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

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC.,	Case No. 3:25-cv-16735-GC-JBD
Plaintiffs,	Hon. Georgette Castner, U.S.D.J. Hon. J. Brendan Day, U.S.M.J.
v.	
ORBICULAR PHARMACEUTICAL TECHNOLOGIES PVT. LTD.,	
Defendant.	

DEFENDANT ORBICULAR PHARMACEUTICAL TECHNOLOGIES PVT. LTD.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFF VIFOR (INTERNATIONAL) AG AND AMERICAN REGENT, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Orbicular Pharmaceutical Technologies Pvt. Ltd. ("Orbicular") hereby answers Plaintiffs Vifor (International) AG and American Regent, Inc.'s (collectively, "Vifor") Complaint for Patent Infringement.

The headings in Vifor's Complaint are reproduced herein for the convenience of the reader. To the extent such headings include or infer allegations, they are denied.

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®.

ANSWER: Orbicular admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, Title 35, United States Code. Orbicular admits that this action relates to Abbreviated New Drug Application ("ANDA") No. 212136, which Orbicular prepared and submitted to the FDA. Orbicular further admits that Orbicular's ANDA seeks approval from the FDA to market the product described in Orbicular's ANDA ("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"); 11,433,091 ("the '091 patent"); and 11,478,502 ("the '502 patent"). Orbicular admits that '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®. Orbicular denies the remaining allegations in this paragraph.

THE PARTIES

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

ANSWER: Orbicular lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore denies them.

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

ANSWER: Orbicular lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies them.

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."

ANSWER: Orbicular lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and therefore denies them.

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.

ANSWER: Orbicular lacks knowledge or information sufficient to form a belief as to the truth of allegations in paragraph 5 and therefore denies them.

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.

ANSWER: Orbicular admits that Orbicular Pharmaceutical Technologies Pvt. Ltd. is a company 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. Orbicular admits that it has no place of business in the United States. Orbicular admits that it develops, manufactures, and/or distributes generic drug products that are ultimately marketed, sold, and/or used throughout the United States, including in this judicial district. Orbicular denies the remaining allegations in paragraph 6.

JURISDICTION

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.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Orbicular does not contest subject matter jurisdiction.

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.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Orbicular does not contest personal jurisdiction over Orbicular Pharmaceutical Technologies Pvt. Ltd.

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 it 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).

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. Orbicular admits that it did not contest personal jurisdiction and that it asserted counterclaims in *Vifor (Int'l) AG et al. v. Orbicular Pharm. Techs. PVT. LTD.*, C.A. No. 25-540 (Del.) and *Novo Nordisk Inc. et al v. Orbicular Pharmaceutical Technologies Pvt. Ltd.*, C.A. No. 22-856 (Del.). Orbicular denies the remaining allegations in paragraph 9.

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.

ANSWER: Orbicular admits that if ANDA No. 212136 is approved, the product described in Orbicular's ANDA 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. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 10 and therefore denies them.

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.

ANSWER: Orbicular admits that if ANDA No. 212136 is approved, Orbicular's ANDA Product will be imported, marketed, distributed, offered for sale, and/or sold in the United States, including in Delaware. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 11 and therefore denies them.

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.

ANSWER: Denied.

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).

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. Orbicular admits that it is a foreign company not residing in any United States judicial district.

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.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations in paragraph 14.

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.

ANSWER: Orbicular admits that it prepared ANDA No. 212136 and submitted ANDA No. 212136 to the FDA, and that Orbicular's ANDA seeks approval from the FDA to market the product described in Orbicular's ANDA. Orbicular admits that it has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. Orbicular denies the remaining allegations in paragraph 15.

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**.

ANSWER: Orbicular admits that the '109 patent is titled "Water-Soluble Iron-Carbohydrate Complexes, Production Thereof, and Medicaments Containing Said Complexes," lists November 3, 2009 as the issue date, and lists Peter Geisser, Erik Philipp, and Walter Richle as the inventors. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists Vifor as the current assignee of the '109 patent. Orbicular admits that Exhibit A purports to be a copy of the '109 patent. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 16 and therefore denies them.

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**.

ANSWER: Orbicular admits that the '702 patent is titled "Methods and Compositions For Administration of Iron," lists July 13, 2010 as the issue date, and lists Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the inventors. Orbicular admits that The Change of Name of the assignee for the '702 patent is listed by the U.S. Patent and Trademark Office assignment database at Reel 048067, Frame 0271. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists American Regent as the current assignee of the '702 patent. Orbicular admits that Exhibit B purports to be a copy of the '702 patent. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 17 and therefore denies them.

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.**

ANSWER: Orbicular admits that the '612 patent is titled "Methods and Compositions For Administration of Iron," lists November 25, 2014 as the issue date, and lists Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the inventors. Orbicular admits that The Change of Name of the assignee for the '612 patent is listed by the U.S. Patent and Trademark Office assignment database at Reel 048067, Frame 0271. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists American Regent as the current assignee of the '612 patent. Orbicular admits that Exhibit C purports to be a copy of the '612 patent. Orbicular lacks

sufficient information or knowledge to admit or deny the remaining allegations in paragraph 18 and therefore denies them.

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 '091 patent is attached hereto as **Exhibit D**.

ANSWER: Orbicular admits that the '260 patent is titled "Methods and Compositions For Administration of Iron," lists September 6, 2022 as the issue date, and lists Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the inventors. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists American Regent as the current assignee of the '260 patent. Orbicular admits that Exhibit D purports to be a copy of the '260 patent. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 19 and therefore denies them.

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**.

ANSWER: Orbicular admits that the '091 patent is titled "Methods and Compositions For Administration of Iron," lists September 6, 2022 as the issue date, and lists Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the inventors. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists American Regent as the current assignee of the '091 patent. Orbicular admits that Exhibit E purports to be a copy of the '091 patent. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 20 and therefore denies them.

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**.

ANSWER: Orbicular admits that the '502 patent is titled "Methods and Compositions For Administration of Iron," lists October 25, 2022 as the issue date, and lists Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the inventors. Orbicular admits that the U.S. Patent and Trademark Office assignment database lists American Regent as the current assignee of the '502 patent. Orbicular admits that Exhibit F purports to be a copy of the '502 patent. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 21 and therefore denies them.

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.

ANSWER: Orbicular admits that FDA's electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") lists American Regent as the holder of NDA 203565. Orbicular admits that New Drug Application ("NDA") No. 203565 is approved by FDA and is associated with Injectafer® (ferric carboxymaltose). Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 22 and therefore denies them.

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 five patents—the '109, '702, '612, '260, '091, and '502 patents—are currently listed in the Orange Book for Injectafer®.

ANSWER: Orbicular admits that FDA's Orange Book lists the '109, '702, '612, '260, '091, and '502 patents with NDA 203565. Orbicular denies any remaining allegations of paragraph 23.

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

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Orbicular lacks sufficient information or knowledge to admit or deny the allegations in paragraph 24 and therefore denies them.

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**.

ANSWER: Orbicular admits that according to the prescribing information for Injectafer® (*see* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203565s027lbl.pdf (last visited October 24, 2025)), "Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients[.]" Orbicular admits that a purported copy of the Injectafer® label is attached as Exhibit G. Orbicular lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 25 and therefore denies them.

ORBICULAR'S INFRINGING ANDA SUBMISSION

26. Plaintiffs and/or Plaintiffs' counsel received a letter from the Orbicular 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. 11,364,260, 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").

ANSWER: Orbicular admits that it sent a letter to Plaintiffs and/or Plaintiffs' counsel on March 20, 2025, regarding Orbicular's "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 lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 26 and therefore denies them.

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®."

ANSWER: Admitted.

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 patent, '091, and '502 patents.

ANSWER: Orbicular admits that 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. Orbicular denies the remaining allegations in paragraph 28.

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."

ANSWER: Admitted.

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.

ANSWER: Orbicular admits that it submitted an ANDA seeking approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the product described in Orbicular's ANDA prior to the expiration of the Patents-in-Suit. Orbicular denies the remaining allegations of paragraph 30.

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®.

ANSWER: Orbicular admits that Orbicular's Notice Letter states, "the active ingredient of Orbicular's proposed drug product is ferric carboxymaltose. The dosage form of the proposed drug product is an intravenous solution with a dosage strength of 750 mg iron/15 ml." Orbicular admits that Orbicular's Notice Letter also states, "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 denies the remaining allegations in paragraph 31.

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

ANSWER: Orbicular admits that it is seeking approval to market the product described in Orbicular's ANDA for at least some of the same approved indications as Injectafer®. Orbicular denies the remaining allegations in paragraph 32.

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."

ANSWER: Orbicular admits that the Orbicular Notice Letter states "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 Orbicular 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.).

ANSWER: Orbicular admits that Plaintiffs and/or Plaintiffs' counsel previously received a letter from Defendant dated March 20, 2025, titled "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"). Orbicular admits that Plaintiffs filed an action asserting the patents identified in Orbicular's Prior Notice Letter, which is currently pending. Orbicular denies that the currently pending case has the caption *Vifor (Int'l) AG et al. v. Orbicular Pharm. Techs. PVT. LTD.*, C.A. No. 25-540 (Del.) because that case has

been transferred to the District of New Jersey. *See Vifor (Int'l) AG et al. v. Orbicular Pharm. Techs. PVT. LTD.*, Civ. A. No. 3:25-cv-16735 (D.N.J. 2025).

COUNT I (INFRINGEMENT OF THE '109 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 34 as its answers to paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that the claims of the '109 patent are valid.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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)

ANSWER: Denied.

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.

ANSWER: Denied.

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).

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 48.

COUNT II (INFRINGEMENT OF THE '702 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 48 as its answers to paragraph 49.

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.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that claims 4–9, 16–22, 24, 26, 31–40, and 44–57 of the '702 patent are valid.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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)

ANSWER: Denied.

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.

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 61.

COUNT III (INFRINGEMENT OF THE '612 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 61 as its answers to paragraph 62.

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

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that claims of the '612 patent are valid.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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)

ANSWER: Denied.

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.

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 73.

COUNT IV (INFRINGEMENT OF THE '260 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 73 as its answers to paragraph 74.

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

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that claims of the '260 patent are valid.

76. Under 35 U.S.C. § 271(e)(2)(A), Orbicular 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).

ANSWER: Denied.

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.

ANSWER: Denied.

78. 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 '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.

ANSWER: Denied.

79. 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 '260 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

80. On information and belief, Orbicular 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 Orbicular's provided instructions and/or label.

ANSWER: Denied.

81. 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 '260 patent with the requisite intent under 35 U.S.C. § 271(b)

ANSWER: Denied.

82. 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 '260 patent for the pecuniary benefit of Orbicular. Upon information and belief, Orbicular 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, Orbicular 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.

ANSWER: Denied.

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 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 '260 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 '260 patent under 35 U.S.C. § 271(c).

ANSWER: Denied.

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

ANSWER: Denied.

85. If Orbicular'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.

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 85.

COUNT V (INFRINGEMENT OF THE '091 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 85 as its answers to paragraph 86.

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

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that claims of the '091 patent are valid.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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)

ANSWER: Denied.

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.

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 97.

COUNT VI (INFRINGEMENT OF THE '502 PATENT)

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

ANSWER: Orbicular incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 97 as its answers to paragraph 98.

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

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies that claims of the '502 patent are valid.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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)

ANSWER: Denied.

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.

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Orbicular denies the allegations of paragraph 109.

VIFOR'S PRAYER FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required Orbicular denies that Plaintiffs are entitled to any remedy or relief sought in paragraphs 1 through 6 on pages 27 through 28 of the Complaint. Should Vifor receive any of their requested relief, no such relief should prevent Orbicular from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Orbicular's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 109 of the Complaint, Orbicular alleges the following Separate Defenses to the Complaint. Orbicular expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Orbicular does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST DEFENSE
(Invalidity and Ineligibility of the '109 Patent)

Each claim of the '109 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

SECOND DEFENSE
(Noninfringement of the '109 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '109 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '109 patent, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(Invalidity and Ineligibility of the '702 Patent)

Each claim of the '702 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

FOURTH DEFENSE
(Noninfringement of the '702 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '702 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '702 patent, either literally or under the doctrine of equivalents.

FIFTH DEFENSE
(Invalidity and Ineligibility of the '612 Patent)

Each claim of the '612 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

SIXTH DEFENSE
(Noninfringement of the '612 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '612 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '612 patent, either literally or under the doctrine of equivalents.

SEVENTH DEFENSE
(Invalidity and Ineligibility of the '260 Patent)

Each claim of the '260 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

EIGHTH DEFENSE
(Noninfringement of the '260 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '260 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA

Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '260 patent, either literally or under the doctrine of equivalents.

NINTH DEFENSE
(Invalidity and Ineligibility of the '091 Patent)

Each claim of the '091 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

TENTH DEFENSE
(Noninfringement of the '091 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '091 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '091 patent, either literally or under the doctrine of equivalents.

ELEVENTH DEFENSE
(Invalidity and Ineligibility of the '502 Patent)

Each claim of the '502 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

TWELFTH DEFENSE
(Noninfringement of the '502 Patent)

Orbicular has not, does not, and will not infringe any valid and enforceable claim of the '502 patent. The manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '502 patent, either literally or under the doctrine of equivalents.

THIRTEENTH DEFENSE
(Waiver)

Plaintiffs have waived any defect in the manner in which Orbicular served Orbicular's Notice Letter and/or are estopped from contesting any alleged defect in service of Orbicular's Notice Letter.

FOURTEENTH DEFENSE
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, equitable estoppel, unclean hands, waiver, implied waiver, acquiescence, disclaimer, judicial estoppel, and/or other equitable doctrines.

FIFTEENTH DEFENSE
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

SIXTEENTH DEFENSE
(No Exceptional Case)

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

SEVENTEENTH DEFENSE
(No Willful Infringement)

Orbicular has not willfully infringed any claim of the Patents-in-Suit.

EIGHTEENTH DEFENSE
(Ensnarement)

To the extent Plaintiffs claims infringement of one or more claims of the patent-in-suit under the doctrine of equivalents, Plaintiffs' claims are barred under the ensnarement doctrine, which prohibits Plaintiffs from asserting an infringement theory under the doctrine of equivalents that encompasses or ensnares the prior art.

NINETEENTH DEFENSE
(Lack of Standing)

To the extent that Plaintiffs did not, or do not, hold all substantial rights, title, and interest to the Patents-in-Suit, Plaintiffs lack standing to bring, or maintain, this lawsuit in connection with such patent.

TWENTIETH DEFENSE
(Reservation of Defenses)

Defendants reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future, including, but not limited to, those related to the unenforceability of any claim of the Patents-in-Suit based on inequitable conduct, as may be determined through discovery and further factual investigation in this actions.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs Vifor (International) AG and American Regent, Inc.'s (collectively, "Vifor" or "Plaintiffs" or "Counterclaim Defendants"), other than those expressly admitted herein, Defendant Orbicular Pharmaceutical Technologies Pvt. Ltd. ("Orbicular" or "Defendants" or "Counterclaim Plaintiffs") brings the following Counterclaims against Plaintiffs for declaratory judgment that U.S. 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") (collectively, the "Patents-in-Suit") are invalid and/or not infringed by Orbicular and the product as described in Orbicular's Abbreviated New Drug Application ("ANDA") No. 212136 ("Orbicular's ANDA Product"):

THE PARTIES

1. Orbicular is an entity organized and existing under the laws of India, having a place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar Kukatpally, Hyderabad, 500 090 Telangana, India.

2. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Vifor (International) AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Rechenstraβe 37, CH-9001, St. Gallen, Switzerland.

3. Upon information and belief, based on the allegations in the Complaint, 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.

4. Upon information and belief, 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. Upon information and belief, and based on the FDA's Orange Book, Counterclaim Defendant American Regent is the holder of New Drug Application ("NDA") No. 203565.

6. Upon information and belief, and based on the allegations in the Complaint, Counterclaim Defendant American Regent currently markets, manufactures, distributes, and sells Injectafer® in the United States.

7. Upon information and belief, based on the allegations in the Complaint, Vifor and American Regent developed Injectafer®, and American Regent manufactures Injectafer® under license from Vifor.

Jurisdiction and Venue

8. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

9. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Orbicular in this judicial district.

10. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

11. On or about May 2, 2025, Counterclaim Defendants filed a civil action in this judicial district against Orbicular alleging infringement of the Patents-in-Suit. There is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Orbicular and Orbicular's ANDA Product's non-infringement of the Patents-in-Suit and the invalidity of the Patents-in-Suit.

THE PATENTS-IN-SUIT

12. Based on the allegations in the Complaint, the '109 patent, titled "Water-Soluble Iron-Carbohydrate Complexes, Production Thereof, and Medicaments Containing Said Complexes," was issued on November 3, 2009 to inventors Peter Geisser, Erik Philipp, and Walter Richle. The face of the '109 patent lists Vifor (International) AG as the assignee. According to the U.S. Patent and Trademark Office assignment database, Vifor (International) AG is listed as the assignee of the '109 patent.

13. Based on the allegations in the Complaint, the ’702 patent, titled “Methods and Compositions for Administration of Iron,” was issued on July 13, 2010 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. The face of the ’702 patent lists Luitpold Pharmaceuticals, Inc. as the assignee. Based on the allegations in the Complaint, the assignment records for the ’702 patent were amended to reflect that Luitpold Pharmaceuticals, Inc. had changed its name to “American Regent, Inc,” and the Change of Name of the assignee for the ’702 patent is recorded by the PTO at Reel 048067, Frame 0271. According to the U.S. Patent and Trademark Office assignment database, American Regent, Inc. is listed as the assignee of the ’702 patent.

14. Based on the allegations in the Complaint, the ’612 patent, titled “Methods and Compositions for Administration of Iron,” was issued on November 25, 2014 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. The face of the ’612 patent lists Luitpold Pharmaceuticals, Inc. as the assignee. Based on the allegations in the Complaint, the assignment records for the ’612 patent were amended to reflect that Luitpold Pharmaceuticals, Inc. had changed its name to “American Regent, Inc,” and the Change of Name of the assignee for the ’612 patent is recorded by the PTO at Reel 048067, Frame 0271. According to the U.S. Patent and Trademark Office assignment database, American Regent, Inc. is listed as the assignee of the ’612 patent.

15. Based on the allegations in the Complaint, the ’260 patent, titled “Methods and Compositions For Administration of Iron,” was issued on September 6, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. The face of the ’260 patent lists American Regent, Inc. as the assignee. According to the U.S. Patent and Trademark Office assignment database, American Regent, Inc. is listed as the assignee of the ’260 patent.

16. Based on the allegations in the Complaint, the '091 patent, titled "Methods and Compositions for Administration of Iron," was issued on September 6, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. The face of the '091 patent lists American Regent, Inc. as the assignee. According to the U.S. Patent and Trademark Office assignment database, American Regent, Inc. is listed as the assignee of the '091 patent.

17. Based on the allegations in the Complaint, the '502 patent, titled "Methods and Compositions for Administration of Iron," was issued on October 25, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. The face of the '502 patent lists American Regent, Inc. as the assignee. According to the U.S. Patent and Trademark Office assignment database, American Regent, Inc. is listed as the assignee of the '502 patent.

18. The Patents-in-Suit are listed in the electronic version of the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in association with Injectafer®.

19. On March 20, 2025, pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 319.95, Orbicular sent Plaintiffs notification of Paragraph IV Certification for the Patents-in-Suit with respect to Orbicular's Abbreviated New Drug Application ("ANDA") No. 212136 ("Orbicular's ANDA"), which seeks approval from the FDA to engage in the commercial manufacture, distribution, use, offer for sale, sale, and/or import of the product described in Orbicular's ANDA ("Orbicular's ANDA Product") ("Orbicular's Notice Letter").

20. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Orbicular's Notice Letter included, among other things, Orbicular's detailed factual and legal basis for the paragraph IV certification regarding the Patents-in-Suit as it pertains to Orbicular's ANDA Product and an offer of confidential access ("Orbicular's OCA").

21. On or about August 21, 2025, Counterclaim Defendants brought this present action alleging infringement of the Patents-in-Suit.

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '109 Patent)

22. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 21 of the Counterclaims as if fully set forth herein.

23. Counterclaim Defendants have accused Orbicular of infringing the '109 patent.

24. Orbicular denies infringement of the '109 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '109 patent.

25. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '109 patent.

26. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '109 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '109 Patent)

27. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 26 of the Counterclaims as if fully set forth herein.

28. The claims of the '109 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

29. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '109 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

30. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '109 patent and will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

31. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '109 patent.

32. Orbicular is entitled to a judicial declaration that all claims of the '109 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

THIRD COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '702 Patent)

33. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 32 of the Counterclaims as if fully set forth herein.

34. Counterclaim Defendants have accused Orbicular of infringing the '702 patent.

35. Orbicular denies infringement of the '702 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '702 patent.

36. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '702 patent.

37. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '702 patent.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '702 Patent)

38. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 37 of the Counterclaims as if fully set forth herein.

39. The claims of the '702 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

40. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '702 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

41. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '702 patent and

will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

42. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '702 patent.

43. Orbicular is entitled to a judicial declaration that all claims of the '702 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '612 Patent)

44. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 43 of the Counterclaims as if fully set forth herein.

45. Counterclaim Defendants have accused Orbicular of infringing the '612 patent.

46. Orbicular denies infringement of the '612 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '612 patent.

47. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '612 patent.

48. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '612 patent.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '612 Patent)

49. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 48 of the Counterclaims as if fully set forth herein.

50. The claims of the '612 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

51. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '612 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

52. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '612 patent and will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

53. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '612 patent.

54. Orbicular is entitled to a judicial declaration that all claims of the '612 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code

including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '260 Patent)

55. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 54 of the Counterclaims as if fully set forth herein.

56. Counterclaim Defendants have accused Orbicular of infringing the '260 patent.

57. Orbicular denies infringement of the '260 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '260 patent.

58. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '260 patent.

59. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '260 patent.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '260 Patent)

60. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 59 of the Counterclaims as if fully set forth herein.

61. The claims of the '260 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

62. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '260 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

63. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '260 patent and will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

64. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '260 patent.

65. Orbicular is entitled to a judicial declaration that all claims of the '260 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

NINTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '091 Patent)

66. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 65 of the Counterclaims as if fully set forth herein.

67. Counterclaim Defendants have accused Orbicular of infringing the '091 patent.

68. Orbicular denies infringement of the '091 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '091 patent.

69. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '091 patent.

70. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '091 patent.

TENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '091 Patent)

71. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 70 of the Counterclaims as if fully set forth herein.

72. The claims of the '091 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

73. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '091 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

74. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '091 patent and

will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

75. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '091 patent.

76. Orbicular is entitled to a judicial declaration that all claims of the '091 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

ELEVENTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '502 Patent)

77. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 76 of the Counterclaims as if fully set forth herein.

78. Counterclaim Defendants have accused Orbicular of infringing the '502 patent.

79. Orbicular denies infringement of the '502 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '502 patent.

80. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '502 patent.

81. Orbicular is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '502 patent.

TWELFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '502 Patent)

82. Orbicular incorporates by reference the allegations set forth in paragraphs 1 through 81 of the Counterclaims as if fully set forth herein.

83. The claims of the '502 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

84. For at least the reasons stated in Orbicular's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '502 patent are not infringed by Orbicular's ANDA Product and/or are invalid.

85. Upon information and belief, Orbicular believes that Counterclaim Defendants will continue to assert that Orbicular's ANDA Product is infringing the claims of the '502 patent and will continue to try to interfere with Orbicular's business with respect to Orbicular's ANDA Product.

86. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Orbicular and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '502 patent.

87. Orbicular is entitled to a judicial declaration that all claims of the '502 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code

including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

RELIEF REQUESTED

WHEREFORE, Orbicular requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Orbicular's ANDA Product does not and will not directly or indirectly infringe any claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patents-in-Suit are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Orbicular;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the Patents-in-Suit against Orbicular or any person or entity working in concert with Orbicular;

E. Awarding Orbicular its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Orbicular and awarding Orbicular its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Orbicular such other and further relief as the Court may deem proper.

Dated: October 24, 2025

K&L GATES LLP

By: */s/ Loly G. Tor*

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Attorneys for Defendant Orbicular Pharmaceutical Technologies Pvt. Ltd.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Orbicular Pharmaceutical Technologies Pvt. Ltd. hereby certifies that, to the best of my knowledge, the following pending actions involve some of the same patents as the Patents-in-Suit and Counterclaim Patents:

- *American Regent, Inc. f/k/a Luitpold Pharmaceuticals, Inc. v. MSN Laboratories Private Limited et al*, Civ. No. 3:24-10674-GC-JBD;
- *Vifor (International) AG et al v. Apotex Inc. et al*, Civ. No. 25-211-CFC; and
- *Vifor (International) AG et al v. Orbicular Pharmaceutical Technologies, Pvt. Ltd.*, Civ. No. 3:25-cv-15336-GC-JBD

I certify under penalty of perjury that the foregoing is true and correct.

Dated: October 24, 2025

/s/*Loly G. Tor*
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Orbicular Pharmaceutical Technologies Pvt. Ltd. hereby certifies that this action seeks declaratory judgement and therefore this action is not appropriate for compulsory arbitration.

Dated: October 24, 2025

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CERTIFICATION OF SERVICE

I, Loly G. Tor, hereby certify that DEFENDANT ORBICULAR PHARMACEUTICAL TECHNOLOGIES PVT. LTD.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFF VIFOR (INTERNATIONAL) AG AND AMERICAN REGENT, INC.'S COMPLAINT FOR PATENT INFRINGEMENT was served upon all counsel of record in this action upon filing of same with the Court via ECF.

Dated: October 24, 2025

/s/*Loly G. Tor*

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