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.,	)	
Plaintiffs,	)	C.A. No. 20-911-MN
v.	)	
TEVA PHARMACEUTICALS USA, INC.	)	
Defendant.	)	

SECOND 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 Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 10,682,376 ("the '376 patent"), 10,695,367 ("the '367 patent"), and 11,013,761 ("the '761 patent") (collectively, "the Patents-in-Suit") under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Teva's filing of Abbreviated New Drug Applications ("ANDAs") 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 Patents-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, CH-9014 St. Gallen, 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 Tour Franklin, 100-101 Terrasse Boieldieu, La Défense 8, F-92042 Paris La Défense, France. VFMCRP France is a wholly-owned subsidiary of VFMCRP Switzerland.

4. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

THE PATENTS-IN-SUIT

5. On June 16, 2020, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 10,682,376, entitled "Pharmaceutical Compositions." The inventors of the '376 Patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the '376 patent. A copy of the '376 patent is attached hereto as Exhibit A.

6. On June 30, 2020, the PTO issued U.S. Patent No. 10,695,367, entitled "Pharmaceutical Compositions." The inventors of the '367 Patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the '367 patent. A copy of the '367 patent is attached hereto as Exhibit B.

7. On May 25, 2021, the PTO issued U.S. Patent No. 11,013,761, entitled "Pharmaceutical Compositions." The inventors of the '761 Patent are Ludwig Daniel Weibel

and Erik Philipp. VFMCRP Switzerland is the assignee of the '761 patent. A copy of the '761 patent is attached hereto as Exhibit C.

THE VELPHORO® DRUG PRODUCT

8. 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.

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

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are 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

11. On information and belief, Teva submitted Abbreviated New Drug Application No. 211411 (the "Teva ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Teva ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablets, 500 mg, (the "Teva Proposed ANDA Product"), a generic version of VELPHORO®. The Teva ANDA specifically seeks FDA approval to market the Teva Proposed ANDA Product prior to the expiration of the Patents-in-Suit.

12. On information and belief, following any FDA approval of the Teva ANDA, Teva will make, use, offer to sell, or sell the Teva Proposed ANDA Product throughout the United States, or import such generic products into the United States.

SUBJECT MATTER JURISDICTION

13. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. *See Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1123–25 (Fed. Cir. 2018), *cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, 140 S. Ct. 911, 205 L. Ed. 2d 454 (2020).

PERSONAL JURISDICTION AND VENUE OVER TEVA

14. This Court has personal jurisdiction over Teva because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

15. Venue is proper for Teva under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

COUNT I: INFRINGEMENT OF THE '376 PATENT BY TEVA

16. Plaintiffs repeat and reallege paragraphs 1-15 above as if fully set forth herein.

17. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '376 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

18. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '376 patent, Teva will further infringe at least claim 40 of the '376 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, Teva's Proposed ANDA Product

is a pharmaceutical composition in the form of a chewable tablet for oral administration containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, thereby establishing infringement of at least claim 40 of the '376 patent.

19. Teva has had knowledge of the '376 patent since at least the date of service of this Complaint.

20. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '376 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '367 PATENT BY TEVA

21. Plaintiffs repeat and reallege paragraphs 1-20 above as if fully set forth herein.

22. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '367 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '367 patent, Teva will further infringe at least claim 1 of the '367 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, Teva's ANDA Product is a pharmaceutical composition in the form of a chewable tablet for oral administration containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, thereby establishing infringement of at least claim 1 of the '367 patent.

24. Teva has had knowledge of the '367 patent since at least the date of service of this Complaint.

25. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '367 patent. Plaintiffs do not have an adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '761 PATENT BY TEVA

26. Plaintiffs repeat and reallege paragraphs 1-25 above as if fully set forth herein.

27. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '761 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

28. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '761 patent, Teva will further infringe at least claims 1 and 16 of the '761 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, Teva's ANDA Product is a pharmaceutical composition in the form of a chewable tablet for oral administration containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, wherein the iron oxy-hyroxide is essentially non-bioabsorbable, thereby establishing infringement of at least claims 1 and 16 of the '761 patent.

29. Teva has had knowledge of the '761 patent since at least the date of service of this Complaint.

30. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '761 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '376 PATENT BY TEVA

31. Plaintiffs repeat and reallege paragraphs 1-30 above as if fully set forth herein.

32. On information and belief, Teva has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '376 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Teva's planned manufacture, use, offer to sell, or sale the Teva Proposed ANDA Product within the United States, including in Delaware, or importation of the Teva Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '376 patent, infringes any valid claim of the '376 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

33. Plaintiffs seek a declaratory judgment that Teva's manufacture, use, offer to sell, or sale of the Teva Proposed ANDA Product within the United States or importation of the Teva Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claim 40 of the '376 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT V: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '367 PATENT BY TEVA

34. Plaintiffs repeat and reallege paragraphs 1-33 above as if fully set forth herein.

35. On information and belief, Teva has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '367 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Teva's planned manufacture, use, offer to sell, or sale the Teva Proposed ANDA Product within the United States, including in Delaware, or importation of the Teva Proposed ANDA Product into the United States, including

in Delaware, or inducement or contribution to any such conduct during the term of the '367 patent, infringes any valid claim of the '367 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

36. Plaintiffs seek a declaratory judgment that Teva's manufacture, use, offer to sell, or sale of the Teva Proposed ANDA Product within the United States or importation of the Teva Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claim 1 of the '367 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '761 PATENT BY TEVA

37. Plaintiffs repeat and reallege paragraphs 1-36 above as if fully set forth herein.

38. On information and belief, Teva has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '761 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Teva's planned manufacture, use, offer to sell, or sale the Teva Proposed ANDA Product within the United States, including in Delaware, or importation of the Teva Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '761 patent, infringes any valid claim of the '761 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

39. Plaintiffs seek a declaratory judgment that Teva's manufacture, use, offer to sell, or sale of the Teva Proposed ANDA Product within the United States or importation of the Teva Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1 and 16 of the '761 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed one or more claims of the '376 patent by filing the Teva ANDA;

B. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '376 patent, and/or induce or contribute to the infringement of one or more claims of the '376 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '376 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '376 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Teva has infringed one or more claims of the '367 patent by filing the Teva ANDA;

F. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '367 patent, and/or induce or contribute to the infringement of one or more claims of the '367 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '367 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '367 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. A Judgment that Teva has infringed one or more claims of the '761 patent by filing the Teva ANDA;

J. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '761 patent, and/or induce or contribute to the infringement of one or more claims of the '761 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

K. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '761 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

L. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '761

patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

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

Date: June 24, 2021

FARNAN LLP

/s/ Brian E. Farnan

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