IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD. and VIFOR (INTERNATIONAL) INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
CIPLA LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. ("VFMCRP") and Vifor (International) Inc. ("Vifor (International)") (together, "Plaintiffs" or "Vifor") hereby assert the following claims for patent infringement against Defendant Cipla Ltd. ("Cipla") and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,402,564 ("the '564 patent") under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Cipla's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Plaintiffs' KORSUVA® drug product prior to the expiration of the '564 patent.

THE PARTIES

2. Plaintiff VFMCRP 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 Vifor (International) is a limited company organized and existing under the laws of Switzerland, with its principal place of business at Rechenstraße 37, St. Gallen, 9000, Switzerland.

4. On information and belief, Cipla is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra, India 400013.

THE '564 PATENT

5. On July 22, 2008, the United States Patent and Trademark Office ("PTO") issued the '564 patent, entitled "Synthetic Peptide Amides." The inventors of the '564 patent are Claudio D. Schteingart, Frederique Menzaghi, Guangcheng Jiang, Roberta Vezza Alexander, Javier Sueiras-Diaz, Robert H. Spencer, Derek T. Chalmers, and Zhiyong Luo. VFMCRP is the assignee of the '564 patent. A copy of the '564 patent is attached hereto as Exhibit A.

THE KORSUVA® DRUG PRODUCT

6. Vifor (International) 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 difelikefalin acetate, EQ 0.065 mg base/1.3 mL (EQ 0.05 mg base/mL) (NDA No. 214916), sold under the trade name KORSUVA®. KORSUVA® is a kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adult patients undergoing hemodialysis. The FDA approved KORSUVA® in August 2021.

7. The claims of the '564 patent cover, *inter alia*, difelikefalin, including, *inter alia*, salts of difelikefalin, formulations of difelikefalin, and methods of using difelikefalin.

8. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '564 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with KORSUVA®.

ACTS GIVING RISE TO THIS ACTION

9. On information and belief, Cipla submitted ANDA No. 220760 (the "Cipla ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Cipla ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of difelikefalin injection, 65 mcg/1.3 mL (50 mcg/mL), (the "Cipla Proposed ANDA Product"), a generic version of KORSUVA®. The Cipla ANDA specifically seeks FDA approval to market the Cipla Proposed ANDA Product prior to the expiration of the '564 patent.

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

11. On or about October 9, 2025, Vifor received a letter dated October 8, 2025 from Cipla's counsel stating that the Cipla ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Cipla Paragraph IV Certification Letter"), which provides that, in Cipla's opinion, the '564 patent is "invalid, unenforceable, and/or not be infringed" by the commercial manufacture, use or sale of the Cipla Proposed ANDA Product.

12. This action is being commenced before the expiration of 45 days from the date Vifor received the Cipla Paragraph IV Certification Letter.

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, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within this Court's jurisdiction.

PERSONAL JURISDICTION AND VENUE

14. This Court has personal jurisdiction over Cipla because, *inter alia,* Cipla has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) 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 Cipla ANDA, Cipla will make, use, offer for sale, sell, and/or import the Cipla Proposed ANDA Product in the United States, including in Delaware, prior to the expiration of the '564 patent.

15. This Court also has personal jurisdiction over Cipla because Cipla has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Cipla regularly and continuously transacts business within Delaware, including by marketing, distributing, and selling pharmaceutical products in Delaware. On information and belief, Cipla derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

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

17. On information and belief, Cipla derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

18. On information and belief, Cipla has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in prior patent cases. On information and belief, Cipla has been sued for patent infringement in this District and did not contest personal

jurisdiction in this District in, for example, the following cases: *Sumitomo Pharma Switzerland GmbH et al. v. Cipla Limited et al.*, C.A. No. 1-25-cv-00312 (D. Del); *Astellas Pharma Inc. et al. v. Cipla Limited et al.*, C.A. No. 1-24-cv-01333 (D. Del); and *Acerta Pharma BV et al. v. Cipla Limited et al.*, C.A No. 1-24-cv-00587 (D. Del).

19. Additionally, on information and belief, Cipla has availed itself of the benefits of this forum through assertions of counterclaims in suits brought in this district, such as: *Sumitomo Pharma Switzerland GmbH et al. v. Cipla Limited et al.*, C.A. No. 1-25-cv-00312 (D. Del); *Astellas Pharma Inc. et al. v. Cipla Limited et al.*, C.A. No. 1-24-cv-01333 (D. Del); and *Acerta Pharma BV et al. v. Cipla Limited et al.*, C.A No. 1-24-cv-00587 (D. Del).

20. In the alternative, this Court has jurisdiction over Cipla because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Vifor's claims arise under federal law; (b) Cipla is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla has sufficient contacts with the United States as a whole, including, but not limited to, participating in the preparation and submission of the Cipla ANDA for the Cipla 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 Cipla satisfies due process.

21. Venue is proper for Cipla under 28 U.S.C. §§ 1391 and/or 1400(b).

22. Venue is proper in this district with respect to Cipla for the reasons set forth above, including because, *inter alia,* Cipla is a foreign corporation and is subject to personal jurisdiction in this Judicial District, as set forth above. In addition, Cipla has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraph 14

above, and continuously transacts business in this Judicial District, as set forth in paragraphs 15-17 above.

COUNT I: INFRINGEMENT OF THE '564 PATENT

23. Plaintiffs repeat and reallege paragraphs 1-22 above as if fully set forth herein.

24. By filing the Cipla 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 Cipla Proposed ANDA Product before the expiration of the '564 patent, Cipla committed an act of infringement under 35 U.S.C. § 271(e)(2).

25. Moreover, if Cipla commercially makes, uses, offers to sell, or sells the Cipla Proposed ANDA Product within the United States, or imports the Cipla Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '564 patent, Cipla will further infringe the '564 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Upon information and belief, the Cipla Proposed ANDA Product includes the active ingredient difelikefalin acetate and claims bioequivalence to KORSUVA®. Accordingly, the Cipla Proposed ANDA Product infringes at least claim 1 of the '564 patent.

27. Cipla has infringed at least claim 1 of the '564 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Cipla's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Cipla Proposed ANDA Product and the methods of using the Cipla Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '564 patent, either literally or under the doctrine of equivalents.

28. Cipla has had knowledge of the '564 patent since at least the date Cipla submitted the Cipla ANDA and was aware that submission of its ANDA constituted an act of infringement

under 35 U.S.C. § 271(e)(2). Cipla has had knowledge of the '564 patent by at least the date of service of this Complaint.

29. Upon information and belief, Cipla has knowledge that if it were to receive approval from the FDA to market the Cipla Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '564 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Cipla has knowledge of such infringing use and also knows that the Cipla Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '564 patent.

30. Upon information and belief, Cipla was aware of the '564 patent prior to filing the Cipla ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Cipla Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '564 patent, and based on Cipla's Paragraph IV Certification allegations, Cipla possesses the specific intent to encourage others to infringe.

31. Plaintiffs will be irreparably harmed if Cipla is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '564 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Cipla has infringed one or more claims of the '564 patent by filing the Cipla ANDA;

B. A Judgment that Cipla has infringed, and that Cipla's making, using, offering to sell, selling, or importing the Cipla Proposed ANDA Product would constitute infringement of one or more claims of the '564 patent, and/or induce or contribute to the infringement of one or more claims of the '564 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Cipla, 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 Cipla Proposed ANDA Product until after the expiration of the '564 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 Cipla ANDA relating to the Cipla Proposed ANDA Product be a date that is not earlier than the expiration date of the '564 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. Damages or other monetary relief to Vifor if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Cipla ANDA prior to the latest expiration date of the '564 patent, including any extensions and/or additional periods of exclusivity to which Vifor is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C).

F. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and Plaintiffs be awarded their attorneys' fees; and

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

Dated: November 21, 2025

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