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., Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pacira Pharmaceuticals, Inc. and Pacira BioSciences, Inc. (collectively "Pacira" or "Plaintiffs"), by their attorneys, bring this complaint against Defendants eVenus Pharmaceuticals Laboratories Inc. ("eVenus") and Jiangsu Hengrui Medicine Co. Ltd., ("Jiangsu Hengrui") (collectively, "Defendants"), and hereby allege as follows:

NATURE OF THE 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"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Defendants' submission of an Abbreviated New Drug

Application ("ANDA") to the U.S. Food and Drug Administration ("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)), NDA No. 022496, prior to the expiration of U.S. Patent No. 11,033,495 ("the '495 patent" or "the patent-in-suit"). Pacira seeks 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 California with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey, 07054.

3. Plaintiff Pacira BioSciences, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey, 07054.

4. On information and belief, 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. On information and belief, eVenus is in the business of, among other things, manufacturing, promoting, marketing, selling,

offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

5. On information and belief, Defendant Jiangsu Hengrui Medicine Co. Ltd., is a corporation organized and existing under the laws of China with its principal place of business at No. 7 Kunlunshan Road, Lianyugang Eco & Tech Development Zone, Lianyungang, Jiangsu, 222002, China. On information and belief, Jiangsu Hengrui is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through its subsidiary, eVenus. On information and belief, the acts of eVenus complained of herein were done with the cooperation, participation, and assistance of Jiangsu Hengrui. On information and belief, 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 the eVenus ANDA Product.

6. On information and belief, eVenus is a wholly owned subsidiary of Jiangsu Hengrui.

7. By a letter dated September 20, 2021 ("eVenus Notice Letter"), eVenus notified Pacira that eVenus had submitted to the FDA ANDA No. 214348 ("eVenus's ANDA") for a purported generic version of Bupivacaine Liposome

Injectable Suspension, 266 mg/20 mL (13.3 mg/mL) ("eVenus ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the eVenus ANDA Product in or into the United States, including New Jersey, prior to the expiration of the '495 patent.

8. On information and belief, Defendants work in collaboration with each other or through their subsidiaries, agents, and affiliates to manufacture, market, distribute, offer for sale, and sell generic versions of branded pharmaceutical products in the United States. As part of that work, Defendants participate together in preparing and filing ANDAs with the FDA. In conjunction with filing ANDAs with the FDA, Defendants also cooperate in filing certifications pursuant to Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacturer, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such branded pharmaceutical products.

9. On information and belief, Defendants acted in concert to prepare and submit eVenus's ANDA and the eVenus Notice Letter.

10. On information and belief, Defendants know and intend that upon approval of eVenus's ANDA, eVenus and/or Jiangsu Hengrui will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the eVenus ANDA Product throughout the United States, including New Jersey. On information and

belief, eVenus and Jiangsu Hengrui are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the eVenus ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Defendants participated, assisted, and cooperated in carrying out the acts complained of herein.

11. On information and belief, following any FDA approval of eVenus's ANDA, Defendants will act in concert to manufacture, promote, market, sell, offer for sale, import, use and/or distribute the eVenus ANDA Product throughout the United States, including New Jersey.

JURISDICTION AND VENUE

12. Pacira incorporates each of the preceding paragraphs 1–11 as if fully set forth herein.

13. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, et seq., including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. eVenus is subject to personal jurisdiction in New Jersey 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.

15. 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 is should reasonably anticipate being sued in this Court.

16. On information and belief, 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.

17. On information and belief, 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 ANDA Product throughout the United States, including New Jersey.

18. On information and belief, 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.

19. 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 patent 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 the eVenus ANDA Product nationwide, including within New Jersey.

20. 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.

21. 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.

22. On information and belief, Jiangsu Hengrui is subject to personal jurisdiction in New Jersey because it controls and dominates 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.

23. On information and belief, Jiangsu Hengrui has been and is engaging in activities directed toward infringement of the patent-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 the eVenus ANDA Product throughout the United States, including New Jersey, before expiration of the patent-in-suit. On information and belief, Jiangsu Hengrui will manufacture the API for the eVenus ANDA Product.

24. On information and belief, Jiangsu Hengrui and eVenus will operate and act in concert as an integrated, unitary business with respect to the eVenus ANDA Product. 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.

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

26. On information and belief, Jiangsu Hengrui consented to jurisdiction in New Jersey in 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.).

27. 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.

28. 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.

29. 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 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.

30. 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.

THE PATENT-IN-SUIT

31. United States Patent Number 11,033,495, entitled "Manufacturing of Bupivacaine Multivesicular Liposomes" was duly and legally issued on June 15, 2021, and names Jeffrey S. Hall, David J. Turnbull, John J. Grigsby, Jr., Souroush M. Ardekani, Paige N. Davis, Louie D. Garcia, Stephanie M. Kurz, and Kathleen D. A. Los as the inventors. Attached as Exhibit A is a true and correct copy of the '495 patent.

32. The '495 patent includes claims for preparing by a commercial scale process bupivacaine encapsulated in multivesicular liposomes ("MVLs").

33. Pacira Pharmaceuticals, Inc. is the owner and assignee of the '495 patent and has the right to enforce the '495 patent.

34. The FDA's Approved Drug Product with Therapeutic Equivalence Evaluations ("Orange Book") currently lists the expiration of the '495 patent as January 22, 2041.

THE EXPAREL® DRUG PRODUCT

35. 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, 266 mg/20 mL (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 approved for single-dose infiltration into the surgical site to produce postsurgical analgesia. Pacira distributes EXPAREL® in the United States in a 266 mg/20 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 B.

36. 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 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 multivesicular liposome 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.

37. EXPAREL®, as well as methods of manufacturing EXPAREL®, are

covered by one or more claims of the ’495 patent. The ’495 patent has been listed in connection with NDA No. 022496 in the FDA’s Orange Book.

DEFENDANTS’ ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

38. On information and belief, Defendants have submitted or caused the submission of eVenus’s ANDA 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 the eVenus ANDA Product, a purported generic version of EXPAREL®, prior to the expiration of the ’495 patent.

39. On information and belief, the FDA has not yet approved eVenus’s ANDA.

40. In the eVenus Notice Letter, eVenus notified Pacira of the submission of eVenus’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of the eVenus ANDA Product prior to the expiration of the ’495 patent.

41. In the eVenus Notice Letter, eVenus acknowledged that the Reference Listed Drug for eVenus’s ANDA is EXPAREL®.

42. In the 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 ’495 patent.

43. 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 '495 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the eVenus ANDA Product.

44. In the eVenus Notice Letter, eVenus stated that the eVenus ANDA Product contains bupivacaine as an active ingredient.

45. On information and belief, eVenus submission of eVenus's ANDA was based upon the use of Jiangsu Hengrui's DMF.

46. On information and belief, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted eVenus's ANDA to the FDA, and intend to further prosecute eVenus's ANDA. On information and belief, if the FDA approves eVenus's ANDA, Defendants will manufacture, distribute, promote, market, offer for sale, or sell the eVenus ANDA Product within the United States, or will import the eVenus ANDA Product into the United States. On information and belief, if the FDA approves eVenus's ANDA, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the eVenus ANDA Product in or into the United States.

47. Pacira brings this action within forty-five days of receipt of the eVenus Notice Letter. Accordingly, Pacira is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '495 PATENT

48. Pacira incorporates each of the preceding paragraphs 1–47 as if fully set forth herein.

49. On information and belief, Defendants submitted or caused submission of eVenus's ANDA to obtain FDA approval for the eVenus ANDA Product in the United States before expiration of the '495 patent.

50. The eVenus ANDA Product, and the use of the eVenus ANDA Product, are covered by one or more claims of the '495 patent.

51. Defendants' submission of eVenus's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the eVenus ANDA Product in or into the United States before the expiration of the '495 patent is an act of infringement of the '495 patent under 35 U.S.C. § 271(e)(2)(A).

52. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively

induce the infringement of one or more claims of the '495 patent under 35 U.S.C. § 271(a)-(c).

53. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus ANDA Product in or into the United States immediately and imminently upon approval of eVenus's ANDA.

54. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product in or into the United States would infringe one or more claims of the '495 patent.

55. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '495 patent.

56. On information and belief, upon FDA approval of eVenus's ANDA, Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the eVenus ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Defendants will knowingly and intentionally accompany the eVenus ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus ANDA Product,

which are substantially similar to the instructions in the prescribing information for EXPAREL® (Exhibit B) and which, if followed, will infringe claims of the '495 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus ANDA Product to directly infringe the '495 patent. On information and belief, Defendants will encourage acts of direct infringement with knowledge of the '495 patent and knowledge that Defendants are encouraging infringement.

57. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '495 patent when eVenus's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Defendants' activities will be done with knowledge of the '495 patent and specific intent to infringe that patent.

58. On information and belief, Defendants know that the eVenus ANDA Product and proposed labeling are especially made or adapted for use in infringing the '495 patent, that the eVenus ANDA Product is not a staple article or commodity of commerce, and that the eVenus ANDA Product and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '495 patent immediately and imminently upon approval of eVenus's ANDA.

59. Notwithstanding Defendants' knowledge of the claims of the '495

patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus ANDA Product with its product labeling in or into the United States following FDA approval of eVenus's ANDA prior to the expiration of the '495 patent.

60. The foregoing actions by Defendants constitute and/or will constitute direct infringement of the '495 patent; active inducement of infringement by others of the '495 patent; and contribution to the infringement by others of the '495 patent.

61. On information and belief, Defendants, in concert with their agents, affiliates, and subsidiaries, filed eVenus's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '495 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the eVenus ANDA Product.

62. On information and belief, Defendants have acted with full knowledge of the '495 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '495 patent; active inducement of infringement by others of the '495 patent; and/or contribution to the infringement by others of the '495 patent. On information and belief, the direct and indirect infringement by Defendants of the '495 patent was and is willful. Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

63. Pacira will be substantially and irreparably damaged by infringement

of the ’495 patent. Unless Defendants are enjoined from directly infringing the ’495 patent, actively inducing infringement of the ’495 patent, and contributing to the infringement of the ’495 patent, Pacira will suffer irreparable injury. Pacira has no adequate remedy at law and considering the balance of hardships between Pacira and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’495 PATENT

64. Pacira incorporates each of the preceding paragraphs 1–63 as if fully set forth herein.

65. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

67. On information and belief, Defendants submitted or caused submission of eVenus’s ANDA to obtain FDA approval for the eVenus ANDA Product in the United States before expiration of the ’495 patent.

68. The eVenus ANDA Product, and the use of the eVenus ANDA Product,

are covered by one or more claims of the ’495 patent.

69. The Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import eVenus’s ANDA Product before the expiration date of the ’495 patent, including eVenus’s filing of ANDA No. 214348.

70. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the ’495 patent under 35 U.S.C. § 271(a)-(c).

71. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus ANDA Product in or into the United States immediately and imminently upon approval of eVenus’s ANDA.

72. The commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product in or into the United States will infringe one or more claims of the ’495 patent.

73. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product in accordance with, and as

directed by, its proposed product labeling will infringe one or more claims of the ’495 patent.

74. On information and belief, upon FDA approval of eVenus’s ANDA, Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the eVenus ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Defendants will knowingly and intentionally accompany the eVenus ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus ANDA Product, which are substantially similar to the instructions in the prescribing information for EXPAREL®, (Exhibit B), and which, if followed, will infringe the ’495 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus ANDA Product to directly infringe the ’495 patent. On information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’495 patent and knowledge that Defendants are encouraging infringement.

75. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’495 patent when eVenus’s ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

Defendants' activities will be done with knowledge of the '495 patent and specific intent to infringe that patent.

76. On information and belief, Defendants know that the eVenus ANDA Product and proposed labeling are especially made or adapted for use in infringing the '495 patent, that the eVenus ANDA Product is not a staple article or commodity of commerce, and that the eVenus ANDA Product and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '495 patent immediately and imminently upon approval of eVenus's ANDA.

77. Notwithstanding Defendants' knowledge of the claims of the '495 patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus ANDA Product with its product labeling in or into the United States following FDA approval of eVenus's ANDA prior to the expiration of the '495 patent.

78. The foregoing actions by Defendants will constitute direct infringement of the '495 patent; active inducement of infringement by others of the '495 patent; and contribution to the infringement by others of the '495 patent.

79. On information and belief, Defendants, in concert with their agents, affiliates, and subsidiaries filed eVenus's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '495 patent is invalid,

unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the eVenus ANDA Product. On information and belief, Defendants have acted with full knowledge of the '495 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '495 patent; active inducement of infringement by others of the '495 patent; and/or contribution to the infringement by others of the '495 patent. On information and belief, the direct and indirect infringement by Defendants of the '495 patent was and is willful. Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

80. Pacira will be substantially and irreparably damaged by infringement of the '495 patent. Unless Defendants are enjoined from directly infringing the '495 patent, actively inducing infringement of the '495 patent, and contributing to the infringement of the '495 patent, Pacira will suffer irreparable injury. Pacira has no adequate remedy at law, and considering the balance of hardships between Pacira and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

81. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the eVenus ANDA Product will constitute infringement of one or more claims of the '495 patent.

PRAYER FOR RELIEF

WHEREFORE, Pacira requests the following relief:

(a) A judgment that the ’495 patent has been infringed under 35 U.S.C. § 271(e)(2) by Defendants’ submission to the FDA of eVenus’s ANDA;

(b) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of eVenus’s ANDA, or the commercial manufacture, use, or sale of the eVenus ANDA Product, or any other drug product that infringes or the use of which infringes the ’495 patent, be not earlier than the expiration date of the ’495 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, enjoining Defendants, and all persons acting in concert with Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the eVenus ANDA Product, or any other drug product covered by or whose use is covered by the ’495 patent, prior to the expiration of the’495 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the eVenus ANDA Product, or any other drug product that is covered by or whose use is covered

by the ’495 patent, prior to the expiration of the ’495 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the ’495 patent;

(e) A declaration that Defendants’ commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the eVenus ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the ’495 patent by Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the eVenus ANDA Product, or any product that infringes the ’495 patent, or induces or contributes to such conduct, prior to the expiration of the ’495 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Defendants willfully and deliberately infringed the ’495 patent;

(h) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated, November 8, 2021

Respectfully submitted,

/s/ John E. Flaherty
John E. Flaherty
Cynthia S. Betz
McCarter & English, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Phone: (973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Of Counsel:

Shannon M. Bloodworth (*pro hac vice* to be submitted)
Perkins Coie LLP
700 Thirteenth Street, NW
Suite 800
Washington DC 20005-3960
Phone: 202-654-6200

David L. Anstaett (*pro hac vice* to be submitted)
Autumn N. Nero (*pro hac vice* to be submitted)
Emily J. Greb (*pro hac vice* to be submitted)
Perkins Coie LLP
33 East Main Street
Suite 201
Madison, WI 53703
Phone: 603-663-7460

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon information available to be, the matter in controversy is not the subject of any other action pending or any court or of any pending arbitration or administrative proceeding.

Dated, November 8, 2021

/s/ John E. Flaherty
John E. Flaherty
Cynthia S. Betz
McCarter & English, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Phone: (973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Of Counsel:

Shannon M. Bloodworth (*pro hac vice* to be submitted)
Perkins Coie LLP
700 Thirteenth Street, NW
Suite 800
Washington DC 20005-3960
Phone: 202-654-6200

David L. Anstaett (*pro hac vice* to be submitted)
Autumn N. Nero (*pro hac vice* to be submitted)
Emily J. Greb (*pro hac vice* to be submitted)
Perkins Coie LLP
33 East Main Street
Suite 201

Madison, WI 53703
Phone: 603-663-7460

Attorneys for Plaintiffs Pacira Pharmaceuticals, Inc.
and Pacira BioSciences, Inc.