '702 patent in MSN's Notice Letter, the fact that the MSN Defendants have represented to the FDA that MSN's ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the MSN Defendants are required to substantially copy the FDA-approved Injectafer® labeling, MSN's ANDA Products comprise an iron carboxymaltose complex having a molecular weight of about 100,000 daltons to about 350,000 daltons, and will be used in a method of treating iron deficiency anemia, whereby MSN's ANDA Products will be administered intravenously in about 15 minutes or less to a subject in need thereof in a single dosage unit of at least about 0.6 grams of

elemental iron, and the use of MSN's ANDA Products will satisfy all of the limitations of one or more claims of the '702 patent.

43. On information and belief, the MSN Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of MSN's ANDA Products prior to the expiration of the '702 patent immediately and imminently upon final approval of ANDA No. 219580. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of MSN's ANDA Products prior to the expiration of the '702 patent would infringe one or more claims of the '702 patent.

44. On information and belief, upon FDA approval of MSN's ANDA Products, the MSN Defendants will induce and/or contribute to the infringement of one or more claims of the '702 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

45. On information and belief, the MSN Defendants have knowledge of the '702 patent and have filed ANDA No. 219580 seeking authorization to engage in the commercial manufacture, use, or sale of MSN's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 219580, healthcare professionals and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '702 patent by the use MSN's ANDA Products according to the MSN Defendants' provided instructions and/or label.

46. On information and belief, the MSN Defendants know and intend that healthcare professionals and/or patients will use MSN's ANDA Products according to the MSN Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '702 patent with the requisite intent under 35 U.S.C. § 271(b).

47. Upon information and belief, upon approval, the MSN Defendants will take active steps to encourage the use of MSN's ANDA Products by healthcare professionals and/or patients with the knowledge and intent that it will be used by healthcare professionals and/or patients in a manner that infringes at least one claim of the '702 patent for the pecuniary benefit of the MSN Defendants. Upon information and belief, the MSN Defendants will thus induce infringement of at least one claim of the '702 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, the MSN Defendants will have actual knowledge of the '702 patent and will actively induce infringement of the '702 patent immediately and imminently upon approval of its ANDA.

48. On information and belief, if the FDA approves ANDA No. 219580, MSN's ANDA Products will be specifically labeled for use in practicing at least one claim of the '702 patent, wherein MSN's ANDA Products are a material part of the claimed invention, wherein the MSN Defendants know and intend that healthcare professionals and/or patients will use MSN's ANDA Products in accordance with the instructions and/or label provided by the MSN Defendants in practicing at least one claim of the '702 patent, and wherein MSN's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the MSN Defendants will thus contribute to the infringement of at least one claim of the '702 patent under 35 U.S.C. § 271(c).

49. Upon information and belief, the MSN Defendants' actions relating to ANDA No. 219580 complained of herein were done by and for the benefit of the MSN Defendants.

50. If the MSN Defendants' marketing and sale of MSN's ANDA Products prior to the expiration of the '702 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff respectfully requests that this Court grant the following relief:

1. A judgment that the claims of the '702 patent are not invalid or unenforceable, and are infringed by the MSN Defendants' submission of ANDA No. 219580 under 35 U.S.C. §271(e)(2)(A), and that the MSN Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States, MSN's ANDA Products will infringe the '702 patent under 35 U.S.C. §§ 271(b), (c), and/or (e);
2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval by the FDA of ANDA No. 219580 shall be a date that is not earlier than the latest expiration date of the '702 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;
3. An order permanently enjoining each of the MSN Defendants and its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States MSN's ANDA Products until after the last expiration date of the '702 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;
4. Damages or other monetary relief to Plaintiff if the MSN Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of MSN's ANDA Products prior to the latest expiration date of the '702 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C); and

5. Such further and additional relief as this Court deems just and proper, including any appropriate relief under 35 U.S.C. § 285.

Dated: November 22, 2024

Respectfully submitted,

**McCARTER & ENGLISH, LLP**

Of Counsel:

Jane M. Love, Ph.D. (*pro hac vice* forthcoming)  
Robert Trenchard (*pro hac vice* forthcoming)  
Allyson E. Parks (*pro hac vice* forthcoming)  
Emil Nachman (*pro hac vice* forthcoming)  
Spencer W. Vaughan (*pro hac vice* forthcoming)

**GIBSON, DUNN & CRUTCHER LLP**

200 Park Avenue

New York, NY 10166-0193

212-351-4000

jlove@gibsondunn.com

rtrenchard@gibsondunn.com

aparks@gibsondunn.com

enachman@gibsondunn.com

svaughan@gibsondunn.com

By: /s/ Cynthia S. Betz

Cynthia S. Betz

Mark M. Makhail

Four Gateway Center

100 Mulberry Street

4 Gateway Center

Newark, NJ 07102

973-622-4444

cbetz@mccarter.com

mmakhail@mccarter.com

*Attorneys for Plaintiff American Regent, Inc.*

**LOCAL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

United States Patent No. 7,754,702 (“the ’702 patent”) is currently the subject of proceedings before this Court in *VIFOR (INTERNATIONAL) AG et al v. DR REDDY’S LABORATORIES, LTD. et al.*, 3:24-cv-06833-GC-JBD. The Defendants in this matter are not involved in that case.

United States Patent No. 7,754,702 (“the ’702 patent”) was previously the subject of now-closed proceedings before this Court including those cases consolidated under the matter *VIFOR (INTERNATIONAL) AG et al v. MYLAN LABORATORIES Ltd.*, 3:19-cv-13955-FLW-DEA. The Defendants in this matter were not involved in those cases.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: November 22, 2024

/s/ Cynthia S. Betz  
Cynthia S. Betz