

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE	)	
RENAL PHARMA LTD. and VIFOR	)	
FRESENIUS MEDICAL CARE RENAL	)	
PHARMA FRANCE S.A.S.,	)	
	)	C.A. No. 18-1996-LPS
Plaintiffs,	)	
	)	
v.	)	
	)	
ANNORA PHARMA PRIVATE LTD., and	)	
HETERO LABS LIMITED,	)	
	)	
Defendants.	)	
	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. (“VFMCRP Switzerland”) and Vifor Fresenius Medical Care Renal Pharma France S.A.S. (“VFMCRP France”) (collectively, “Plaintiffs” or “Vifor Fresenius”) hereby assert the following claims for patent infringement against Defendants Annora Pharma Private Limited (“Annora”) and Hetero Labs Limited (“Hetero”) (collectively, “Defendants”) and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 9,561,251 as corrected by the Certificate of Correction that issued on August 13, 2019 (“the ’251 patent” or “the Patent-in-Suit”) under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Defendants’ filing of an Abbreviated New Drug Applications (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of Plaintiffs’ VELPHORO® drug product prior to the expiration of the Patent-in-Suit.

THE PARTIES

2. Plaintiff VFMCRP Switzerland is a corporation organized and existing under the laws of Switzerland with its principal place of business at Rechenstraße 37, St. Gallen, 9011, Switzerland.

3. Plaintiff VFMCRP France is a simplified joint stock company (*société par actions simplifiée*) organized and existing under the laws of the Republic of France which has its principal place of business at 100-101 Terrasse Boieldieu Tour Franklin La Défense 8 F-92042 Paris La Défense Cedex, France. VFMCRP France is a wholly-owned subsidiary of VFMCRP Switzerland.

4. On information and belief, Hetero is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

5. On information and belief, Annora is a corporation organized and existing under the laws of India, with a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist., Telangana State 502313, India.

6. On information and belief, Hetero owns 100% of the ownership and voting interest in Annora.

7. On information and belief, Annora is controlled and/or dominated by Hetero.

8. On information and belief, Annora and Hetero collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

THE PATENT-IN-SUIT

9. On February 7, 2017, the PTO issued U.S. Patent No. 9,561,251, entitled “Pharmaceutical compositions.” The inventors of the ’251 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’251 patent. On August 13, 2019, the PTO issued a Certificate of Correction regarding the ’251 patent. A copy of the ’251 patent, as corrected by the Certificate of Correction, is attached hereto as Exhibit A.

THE VELPHORO® DRUG PRODUCT

10. VFMCRP France holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for sucroferric oxyhydroxide chewable tablets, 500 mg (NDA No. 205109), sold under the trade name VELPHORO®. VELPHORO® is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. VFMCRP France received approval for VELPHORO® from the FDA in November 2013.

11. The claims of the Patent-in-Suit cover, *inter alia*, pharmaceutical formulations containing sucroferric oxyhydroxide.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patent-in-Suit is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), in connection with VELPHORO®.

ACTS GIVING RISE TO THIS ACTION

13. On information and belief, Annora submitted Abbreviated New Drug Application No. 212276 (the “Annora ANDA”) to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Annora ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablet, 500 mg (the “Annora Proposed ANDA Product”), a generic version of VELPHORO®.

The Annora ANDA specifically seeks FDA approval to market the Annora Proposed ANDA Product prior to the expiration of the Patent-in Suit.

14. On or about November 30, 2018, Plaintiffs received a letter from Annora dated November 28, 2018, notifying Plaintiffs that the Annora ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Annora Paragraph IV Certification”), that, in Annora’s opinion, the Patent-in-Suit is “invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale” of Annora’s Proposed ANDA Product.

15. On information and belief, Hetero and Annora acted collaboratively in the preparation and submission of the Annora ANDA. For example, the return address on the envelope containing Annora’s Paragraph IV Certification reads “HETERO, 9174340797, HETERO USA, 1035 CENTENNIAL AVE, PISCATAWAY NJ 08854.” Furthermore, the address for Annora’s agent, Somaraju Indukuri, is provided in the Annora Paragraph IV Certification as 1035 Centennial Avenue, Piscataway, New Jersey, 08854. Upon information and belief, 1035 Centennial Avenue, Piscataway, New Jersey, 08854 is the address of Hetero’s U.S. subsidiary, Hetero USA, Inc.

16. On information and belief, Hetero made the ultimate decision to file the Annora ANDA with the FDA, and encouraged and directed Annora to file the Annora ANDA and the Annora Paragraph IV Certification, and Annora did so at Hetero’s direction.

17. On information and belief, following FDA approval of the Annora ANDA, Hetero and Annora will act in concert to market, distribute and sell the Annora Proposed ANDA Product throughout the United States, including the State of Delaware.

18. This action is being commenced before the expiration of 45 days from the date Plaintiffs received the Annora Paragraph IV Certification.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Annora because, *inter alia*, Annora has filed the Annora ANDA and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of the Annora ANDA, Annora will make, use, offer for sale, sell, and/or import the Annora Proposed ANDA Product in the United States, including in Delaware, prior to the expiration of the Patent-in-Suit.

21. On information and belief, Annora acts as an agent of Hetero with respect to the acts complained of herein.

22. On information and belief, the acts of Annora complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and, in part, for the benefit of Hetero.

23. On information and belief, Hetero directed Annora to perform the acts complained of herein, in whole or in part, to shield itself from liability for patent infringement based upon those acts.

24. Annora's acts and contacts with this District, as an agent of Hetero, are attributable to Hetero for jurisdictional purposes.

25. This Court also has personal jurisdiction over Defendants because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Defendants regularly and continuously transact business within Delaware, including by selling

pharmaceutical products in Delaware. On information and belief, Defendants derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within Delaware.

26. On information and belief, Defendants have continuously placed their products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, and thus have engaged in the regular conduct of business within this Judicial District.

27. On information and belief, Defendants derive substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

28. On information and belief, Hetero has not contested jurisdiction in one or more prior cases arising out of the filing of its ANDAs. *H. Lundbeck A/S et al v. Hetero USA Inc. et al*, 1:18-cv-00176 (D. Del.).

29. In the alternative, this Court has jurisdiction over Defendants because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Vifor Fresenius's claims arise under federal law; (b) Defendants are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Defendants have sufficient contacts with the United States as a whole, including, but not limited to, participating in the preparation and submission of the Annora ANDA for the Annora Proposed ANDA Product to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Defendants satisfies due process.

30. Venue is proper for Defendants under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Defendants are foreign corporations and are subject to personal jurisdiction in this Judicial District, as set forth above.

COUNT I: DIRECT INFRINGEMENT OF THE '251 PATENT BY DEFENDANTS

31. Vifor Fresenius repeats and realleges paragraphs 1-30 above as if fully set forth herein.

32. By acting collaboratively to prepare and submit the Annora ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Annora Proposed ANDA Product before the expiration of the '251 patent, Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2).

33. On information and belief, if Defendants commercially make, use, offer to sell, or sell the Annora Proposed ANDA Product within the United States, or import the Annora Proposed ANDA Product into the United States, Defendants will infringe at least claims 1, 10, 21, 24, 27, 28, 34, 35, 38, 39, and 40 of the '251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, in order to claim bioequivalence between the Annora Proposed ANDA Product and VELPHORO[®], Defendants were required to select an oral dosage form containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, thereby establishing infringement of the '251 patent. In addition, the Annora Paragraph IV Certification does not dispute that it infringes at least claim 1 of the '251 patent.

34. Annora has had knowledge of the '251 patent since at least the date that Annora submitted the Annora ANDA. On information and belief, Hetero was necessarily aware of the '251 patent when it directed Annora to file the Annora ANDA. In addition, Defendants will have knowledge of the '251 patent by at least the date of service of this Complaint.

35. Vifor Fresenius will be irreparably harmed if Defendants are not enjoined from making, selling, using, or importing the Annora Proposed ANDA Product, which upon

information and belief will infringe the '251 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II: INDUCEMENT OF INFRINGEMENT OF THE '251 PATENT BY HETERO

36. Vifor Fresenius repeats and realleges paragraphs 1-35 above as if fully set forth herein.

37. By acting in concert with Annora in the preparation and filing of the Annora ANDA and by directing Annora to file the Annora ANDA, Hetero has knowingly and actively induced Annora to infringe, and to continue to infringe, one or more claims of the '251 patent.

38. On information and belief, Hetero was necessarily aware of the '251 patent when it directed Annora to file the Annora ANDA. In addition, Hetero will have knowledge of the '251 patent by at least the date of service of this Complaint.

39. Unless enjoined by this Court, upon FDA approval, Hetero will continue to actively induce Annora's direct infringement of the '251 patent.

40. Vifor Fresenius will be irreparably harmed if Hetero is not enjoined from inducing Annora's infringement of the '251 patent. Vifor Fresenius has no adequate remedy at law for Hetero's inducement of Annora's direct infringement of the '251 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Defendants have infringed one or more claims of the '251 patent by filing the Annora ANDA;

B. A Judgment that Hetero has induced infringement of one or more claims of the '251 patent;

C. A Judgment that Defendants' making, using, offering to sell, selling, or importing the Annora Proposed ANDA Product would constitute infringement of one or more claims of the

'251 patent, and/or induce or contribute to the infringement of one or more claims of the '251 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

D. A permanent injunction restraining and enjoining Defendants, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Annora Proposed ANDA Product until after the expiration of the '251 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. An Order that the effective date of any approval of the Annora ANDA relating to the Annora Proposed ANDA Product be a date that is not earlier than the expiration date of the '251 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

F. Such other and further relief as the Court may deem just and proper.

Date: August 29, 2019

FARNAN LLP

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

*Attorneys for Plaintiffs Vifor Fresenius Medical
Care Renal Pharma, Ltd. and Vifor Fresenius
Medical Care Renal Pharma France S.A.S.*

OF COUNSEL:

Raymond N. Nimrod
Steven C. Cherny
Matthew A. Traupman
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Lauren N. Martin
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Ave, Suite 520
Boston, MA 02199
(617) 712-7100

Nancy Zhang
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
50 California St
San Francisco, CA 94111
(415) 875-6600