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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVENUS PHARMACEUTICAL LABORATORIES, INC. and JIANGSU HENGRUI PHARMACEUTICALS CO., LTD., Plaintiffs, v. PACIRA PHARMACEUTICALS, INC. and PACIRA BIOSCIENCES, INC., Defendants.	Civil Action No.

PLAINTIFFS' COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 12,156,940

1. More than a decade after the launch of EXPAREL® in 2012, defendants Pacira Pharmaceuticals, Inc. and Pacira Biosciences, Inc. (collectively, "Pacira") are attempting to throttle generic competition through a prolonged campaign of patent harassment. Plaintiff Jiangsu Hengrui Pharmaceuticals, Inc. ("Jiangsu Hengrui") successfully developed a bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL) and 133 mg/10 ml (13.3 mg/mL) products (the "ANDA Products"); those efforts lead to the filing of an Abbreviated New Drug Application ("ANDA") by Jiangsu Hengrui and its wholly-owned subsidiary and regulatory agent Plaintiff eVenus Pharmaceutical Laboratories, Inc. ("eVenus"), which identified Pacira's EXPAREL® as the reference-listed drug. In July 2024, the U.S. Food & Drug Administration ("FDA") granted final approval of Jiangsu Hengrui's ANDA No. 214348 for the ANDA Products.

2. By the time that Jiangsu Hengrui had completed its development of the ANDA Products in 2021, only one patent was listed in the Orange Book for EXPAREL®: U.S. Patent No. 9,585,838, which was set to expire in December 2021. Thus, after December 2021, there would have been no patent barriers to a company seeking to market a generic version of EXPAREL®. On August 20, 2021, Jiangsu Hengrui submitted its ANDA to the FDA for the 266 mg/20 mL product, and later amended its ANDA to seek approval for the 133 mg/10 mL product.

3. But before Jiangsu Hengrui could file its ANDA, Pacira engaged in a systematic campaign to obtain and assert invalid patents to attempt to block generic competition. The first patent—Pacira's U.S. Patent No. 11,033,495 ("'495 Patent)—surfaced in June 2021. Pacira has brought five (5) lawsuits in this District over the course of three (3) years against Jiangsu Hengrui and eVenus—the most recent of which Pacira filed in July 2024—alleging infringement of six (6) patents in relation to Jiangsu Hengrui's ANDA Products: C.A. No. 2:21-cv-19829 (alleging infringement of the '495 Patent); C.A. No. 2:22-cv-00718 (alleging infringement of the '495 Patent

and U.S. Patent No. 11,179,336 and consolidated with 2:21-cv-19829); C.A. No. 2:23-cv-02367 (alleging infringement of U.S. Patent No. 11,426,348); C.A. No. 2:24-cv-06294 (alleging infringement of U.S. Patent Nos. 11,819,574 ("'574 Patent") and 11,819,575 ("'575 Patent")); and C.A. 2:24-cv-07680 (alleging infringement of U.S. Patent No. 11,925,706 ("'706 Patent")). Jiangsu Hengrui and eVenus have also asserted counterclaims in this Court for non-infringement, invalidity, and/or the unenforceability of five (5) additional patents in the same family.

4. In February 2024, a trial was held in this Court in C.A. No. 2:21-cv-19829 and C.A. No. 2:22-cv-00718; this Court found that the claims of the '495 Patent asserted by Pacira were invalid as anticipated and obvious. C.A. No. 2:21-cv-19829 (consolidated with C.A. No. 2:22-cv-00718) is on appeal to the U.S. Court of Appeals for the Federal Circuit. C.A. No. 2:23-cv-02367 is stayed in this Court pending the outcome of the appeal in C.A. 2:21-cv-19829. The parties are actively litigating, in this Court, C.A. No. 2:24-cv-06294, involving the '574 Patent, the '575 Patent, and the '706 Patent.

5. Trying to avoid further unfavorable rulings in this Court, Pacira has now resorted to forum shopping by filing related litigation against Jiangsu Hengrui on yet another patent in a different court. More specifically, on December 3, 2024, the day U.S. Patent No. 12,156,940 ("'940 Patent") issued, Pacira filed suit against Jiangsu Hengrui (but not eVenus) in the U.S. District Court for the Northern District of Illinois, alleging that the ANDA Products infringe the '940 Patent; conveniently, Pacira did not identify any "related" cases to the Northern District of Illinois court. The '940 Patent, like the '495 Patent, is listed in FDA's Orange Book in connection with Pacira's EXPAREL® product. The '940 Patent claims, like the '495 Patent claims held invalid by this Court, are directed to bupivacaine encapsulated multivesicular liposomes ("MVLs").

6. In a press release on December 3, 2024, Pacira announced that "[t]o be successful commercially, eVenus, Jiangsu Hengrui, and Fresenius will have to overcome each of Pacira's patents," including the '940 Patent.

7. Pacira's campaign of sequential litigation has created an actual case or controversy concerning the '940 Patent. Plaintiffs therefore bring these claims for declaratory judgment of non-infringement and invalidity of the '940 Patent to address this patent in the same forum as all of Pacira's prior litigation concerning Jiangsu Hengrui's ANDA Products.

THE '940 PATENT

8. The '940 Patent claims earliest priority to a provisional patent application filed by Pacira on May 20, 2024, nearly three years after Jiangsu Hengrui submitted its ANDA to the FDA seeking approval of the ANDA Products. On July 2, 2024, Pacira filed a patent application, claiming priority to the provisional application, that ultimately issued as the '940 Patent.

9. The '940 Patent issued on December 3, 2024, six (6) months after the FDA approved the ANDA Products in July 2024.

10. The '940 Patent lists three named inventors: Eran Levy, Jeffrey S. Hall, and John J. Grigsby, Sr. Two of the named inventors—Mr. Hall and Mr. Grigsby—are also named inventors on each of the six (6) patents asserted by Pacira in C.A. No. 2:21-cv-19829, C.A. No. 2:22-cv-00718, C.A. No. 2:23-cv-02367, C.A. No. 2:24-cv-06294, and C.A. 2:24-cv-07680, filed in this Court.

11. Mr. Hall and Mr. Grigsby also testified in this Court in the trial in February 2024 in C.A. No. 2:21-cv-19829 and C.A. No. 2:22-cv-00718.

12. The title of the '940 Patent is "Manufacturing of Bupivacaine Multivesicular Liposomes," exactly the same as five (5) of the six (6) patents asserted by Pacira in C.A. No. 2:21-

cv-19829, C.A. No. 2:22-cv-00718, C.A. No. 2:23-cv-02367, C.A. No. 2:24-cv-06294, and C.A. 2:24-cv-07680, filed in this Court.

13. The specification of the ’940 Patent contains portions that are substantially similar to the specification for each of the patents asserted by Pacira in C.A. No. 2:21-cv-19829, C.A. No. 2:22-cv-00718, C.A. No. 2:23-cv-02367, C.A. No. 2:24-cv-06294, and C.A. 2:24-cv-07680. The specification of the ’940 Patent also explicitly incorporates by reference the specification for the ’495 Patent.

14. The claims of the ’940 Patent do not recite a new method to manufacture batches of bupivacaine encapsulated MVLs.

15. The claims of the ’940 Patent purport to relate to batches of bupivacaine encapsulated MVLs with a certain *in vitro* release profile. The claims of the ’940 Patent do not recite a new technique to measure the *in vitro* release profile of batches of bupivacaine encapsulated MVLs.

16. The claims of the ’940 Patent do not recite a new composition. Upon information and belief, before May 9, 2024, Pacira sold batches and compositions of EXPAREL® that practiced each limitation of the claims of the ’940 Patent.

PARTIES

17. Plaintiff Jiangsu Hengrui Pharmaceuticals Co. Ltd. is a corporation organized and existing under the laws of China with a place of business at No. 7 Kunlunshan Road, Lianyungang Eco & Tech Development Zone, Lianyungang, Jiangsu, 222002, China. Jiangsu Hengrui is the holder of ANDA No. 214348.

18. Plaintiff eVenus Pharmaceutical Laboratories Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 506 Carnegie

Center, Suite 100, Princeton, New Jersey, 08540. eVenus is a wholly-owned subsidiary of Jiangsu Hengrui, and serves as Jiangsu Hengrui's regulatory agent for ANDA No. 214348.

19. On information and belief, Defendant Pacira Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California with a principal place of business at 5 Sylvan Way, Parsippany, New Jersey, 07054. Pacira Pharmaceuticals, Inc. is registered to do business in New Jersey as Entity ID No. 0199989348.

20. On information and belief, Pacira Pharmaceuticals, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

21. On information and belief, Pacira Pharmaceuticals, Inc. is a wholly-owned subsidiary of Pacira Biosciences, Inc.

22. On information and belief, Defendant Pacira BioSciences, Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 5 Sylvan Way, Parsippany, New Jersey, 07054.

23. On information and belief, Pacira Biosciences, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

24. This action arises under the patent laws of the United States of America, U.S. Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act.

25. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

26. This Court can provide the declaratory relief sought in this Complaint because an actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201, at least because Pacira has already sued Plaintiffs for infringing the '940 Patent, and six (6) related patents, concerning the same ANDA Products. As stated above, litigation concerning these patents remains active before this Court.

Personal Jurisdiction and Venue

27. This Court has personal jurisdiction over Pacira Pharmaceuticals Inc. and Pacira BioSciences, Inc. because they both have a primary place of business in New Jersey, 5 Sylvan Way, Parsippany, New Jersey, 07054.

28. This Court has personal jurisdiction over Pacira Pharmaceuticals, Inc. because it is registered to do business in New Jersey.

29. Pacira Pharmaceuticals, Inc. and Pacira BioSciences Inc. are also subject to personal jurisdiction in New Jersey because they have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being sued in this Court. For example, on information and belief, Pacira Pharmaceuticals, Inc. and Pacira BioSciences Inc. develop, manufacture, import, market, distribute, use, offer to sell, and/or sell drugs throughout the United States, including in the State of New Jersey, and therefore transact business within the State of New Jersey, and/or have engaged in systematic and continuous business contacts within the State of New Jersey. Pacira Pharmaceuticals, Inc. and Pacira BioSciences Inc. also issue press releases, including the Dec. 6, 2024 press release concerning the '940 Patent, from their principal place of business in Parsippany, New Jersey. On information and belief, one or more officers of the management team of Pacira Pharmaceuticals, Inc. and Pacira BioSciences Inc. are located in their principal place of business in Parsippany, New Jersey.

30. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) and 28 U.S.C. § 1391(b) because Pacira Pharmaceuticals, Inc. and Pacira BioSciences Inc. have a regular and established place of business in New Jersey.

31. Personal jurisdiction and venue are also proper because Defendants have affirmatively filed five (5) lawsuits in this District against Plaintiffs concerning the same ANDA Products.

FIRST CAUSE OF ACTION

(Declaratory Judgment of Non-infringement of the '940 Patent Under 35 U.S.C. § 271(a), (b), and (c))

32. Plaintiffs reassert and reallege Paragraphs 1–31 of the Complaint as if fully set forth herein.

33. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiffs and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Plaintiffs' non-infringement of the '940 Patent under 35 U.S.C. § 271(a), (b), and (c).

34. The manufacture, use, sale, offer for sale, and/or importation of the ANDA Products has not infringed, do not infringe, and will not, if marketed, infringe any valid claim of the '940 Patent under 35 U.S.C. § 271(a).

35. For example, batches of the ANDA Products do not have "a volume of about 100 liters to about 300 liters," as recited in each claim of the '940 Patent. Batches of the ANDA Products also do not have "an average rate of change in the cumulative percentage release of bupivacaine of the batches at the 24-hour time point is 0.05%/month to 0.5%/month after storage of the aliquots of each batch at 2° C. to 8° C. for about 12 months," as recited in each claim of the '940 Patent.

36. Plaintiffs have not, and will not, induce infringement under 35 U.S.C. § 271(b) of any valid claim of the ’940 Patent at least because the ANDA Products do not, and will not, practice any valid claim of the ’940 Patent.

37. Plaintiffs have not, and will not, contribute to infringement under 35 U.S.C. § 271(c) of any valid claim of the ’940 Patent at least because the ANDA Products do not, and will not, practice any valid claim of the ’940 Patent.

38. Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the bupivacaine liposome injectable suspension, 133 mg/10 mL and 266 mg/20 mL, products that are the subject of ANDA No. 214348 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the ’940 Patent under 35 U.S.C. § 271(a), and that Plaintiffs will not induce or contribute to infringement of any valid claim under 35 U.S.C. § 271(b) or 271(c).

SECOND CAUSE OF ACTION

(Declaratory Judgment of Invalidity of the ’940 Patent)

39. Plaintiffs reassert and reallege Paragraphs 1–38 of the Counterclaims as if fully set forth herein.

40. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiffs and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the ’940 Patent.

41. The claims of the ’940 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

42. For example, and not by way of limitation, upon information and belief, one or more claims of the '940 Patent are invalid under 35 U.S.C. § 102 because the subject matter of the claims was anticipated by Pacira's prior art sales and/or public uses of its EXPAREL® product. That is, on information and belief, batches of Pacira's EXPAREL®, sold or publicly available before May 20, 2024, practiced claims of the '940 Patent.

43. As an additional example, and not by way of limitation, one or more claims of the '940 Patent are invalid under 35 U.S.C. § 103 because the subject matter recited in the claims would have been obvious to a person of ordinary skill in the art, including in view of batches of Pacira's EXPAREL®, sold or publicly available before May 20, 2024. Furthermore, there is no objective evidence of non-obviousness of the claims of the '940 Patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '940 Patent or outweigh the evidence in support of obviousness, including because, on information and belief, Pacira continues to sell batches of EXPAREL® that do not practice the claims of the '940 Patent.

44. As an additional example, and not by way of limitation, one or more claims of the '940 Patent are invalid under 35 U.S.C. § 112 because the specification of the '940 Patent does not provide adequate information to a person of ordinary skill in the art to manufacture, without undue experimentation, batches of bupivacaine encapsulated multivesicular liposomes that would practice the claims of the '940 Patent.

45. Plaintiffs are entitled to a judicial declaration that the claims of the '940 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment in their favor and against Pacira:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of the

bupivacaine liposome injectable suspension, 133 mg/10 mL and 266 mg/20 mL, products that are the subject of ANDA No. 214348 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '940 Patent under 35 U.S.C. § 271(a), and that Plaintiffs will not induce or contribute to infringement of any valid claim under 35 U.S.C. §§ 271(b) or 271(c);

B. Declaring that the claims of the '940 Patent are invalid;

C. Ordering that judgment be entered in favor of Plaintiffs;

D. Declaring this case exceptional and awarding Plaintiffs their reasonable attorneys' fees and costs under 35 U.S.C. § 285; and

E. Awarding Plaintiffs such other and further relief as the Court may deem just and proper.

Dated: December 10, 2024

Respectfully submitted,

s/ Eric Abraham

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2 Plaintiffs eVenus Pharmaceutical Laboratories, Inc., and Jiangsu Hengrui Pharmaceuticals Co., submit that, to their knowledge, this matter is related to the following actions:

- *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals Labs. Inc., et al.* Civil Action No. 2:21-cv-00718 (D.N.J.)
- *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals Labs. Inc., et al.* Civil Action No. 2:23-cv-02367 (D.N.J.)
- *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals Labs. Inc., et al.* Civil Action No. 2:21-cv-19829 (D.N.J.)
- *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals Labs. Inc., et al.* Civil Action No. 2:24-cv-07680 (D.N.J.)
- *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals Labs. Inc., et al.* Civil Action No. 2:24-cv-06294 (D.N.J.)
- *Pacira Pharmaceuticals, Inc., et al. v. Jiangsu Hengrui Pharmaceuticals Co., Ltd., et al.* Civil Action No. 1:24-cv-12416 (N.D. Ill.)

Dated: December 10, 2024

Respectfully submitted,

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