IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

Biofer S.p.A., Plaintiff, v. Vifor (International) AG., Defendant.	C.A. No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biofer S.p.A. ("Plaintiff" or "Biofer"), by its undersigned attorneys brings this action against Defendant Vifor (International) AG. ("Vifor" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 8,759,320 ("the '320 Patent" or "the Asserted Patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(a) and (g), arising from Vifor's unauthorized development, manufacturing, importation, commercial marketing, distribution, offers for sale, sales and/or use of ferric carboxymaltose active pharmaceutical ingredient ("API") and/or Injectafer® (ferric carboxymaltose injection), an iron replacement product, as detailed herein. A true and correct copy of the '320 Patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Biofer S.p.A. is a company organized and existing under the laws of Italy, having a registered address of Via Canina, 2A, 41036 Medolla MO, Italy.

3. Biofer is the owner of all rights, including the right to enforcement, of the Asserted Patent.

4. Biofer is in the business of, *inter alia*, developing pharmaceutical products, including pharmaceutical products containing iron complexes.

5. Upon information and belief, Defendant Vifor is a company organized and existing under the laws of Switzerland having a registered address of Rechenstrasse 37, CH-9001, St. Gallen, Switzerland.

6. Upon information and belief, Vifor is a pharmaceutical company in the business of, among other activities, developing, manufacturing, and/or commercializing pharmaceutical products containing iron.

7. Upon information and belief, Vifor developed the drug product ferric carboxymaltose injection, and commercially manufactures, distributes, markets, offers for sale and/or sells it under the name Ferinject® outside of the United States.

8. Upon further information and belief, Ferinject® is known as Injectafer® (ferric carboxymaltose injection) in the United States.

9. Upon information and belief, both Ferinject® and Injectafer® contain the same or substantially identical API, known as ferric carboxymaltose.

10. Upon information and belief, Vifor manufactures the API contained in Ferinject® and Injectafer®.

11. Upon information and belief, the API in Ferinject® and Injectafer® is manufactured using the same or substantially identical processes.

12. Upon information and belief, the drug product Ferinject® is the same or substantially identical to Injectafer®.

13. Upon information and belief, Vifor manufactures ferric carboxymaltose API and/or Injectafer® outside of the United States.

14. Upon further information and belief, Vifor imports ferric carboxymaltose and/or Injectafer® into the United States.

15. Upon further information and belief, Vifor licenses Injectafer® to American Regent Inc. ("American Regent") for the commercial marketing, distribution, and sales of Injectafer® to residents throughout the United States, including in this district.

16. Upon information and belief, 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. 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. Upon information and belief, American Regent is a subsidiary of Daiichi Sankyo, Inc., which is located at 211 Mt. Airy Road, Basking Ridge, New Jersey 07920.

17. Upon information and belief, American Regent is a pharmaceutical company in the business of, among other activities, developing, manufacturing, and/or commercializing pharmaceutical products containing iron complexes.

18. Upon information and belief, American Regent licenses Injectafer® from Vifor in the United States.

19. Upon information and belief, American Regent purchases ferric carboxymaltose and/or Injectafer® from Vifor in the United States.

20. Upon further information and belief, American Regent commercially markets, offers for sale, and/or sells Injectafer® to residents throughout the United States, including in this District.

JURISDICTION AND VENUE

21. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., including §§ 271(a) and 271(g).

22. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332 and 1338(a).

23. This Court has personal jurisdiction over Vifor.

24. Upon information and belief, this Court has personal jurisdiction over Vifor, under New York's long arm statute, New York Civil Practice Law § 302, because Vifor, through partnership with American Regent, commercially markets, distributes, offers for sale and sells Injectafer® to residents throughout the United States, including in New York. Upon further information and belief, Vifor regularly does business in New York, derives substantial revenue from goods used or consumed in New York, and expects or should reasonably expect its acts to have consequences in New York. Upon further information and belief, Vifor has established, and will continue to maintain, minimum contacts with this forum such that the exercise of jurisdiction over Vifor would not offend traditional notions of fair play and substantial justice.

25. Venue is proper in this Judicial District as to Defendant Vifor under 28 U.S.C. § 1400(b) at least because, upon information and belief, Vifor has committed acts of infringement and has a regular and established place of business in this Judicial District.

26. Upon further information and belief, venue is proper in this judicial district as to Vifor under 28 U.S.C. §§ 1391 and 1400(b) for at least the reason that Vifor is a foreign corporation not residing in any United States district and may be sued in any judicial district that has personal jurisdiction, including this judicial district.

FACTUAL BACKGROUND

Iron Replacement Therapy Introduction

27. Iron replacement therapy is an important field of medicine due to the prevalence of iron deficiency anemia (IDA). IDA is a common type of anemia, a condition in which blood lacks adequate healthy red blood cells for carrying oxygen to the body's tissues. IDA occurs due to insufficient iron. Without enough iron, a person cannot produce enough hemoglobin in red blood cells to carry adequate amounts oxygen throughout the body. As a result, IDA may cause a person to be tired and/or short of breath. IDA can be treated with iron supplementation.

28. Trivalent iron (III) complexes have been used in the treatment of IDA. However, it is important that such complexes possess certain characteristics, such as high bioavailability, low toxicity, and ease of production. In addition, stability of the complex is important because it impacts not only the shelf life of the selected pharmaceutical form, but also the bioavailability of the complexed iron.

The Asserted Patent

29. Biofer is owner of all title, right and interest in the '320 Patent and has the right to enforce it. The '320 Patent, entitled "Process for the Preparation of Trivalent Iron Complexes with Mono-, Di- and Polysaccharide Sugars," was duly and legally issued on June 24, 2014 and lists Stefania Sacchi, Mauro Montorsi, and Egidio Marchi as inventors. The '320 Patent issued from

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