IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC. Plaintiffs v. eVenus PHARMACEUTICALS LABORATORIES INC. and JIANGSU HENGRUI MEDICINE CO. LTD., a Chinese Pharmaceutical Co., and FRESENIUS KABI USA, LLC, Defendants.	Civil Action No. **COMPLAINT FOR INFRINGEMENT OF U.S. PATENT NOS. 11,819,574 AND 11,819,575**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pacira Pharmaceuticals, Inc. and Pacira BioSciences, Inc. (collectively, "Plaintiffs" or "Pacira") bring this Hatch-Waxman patent infringement suit against Defendants eVenus Pharmaceuticals Laboratories Inc. ("eVenus"), Jiangsu Hengrui Medicine Co. Ltd. ("Jiangsu Hengrui"), and Fresenius Kabi USA, LLC ("Fresenius Kabi") (collectively, "Defendants"). Pacira alleges as follows.

PRELIMINARY STATEMENT

Pacira just completed trial against Defendants in February, during which Defendants raised every defense in the book. But the majority of Defendants' effort to evade infringement rested on invalidity and inequitable conduct due to allegedly withheld batch data. Pacira disclosed those defenses to the USPTO—including by providing the Examiner copies of the expert reports of Dr. Anna Schwendeman (invalidity) and Mr. Russell Slifer (inequitable conduct), as well as copies of

allegedly withheld batch data—and the USPTO issued the patents now asserted in this case rendering Defendants defenseless.

CASE OVERVIEW

1. Pacira filed a Hatch-Waxman patent infringement suit against defendants eVenus and Jiangsu Hengrui in this Court on November 8, 2021, alleging infringement of U.S. Patent No. 11,033,495 ("the '495 patent").[1] That First Action arose out of eVenus's submission of an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a purported generic version of EXPAREL® bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL) approved in NDA No. 022496, and Plaintiffs' receipt of a Notification of Paragraph IV Certification from eVenus on the '495 patent ("the September eVenus Notice Letter"). Ex. C ("the September eVenus Notice Letter").

2. After Plaintiffs filed the First Action, they received a second Notification of Paragraph IV Certification from eVenus on or around December 28, 2021 ("the December eVenus Notice Letter"), this time disclosing that the ANDA had been amended to seek approval to commercially manufacture, use, offer for sale, sell and/or import purported generic versions of both the 266 mg/20 mL version and 133 mg/10 mL version of EXPAREL® bupivacaine liposome injectable suspension, approved in NDA No. 022496, and certifying as to both the '495 patent and U.S. Patent No. 11,179,336 ("the '336 patent"). Ex. D ("the December eVenus Notice Letter"). On February 10, 2022, Plaintiffs filed a second patent lawsuit asserting both the '495 patent and

[1] *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:21-cv-19829-MCA-JRA (hereinafter, "the First Action").

the ’336 patent against defendants eVenus and Jiangsu Hengrui.[2] Plaintiffs subsequently amended the complaints in both the First and Second Actions to add defendant Fresenius Kabi. On May 9, 2022, the Court granted the parties’ request to consolidate the First and Second Actions for all purposes.[3] On October 23, 2023, the parties filed a Stipulated Order of Dismissal of Claims and Counterclaims regarding patent-in-suit 11,179,336 and requested that the Court so order the Stipulated Order. The First Action, ECF No. 231-1. The Court conducted a five-day bench trial from February 6, 2024, to February 13, 2024, concerning infringement and invalidity of claim 7 of the ’495 patent. Closing arguments were held May 7, 2024.

3. The thirty-month stay will expire on July 1, 2024, for the 266 mg/20 mL ANDA product and 133 mg/10 mL ANDA product. The Court requested Defendants’ agreement to delay launch by at least an additional 30-days to allow sufficient time to issue its decision. Defendants responded in a filing that is currently conditionally sealed. The First Action, ECF No. 380.

4. On or around April 14, 2023, Defendants served a third Notification of Paragraph IV Certification (“the April eVenus Notice Letter”) regarding, *inter alia*, U.S. Patent No. 11,426,348 (“the ’348 patent”), which issued on August 30, 2022, and was listed in the FDA’s Orange Book in connection with EXPAREL® since September 2, 2022. Ex. E (“the April eVenus Notice Letter”). The ’348 patent shares a specification with the ’495 and ’336 patents. And like the ’495 and ’336 patents, the ’348 patent is directed to the scaled-up manufacture of EXPAREL®. Plaintiffs filed a third patent lawsuit in this Court on April 28, 2023, asserting the ’348 patent against Defendants.[4]

---

[2] *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:22-cv-00718 (hereinafter “the Second Action”).

[3] The First Action, ECF No. 85

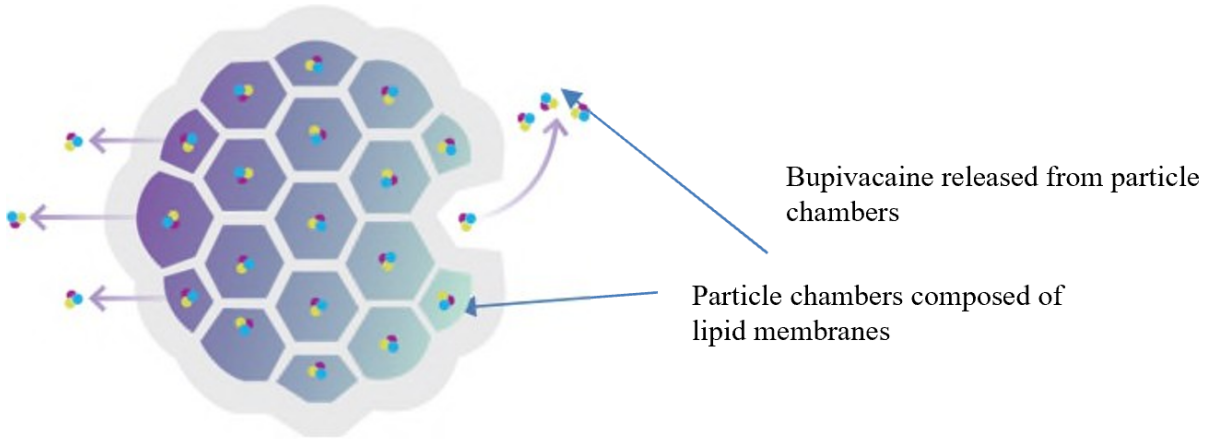
[4] *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:23-cv-02367 (hereinafter “the Third Action”).

5. On or around March 11, 2024, Defendants served a fourth Notification of Paragraph IV Certification ("the March Jiangsu Hengrui Notice Letter") regarding, *inter alia*, U.S. Patent Nos. 11,819,574 ("the '574 patent") and 11,819,575 ("the '575 patent"), which were both issued on November 21, 2023, and listed in the FDA's Orange Book in connection with EXPAREL® since December 6, 2023. Ex. F ("the March eVenus Notice Letter"). The '574 and '575 patents share a specification with the '495, '336, and '348 patents, and like the '336 patent, claim priority to the application from which the '495 patent issued. And like the '495, '336, and '348 patents, the '574 and '575 patents are directed to the scaled-up manufacture of EXPAREL®.

6. Pacira now files the instant complaint asserting the '574 and '575 patents against Defendants.

****

7. While reciting various different limitations than the patents asserted in the preceding actions, the '574 and '575 patents are also directed to Pacira's scaled-up manufacturing process for EXPAREL®. A true and correct copy of the '574 patent and the '575 patent are attached as Exhibits A and B, respectively. EXPAREL® is not a pill, nor a simple drug-containing solution. Rather, EXPAREL® is an injectable suspension, consisting of millions of microscopic, spherical particles called multivesicular liposomes (MVLs). Each MVL particle comprises tens of thousands of chambers which contain the drug (bupivacaine). Following administration to a patient, the particle chambers begin to release the drug slowly, through a complex rearrangement process, over a period of days. Shown below is a cross-sectional diagram of an MVL, showing how each individual vesicle contains and releases bupivacaine:



8. MVL drug products like EXPAREL® are challenging to make because they are inherently unstable during the manufacturing process. The manufacturing process required to form the MVLs that comprise EXPAREL® is very complex and involves multiple emulsion steps that must be performed under precisely controlled conditions. Two of the process steps, and the conditions of those steps, are especially critical—the first and second emulsification steps. Both steps require, among other things, determining the right blade diameter, mixing speed, mixing time, and temperature to form the complex honeycomb structure that is the hallmark of MVLs.

9. The first emulsion step comprises a mixture of aqueous and organic solutions to encapsulate water, bupivacaine, and lipid membranes, to form a solution of free-floating droplets suspended in oil. These fragile droplets on their own, however, are not useful as a final product and must undergo a second emulsion. During the second emulsion, an excess of an aqueous solution of dextrose (a sugar) and lysine is added to the first emulsion and mixed to create a final water-in-oil-in-water emulsion. When the droplets from the first emulsion are combined with this large amount of aqueous solution during the second emulsion step, they are forced together to form the structure of the MVL. But if the second emulsion step goes wrong, bupivacaine is lost to the external solution and forms precipitants, the product falls apart, and the batch must be aborted.

10. Moreover, the timing of the water-in-oil-in-water emulsification steps is critical. You only have about sixty seconds to complete the crucial, yet highly sensitive, second emulsion step—the mixing step during which the MVLs are formed. During the second emulsion, the lipid membranes contain solvent and are very fluid and vulnerable to disruption, potentially exposing the bupivacaine to high pH that may cause it to crystallize and destroy particles (as described above). The mixing time limit is thus virtually the same regardless of batch size—whether a few mL on a lab bench or a 200L commercial batch. The bigger the batch, the more time and mixing energy is required to emulsify the components. The challenge of the second emulsification step timing was considered by Pacira scientists to be potentially insurmountable. Pacira engineers were so skeptical that developing a 200L batch process would be possible, that they invested several years into the development of an alternative "spray" processing approach (which ultimately failed) before attempting development of a 200L batch process.

11. But out of these challenges—solved through approximately 7 years of experimentation and tens of millions of development dollars—Pacira discovered unexpected advantages of the EXPAREL® resulting from this scaled-up process. For example, the second emulsion step done in a larger scale unexpectedly led to a wider MVL particle size distribution, along with unexpectedly higher internal lysine concentration. And while common manufacturing wisdom suggests that a narrow particle size distribution is preferred and that lysine encapsulation should be avoided, these batches nonetheless demonstrate better stability than those from Pacira's prior process, showing lower levels of lipid degradation products (e.g., erucic acid) after 6 months at 25 degrees Celsius (°C).

12. During prosecution of the related '495 patent, the examiner considered the same prior art references cited for the '574 and '575 patents. The examiner considered the difference

between the erucic acid levels at 25 °C for six months of the old 45L and new 200L process disclosed in the '495 patent and, in allowing the claims and providing specific reasons for doing so, considered the differences to be patentable. Ex. G (Notice of Allowance of the '495 patent). The Examiner relied on a declaration by inventor Ms. Kathy Los and stated "[t]he prior art [Camu in view of Li] fails to teach the claimed degradation product of erucic acid after 6 months storage at 25 °C. Furthermore the combined prior art does not teach the claimed concentration of bupivacaine. The Office finds the declaration persuasive that the combined prior art does not teach the claimed method of preparation of MVL having the claimed storage stability."

13. During prosecution of the '574 patent, Pacira submitted multiple Information Disclosure Statements ("IDSs") to the USPTO informing the USPTO of the information Defendants have relied on in invalidity defenses and inequitable conduct allegations for related patents, including 45L EXPAREL® stability data, statements Pacira made to FDA, Defendants' Paragraph IV letters on the related '495 and '336 patents, Defendants' Preliminary Invalidity Contentions from the litigation on the '495 and '336 patents, and Defendants' Expert Reports on Invalidity and Inequitable Conduct from the litigation on the '495 and '336 patents. *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:21-cv-19829-MCA-JRA, ECF No. 227-1 (Plaintiffs' Rule 56.1 Statement of Undisputed Material Facts in Support of Its Motion for Summary Judgment) at ¶¶176-180. With all that information submitted, the Examiner still allowed the claims of the '574 patent.

NATURE OF ACTION

14. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984; 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"); 35 U.S.C. § 271(a)-

(c); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Defendants' submission of an ANDA to the FDA seeking approval to commercially manufacture, use, offer for sale, sell and/or import proposed generic versions of EXPAREL® (bupivacaine liposome injectable suspension, 133 mg/10 mL and 266 mg/20 mL (13.3 mg/mL))[5] prior to the expiration of the '574 and '575 patents. Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

15. Plaintiff Pacira Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of California with its principal place of business at 5401 West Kennedy Blvd, Lincoln Center, Suite 890, Tampa, FL 33609.

16. Plaintiff Pacira BioSciences, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 5401 West Kennedy Blvd, Lincoln Center, Suite 890, Tampa, FL 33609.

17. Defendant eVenus Pharmaceuticals Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 506 Carnegie Center, Suite 100, Princeton, New Jersey, 08540. eVenus is in the business of selling and distributing generic drugs for the U.S. market.

18. Defendant Jiangsu Hengrui Pharmaceuticals Co., Ltd. is a corporation organized and existing under the laws of China with its principal place of business at No. 7 Kunlunshan Road, Lianyungang Eco & Tech Development Zone, Lianyungang, Jiangsu, 222002, China. Jiangsu Hengrui is in the business of, among other things, manufacturing, marketing, selling, and distributing generic drugs for the U.S. market, including through its subsidiary eVenus. Jiangsu

[5] Hereinafter, "eVenus's Proposed ANDA Products."

Hengrui is the holder of Drug Master File ("DMF") No. 34900, bupivacaine base. On information and belief, Jiangsu Hengrui will manufacture the active pharmaceutical ingredient ("API") for eVenus's Proposed ANDA Products.

19. Defendant Fresenius Kabi USA, LLC is a limited liability corporation organized and existing under the laws of the state of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi is in the business of manufacturing, marketing, and selling generic drugs for the U.S. market. On information and belief, Fresenius Kabi is licensed to commercialize eVenus's Proposed ANDA Products in the United States, including in the State of New Jersey, in the event FDA approves the eVenus ANDA.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

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

22. This Court can provide the relief sought in the Declaratory Judgment counts of 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 Plaintiffs have already sued Defendants for infringing three related patents on the same drug product.

Personal Jurisdiction and Venue

23. This Court has personal jurisdiction over eVenus because eVenus is incorporated in New Jersey and has its primary place of business in New Jersey, at 506 Carnegie Center, Suite 100, Princeton, New Jersey, 08540.

24. eVenus is also subject to personal jurisdiction in New Jersey because, among other things, eVenus, itself and through its affiliates, has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court.

25. eVenus, itself and through its affiliates, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pacira's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

26. eVenus is registered as wholesaler with the State of New Jersey's Department of Health under Registration No. 5004028. On information and belief, eVenus, itself and through its affiliates, will use this license to offer for sale and to sell eVenus's Proposed ANDA Products throughout the United States, including New Jersey.

27. eVenus is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400276509.

28. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) as to eVenus because, on information and belief, eVenus has a regular and established place of business in New Jersey and because, on information and belief, eVenus has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Pacira by preparing or assisting in preparing eVenus's ANDA in New Jersey and/or with the intention of seeking to market eVenus's Proposed ANDA Products nationwide, including within New Jersey.

29. On information and belief, Jiangsu Hengrui is subject to personal jurisdiction in New Jersey because, among other things, Jiangsu Hengrui itself and through its wholly owned

subsidiary, eVenus, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court.

30. On information and belief, Jiangsu Hengrui, itself and through its affiliates, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pacira's claims, and/or has engaged in systematic and continuous business with contacts within the State of New Jersey.

31. On information and belief, Jiangsu Hengrui is subject to personal jurisdiction in New Jersey because it directs and controls eVenus and therefore the activities of eVenus in this jurisdiction are attributed to Jiangsu Hengrui. Moreover, Jiangsu Hengrui, through its wholly owned subsidiary, eVenus, has a regular and established place of business in New Jersey. On information and belief, Jiangsu Hengrui has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the Jiangsu Hengrui DMF, and acting in concert with eVenus in the preparation and submission of eVenus's ANDA seeking FDA approval to market eVenus's Proposed ANDA Products throughout the United States, including New Jersey, before expiration of the '574 and '575 patents. On information and belief, Jiangsu Hengrui will manufacture the API for eVenus's Proposed ANDA Products.

32. On information and belief, Jiangsu Hengrui and eVenus operate and act, and will continue to operate and act, in concert as an integrated, unitary business with respect to eVenus's Proposed ANDA Products. Jiangsu Hengrui and eVenus work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including New Jersey.

33. On information and belief, eVenus acts at the direction, and for the benefit, of Jiangsu Hengrui and is controlled by Jiangsu Hengrui.

34. Jiangsu Hengrui consented to jurisdiction in New Jersey in at least one prior case arising out of the filing of an ANDA. *See Janssen Prods., L.P. v. eVenus Pharma. Labs. Inc*., No. 20-cv-9369 (D.N.J.). Moreover, Jiangsu Hengrui did not challenge personal jurisdiction in the First, Second, or Third Action.

35. Venue is proper in this district for Jiangsu Hengrui pursuant to 28 U.S.C. §§ 1391(c) and/or 1400(b) because Jiangsu Hengrui is a company organized and existing under the laws of China and may be sued in any judicial district.

36. In the alternative, as to Jiangsu Hengrui, this Court's exercise of personal jurisdiction is proper pursuant to Fed. R. Civ. P. 4. On information and belief, Jiangsu is a foreign company organized and existing under the laws of China, with a principal place of business in Lianyungang, Jiangsu, China.

37. This Court has personal jurisdiction over Jiangsu Hengrui because the requirements of Fed. R. Civ. P. 4(k)(2)(A) are met. First, Plaintiffs' claims arise under federal law. Second, Jiangsu Hengrui is a foreign defendant that is not subject to jurisdiction in any state's courts of general jurisdiction. Third, Jiangsu Hengrui has sufficient contacts with the United States, including, for example, on information and belief, participating in the preparation and submission of eVenus's ANDA, preparing and submitting the Jiangsu Hengrui DMF to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Jiangsu Hengrui satisfies due process.

38. Litigation in the District of New Jersey would not unduly burden Jiangsu Hengrui. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws, and Plaintiffs have a substantial interest in obtaining convenient and effective relief for violations of their property interests. Also, the States have a shared interest in the substantive policy of the intellectual property laws of the United States.

39. This Court has personal jurisdiction over Fresenius Kabi because on information and belief, Fresenius Kabi has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

40. This Court has personal jurisdiction over Fresenius Kabi because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey; (2) intends to import, market, sell, and/or distribute eVenus's Proposed ANDA Products to residents of New Jersey; (3) has continuous and systematic contacts with the State of New Jersey and regularly conducts business in the State of New Jersey, either directly or through one or more of its affiliates, agents, and/or alter egos; (4) makes its generic pharmaceutical products available in New Jersey; (5) maintains a broad distributorship network within New Jersey; and (6) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

41. On information and belief, Fresenius Kabi is registered to do business in New Jersey under Entity Identification No. 0600313148.

42. On information and belief, Fresenius Kabi is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003710.

43. On information and belief, Fresenius Kabi has had persistent and continuous contacts with this judicial district, including developing and marketing pharmaceutical products that are sold in this judicial district and selling pharmaceutical products in this judicial district.

44. On information and belief, Fresenius Kabi directly and/or through one or more of its affiliates, agents, and/or alter egos, distributes, and sells generic pharmaceutical products throughout the United States, including in this judicial district.

45. On information and belief, Fresenius Kabi derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

46. On information and belief, Fresenius Kabi directly and/or through one or more of its affiliates, agents, and/or alter egos has an extensive network of physicians, medical facilities, wholesalers, and distributors in this judicial district.

47. On information and belief, Fresenius Kabi has been and is engaging in activities directed toward infringement of the patents-in-suit, including by acting in concert with eVenus and Jiangsu Hengrui with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of eVenus's Proposed ANDA Products before expiration of the '574 and '575 patents. On information and belief, Fresenius Kabi intends to engage in importing, marketing, selling, distributing, and/or using eVenus's Proposed ANDA Products before expiration of the '574 and '575 patents throughout the United States, including in New Jersey.

48. On information and belief, Fresenius Kabi intends to take advantage of its established channels of distribution in New Jersey for the sale of eVenus's Proposed ANDA Products.

49. On information and belief, eVenus and Jiangsu act for the benefit of Fresenius Kabi with respect to eVenus's Proposed ANDA Products.

50. On information and belief, Fresenius Kabi has a regular and established place of business in New Jersey. For instance, at least one Fresenius Kabi employee has a LinkedIn page identifying a Fresenius Kabi business location in New Jersey.

51. On information and belief, the regular and established place of business in New Jersey of eVenus and the infringing acts in New Jersey by eVenus are imputable to Fresenius Kabi and Jiangsu Hengrui because that location and those acts were instrumental in furtherance of a partnership among the Defendants to obtain FDA approval to market and subsequently commercialize eVenus's Proposed ANDA Products.

52. On information and belief, Fresenius Kabi knows and intends that eVenus's Proposed ANDA Products will be distributed and sold in New Jersey and will thereby displace sales of EXPAREL®, 133 mg/10 mL and 266 mg/20 mL (13.1 mg/mL), causing injury to Plaintiffs.

53. Venue is proper in this district for Fresenius Kabi pursuant to 28 U.S.C. § 1400(b).

THE EXPAREL® DRUG PRODUCT

54. Pacira Pharmaceuticals, Inc. is the holder of the New Drug Application (NDA) No. 022496, under which the FDA approved the commercial marketing of EXPAREL® (bupivacaine liposome injectable suspension) in two different dosage forms—266 mg/20 mL and 133 mg/10 mL (both 13.3 mg/mL)—on October 28, 2011, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). EXPAREL® is currently approved in patients 6 years of age and older for single dose infiltration into the surgical site to produce postsurgical analgesia and in adults as an interscalene brachial plexus nerve block to product postsurgical regional analgesia. Pacira distributes EXPAREL® in the United States in a 266 mg/20 mL (13.3 mg/mL) strength single-dose vial and a 133 mg/10 mL (13.3 mg/mL) strength single dose vial.

A true and correct copy of the current prescribing information for EXPAREL® is attached as Exhibit H (November 2023 Highlights of Prescribing Information).

55. EXPAREL® is a first-of-its-kind, single dose local anesthetic administered at the time of surgery to control pain and reduce or eliminate the use of opioids for acute postsurgical pain. The active ingredient in EXPAREL®, bupivacaine, is encapsulated in multivesicular liposomes (MVLs) allowing for gradual release of bupivacaine over time as the lipid membranes are absorbed, prolonging the action of bupivacaine. The administration of bupivacaine in an encapsulated MVL at the surgical site can control pain for several days following a surgery. The delivery mechanism of the drug and gradual release reduces or eliminates the use of highly addictive opioids for acute postsurgical pain. The delivery system also eliminates the need for catheters or pumps, decreasing cost. Because of at least these unique features, EXPAREL® has been viewed as a significant advance in the field of anesthesiology.

THE PATENTS-IN-SUIT

U.S. Patent No. 11,819,574

56. The ’574 patent, entitled “Manufacturing of Bupivacaine Multivesicular Liposomes,” was duly and legally issued on November 21, 2023, and names Jeffrey S. Hall, David J. Turnbull, John J. Grigsby, Jr., Soroush M. Ardekani, and Kathleen D. A. Los as the inventors. Ex. A (the ’574 patent).

57. Pacira Pharmaceuticals, Inc. is the owner and assignee of the ’574 patent and has the right to enforce the ’574 patent.

58. Since December 6, 2023, the ’574 patent has been listed in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book,” which provides notice concerning patents covering FDA-approved drugs.

59. The Orange Book lists the expiration of the ’574 patent as January 22, 2041.

60. The ’574 patent is directed to compositions of bupivacaine encapsulated MVLs with enhanced stability that unexpectedly resulted from new and improved commercial scale manufacturing processes for making bupivacaine encapsulated MVLs. The newly developed processes provide up to 5-fold increase in final product volume as compared to the prior methods for the manufacturing of EXPAREL®. Representative claim 2 (and claim 1 from which claim 2 depends) are reproduced below:

> 1. Batches comprising compositions of bupivacaine multivesicular liposomes (MVLs) prepared by a process, the process of preparing a batch comprising:
>
> a) mixing a first aqueous solution comprising phosphoric acid with a volatile water-immiscible solvent solution to form a first water-in-oil emulsion, wherein the volatile water-immiscible solvent solution comprises bupivacaine, 1,2,-dierucoylphosphadtidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3 phospho-rac-(1-glycerol) (DPPG), and at least one neutral lipid;
>
> b) mixing the first water-in-oil emulsion with a second aqueous solution to form a second water-in-oil-in-water emulsion, wherein the second aqueous solution comprises lysine;
>
> c) removing the volatile water-immiscible solvent from the second water-in-oil-in-water emulsion to form a first aqueous suspension of bupivacaine encapsulated MVLs having a first volume;
>
> d) reducing the first volume of the first aqueous suspension of bupivacaine encapsulated MVLs by microfiltration to provide a second aqueous suspension of bupivacaine encapsulated MVLs having a second volume;
>
> e) exchanging the aqueous supernatant of the second aqueous suspension with a saline solution by diafiltration to provide a third aqueous suspension of bupivacaine encapsulated MVLs having a third volume; and
>
> f) further reducing the third volume of the third aqueous suspension by microfiltration to provide a final aqueous suspension of bupivacaine encapsulated MVLs having a bupivacaine concentration from about 11.3 mg/mL to about 17.0 mg/mL;
>
> wherein each batch has a volume of about 100 L to about 250 L; and

wherein an average erucic acid concentration of at least three batches prepared by the process is about 105 µg/mL or less when measured after the compositions are stored at 25° C. for six months.

2. The batches of claim 1, wherein the average erucic acid concentration of the at least three batches is about 99 µg/mL or less when measured after the compositions are stored at 25º C. for six months.

61. On information and belief, upon approval of eVenus's ANDA, Defendants' conduct will satisfy the preamble of claim 1 by manufacturing batches comprising compositions of bupivacaine multivesicular liposomes (MVLs). On information and belief, Defendants will manufacture eVenus's Proposed ANDA Products according to the first and second emulsification steps of limitations (a)-(f) of claim 1. Further, on information and belief, Defendants will manufacture eVenus's Proposed ANDA Products "wherein each batch has a volume of about 100 L to about 250 L" and "wherein the average erucic acid concentration of at least three batches prepared by the process is about 105 µg/mL or less when measured after the compositions are stored at 25° C. for six months."

62. On information and belief, eVenus's Proposed ANDA Products will satisfy the limitation in claim 2 "wherein the average erucic acid concentration of the at least three batches is about 99µg/mL or less when measured after the compositions are stored at 25º C. for six months." Erucic acid is a degradation product that accumulates as the DEPC hydrolyzes and is a stability marker. The more erucic acid, the more degradation has occurred. The FDA required Pacira to submit stability data for EXPAREL® batches stored at 25º C for six months to simulate the product characteristics at the end of a two-year shelf life stored at room temperature. One of the unexpected properties of the claimed batches manufactured in 200L batch sizes is that the compositions have less erucic acid after being stored at 25º C for six months than do 45L batches. On information and belief, eVenus's Proposed ANDA Products will comprise of batches wherein

the average erucic acid concentration of at least three batches is about 99 µg/mL or less when measured after the compositions are stored at 25º C for six months. Claim 7 of the '495 patent and claim 7 of the '336 patent asserted in the First and Second Actions recite "wherein the erucic acid concentration in the composition is about 99 µg/mL or less after the composition is stored at 25º C. for six months." In the March eVenus Notice Letter, Defendants did not dispute that eVenus's Proposed ANDA Products satisfy the limitation. *See* Ex. F (March eVenus Notice Letter).

63. The '574 patent also claims methods for treating or ameliorating pain through the administration of the improved compositions of bupivacaine encapsulated MVLs embodied by EXPAREL®. Claims 23 (which depends from claim 1) and 24 are representative of the method claims. Each claim is reproduced below:

> 23. A method of treating or ameliorating pain in a subject in need thereof, comprising administering a composition of a batch of claim 1 to the subject.
>
> 24. The method of claim 23, wherein the administration is via local infiltration to a surgical site to provide postsurgical local analgesia.

64. EXPAREL® is indicated for use in patients aged 6 years and older for single-dose infiltration to produce postsurgical local analgesia. Ex. H at 1. As explained below, Defendants will include within the packaging of eVenus's Proposed ANDA Products, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs and encourages healthcare providers to infringe at least claims 23 and 24.

U.S. Patent No. 11,819,575

65. The '575 patent, entitled "Manufacturing of Bupivacaine Multivesicular Liposomes," was duly and legally issued on November 21, 2023, and names Jeffrey S. Hall,

David J. Turnbull, John J. Grigsby, Jr., Soroush M. Ardekani, and Kathleen D. A. Los as the inventors. Ex. B (the '575 patent).

66. Pacira Pharmaceuticals, Inc. is the owner and assignee of the '575 patent and has the right to enforce the '575 patent.

67. Since December 6, 2023, the '575 patent has been listed in the FDA's Orange Book.

68. The Orange Book lists the expiration of the '575 patent as January 22, 2041.

69. The '575 patent is directed to compositions of bupivacaine encapsulated MVLs with enhanced stability that unexpectedly resulted from new and improved commercial scale manufacturing processes for making bupivacaine encapsulated MVLs. The newly developed processes provide up to 5-folds increase in final product volume as compared to the prior methods used for the manufacturing of EXPAREL®. Representative claims 1 and 18 are reproduced below:

> 1. A composition of bupivacaine encapsulated multivesicular liposomes (MVLs), comprising:
>
> (a) bupivacaine residing inside a plurality of internal aqueous chambers of the MVLs separated by lipid membranes, wherein the lipid membranes comprise 1, 2-dieru-coylpho sphatidylcholine (DEPC), 1, 2-dip almitoyl-sn-glycero-3 phospho-rac-(l-glycerol) (DPPG), and at least one neutral lipid; and
>
> (b) an aqueous medium in which the bupivacaine encapsulated MVLs are suspended;
>
> (c) wherein an encapsulated lysine concentration in the bupivacaine encapsulated MVLs composition is about 0.03 mg/mL to about 0.08 mg/mL, and
>
> (d) wherein the erucic acid concentration in the composition is about 99 µg/mL or less when measured after the composition is stored at 25° C. for six months.
>
> 18. Batches comprising compositions of bupivacaine encapsulated multivesicular liposomes (MVLs), comprising:

> (a) bupivacaine residing inside a plurality of internal aqueous chambers of the MVLs separated by lipid membranes, wherein the lipid membranes comprise 1, 2-dierucoylphosphatidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3 phospho-rac-(l-glycerol) (DPPG), and at least one neutral lipid; and
>
> (b) an aqueous medium in which the bupivacaine encapsulated MVLs are suspended;
>
> (c) wherein the batches consistently comprise an encapsulated lysine concentration of about 0.03 mg/mL to about 0.08 mg/mL in the bupivacaine encapsulated MVLs compositions, and
>
> (d) wherein the erucic acid concentrations in the compositions of a plurality of batches are about 99 µg/mL or less when measured after the compositions are stored at 25° C. for six months.

70. On information and belief, upon approval of eVenus's ANDA, Defendants' conduct will satisfy the preamble of claim 1 by manufacturing a composition of bupivacaine multivesicular liposomes (MVLs). On information and belief, Defendants will manufacture eVenus's Proposed ANDA Products according to the first and second emulsification steps of limitations (a)-(b) of claim 1. Further, on information and belief, Defendants will manufacture eVenus's Proposed ANDA Products wherein an encapsulated lysine concentration in the bupivacaine encapsulated MVLs composition is about 0.03 mg/mL to about 0.08 mg/mL. Pacira's scaled-up manufacturing process for EXPAREL® surprisingly yielded MVL compositions with higher concentrations of internal lysine. Conventional wisdom teaches that it's desirable to have the lysine restricted to the aqueous solution outside the MVL particles to facilitate MVL particle formation during the second emulsion step. Due to inefficiencies in mixing large volumes during the second emulsion step, an unexpectedly higher amount of lysine becomes trapped inside the MVLs, conferring unexpected stability benefits. Further, on information and belief, Defendants will manufacture eVenus's Proposed ANDA Products wherein the erucic acid concentration in the composition is about 99 µg/mL or less when

measured after the composition is stored at 25° C. for six months. As stated above, erucic acid is a degradation product that accumulates as the DEPC hydrolyzes and is a stability marker. The more erucic acid, the more degradation has occurred. FDA required Pacira to submit stability data for EXPAREL® batches stored at 25º C for six months to simulate the product characteristics at the end of a two-year shelf life stored at room temperature. One of the unexpected properties of the claimed batches manufactured in 200L batch sizes is that the compositions have less erucic acid after being stored at 25º C for six months than 45L batches. On information and belief, batches of eVenus's Proposed ANDA Products will comprise an erucic acid concentration of less than about 99 µg/mL after the compositions are stored at 25º C for six months. Claim 7 of the '495 patent and claim 7 of the '336 patent asserted in the First and Second Actions recite "wherein the erucic acid concentration in the composition is about 99 µg/mL or less after the composition is stored at 25º C. for six months." In the March eVenus Notice Letter, Defendants did not dispute that eVenus's Proposed ANDA Products satisfy the limitation. *See* Ex. F (March eVenus Notice Letter).

71. On information and belief, for eVenus to obtain FDA approval of eVenus's Proposed ANDA Products, Defendants must prove that eVenus's Proposed ANDA Products are bioequivalent to EXPAREL®. For example, the March eVenus Notice Letter stated that the eVenus ANDA contains "any required bioavailability and/or bioequivalence data or information in order to obtain approval to engage in the commercial, manufacture, use or sale of bupivacaine liposome injectable suspension." Ex. F (March eVenus Notice Letter) at 1. On information and belief, eVenus's Proposed ANDA Products must satisfy the preamble and limitations (a)-(b) of claim 1 for eVenus's Proposed ANDA Products to be considered bioequivalent to EXPAREL®. The patents asserted in the First, Second, and Third Actions recite similar limitations to the

preamble and limitations (a)-(b) of claim 1 of the '575 patent. Tellingly, in the March eVenus Notice Letter, Defendants do not dispute that eVenus's Proposed ANDA Products satisfy those limitations.

72. On information and belief, upon approval of eVenus's ANDA, Defendants' conduct will satisfy the limitations of claim 18. On information and belief, Defendants will manufacture eVenus's Proposed ANDA Products according to the first and second emulsification steps of limitations (a)-(b) of claim 18. On information and belief, Defendants will manufacture eVenus's Proposed ANDA Products wherein an encapsulated lysine concentration in the bupivacaine encapsulated MVLs composition is about 0.03 mg/mL to about 0.08 mg/mL in the bupivacaine encapsulated MVLs compositions. Further, on information and belief, Defendants' conduct will satisfy limitation (d) of claim 18 whereby eVenus's Proposed ANDA Products will have a composition wherein the erucic acid concentrations in the compositions of a plurality of batches are about 99 µg/mL or less when measured after the compositions are stored at 25° C. for six months.

73. The '575 patent also claims methods for treating or ameliorating pain through the administration of the improved compositions of bupivacaine encapsulated MVLs embodied by EXPAREL®. Claims 27 (which depends from claim 1) and 28, are representative of the method claims. Each claim is reproduced below:

> 27. A method of treating or ameliorating pain in a subject in need thereof, comprising administering the composition of claim 1 to the subject.
>
> 28. The method of claim 27, wherein the administration is via local infiltration to a surgical site to provide postsurgical local analgesia.

74. EXPAREL® is indicated for use in patients aged 6 years and older for single-dose infiltration to produce postsurgical local analgesia. Ex. H at 1. As explained below, Defendants

will include within the packaging of eVenus's Proposed ANDA Products, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs and encourages healthcare providers to infringe at least claims 27 and 28.

DEFENDANTS' SUBMISSION OF EVENUS'S ANDA

75. On information and belief, Defendants have submitted or caused the submission of eVenus's ANDA No. 214348 to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of eVenus's Proposed ANDA Products, a purported generic version of EXPAREL®, prior to the expiration of the '574 and '575 patents.

76. eVenus served the March eVenus Notice Letter notifying Pacira of the submission of eVenus's ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of eVenus's Proposed ANDA Products prior to the expiration of the '574 and '575 patents.

77. In the March eVenus Notice Letter, eVenus also notified Pacira that, as part of its ANDA, eVenus had filed a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '574 and '575 patents.

78. On information and belief, eVenus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '574 and '575 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products.

COUNT I

(Infringement of the '574 Patent Under 35 U.S.C. § 271(e)(2))

79. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

80. Defendants submitted ANDA No. 214348 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products. By submitting the application, Defendants have committed an act of infringement of the '574 patent under 35 U.S.C. § 271(e)(2)(A).

81. The commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products will constitute an act of direct infringement of the '574 patent, either literally or under the doctrine of equivalents.

82. On information and belief, Defendants became aware of the '574 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using EXPAREL®. Defendants' service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the '574 patent.

83. On information and belief, Defendants knew or should have known that their commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus's Proposed ANDA Products, with its labeling, will actively induce the direct infringement of the '574 patent.

84. On information and belief, Defendants knew or should have known that eVenus's Proposed ANDA Products will be especially made or especially adapted for use in an infringement of the '574 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of their proposed labeling. On information and belief, Defendants' proposed labeling will encourage and instruct healthcare providers to administer eVenus's Proposed ANDA Products to produce postsurgical local analgesia via single-dose infiltration as a method to treat pain. And, on information and belief, Defendants knew or should have known that its commercial offering to sell, selling,

importing, or otherwise distributing of eVenus's Proposed ANDA Products will actively contribute to the direct infringement of the '574 patent.

85. Unless and until Defendants are enjoined from infringing the '574 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

86. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Defendants' ANDA No. 214348 be a date that is not earlier than the expiration date of the '574 patent.

COUNT II

(Infringement of the '575 Patent Under 35 U.S.C. § 271(e)(2))

87. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

88. Defendants submitted ANDA No. 214348 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products. By submitting the application, Defendants have committed an act of infringement of the '575 patent under 35 U.S.C. § 271(e)(2)(A).

89. The commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products will constitute an act of direct infringement of the '575 patent, either literally or under the doctrine of equivalents.

90. On information and belief, Defendants became aware of the '575 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using EXPAREL®. Defendants' service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the '575 patent.

91. On information and belief, Defendants knew or should have known that their commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or

distributing of eVenus's Proposed ANDA Products, with its labeling, will actively induce the direct infringement of the '575 patent.

92. On information and belief, Defendants knew or should have known that eVenus's Proposed ANDA Products will be especially made or especially adapted for use in an infringement of the '575 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of their proposed labeling. On information and belief, Defendants' proposed labeling will encourage and instruct healthcare providers to administer eVenus's Proposed ANDA Products to produce postsurgical local analgesia via single-dose infiltration as a method to treat pain. And, on information and belief, Defendants knew or should have known that its commercial offering to sell, selling, importing, or otherwise distributing of eVenus's Proposed ANDA Products will actively contribute to the direct infringement of the '575 patent.

93. Unless and until Defendants are enjoined from infringing the '575 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

94. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Defendants' ANDA No. 214348 be a date that is not earlier than the expiration date of the '575 patent.

COUNT III

(Declaratory Judgment of Infringement of the '574 Patent Under § 271(a))

95. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

96. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

97. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

98. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

99. Defendants' actions, including but not limited to, the development of eVenus's Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import eVenus's Proposed ANDA Products.

100. On information and belief, eVenus's Proposed ANDA Products practice all limitations of at least claim 2 of the '574 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of eVenus's Proposed ANDA Products will constitute an act of infringement of the '574 patent.

101. The commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

102. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products before patent expiration will constitute direct infringement of at least claim 2 of the '574 patent under 35 U.S.C. § 271(a).

COUNT IV

(Declaratory Judgment of Infringement of the '575 Patent Under § 271(a))

103. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

104. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

106. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

107. Defendants' actions, including but not limited to, the development of eVenus's Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import eVenus's Proposed ANDA Products.

108. On information and belief, eVenus's Proposed ANDA Products practice all limitations of at least claims 1 and 18 of the '575 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of eVenus's Proposed ANDA Products will constitute an act of infringement of the '575 patent.

109. The commercial manufacture, importation, use, sale, or offer for sale of eVenus's Proposed ANDA Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

110. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products before patent expiration will constitute direct infringement of at least claims 1 and 18 of the '575 patent under 35 U.S.C. § 271(a).

COUNT V

(Declaratory Judgment of Infringement of the '574 Patent Under 35 U.S.C. § 271(b))

111. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

112. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

113. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

114. Defendants' service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the '574 patent.

115. On information and belief, Defendants became aware of the '574 patent when it was issued by the Patent Office on November 21, 2023, and/or listed in the publicly available Orange Book on December 6, 2023, as covering methods of using EXPAREL®.

116. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, importation, or other promotion and/or distribution of eVenus's Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

117. Defendants' actions, including but not limited to, the development of eVenus's Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United

States, including in the District of New Jersey, to manufacture, sell, offer to sell, import, or otherwise promote eVenus's Proposed ANDA Products.

118. On information and belief, healthcare providers treating or ameliorating a patient's pain using eVenus's Proposed ANDA Products within the United States according to the instructions in the products' labeling will directly infringe at least claims 23 and 24 of the '574 patent, either literally or under the doctrine of equivalents.

119. On information and belief, Defendants possess specific intent to instruct and encourage direct infringement of at least claims 23 and 24 of the '574 patent, including because Defendants' labeling for eVenus's Proposed ANDA Products instructs users to use the patented compositions and to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because EXPAREL® and eVenus's Proposed ANDA Products have no substantial non-infringing uses, Defendants intend for the use of its generic version of EXPAREL® to directly infringe at least claims 23 and 24 of the '574 patent.

120. On information and belief, upon awareness of the '574 patent, Defendants either actually knew of the potential for infringement of at least claims 23 and 24 of the '574 patent, or were willfully blind as to the potential for that infringement at least because Defendants provide instructions for infringement of at least claims 23 and 24 of the '574 patent in its proposed product labeling.

121. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus's Proposed ANDA Products, with its labeling, will constitute an act of active inducement of infringement of at least claims 23 and 24 of the '574 patent.

122. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus's Proposed ANDA Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

123. Plaintiffs are entitled to a declaratory judgment that the future making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus's Proposed ANDA Products before patent expiration will constitute active inducement of infringement of at least claims 23 and 24 of the '574 patent under 35 U.S.C. § 271(b).

124. Unless and until Defendants are enjoined from infringing the '574 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VI

(Declaratory Judgment of Infringement of the '575 Patent Under 35 U.S.C. § 271(b))

125. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

126. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

127. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

128. Defendants' service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the '575 patent.

129. On information and belief, Defendants became aware of the '575 patent when it was issued by the Patent Office on November 21, 2023, and/or listed in the publicly available Orange Book on December 6, 2023, as covering methods of using EXPAREL®.

130. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, importation, or other promotion and/or distribution of eVenus's Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

131. Defendants' actions, including but not limited to, the development of eVenus's Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, import, or otherwise promote eVenus's Proposed ANDA Products.

132. On information and belief, healthcare providers treating or ameliorating a patient's pain using eVenus's Proposed ANDA Products within the United States according to the instructions in the products' labeling will directly infringe at least claims 27 and 28 of the '575 patent, either literally or under the doctrine of equivalents.

133. On information and belief, Defendants possess specific intent to instruct and encourage direct infringement of at least claims 27 and 28 of the '575 patent, including because Defendants' labeling for eVenus's Proposed ANDA Products instructs users to use the patented compositions and to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because EXPAREL® and eVenus's Proposed ANDA Products have no substantial non-infringing uses, Defendants intend for the use of its generic version of EXPAREL® to directly infringe at least claims 27 and 28 of the '575 patent.

134. On information and belief, upon awareness of the '575 patent, Defendants either actually knew of the potential for infringement of at least claims 27 and 28 of the '575 patent or were willfully blind as to the potential for that infringement at least because Defendants provide

instructions for infringement of at least claims 27 and 28 of the ’575 patent in its proposed product labeling.

135. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus’s Proposed ANDA Products, with its labeling, will constitute an act of active inducement of infringement of at least claims 27 and 28 of the ’575 patent.

136. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus’s Proposed ANDA Products in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs, for which damages are inadequate.

137. Plaintiffs are entitled to a declaratory judgment that the future making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of eVenus’s Proposed ANDA Products before patent expiration will constitute active inducement of infringement of at least claims 27 and 28 of the ’575 patent under 35 U.S.C. § 271(b).

138. Unless and until Defendants are enjoined from infringing the ’575 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VII

(Declaratory Judgment of Infringement of the ’574 Patent Under 35 U.S.C. § 271(c))

139. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

140. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

141. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

142. Defendants' service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the '574 patent.

143. On information and belief, Defendants became aware of the '574 patent when it was issued by the Patent Office on November 21, 2023, and/or listed in the publicly available Orange Book on December 6, 2023, as covering EXPAREL®.

144. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, importation, and/or other distribution of eVenus's Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

145. Defendants' actions, including but not limited to, the development of eVenus's Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to sell, offer to sell, import and/or otherwise distribute eVenus's Proposed ANDA Products.

146. On information and belief, Defendants will include within the packaging of its eVenus's Proposed ANDA Products, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs and encourages healthcare providers to use the Proposed ANDA Products to perform the methods of at least claims 23 and 24 of the '574 patent.

147. On information and belief, healthcare providers administering eVenus's Proposed ANDA Products to patients to treat or ameliorate pain within the United States according to the instructions in the product's labeling will directly infringe at least claims 23 and 24 of the '574 patent, either literally or under the doctrine of equivalents.

148. On information and belief, Defendants know that eVenus's Proposed ANDA Products are a material part of the methods of at least claims 23 and 24 of the '574 patent, including as evidenced in the contents of its proposed label. On information and belief, eVenus's Proposed ANDA Products were especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 23 and 24 of the '574 patent, as evidenced in the contents of its proposed labeling. On information and belief, eVenus's Proposed ANDA Products are not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for eVenus's Proposed ANDA Products other than treating patients pursuant to FDA's approval for such products.

149. Thus, on information and belief, Defendants will contribute to the infringement of at least claims 23 and 24 of the '574 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing eVenus's Proposed ANDA Products, which are material for use in practicing the methods of at least claims 23 and 24 of the '574 patent.

150. The commercial offering to sell, selling, importing, and/or other distribution of eVenus's Proposed ANDA Products for use and for practicing the patented method in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

151. Plaintiffs are entitled to a declaratory judgment that the future offer for sale, sale, importation, and/or other distribution of eVenus's Proposed ANDA Products before expiration of the '574 patent will constitute contributory infringement of the claims of the '574 patent under 35 U.S.C. § 271(c).

152. Unless and until Defendants are enjoined from infringing the ’574 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VIII

(Declaratory Judgment of Infringement of the ’575 Patent Under 35 U.S.C. § 271(c))

153. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

154. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

155. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

156. Defendants’ service of the March eVenus Notice Letter reflects that Defendants had actual knowledge of the ’575 patent.

157. On information and belief, Defendants became aware of the ’575 patent when it was issued by the Patent Office on November 21, 2023, and/or listed in the publicly available Orange Book on December 6, 2023, as covering EXPAREL®.

158. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, importation, and/or other distribution of eVenus’s Proposed ANDA Products immediately and imminently upon FDA approval of ANDA No. 214348.

159. Defendants’ actions, including but not limited to, the development of eVenus’s Proposed ANDA Products, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Defendants have made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to sell, offer to sell, import, and/or otherwise distribute eVenus’s Proposed ANDA Products.

160. On information and belief, Defendants will include within the packaging of its eVenus's Proposed ANDA Products, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs and encourages healthcare providers to use the Proposed ANDA Products to perform the methods of at least claims 27 and 28 of the '575 patent.

161. On information and belief, healthcare providers administering eVenus's Proposed ANDA Products to patients to treat or ameliorate pain within the United States according to the instructions in the product's labeling will directly infringe at least claims 27 and 28 of the '575 patent, either literally or under the doctrine of equivalents.

162. On information and belief, Defendants know that eVenus's Proposed ANDA Products are a material part of the methods of at least claims 27 and 28 of the '575 patent, including as evidenced in the contents of its proposed label. On information and belief, eVenus's Proposed ANDA Products were especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 27 and 28 of the '575 patent, as evidenced in the contents of its proposed labeling. On information and belief, eVenus's Proposed ANDA Products are not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for eVenus's Proposed ANDA Products other than treating patients pursuant to FDA's approval for such products.

163. Thus, on information and belief, Defendants will contribute to the infringement of at least claims 27 and 28 of the '575 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing eVenus's Proposed ANDA Products,

which are material for use in practicing the methods of at least claims 27 and 28 of the '575 patent.

164. The commercial offering to sell, selling, importing, and/or other distribution of eVenus's Proposed ANDA Products for use and for practicing the patented method in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

165. Plaintiffs are entitled to a declaratory judgment that the future offer for sale, sale, importation, and/or other distribution of eVenus's Proposed ANDA Products before expiration of the '575 patent will constitute contributory infringement of the claims of the '575 patent under 35 U.S.C. § 271(c).

166. Unless and until Defendants are enjoined from infringing the '575 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

DEMAND FOR JURY TRIAL

167. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable to a jury. Specifically, Plaintiffs demand a jury trial in the event that there is a launch at risk and damages are in issue.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter judgment in their favor against Defendants:

A. That judgment be issued that Defendants have infringed the '574 and '575 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA 214348 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of eVenus's Proposed ANDA Products will constitute an act of infringement of the '574 and '575 patents;

B. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date

of any FDA approval of Defendants' ANDA No. 214348 shall be a date which is not earlier than the expiration date of the '574 and '575 patents, as extended by any applicable period of exclusivity;

C. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the '574 and '575 patents;

D. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of eVenus's Proposed ANDA Products before expiration of the '574 and '575 patents do and will infringe the '574 and '575 patents;

E. That an order be issued preliminarily and permanently enjoining Defendants and their affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, or acting on their behalf, from infringing the '574 and '575 patents;

F. If Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of eVenus's Proposed ANDA Products disclosed in ANDA No. 214348 prior to the expiration of the '574 and '575 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found and/or assessed together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

G. That this case be declared an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

H. That an accounting be performed of Defendants' infringing activities not presented at trial and an award by the Court of additional damages for any such infringing

sales; and

I. That this Court award such other and further relief as it may deem just and proper.

Dated: May 20, 2024

Respectfully submitted,

By: */s/ Cynthia S. Betz*

Cynthia S. Betz
Mark M. Makhail
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Phone: (973) 622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Thomas P. Scrivo
O'TOOLE SCRIVO, LLC
14 Village Park Road
Cedar Grove, NJ 07009
Phone: (973) 239-5700
tscrivo@oslaw.com

Corrin N. Drakulich (*pro hac vice* forthcoming)
FISH & RICHARDSON P.C.
1180 Peachtree Street NE, 21st Floor
Atlanta, GA 30309
Phone: (404) 892-5005
drakulich@fr.com

Michael T. Zoppo
FISH & RICHARDSON P.C.
7 Times Square, 20th Floor
New York, N.Y. 10038
Telephone: (212) 765-5070
zoppo@fr.com

Deanna J. Reichel (*pro hac vice* forthcoming)
Ryan V. Petty, Ph.D. (*pro hac vice* forthcoming)
FISH & RICHARDSON P.C.

60 South 6th Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
reichel@fr.com
petty@fr.com

Karrie Wheatley, Ph.D. (*pro hac vice* forthcoming)
Jacqueline T. Moran, Ph.D. (*pro hac vice* forthcoming)
FISH & RICHARDSON P.C.
909 Fannin Street, Suite 2100
Houston, TX 77010
Telephone: (713) 654-5300
wheatley@fr.com
jtmoran@fr.com

Attorneys for Plaintiffs
PACIRA PHARMACEUTICALS, INC., and
PACIRA BIOSCIENCES, INC.

LOCAL RULE 11.2 CERTIFICATION

The ANDA and Defendants' Proposed ANDA Products are the subject of three patent litigations in this Court: *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:23-cv-02367, *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:21-cv-19829-MCA-JRA, and *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:22-cv-00718. These matters involve the same parties as the instant suit. *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc,* No. 2:21-cv-19829-MCA-JRA, and *Pacira Pharmaceuticals, Inc. v. eVenus Laboratories, Inc.*, No. 2:22-cv-00718 are consolidated under No. 2:21-19829-MCA-JRA.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 20, 2024 By: */s/ Cynthia S. Betz*