IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC. Plaintiffs v. FRESENIUS KABI USA, LLC and JIANGSU HENGRUI PHARMACEUTICALS CO., LTD. Defendants.	Civil Action No. 1:24-cv-12416 **COMPLAINT FOR INFRINGEMENT OF U.S. PATENT NO. 12,156,940**

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 Fresenius Kabi USA, LLC ("Fresenius Kabi") and Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Jiangsu Hengrui") (collectively, "Defendants"). This lawsuit concerns Fresenius Kabi and Jiangsu Hengrui's infringement of Pacira's recently-issued patent from an entirely new patent family on EXPAREL®, Pacira's blockbuster, non-opiate painkiller used to relieve post-surgical pain and spare patients from opioid addiction. This recently-issued patent is directed to the production of multivesicular liposomes (MVLs) that comprise EXPAREL® by improving the metric for evaluating *in vitro* extended-release. That metric is referred to as "IVRA"—*in vitro* release assay. The improvement yielded by Pacira's claimed invention is notable because that extended-release characteristic is why EXPAREL® spares patients from opioids, and failure to meet Pacira's IVRA release specification—which FDA requires every batch to pass—is the primary cause of batch rejection.

Pacira alleges as follows.

NATURE OF ACTION

1. 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); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Defendants' submission of an ANDA to FDA seeking regulatory 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))[1] prior to the expiration of U.S. Patent No. 12,156,940 (the "'940 patent"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

2. 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.

3. 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.

4. 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 in this District 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

[1] Hereinafter, "Jiangsu Hengrui's Proposed ANDA Products."

belief, Fresenius Kabi has been licensed to commercialize Jiangsu Hengrui's Proposed ANDA Products in the United States, including in Illinois, since FDA approved Jiangsu Hengrui's ANDA.

5. 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. Jiangsu 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 Jiangsu Hengrui's Proposed ANDA Products.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

6. 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.

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

8. 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.

Personal Jurisdiction and Venue

9. This Court has personal jurisdiction over Fresenius Kabi, because Fresenius Kabi has its primary place of business in Illinois, in this District, at Three Corporate Drive, Lake Zurich, Illinois 60047.

10. Fresenius Kabi is also subject to personal jurisdiction in Illinois because Fresenius Kabi has purposely availed itself of the benefits and protections of Illinois's laws such that it should reasonably anticipate being sued in this Court.

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

12. On information and belief, Fresenius Kabi is registered to do business in Illinois under File No. 02387301.

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

14. 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 Illinois.

15. On information and belief, Fresenius Kabi derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in Illinois.

16. 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 Illinois.

17. On information and belief, Fresenius Kabi has been and is engaging in activities directed toward infringement of the '940 patent, including by acting in concert with Jiangsu Hengrui with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of Jiangsu Hengrui's Proposed ANDA Products before expiration of the '940 patent.

18. On information and belief, Fresenius Kabi and Jiangsu Hengrui entered into a license agreement (the "Agreement") to obtain FDA approval to market and subsequently commercialize Jiangsu Hengrui's Proposed ANDA Products throughout the United States, including in Illinois.

19. On information and belief, Fresenius Kabi intends to engage in importing, marketing, selling, distributing, and/or using Jiangsu Hengrui's Proposed ANDA Products before expiration of the '940 patent throughout the United States, including in Illinois.

20. On information and belief, Fresenius Kabi intends to take advantage of its established channels of distribution in Illinois for the sale of Jiangsu Hengrui's Proposed ANDA Products.

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

22. Venue is proper in this District as to Fresenius Kabi pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Fresenius Kabi has a regular and established place of business in this District and because, on information and belief, Fresenius Kabi has committed or aided, abetted, contributed to, and/or participated in the commission of acts of infringement of the '940 patent that will lead to foreseeable harm and injury to Pacira by preparing or assisting in preparing Jiangsu Hengrui's ANDA in this District and/or with the intention of seeking to market Jiangsu Hengrui's Proposed ANDA Products nationwide, including within this District.

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

24. On information and belief, Jiangsu Hengrui has had persistent and continuous contacts with Illinois, including developing and marketing pharmaceutical products that are sold in Illinois and selling pharmaceutical products in Illinois.

25. On information and belief, Jiangsu Hengrui, 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 Illinois.

26. On information and belief, Jiangsu Hengrui derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in Illinois.

27. On information and belief, Jiangsu Hengrui, 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 Illinois.

28. 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 Illinois, and therefore transacts business within Illinois related to Pacira's claims and/or has engaged in systematic and continuous business with contacts within Illinois.

29. On information and belief, Fresenius Kabi and Jiangsu Hengrui entered into the Agreement to obtain FDA approval to market and subsequently commercialize Jiangsu Hengrui's Proposed ANDA Products throughout the United Sates, including in Illinois.

30. On information and belief, Jiangsu Hengrui has been and is engaging in activities directed toward infringement of the '940 patent by, among other things, preparing and submitting the Jiangsu Hengrui DMF and acting in concert with Fresenius Kabi in the preparation and submission of Jiangsu Hengrui's ANDA seeking FDA regulatory approval to market Jiangsu Hengrui's Proposed ANDA Products throughout the United States, including in Illinois. On information and belief, Jiangsu Hengrui will manufacture the API for Jiangsu Hengrui's Proposed ANDA Products.

31. On information and belief, Fresenius Kabi acts for the benefit of Jiangsu Hengrui with respect to Jiangsu Hengrui's Proposed ANDA Products.

32. On information and belief, Jiangsu Hengrui intends to take advantage of Fresenius Kabi's established channels of distribution in Illinois for the sale of Jiangsu Hengrui's Proposed ANDA Products.

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

34. On information and belief, Jiangsu Hengrui knows and intends that Jiangsu Hengrui's Proposed ANDA Products will be distributed and sold in Illinois and will thereby displace sales of EXPAREL®, 133 mg/10 mL and 266 mg/20 mL (13.1 mg/mL), causing injury to Plaintiffs.

35. On information and belief, Jiangsu Hengrui intends to and will directly benefit, in a significant manner, from the sale of the Jiangsu Hengrui Proposed ANDA Products in the United States, including in Illinois.

36. On information and belief, Jiangsu Hengrui prepared, created, approved, and/or assembled documentation in support of Jiangsu Hengrui's ANDA. On information and belief, Jiangsu Hengrui directed its wholly-owned U.S. subsidiary, eVenus Pharmaceuticals Laboratories Inc. ("eVenus"), to act as its agent between FDA and Jiangsu Hengrui during the regulatory process involving the submission of an ANDA seeking regulatory approval to commercially manufacture, use, offer for sale, sell, and/or import proposed generic versions of EXPAREL®.

37. On information and belief, eVenus exists solely to obtain U.S. regulatory approval for products using Jiangsu Hengrui's APIs and to further Jiangsu Hengrui's business objectives. Indeed, eVenus's website states that it is "a wholly owned subsidiary of Jiangsu Hengrui

Medicine Co., Ltd.," that it "was established in the United States in 2009," and that its business "is focused on filing regulatory applications with the US FDA."

38. On information and belief, eVenus is a small company that is not directly involved with drug development, manufacturing, or sales. On information and belief, eVenus has only one office on one floor of an office building and has about seven employees.

39. Venue is proper in this District as to 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 District.

40. 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 Hengrui is a foreign company organized and existing under the laws of China, with a principal place of business in Lianyungang, Jiangsu, China.

41. 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, preparing, submitting, and/or causing to be submitted Jiangsu Hengrui's ANDA to FDA, 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 Illinois, such that this Court's exercise of jurisdiction over Jiangsu Hengrui satisfies due process.

42. Litigation in the Northern District of Illinois 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.

THE EXPAREL® DRUG PRODUCT

43. Pacira Pharmaceuticals, Inc. is the holder of the New Drug Application (NDA) No. 022496, under which 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 product for postsurgical regional analgesia. A true and correct copy of the current prescribing information for EXPAREL® is attached as Exhibit A (November 2023 Highlights of Prescribing Information).

44. 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. 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. The administration of bupivacaine in an encapsulated MVL at the surgical site can control pain for several days following a surgery.

45. Because EXPAREL® provides lasting pain relief through the release of bupivacaine over a period of time, the extended release stability profile of each batch is critical. For

EXPAREL® to meet the high standards of quality set out in the NDA and to maintain a long shelf life, EXPAREL® must have a consistent rate of release even after long-term storage.

46. EXPAREL® is considered to be a significant advance in the field of anesthesiology for many reasons. For example, the gradual release delivery mechanism of bupivacaine in EXPAREL® reduces or eliminates the use of highly addictive opioids for acute postsurgical pain, especially in the most challenging 48 hours following surgery. In addition, the delivery system of EXPAREL® also eliminates the need for catheters or pumps, decreasing costs.

THE PATENT-IN-SUIT

U.S. Patent No. 12,156,940

47. The ’940 patent, entitled “Manufacturing of Bupivacaine Multivesicular Liposomes,” was duly and legally issued on December 3, 2024, and names Eran Levy, Jeffrey S. Hall, and John J. Grigsby Jr. as the inventors. A true and correct copy of the ’940 patent is attached as Exhibit B.

48. Pacira Pharmaceuticals, Inc. is the owner and assignee of the ’940 patent and has the right to enforce the ’940 patent.

49. Since December 3, 2024, the ’940 patent has been listed in 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.

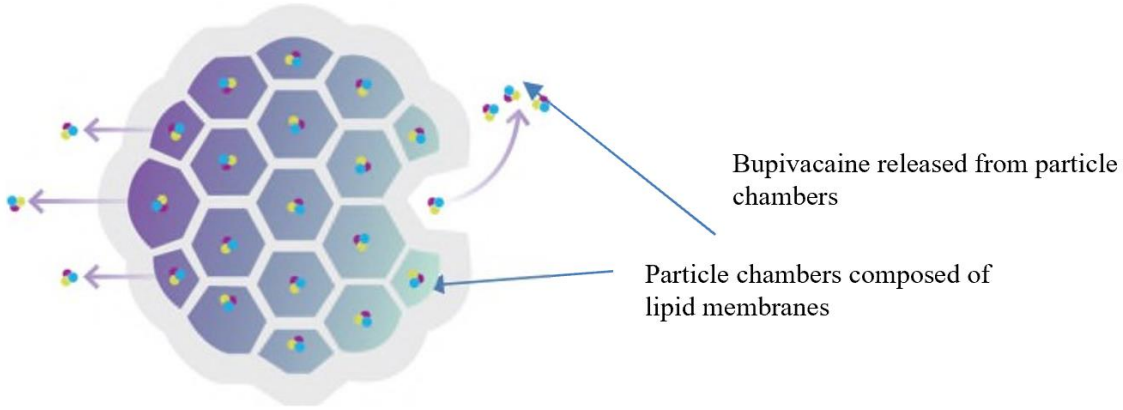
50. The Orange Book lists the expiration of the ’940 patent as July 2, 2044.

51. The ’940 patent is directed to a new and improved manufacturing process for EXPAREL® that leads to improved release characteristics. 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 delivery mechanism of the drug and gradual release over several days reduces or eliminates the use of highly addictive opioids for acute postsurgical pain. This extended-release characteristic—which allows patients to cope with the most challenging 48 hours following surgery without opioids—is a significant advantage of EXPAREL®, and a reason that it has been viewed as a significant advance in the field.

52. EXPAREL® is a complex product to manufacture. It is not a pill, nor a simple drug-containing solution. Rather, EXPAREL® is an injectable suspension, consisting of millions of microscopic, spherical MVLs. Each MVL particle comprises tens of thousands of chambers which contain the API drug (bupivacaine). Following administration to a patient, the particle chambers begin to slowly release the API drug through a complex rearrangement process. This takes place over a period of days.

53. Shown below is a cross-sectional diagram of an MVL, showing how each individual vesicle contains and releases bupivacaine:



54. MVL drug products like EXPAREL® are challenging to make because they are unstable during the manufacturing process. The EXPAREL® manufacturing process is complex and involves multiple emulsion steps that must be performed under precisely controlled conditions.

55. Given these manufacturing complexities and the complex nature of the drug itself, EXPAREL® is subject to batch-by-batch testing to ensure consistency and quality as provided in the NDA. One of those tests is the *in vitro* release assay ("IVRA"). The IVRA test examines the extended-release characteristic—the essential feature of EXPAREL®. Failure of the IVRA test is the most common reason why EXPAREL® batches fail and are rejected. Improvement in IVRA outcomes increases EXPAREL® drug quality, manufacturing yield, and consistency.

56. The new process described in the '940 patent can provide larger batch sizes with an average yield of 82%—a 37% increase from a prior process. The new process can also produce EXPAREL® with an improved *in vitro* release stability profile compared to the products made by prior processes.

57. In one study, five batches of EXPAREL® produced by an embodiment of the new process were stored at 5°C for about 12 months after the batch manufacture date. An IVRA test was performed at 0 months, about 3 months, about 6 months, about 9 months, and about 12 months. The average rates of change in cumulative percentage release of bupivacaine at 24 hours and 48 hours were compared to that of batches of EXPAREL® produced by two older processes. The results are summarized in Table 1 of the '940 patent.

Table 1. Average rate of change in % bupivacaine release comparison

Sample	**24-hour**	**48-hour**
Batch Nos. 1-5 average	0.32%/month	0.02%/month
45 L batches average	-0.41%/month	-0.38%/month
UK 200 L batches	-0.20%/month	-0.33%/month

58. Figure 3A of the '940 patent is a line chart illustrating the average rate of change in cumulative percentage release of bupivacaine at the 24-hour time point as a function of time over 12 months, comparing the batch samples produced by the new process with the batch

samples produced by the two older processes. Figure 3B of the '940 patent is a line chart illustrating the average rate of change in cumulative percentage release of bupivacaine at the 48-hour time point as a function of time over 12 months, comparing batch samples produced by the new process with batch samples manufactured by the two older processes.

Figure 3A

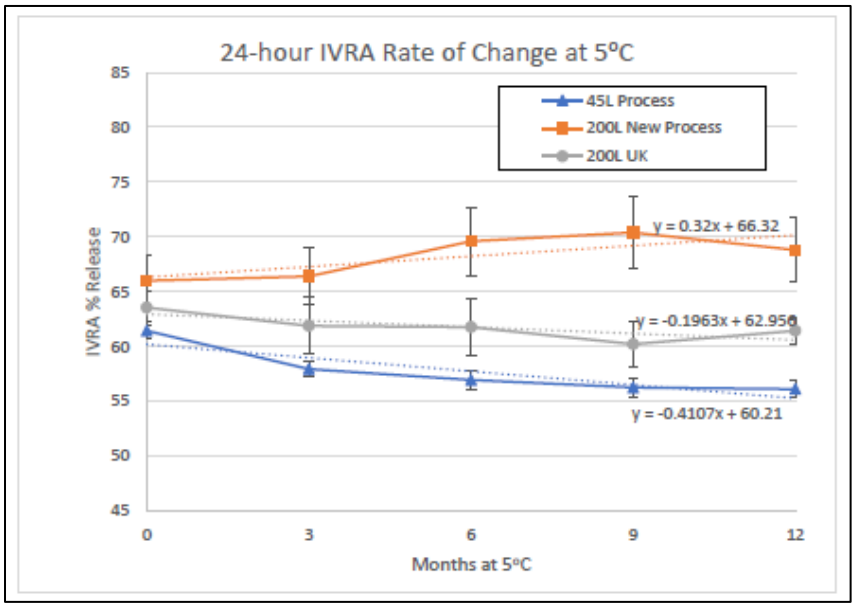
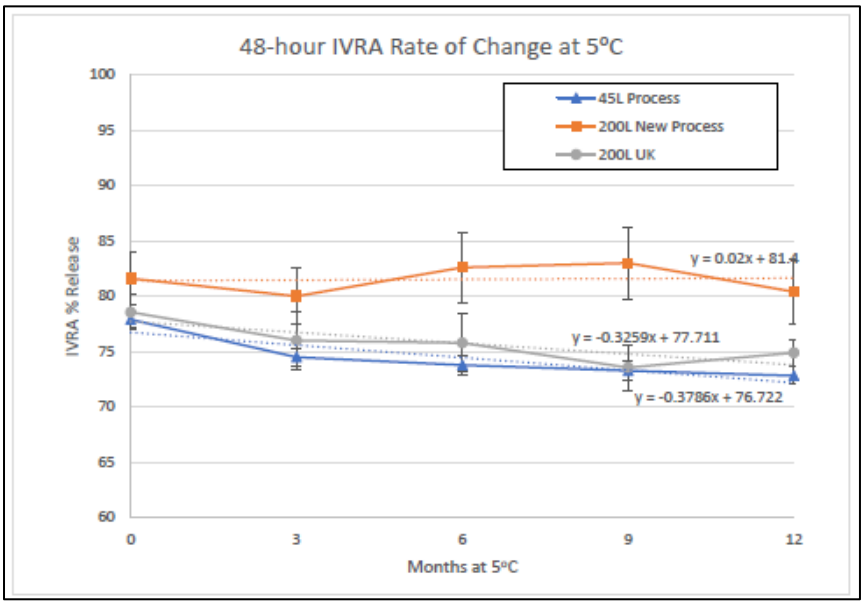


Figure 3B



59. Figures 3A and 3B indicate that the batches generated by the new process have improved IVRA stability profiles as compared to those produced by the older processes. The slope lines for the batches generated by the new process are either flat (48-hour) or trend slightly upward (24-hour). In contrast, the slope lines for the batches generated by the older processes trend downward at both the 24-hour and 48-hour time points. The flatter the trend line illustrating the rate of change in the cumulative percentage release of bupivacaine in the first 12 months, the more likely that the product will meet the IVRA specification during the entire 24 months. Furthermore, a slope line that trends upwards in the first 12 months can also compensate for the expected decrease in the percentage release in the second 12 months. Therefore, the EXPAREL® batches made from the new process of the '940 patent are much more likely to meet the IVRA specification during the entire shelf life of the product.

60. Representative claim 1 is reproduced below:

> 1. Batches comprising compositions of bupivacaine encapsulated multivesicular liposomes (MVLs), the composition comprising:
>
> bupivacaine residing inside a plurality of internal aqueous chambers of MVLs separated by lipid membranes, wherein the lipid membranes comprise 1, 2-dierucoylphosphatidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3-phospho-rac-(1-glycerol) (DPPG) or a salt thereof, cholesterol, and tricaprylin; and
>
> an aqueous medium in which the bupivacaine encapsulated MVLs are suspended, wherein the aqueous medium also comprises unencapsulated bupivacaine;
>
> the total bupivacaine concentration in the composition is from 12 mg/mL to 17 mg/mL;
>
> wherein the batches are manufactured within a period of six months, and each of the batches has a volume of about 100 liters to about 300 liters;
>
> wherein each batch has a cumulative percentage release of bupivacaine from 46% to 71% at a 24-hour time point, measured from two to six aliquots of each batch using a rotator-facilitated in vitro release assay for at least 48 hours, after storage of the aliquots

> of each batch at 2°C. to 8°C. for about 12 months from batch manufacture date; and
>
> wherein 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.

61. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products meet all the limitations of claim 1. On information and belief, Defendants' conduct will satisfy the preamble of claim 1 by manufacturing batches comprising compositions of bupivacaine multivesicular liposomes (MVLs). On information and belief, batches of Defendants' Proposed ANDA Products comprise compositions of bupivacaine encapsulated MVL products wherein the composition contains the claimed components and properties. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products comprise compositions comprising bupivacaine residing inside a plurality of internal aqueous chambers of MVLs separated by lipid membranes, wherein the lipid membranes comprise 1, 2-dierucoylphosphatidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3-phospho-rac-(1-glycerol) (DPPG) or a salt thereof, cholesterol, and tricaprylin. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products comprise compositions comprising an aqueous medium in which the bupivacaine encapsulated MVLs are suspended, wherein the aqueous medium also comprises unencapsulated bupivacaine. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products comprise compositions where the total bupivacaine concentration in the composition is from 12 mg/mL to 17 mg/mL. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products comprise compositions where the batches are manufactured within a period of six months, and each of the batches has a volume of about 100 liters to about 300 liters. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products have a cumulative percentage

release of bupivacaine from 46% to 71% at a 24-hour time point, measured from two to six aliquots of each batch using a rotator-facilitated in vitro release assay for at least 48 hours, after storage of the aliquots of each batch at 2°C to 8°C for about 12 months from batch manufacture date. On information and belief, batches of Jiangsu Hengrui's Proposed ANDA Products have an average rate of change in the cumulative percentage release of bupivacaine of the batches at the 24-hour time point that 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.

DEFENDANTS' SUBMISSION OF JIANGSU HENGRUI'S ANDA

62. On information and belief, Defendants have submitted or caused the submission of Jiangsu Hengrui's ANDA No. 214348 to FDA under 21 U.S.C. § 355(j) and have obtained approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Jiangsu Hengrui's Proposed ANDA Products, a purported generic version of EXPAREL®, prior to the expiration of the '940 patent. [2]

COUNT I

(Infringement of the '940 Patent Under 35 U.S.C. § 271(e)(2))

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

64. Defendants submitted ANDA No. 214348 to FDA under section 505(j) of the FDCA and have obtained approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Jiangsu Hengrui's Proposed ANDA Products. By submitting the application, Defendants have committed an act of infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

[2] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=214348# (last visited December 3, 2024).

65. The commercial manufacture, importation, use, sale, or offer for sale of Jiangsu Hengrui's Proposed ANDA Products will constitute an act of direct infringement of the '940 patent, either literally or under the doctrine of equivalents.

66. On information and belief, Defendants became aware of the '940 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®.

67. Unless and until Defendants are enjoined from infringing the '940 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

68. 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 '940 patent.

COUNT II

(Declaratory Judgment of Infringement of the '940 Patent Under § 271(a))

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

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

71. 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.

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

73. Defendants' actions, including without limitation the development of Jiangsu Hengrui's Proposed ANDA Products and the filing of an ANDA with a Paragraph IV Certification, reliably foreshadow that Defendants have made and will continue to make

substantial preparation in the United States, including in the Northern District of Illinois, to manufacture, sell, offer to sell, and/or import Jiangsu Hengrui's Proposed ANDA Products.

74. On information and belief, Jiangsu Hengrui's Proposed ANDA Products practice all limitations of at least claim 1 of the '940 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 Jiangsu Hengrui's Proposed ANDA Products will constitute an act of infringement of the '940 patent.

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

76. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of Jiangsu Hengrui's Proposed ANDA Products before expiration of the '940 patent will constitute direct infringement of at least claim 1 of the '940 patent under 35 U.S.C. § 271(a).

DEMAND FOR JURY TRIAL

77. 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 '940 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 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 Jiangsu Hengrui's Proposed ANDA Products will constitute an act of infringement of the '940 patent;

B. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA's approval of Defendants' ANDA No. 214348 shall be a date which is not earlier than the expiration date of the '940 patent, 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 the '940 patent;

D. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of Jiangsu Hengrui's Proposed ANDA Products before expiration of the '940 patent does and will infringe the '940 patent;

E. That an order be issued preliminarily and permanently enjoining Defendants, their affiliates, subsidiaries, officers, agents, employees, and attorneys, and all persons in active concert or participation with any of them or acting on their behalf from infringing the '940 patent;

F. If Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of Jiangsu Hengrui's Proposed ANDA Products disclosed in ANDA No. 214348 prior to the expiration of the '940 patent, 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: December 3, 2024

Respectfully submitted,

By: */s/ Louis E. Fogel*

Louis E. Fogel (6281401)
FISH & RICHARDSON P.C.
444 West Lake Street, Suite 1700
Chicago, IL 60606
Phone: (612) 335-5070
fogel@fr.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 (*pro hac vice* forthcoming)
FISH & RICHARDSON P.C.
7 Times Square, 20th Floor
New York, N.Y. 10038
Telephone: (212) 765-5070
zoppo@fr.com

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