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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

Plaintiffs,

Civil Action No. 20-1649

v.

Document Electronically Filed

SANDOZ INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor (International) AG (“Vifor”) and American Regent, Inc. (“American Regent”) (collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Sandoz Inc. (“Sandoz”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 211725, filed by Sandoz with the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of Plaintiffs’ Injectafer®, ferric carboxymaltose injection (750 mg/15 ml) (“Sandoz’s ANDA Product”) prior

to the expiration of United States Patent No. 10,519,252 (“the ’252 patent”). The ’252 patent is listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for Injectafer®.

THE PARTIES

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

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

4. Plaintiff American Regent is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967. American Regent was formerly known as Luitpold Pharmaceuticals, Inc., until January 2, 2019, when its New York Certificate of Incorporation was amended to change the name of the corporation to American Regent, Inc. American Regent is a subsidiary of Daiichi Sankyo, Inc, (“Daiichi Sankyo”) which is located at 211 Mt. Airy Road, Basking Ridge, New Jersey 07920.

5. Vifor and American Regent developed Injectafer®. American Regent licenses Injectafer® from Vifor, and American Regent has contracted with Daiichi Sankyo Inc., through a Marketing Services Agreement, to market Injectafer® in this judicial district and throughout the United States.

6. On information and belief, Defendant Sandoz is a company organized and existing under the laws of the state of Colorado with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

7. On information and belief, Sandoz is a generic pharmaceutical company that develops and manufactures generic pharmaceutical products that are marketed and sold throughout the United States.

JURISDICTION AND VENUE

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

9. On information and belief, this Court has personal jurisdiction over Sandoz, under the New Jersey state long arm statute and consistent with due process of law, because Sandoz maintains its principal place of business in New Jersey. Sandoz has previously admitted that it has a principal place of business in New Jersey. *See, e.g., Celgene Corp. v. Sandoz Inc.*, Civil Action No. 3:18-11026 (D.N.J. Sept. 25, 2018), ECF No. 18 at ¶ 3; *Genentech, Inc., et al. v. Sandoz Inc., et al.*, Civil Action No. 1:17-13507 (D.N.J. Jan. 19, 2018), ECF No. 12 at ¶ 12.

10. On information and belief, Sandoz is subject to personal jurisdiction in New Jersey because it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Sandoz has systematic and continuous contacts with this judicial district.

11. On information and belief, Sandoz 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 by itself or through its parent corporation, subsidiaries and/or affiliates, throughout the United States, including in this judicial district.

12. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265, and Sandoz is also licensed to do business with the New Jersey Department of Health as a “Manufacturer and Wholesale[r]” of pharmaceuticals in the State of New Jersey (Registration Number 5003732).

13. On information and belief, Sandoz is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for Sandoz’s ANDA Product for the commercial manufacture, use, and/or sale of Sandoz’s ANDA Product, if approved, in this judicial district and to residents of this judicial district. Sandoz has submitted to the jurisdiction of this Court in another Hatch-Waxman litigation involving the same parties arising from Sandoz’s filing of the same ANDA, ANDA No. 211725. *Vifor (International) AG, et al. v. Sandoz Inc.*, Civil Action No. 19-16305, ECF No. 11 at ¶ 9 (D.N.J. Sept. 11, 2019). Through at least these activities, Sandoz has purposely availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district.

14. On information and belief, Sandoz has been, and continues to be, wholly responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 211725. Sandoz’s “Notice of Paragraph IV Certification” dated July 10, 2019 (“Sandoz’s Notice Letter”) identified “Sandoz Inc.” as the entity which submitted ANDA No. 211725 to the FDA.

15. On information and belief, if ANDA No. 211725 is approved, Sandoz’s ANDA Product will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; administered by healthcare providers located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

16. On information and belief, if ANDA No. 211725 is approved, Sandoz will import, market, distribute, offer for sale, and/or sell Sandoz's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in the state of New Jersey.

17. If ANDA No. 211725 is approved, Vifor and American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of Sandoz's ANDA Product, including in New Jersey.

18. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Sandoz has committed an act of infringement in New Jersey and Sandoz has a regular and established place of business in New Jersey.

19. On information and belief, Sandoz has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting ANDA No. 211725 to the FDA, by taking steps indicating its intent to market Sandoz's ANDA Product in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if its ANDA receives final FDA approval.

20. On information and belief, Sandoz has taken steps in New Jersey, including preparing ANDA No. 211725 and communicating with the FDA regarding ANDA No. 211725, that indicate its intent to market Sandoz's ANDA product. As set forth above, on information and belief, if ANDA No. 211725 is approved, Sandoz intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling Sandoz's ANDA Product.

21. On information and belief, Sandoz has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place

of business is in New Jersey. As set forth above, on information and belief, Sandoz Inc. maintains regular and established places of business in New Jersey, including offices, laboratories, and/or facilities at 100 College Road West, Princeton, NJ 08540 and One Health Plaza, Bldg. 435, East Hanover, NJ 07936.

22. Sandoz has previously consented to venue in this Court in another Hatch-Waxman litigation involving the same parties arising from Sandoz's filing of the same ANDA, ANDA No. 211725. *Vifor (International) AG, et al. v. Sandoz Inc.*, Civil Action No. 19-16305, ECF No. 11 at ¶ 19 (D.N.J. Sept. 11, 2019).

PATENT-IN-SUIT

23. The U.S. Patent and Trademark Office ("PTO") issued the '252 patent, entitled "Aqueous Iron Carbohydrate Complexes, Their Production and Medicaments Containing Them," on December 21, 2019 to inventors Peter Geisser, Erik Philipp, and Walter Richle. Vifor is the assignee of the '252 patent and has the right to enforce it. The '252 patent expires on October 20, 2023. The '252 patent claims, *inter alia*, iron carbohydrate complexes, compositions comprising said complexes, and methods of treating iron deficiency anemia by administering the claimed iron carbohydrate complexes. A true and correct copy of the '252 patent is attached hereto as **Exhibit A**.

24. American Regent is the owner of 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. In conjunction with NDA No. 203565, American Regent listed with the FDA U.S. Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); 8,895,612 ("the '612 patent"); and 9,376,505 ("the '505

patent”). American Regent subsequently timely listed the ’252 patent with the FDA after that patent issued. All five patents—the ’109, ’702, ’612, ’505, ’252 patents—are currently listed in the Orange Book for Injectafer®. The ’252 patent expires on or before the other Orange Book listed patents for Injectafer®.

SANDOZ'S INFRINGING ANDA SUBMISSION

25. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-24.

26. Plaintiffs received a letter from Sandoz dated July 10, 2019, purporting to be a “Notice of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 7,612,109; 7,754,702; 8,895,612; 9,376,505; and Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act” for ANDA No. 211725 pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 § C.F.R. 314.95.

27. Sandoz’s Notice Letter states that “Sandoz Inc.” has submitted to the FDA ANDA No. 211725 seeking approval to engage in the commercial manufacture, use, and/or sale of Sandoz’s ANDA Product before the expiration of the ’109, ’702, ’612, and ’505 patents. On information and belief, Sandoz also seeks approval to engage in the commercial manufacture, use, and/or sale of Sandoz’s ANDA Product before the expiration of the ’252 patent. Sandoz’s Notice Letter did not identify any other entity that is involved in the preparation, filing, and/or maintenance of ANDA No. 211725.

28. Sandoz has made, and continues to make, substantial preparation in the United States to manufacture, use, import, offer to sell, and/or sell Sandoz’s ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, before the expiration of the ’252 patent.

29. By filing ANDA No. 211725, and as indicated in Sandoz's Notice Letter, Sandoz has represented to the FDA that Sandoz's ANDA Product has the same active ingredient as Injectafer®, has the same dosage form and strength as Injectafer®, and is bioequivalent to Injectafer®.

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

31. Plaintiffs filed a complaint for patent infringement of the '109, '702, '612, and '505 patents before the expiration of the forty-five days from the date Plaintiffs received Sandoz's Notice Letter. *Vifor (International) AG, et al. v. Sandoz Inc.*, Civil Action No. 19-16305, ECF No. 1 (D.N.J. Aug. 2, 2019). The '252 patent had not issued at the time.

32. On December 31, 2019, the U.S. Patent and Trademark Office issued the '252 patent. Plaintiffs timely notified the FDA on January 17, 2020, and the '252 patent was listed in the Orange Book for Injectafer®.

33. On January 24, 2020, after the '252 patent was listed in the Orange Book, Plaintiffs' outside counsel notified Sandoz's outside counsel of the listing.

34. On February 4, 2020, Sandoz's outside counsel represented that Sandoz intends to submit a Paragraph IV certification for the '252 patent.

**COUNT I (INFRINGEMENT OF
THE '252 PATENT UNDER § 271(e)(2)(A))**

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

36. Under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '252 patent, including for example claims 1, 13, and 18, by submitting, or causing to be submitted to the FDA, ANDA No. 211725 seeking approval to engage in the commercial

manufacture, use or sale of Sandoz's ANDA Product before the expiration date of the '252 patent. On information and belief, the product described in ANDA No. 211725 would infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claims 1, 13, and 18 of the '252 patent under 35 U.S.C. § 271(e)(2)(A).

37. On information and belief, the fact that Sandoz has represented to the FDA that Sandoz's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Sandoz is required to substantially copy the FDA-approved Injectafer® labeling, Sandoz's ANDA Product comprises an aqueous solution of an iron (III) carboxymaltodextrin complex, wherein the iron (III) carboxymaltodextrin is derived from the oxidation of maltodextrin and has a weight average molecular weight of 80 to 400 kilodaltons, and will be used in a method of treating an iron deficiency condition, and satisfies all of the limitations of at least claims 1, 13, and 18 of the '252 patent.

38. On information and belief, upon FDA approval of Sandoz's ANDA Product, Sandoz will infringe at least one claim, including for example claims 1 and 13 of the '252 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 Sandoz's ANDA Product in the United States.

39. On information and belief, upon FDA approval of Sandoz's ANDA Product, Sandoz will induce and/or contribute to the infringement of one or more claims, including for example claims 1, 13, and 18 of the '252 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

40. Sandoz has knowledge of the '252 patent and has filed ANDA No. 211725 seeking authorization to engage in the commercial manufacture, use or sale of Sandoz's ANDA

Product in the United States. On information and belief, if the FDA approves ANDA No. 211725, healthcare providers 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 '252 patent, including for example claims 1, 13, and 18, by the use Sandoz's ANDA Product according to Sandoz's provided instructions and/or label.

41. On information and belief, Sandoz knows and intends that healthcare providers and/or patients will use Sandoz's ANDA Product according to Sandoz's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '252 patent with the requisite intent under 35 U.S.C. § 271(b).

42. Upon information and belief, upon approval, Sandoz will take active steps to encourage the use of Sandoz's ANDA Product by healthcare providers and/or patients with the knowledge and intent that it will be used by healthcare providers and/or patients in a manner that infringes at least one claim, including for example claims 1, 13, and 18 of the '252 patent for the pecuniary benefit of Sandoz. Upon information and belief, Sandoz will thus induce infringement of at least one claim of the '252 patent with the requisite intent under 35 U.S.C. § 271(b).

43. Upon information and belief, if the FDA approves ANDA No. 211725, Sandoz's ANDA Product will be specifically labeled for use in practicing at least one claim of the '252 patent, wherein Sandoz's ANDA Product is a material part of the claimed invention, wherein Sandoz knows and intends that healthcare providers and/or patients will use Sandoz's ANDA Product in a manner that infringes at least one claim, including for example claims 1, 13, and 18 of the '252 patent, and wherein Sandoz's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Sandoz will

thus contribute to the infringement of at least one claim of the '252 patent under 35 U.S.C. § 271(c).

44. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 211725 complained of herein were done by and for the benefit of Sandoz.

45. If Sandoz's marketing and sale of Sandoz's ANDA Product prior to the expiration of the '252 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT II (DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE '252 PATENT)**

46. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-45.

47. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

49. Sandoz became aware of the '252 patent at least no later than January 24, 2020, when Plaintiffs sent a letter to Sandoz regarding the timely listing of the '252 patent in the Orange Book for Injectafer®.

50. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Sandoz's ANDA Product prior to the expiration of the '252 patent, including Sandoz's filing of ANDA No. 211725.

51. Sandoz's actions, including, but not limited to, the development of Sandoz's ANDA Product, the content of and instructions in Sandoz's proposed label, the filing of ANDA No. 211725, and engaging in litigation to manufacture, offer to sell, sell and/or import Sandoz's ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and reliably predict that Sandoz will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Sandoz's ANDA Product.

52. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz's ANDA Product prior to the expiration of the '252 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '252 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Product prior to the expiration of the '252 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '252 patent.

PRAYER FOR RELIEF

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

1. A judgment that the claims of the '252 patent are not invalid or unenforceable, and are infringed by Sandoz's submission of ANDA No. 211725 under 35 U.S.C. §271(e)(2)(A), and that Sandoz's making, using, offering to sell, or selling in the United States, or importing into the United States, Sandoz's ANDA Product will infringe the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval by the FDA of ANDA No. 211725 shall be a date that is not earlier than the expiration

date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Sandoz, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Sandoz's ANDA Product until after the expiration date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

4. Damages or other monetary relief to Plaintiffs if Sandoz engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sandoz's ANDA Product prior to the expiration date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C);

5. A declaration issued under 28 U.S.C. § 2201 that if Sandoz, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting or attempting to act in privity or concert with them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '252 patent, it will constitute an act of infringement of the '252 patent; and

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

Dated: February 14, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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