

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

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

Plaintiffs,

v.

ORBICULAR PHARMACEUTICAL
TECHNOLOGIES PVT. LTD.,

Defendant.

Case Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor (International) AG (“Vifor”) and American Regent, Inc. (“American Regent”) (collectively, “Plaintiffs”), by their attorneys, through this Complaint, hereby allege 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 Orbicular Pharmaceutical Technologies Private Limited (“Orbicular” or “Defendant”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 212136, filed by Orbicular with the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of Plaintiffs’ Injectafer®, ferric carboxymaltose injection (750 mg Iron/15 mL) (“Orbicular’s ANDA Product”) 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”). The ‘109, ‘702, ‘612, ‘260, ‘091, and ‘502 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations

(“Orange Book”) for Injectafer®.

THE PARTIES

2. Plaintiff Vifor is a company organized and existing under the laws of Switzerland, having a principal place of business at Rechenstraße 37, CH-9001, St. Gallen, Switzerland.

3. Vifor is engaged in the business of creating, developing, and bringing to market revolutionary drug products, including treatments for iron deficiency anemia.

4. 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.”

5. Vifor and American Regent developed Injectafer®. American Regent licenses Injectafer® from Vifor, and American Regent markets, distributes, and sells injectable pharmaceutical drug products, including Injectafer®, in this judicial district and throughout the United States.

6. On information and belief, Orbicular Pharmaceutical Technologies Pvt. Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar Kukatpally, Hyderabad, 500 090 Telangana, India. On information and belief, Orbicular has no place of business in the United States. On information and belief, Orbicular 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

7. 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.

8. On information and belief, this Court has personal jurisdiction over Orbicular, under the Delaware state long arm statute and consistent with due process of law because Orbicular regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Orbicular has systematic and continuous contacts with this judicial district. On information and belief, Orbicular purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either alone or through its parent corporation, subsidiaries, affiliates, and/or agents, throughout the United States, including in this judicial district. Further, Orbicular plans to sell its ANDA product in the State of Delaware, which provides an independent basis for personal jurisdiction here.

9. Orbicular has previously availed itself of the legal protections of the State of Delaware by, among other things, admitting to jurisdiction in this judicial district, and/or pursuing counterclaims in this judicial district. *See, e.g., Vifor (Int'l) AG et al. v. Orbicular Pharm. Techs. PVT. LTD.*, C.A. No. 25-540 (Del.); *Novo Nordisk Inc. et al v. Orbicular Pharmaceutical Technologies Pvt. Ltd.*, C.A. No. 22-856 (Del.) (Orbicular did not contest personal jurisdiction and asserted counterclaims).

10. On information and belief, if ANDA No. 212136 is approved, Orbicular's ANDA Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; administered by healthcare professionals located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on

Delaware.

11. On information and belief, if ANDA No. 212136 is approved, Orbicular will import, market, distribute, offer for sale, and/or sell Orbicular's ANDA Product, alone or through its parent corporation, subsidiaries, affiliates, and/or agents in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Orbicular's ANDA Product in the State of Delaware.

12. If ANDA No. 212136 is approved, Vifor and American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of Orbicular's ANDA Product, including in Delaware.

13. On information and belief, venue is proper in this judicial district under 28 U.S.C. § 1391 at least because Orbicular 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).

14. On information and belief, venue is also proper under 28 U.S.C. § 1400(b) because Orbicular has committed acts of infringement under the meaning of this statute by submitting ANDA No. 212136 to the FDA, by taking steps indicating its intent to market Orbicular's ANDA Product in Delaware, and by the acts that it non-speculatively intends to take in Delaware if Orbicular's ANDA receives final FDA approval.

15. On information and belief, Orbicular has taken steps in the United States, including preparing ANDA No. 212136 and communicating with the FDA regarding ANDA No. 212136, that indicate its intent to market Orbicular's ANDA Product. As set forth above, on information and belief, if ANDA No. 212136 is approved, Orbicular intends to commit acts of patent infringement in Delaware, including marketing, distributing, offering for sale, and/or selling Orbicular's ANDA Product. Moreover, Orbicular has litigated previous Hatch-Waxman

patent infringement disputes in the District of Delaware.

PATENTS-IN-SUIT

16. The U.S. Patent and Trademark Office (“PTO”) issued the ’109 patent, entitled “Water-Soluble Iron-Carbohydrate Complexes, Production Thereof, and Medicaments Containing Said Complexes,” on November 3, 2009 to inventors Peter Geisser, Erik Philipp, and Walter Richle. Vifor is the current assignee of the ’109 patent and has the right to enforce it. The ’109 patent had an expiration date of February 5, 2026, subject to an interim extension of patent term for a period of 1 year and any other further extensions. The ’109 patent claims, *inter alia*, compositions and methods of making iron carbohydrate complexes. A true and correct copy of the ’109 patent is attached hereto as **Exhibit A**.

17. The 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 B**.

18. The PTO issued the ’612 patent entitled “Methods and Compositions For Administration of Iron,” on November 25, 2014 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. At the time of its issuance, the ’612 patent was assigned to Luitpold Pharmaceuticals, Inc., and on January 11, 2019, the assignment records for the ’612

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 ’612 patent is recorded by the PTO at Reel 048067, Frame 0271. American Regent is the current assignee of the ’612 patent and has the right to enforce it. The ’612 patent expires on January 8, 2027. The ’612 patent claims, *inter alia*, methods of treating iron deficiency anemia by the administration of an iron carboxymaltose complex. A true and correct copy of the ’612 patent is attached hereto as

Exhibit C.

19. The PTO issued the ’260 patent entitled “Methods and Compositions For Administration of Iron,” on June 21, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. American Regent is the current assignee of the ’260 patent and has the right to enforce it. The ’260 patent expires on January 8, 2027. The ’260 patent claims, *inter alia*, methods of treating iron deficiency or dysfunctional iron metabolism by the administration of an iron carboxymaltose complex. A true and correct copy of the ’260 patent is attached hereto as **Exhibit D.**

20. The PTO issued the ’091 patent entitled “Methods and Compositions For Administration of Iron,” on September 6, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. American Regent is the current assignee of the ’091 patent and has the right to enforce it. The ’091 patent expires on January 8, 2027. The ’091 patent claims, *inter alia*, methods of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism by the administration of an iron carboxymaltose complex. A true and correct copy of the ’091 patent is attached hereto as **Exhibit E.**

21. The PTO issued the ’502 patent entitled “Methods and Compositions For Administration of Iron,” on October 25, 2022 to inventors Mary Jane Helenek, Marc L. Tokars,

and Richard P. Lawrence. American Regent is the current assignee of the '502 patent and has the right to enforce it. The '502 patent expires on January 8, 2027. The '502 patent claims, *inter alia*, methods of treating iron deficiency anemia and functional iron deficiency by the administration of an iron carboxymaltose complex. A true and correct copy of the '502 patent is attached hereto as **Exhibit F**.

NDA NO. 203565 AND INJECTAFER®

22. 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.

23. In conjunction with NDA No. 203565, American Regent listed with the FDA, *inter alia*, the '109, '702, and '612 patents. American Regent subsequently timely listed the '260, '091, and '502 patents with the FDA after those patents issued. All six patents—the '109, '702, '612, '260, '091, and '502 patents—are currently listed in the Orange Book for Injectafer®.

24. Injectafer® is covered by one or more claims of each of the '109, '702, '612, '260, '091, and '502 patents.

25. 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 G**.

ORBICULAR'S INFRINGING ANDA SUBMISSION

26. Plaintiffs and/or Plaintiffs' counsel received a letter from Defendant dated July 10, 2025, purporting to be a "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act regarding U.S. Patent No. 7,612,109, U.S. Patent No. 7,754,702, U.S. Patent No.

8,895,612, U.S. Patent No. 11,364,260, U.S. Patent No. 11,433,091, and U.S. Patent No. 11,478,502 pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95; ANDA 212136 and Injectafer.” (“Orbicular’s Notice Letter”).

27. Orbicular’s Notice Letter states that “[p]ursuant to 21 U.S.C. § 355(j)(2)(B)(ii), (iv) and Section 314.95(c)(1), we advise you that the FDA has received an Abbreviated New Drug Application from Orbicular, containing any required bioavailability and/or bioequivalence data from studies on the ferric carboxymaltose product that is the subject of Orbicular’s ANDA. Orbicular’s ANDA was submitted under 21 U.S.C. § 355(j)(1) and (j)(2)(A) and includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of ferric carboxymaltose injection, 750 mg iron/15 mL, before the expiration of the ’109 patent, the ’702 patent, the ’612 patent, the ’260 patent, the ’091 patent, and the ’502 patent, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation (“Orange Book”) in connection with Injectafer®.”

28. On information and belief, Orbicular submitted ANDA No. 212136 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 Orbicular’s ANDA Product, either by itself or through its parent corporation, subsidiaries, affiliates, and/or agents, throughout the United States before the expiration of the ’109, ’702, ’612, ’260, ’091, and ’502 patents.

29. Orbicular’s Notice Letter further states that “the patents subject to the paragraph IV certification alleged to be invalid, and/or not infringe, and/or unenforceable, are the ’109 patent, the ’702 patent, the ’612 patent, the ’260 patent, the ’091 patent, and the ’502 patent, which are listed in the Orange book in connection with NDA No. 203565.”

30. On information and belief, Orbicular has made, and continues to make, substantial

preparation in the United States to manufacture, use, import, offer to sell, and/or sell Orbicular's ANDA Product, either by itself or through its parent corporation, subsidiaries, affiliates, and/or agents, before the expiration of the '109, '702, '612, '260, '091, and '502 patents.

31. By filing ANDA No. 212136, and as indicated in Orbicular's Notice Letter, Orbicular has represented to the FDA that Orbicular's ANDA Product have the same active ingredient as Injectafer®, have the same dosage form and strength as Injectafer®, and are bioequivalent to Injectafer®.

32. On information and belief, Orbicular is seeking approval to market Orbicular's ANDA Product for the same approved indications as Injectafer®.

33. Orbicular's Notice Letter states that "Orbicular alleges, and has certified to the FDA, that in its opinion and to the best of its knowledge, each claim of the '109 patent, the '702 patent, the '612 patent, the '260 patent, the '091 patent, and the '502 patent, is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the drug product described in Orbicular's ANDA" and that it has attached "pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Orbicular's detailed statement of the legal and factual bases for certifications set forth in Orbicular's ANDA."

34. Plaintiffs and/or Plaintiffs' counsel had previously received a letter from Defendant dated March 20, 2025, purporting to be a "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act regarding U.S. Patent No. 7,612,109, U.S. Patent No. 7,754,702, U.S. Patent No. 8,895,612, U.S. Patent No. 11,433,091, and U.S. Patent No. 11,478,502 pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95; ANDA 212136 and Injectafer." ("Orbicular's Prior Notice Letter")

Plaintiffs timely filed an action asserting the patents identified in Orbicular's Prior Notice Letter, which is currently pending. *See, e.g., Vifor (Int'l) AG et al. v. Orbicular Pharm. Techs. PVT. LTD.*, C.A. No. 25-540 (Del.).

COUNT I (INFRINGEMENT OF THE '109 PATENT)

35. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–34.

36. The claims of the '109 patent are presumed valid under 35 U.S.C. § 282.

37. Under 35 U.S.C. § 271(e)(2)(A), Orbicular has infringed at least one claim of the '109 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '109 patent. On information and belief, the product described in ANDA No. 212136 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '109 patent under 35 U.S.C. § 271(e)(2)(A).

38. In Orbicular's Notice Letter, Orbicular did not provide any allegation that Orbicular's ANDA Product does not fall within the scope of certain claims of the '109 patent, and therefore admits infringement of at least one claim of the '109 patent.

39. On information and belief, based on Orbicular's Notice Letter, the absence of any allegation that Orbicular's ANDA Product does not fall within the scope of claims of the '109 patent in Orbicular's Notice Letter, the fact that Orbicular has represented to the FDA that Orbicular's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Orbicular is required to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprises an aqueous solution of ferric carboxymaltose which is formulated for parenteral application, wherein the ferric carboxymaltose, an iron carbohydrate complex, has a weight

average molecular weight of 80,000 to 300,000 daltons, and satisfies all of the limitations of one or more claim of the '109 patent.

40. On information and belief, Orbicular intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '109 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '109 patent would infringe one or more claims of the '109 patent.

41. On information and belief, upon FDA approval of Orbicular's ANDA Product, Orbicular will infringe at least one claim of the '109 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling Orbicular's ANDA Product in the United States, and/or will induce and/or contribute to infringement of one or more claims of the '109 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

42. On information and belief, Orbicular has knowledge of the '109 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 '109 patent by the use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label.

43. On information and belief, Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Orbicular's

provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '109 patent with the requisite intent under 35 U.S.C. § 271(b).

44. Upon information and belief, upon approval, Orbicular will take active steps to encourage the use of Orbicular's ANDA Product 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 '109 patent for the pecuniary benefit of Orbicular. Upon information and belief, Orbicular will thus induce infringement of at least one claim of the '109 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, Orbicular will have actual knowledge of the '109 patent and will actively induce infringement of the '109 patent immediately and imminently upon approval of its ANDA.

45. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's ANDA Product will be specifically labeled for use in practicing at least one claim of the '109 patent, wherein Orbicular's ANDA Product is a material part of the claimed invention, wherein Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Orbicular in practicing at least one claim of the '109 patent, and wherein Orbicular's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Orbicular will thus contribute to the infringement of at least one claim of the '109 patent under 35 U.S.C. § 271(c).

46. Upon information and belief, Orbicular's ANDA Product will be manufactured using a method or methods claimed by the '109 patent and therefore will infringe one or more claims of the '109 patent under 35 U.S.C. § 271(g).

47. Upon information and belief, Orbicular's actions relating to ANDA No. 212136 complained of herein were done by and for the benefit of Orbicular.

48. If Orbicular's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '109 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '702 PATENT)

49. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–48.

50. Claims 4–9, 16–22, 24, 26, 31–40, and 44–57 of the '702 patent are presumed valid under 35 U.S.C. § 282.

51. Under 35 U.S.C. § 271(e)(2)(A), Orbicular has infringed at least one claim of the '702 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '702 patent. On information and belief, the product described in ANDA No. 212136 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).

52. In Orbicular's Notice Letter, Orbicular did not provide any allegation that Orbicular's ANDA Product does not fall within the scope of certain claims of the '702 patent, and therefore admits infringement of at least one claim of the '702 patent.

53. On information and belief, based on Orbicular's Notice Letter, the absence of any allegation that Orbicular's ANDA Product does not fall within the scope of the claims of the '702 patent in Orbicular's Notice Letter, the fact that Orbicular has represented to the FDA that Orbicular's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Orbicular is required

to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprises 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 Orbicular's ANDA Product 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 Orbicular's ANDA Product will satisfy all of the limitations of one or more claims of the '702 patent.

54. On information and belief, Orbicular intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '702 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '702 patent would infringe one or more claims of the '702 patent.

55. On information and belief, upon FDA approval of Orbicular's ANDA Product, Orbicular 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.

56. On information and belief, Orbicular has knowledge of the '702 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 Orbicular's ANDA Product according to Orbicular's provided instructions and/or label.

57. On information and belief, Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Orbicular's 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).

58. Upon information and belief, upon approval, Orbicular will take active steps to encourage the use of Orbicular's ANDA Product 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 Orbicular. Upon information and belief, Orbicular 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, Orbicular 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.

59. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's ANDA Product will be specifically labeled for use in practicing at least one claim of the '702 patent, wherein Orbicular's ANDA Product is a material part of the claimed invention, wherein Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Orbicular in practicing at least one claim of the '702 patent, and wherein Orbicular's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Orbicular will thus contribute to the infringement of at least one claim of the '702 patent under 35 U.S.C. § 271(c).

60. Upon information and belief, Orbicular's actions relating to ANDA No. 212136

complained of herein were done by and for the benefit of Orbicular.

61. If Orbicular's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '702 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III (INFRINGEMENT OF THE '612 PATENT)

62. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–61.

63. The claims of the '612 patent are presumed valid under 35 U.S.C. § 282.

64. Under 35 U.S.C. § 271(e)(2)(A), Orbicular has infringed at least one claim of the '612 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '612 patent. On information and belief, the product described in ANDA No. 212136 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

65. On information and belief, based on Orbicular's Notice Letter, the absence of any allegation that Orbicular's ANDA Product does not fall within the scope of the claims of the '612 patent in Orbicular's Notice Letter, the fact that Orbicular has represented to the FDA that Orbicular's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Orbicular is required to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprises an iron carboxymaltose complex having a substantially non-immunogenic carbohydrate component and substantially no cross reactivity with anti-dextran antibodies, and will be used in a method of treating iron deficiency anemia associated with chronic kidney disease and/or heavy uterine bleeding, whereby Orbicular's ANDA Product will be administered

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 Orbicular's ANDA Product will satisfy all of the limitations of one or more claims of the '612 patent.

66. On information and belief, Orbicular intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '612 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '612 patent would infringe one or more claims of the '612 patent.

67. On information and belief, upon FDA approval of Orbicular's ANDA Product, Orbicular will induce and/or contribute to the infringement of one or more claims of the '612 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

68. On information and belief, Orbicular has knowledge of the '612 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 '612 patent by the use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label.

69. On information and belief, Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '612 patent with the requisite intent under 35 U.S.C.

§ 271(b).

70. Upon information and belief, upon approval, Orbicular will take active steps to encourage the use of Orbicular's ANDA Product 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 '612 patent for the pecuniary benefit of Orbicular. Upon information and belief, Orbicular will thus induce infringement of at least one claim of the '612 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, Orbicular will have actual knowledge of the '612 patent and will actively induce infringement of the '612 patent immediately and imminently upon approval of its ANDA.

71. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's ANDA Product will be specifically labeled for use in practicing at least one claim of the '612 patent, wherein Orbicular's ANDA Product is a material part of the claimed invention, wherein Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Orbicular in practicing at least one claim of the '612 patent, and wherein Orbicular's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Orbicular will thus contribute to the infringement of at least one claim of the '612 patent under 35 U.S.C. § 271(c).

72. Upon information and belief, Orbicular's actions relating to ANDA No. 212136 complained of herein were done by and for the benefit of Orbicular.

73. If Orbicular's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '612 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV (INFRINGEMENT OF THE '260 PATENT)

74. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–73.

75. The claims of the '260 patent are presumed valid under 35 U.S.C. § 282.

76. Under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed at least one claim of the '260 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '260 patent. On information and belief, the product described in ANDA No. 212136 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '260 patent under 35 U.S.C. § 271(e)(2)(A).

77. On information and belief, based on Orbicular's Notice Letter, the absence of any allegation that Orbicular's ANDA Product do not fall within the scope of the claims of the '260 patent in Orbicular's Notice Letter, the fact that Defendant has represented to the FDA that Orbicular's ANDA Product are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Defendant is required to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprise an iron carboxymaltose complex having a substantially non-immunogenic carbohydrate component and substantially no cross reactivity with anti-dextran antibodies, and will be used in a method of treating iron deficiency or dysfunctional iron metabolism associated with cardiomyopathy, whereby Orbicular's ANDA Product 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 Orbicular's ANDA Product will satisfy all of the limitations of one or more claims of the '260 patent.

78. On information and belief, Defendant intends to engage in the commercial

manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '260 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '260 patent would infringe one or more claims of the '260 patent.

79. On information and belief, upon FDA approval of Orbicular's ANDA Product, Defendant will induce and/or contribute to the infringement of one or more claims of the '260 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

80. On information and belief, Defendant has knowledge of the '260 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 '260 patent by the use Orbicular's ANDA Product according to Defendant's provided instructions and/or label.

81. On information and belief, Defendant knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Defendant's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '260 patent with the requisite intent under 35 U.S.C. § 271(b).

82. Upon information and belief, upon approval, Defendant will take active steps to encourage the use of Orbicular's ANDA Product 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 '260 patent for the pecuniary benefit of Defendant. Upon information and belief, Defendant will thus induce infringement of at least one claim of the '260 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, Defendant will have actual knowledge of the '260 patent and will actively induce infringement of the '260 patent immediately and imminently upon approval of its ANDA.

83. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's ANDA Product will be specifically labeled for use in practicing at least one claim of the '260 patent, wherein Orbicular's ANDA Product are a material part of the claimed invention, wherein Defendant knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Defendant in practicing at least one claim of the '260 patent, and wherein Orbicular's ANDA Product are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Defendant will thus contribute to the infringement of at least one claim of the '260 patent under 35 U.S.C. § 271(c).

84. Upon information and belief, Defendant's actions relating to ANDA No. 212136 complained of herein were done by and for the benefit of Defendant.

85. If Defendant's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '260 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V (INFRINGEMENT OF THE '091 PATENT)

86. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–85.

87. The claims of the '091 patent are presumed valid under 35 U.S.C. § 282.

88. Under 35 U.S.C. § 271(e)(2)(A), Orbicular has infringed at least one claim of the

'091 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '091 patent. On information and belief, the product described in ANDA No. 212136 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '091 patent under 35 U.S.C. § 271(e)(2)(A).

89. On information and belief, based on Orbicular's Notice Letter, the absence of any allegation that Orbicular's ANDA Product does not fall within the scope of the claims of the '091 patent in Orbicular's Notice Letter, the fact that Orbicular has represented to the FDA that Orbicular's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Orbicular is required to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprises an iron carboxymaltose complex, and will be used in a method of treating anemia, whereby Orbicular's ANDA Product will be administered intravenously to a human subject in need thereof in a single dosage unit of at least about 0.7 grams of elemental iron in 15 minutes or less, and the use of Orbicular's ANDA Product will satisfy all of the limitations of one or more claims of the '091 patent.

90. On information and belief, Orbicular intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '091 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '091 patent would infringe one or more claims of the '091 patent.

91. On information and belief, upon FDA approval of Orbicular's ANDA Product,

Orbicular will induce and/or contribute to the infringement of one or more claims of the '091 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

92. On information and belief, Orbicular has knowledge of the '091 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 '091 patent by the use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label.

93. On information and belief, Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '091 patent with the requisite intent under 35 U.S.C. § 271(b).

94. Upon information and belief, upon approval, Orbicular will take active steps to encourage the use of Orbicular's ANDA Product 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 '091 patent for the pecuniary benefit of Orbicular. Upon information and belief, Orbicular will thus induce infringement of at least one claim of the '091 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, Orbicular will have actual knowledge of the '091 patent and will actively induce infringement of the '091 patent immediately and imminently upon approval of its ANDA.

95. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's

ANDA Product will be specifically labeled for use in practicing at least one claim of the '091 patent, wherein Orbicular's ANDA Product is a material part of the claimed invention, wherein Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Orbicular in practicing at least one claim of the '091 patent, and wherein Orbicular's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Orbicular will thus contribute to the infringement of at least one claim of the '091 patent under 35 U.S.C. § 271(c).

96. Upon information and belief, Orbicular's actions relating to ANDA No. 212136 complained of herein were done by and for the benefit of Orbicular.

97. If Orbicular's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '091 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI (INFRINGEMENT OF THE '502 PATENT)

98. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–97.

99. The claims of the '502 patent are presumed valid under 35 U.S.C. § 282.

100. Under 35 U.S.C. § 271(e)(2)(A), Orbicular has infringed at least one claim of the '502 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212136 seeking approval to engage in the commercial manufacture, use, or sale of Orbicular's ANDA Product before the expiration date of the '502 patent. On information and belief, the product described in ANDA No. 212136 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '502 patent under 35 U.S.C. § 271(e)(2)(A).

101. On information and belief, based on Orbicular's Notice Letter, the absence of any

allegation that Orbicular's ANDA Product does not fall within the scope of the claims of the '502 patent in Orbicular's Notice Letter, the fact that Orbicular has represented to the FDA that Orbicular's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Orbicular is required to substantially copy the FDA-approved Injectafer® labeling, Orbicular's ANDA Product comprises a polynuclear iron (III)-hydroxide 4(R)-(poly-(1→4)-O- α -D-glucopyranosyl)-oxy-2(R),3(R),5(R),6-tetrahydroxy-hexanoate, and will be used in a method of treating iron deficiency anemia or functional iron deficiency and result in increased transferrin saturation, whereby Orbicular's ANDA Product will be administered intravenously in about 15 minutes or less to an adult human subject in need thereof in a single dosage unit of at least about 0.6 grams of elemental iron, and the use of Orbicular's ANDA Product will satisfy all of the limitations of one or more claims of the '502 patent.

102. On information and belief, Orbicular intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '502 patent immediately and imminently upon final approval of ANDA No. 212136. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Orbicular's ANDA Product prior to the expiration of the '502 patent would infringe one or more claims of the '502 patent.

103. On information and belief, upon FDA approval of Orbicular's ANDA Product, Orbicular will induce and/or contribute to the infringement of one or more claims of the '502 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

104. On information and belief, Orbicular has knowledge of the '502 patent and has filed ANDA No. 212136 seeking authorization to engage in the commercial manufacture, use, or

sale of Orbicular's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212136, 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 '502 patent by the use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label.

105. On information and belief, Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product according to Orbicular's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '502 patent with the requisite intent under 35 U.S.C. § 271(b).

106. Upon information and belief, upon approval, Orbicular will take active steps to encourage the use of Orbicular's ANDA Product 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 '502 patent for the pecuniary benefit of Orbicular. Upon information and belief, Orbicular will thus induce infringement of at least one claim of the '502 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, Orbicular will have actual knowledge of the '502 patent and will actively induce infringement of the '502 patent immediately and imminently upon approval of its ANDA.

107. On information and belief, if the FDA approves ANDA No. 212136, Orbicular's ANDA Product will be specifically labeled for use in practicing at least one claim of the '502 patent, wherein Orbicular's ANDA Product is a material part of the claimed invention, wherein Orbicular knows and intends that healthcare professionals and/or patients will use Orbicular's ANDA Product in accordance with the instructions and/or label provided by Orbicular in

practicing at least one claim of the '502 patent, and wherein Orbicular's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Orbicular will thus contribute to the infringement of at least one claim of the '502 patent under 35 U.S.C. § 271(c).

108. Upon information and belief, Orbicular's actions relating to ANDA No. 212136 complained of herein were done by and for the benefit of Orbicular.

109. If Orbicular's marketing and sale of Orbicular's ANDA Product prior to the expiration of the '502 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. A judgment that the claims of the '109, '702, '612, '260, '091, and '502 patents are not invalid or unenforceable, and are infringed by Orbicular's submission of ANDA No. 212136 under 35 U.S.C. §271(e)(2)(A), and that Orbicular's making, using, offering to sell, or selling in the United States, or importing into the United States, Orbicular's ANDA Product will infringe the '109, '702, '612, '260, '091, and '502 patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (g);

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. 212136 shall be a date that is not earlier than the latest expiration date of the '109, '702, '612, '260, '091, and '502 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Orbicular and its 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

Orbicular's ANDA Product until after the last expiration date of the '109, '702, '612, '260, '091, and '502 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

4. A declaration issued under 28 U.S.C. § 2201 that if Orbicular, its affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting in privity or in concert with them, engage in the importation, offer for sale, sale, or use within the United States of Orbicular's ANDA Product prior to the expiration of the '109 patent, that will constitute an act of infringement under 35 U.S.C. § 271(g);

5. Damages or other monetary relief to Plaintiffs if Orbicular engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Orbicular's ANDA Product prior to the latest expiration date of the '109, '702, '612, '260, '091, and '502 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C); and

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

Dated: August 21, 2025

Respectfully submitted,

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