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 PHARMACEUTICALS CO. LTD., a Chinese Pharmaceutical Co., Defendants.	Civil Action No. CaseNumber

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 Pharmaceuticals 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, 133 mg/10 mL and 266 mg/20 mL (13.3 mg/mL)), NDA No. 022496, prior to the expiration of U.S. Patent Nos. 11,033,495 ("the '495 patent") and 11,179,336 ("the '336 patent") (collectively "the patents-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 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, 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 Products.

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

7. By letters dated September 30, 2021 ("September eVenus Notice Letter") and December 28, 2021 ("December eVenus Notice Letter"), eVenus notified Pacira that eVenus had submitted to the FDA ANDA No. 21438 ("eVenus's ANDA").

8. By the September eVenus Notice Letter, eVenus notified Pacira that eVenus had submitted eVenus's ANDA to the FDA for a purported generic version of Bupivacaine Liposome Injectable Suspension, 266 mg/20 mL (13.3 mg/mL) ("eVenus 20 mL ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the eVenus 20 mL ANDA Product in or into the United States, including New Jersey, prior to the expiration of the '495 patent. Pacira filed a complaint alleging infringement based on the September eVenue Notice Letter, and that lawsuit is currently pending. *See Pacira Pharms., Inc. et al v. eVenus Pharms, et al*, C.A. No. 2:21-cv-19829-MCA (D.N.J.).

9. By the December eVenus Notice Letter, eVenus notified Pacira that eVenus had submitted eVenus's ANDA to the FDA for a purported generic version of Bupivacaine Liposome Injectable Suspension, 133 mg/10 mL ("eVenus 10 mL ANDA Product") and the eVenus 20 mL ANDA Product (collectively "eVenus ANDA Products"), seeking FDA approval to engage in the commercial manufacture,

use, sale, offer for sale, and/or importation of the eVenus 10 mL ANDA Product in or into the United States, including New Jersey, prior to the expiration of the '495 and '336 patents, and seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the eVenus 20 mL ANDA Product in or into the United States, including New Jersey, prior to the expiration of the '336 patent.

10. 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.

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

12. 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 Products 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 Products, 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.

13. 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 Products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

14. Pacira incorporates each of the preceding paragraphs 1–13 as if fully set forth herein.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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 Products throughout the United States, including New Jersey.

20. 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.

21. 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 Products nationwide, including within New Jersey.

22. 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.

23. 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.

24. 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.

25. 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 the eVenus ANDA Products throughout the United States, including New Jersey, before expiration of the patents-in-suit. On information and belief, Jiangsu Hengrui will manufacture the API for the eVenus ANDA Products.

26. 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 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.

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

28. On information and belief, Jiangsu Hengrui consented to jurisdiction in New Jersey in prior cases arising out of the filing of an ANDA. *See Pacira Pharms., Inc. et al v. eVenus Pharms, et al*, C.A. No. 2:21-cv-19829-MCA (D.N.J.); *see also Janssen Prods., L.P. v. eVenus Pharma. Labs. Inc.*, No. 20-cv-9369 (D.N.J.).

29. 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.

30. 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.

31. 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.

32. 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 PATENTS-IN-SUIT

33. 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.

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

35. Pacira Pharmaceuticals, Inc. is the owner and assignee of the '495

patent and has the right to enforce the ’495 patent.

36. The FDA’s Approved Drug Product with Therapeutic Equivalence Evaluations (“Orange Book”) currently lists the expiration of the ’495 patent as January 22, 2041.

37. United States Patent Number 11,179,336, entitled “Manufacturing of Bupivacaine Multivesicular Liposomes” was duly and legally issued on November 23, 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 C is a true and correct copy of the ’336 patent.

38. The ’336 patent includes claims for a composition of bupivacaine encapsulated MVLs.

39. Pacira Pharmaceuticals, Inc. is the owner and assignee of the ’336 patent and has the right to enforce the ’336 patent.

40. The Orange Book currently list the expiration of the ’336 patent as January 22, 2041.

THE EXPAREL® DRUG PRODUCT

41. 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, 133 mg/10 mL and 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 133 mg/10 mL and 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.

42. 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.

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

covered by one or more claims of the ’495 and ’336 patents. The ’495 and ’336 patents have been listed in connection with NDA No. 022496 in the FDA’s Orange Book.

DEFENDANTS’ ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

44. 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 Products, purported generic versions of EXPAREL®, prior to the expiration of the ’495 and ’336 patents.

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

46. In the eVenus Notice Letters, 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 Products prior to the expiration of the ’495 and ’336 patents.

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

48. In the eVenus Notice Letters, 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 and ’336 patents.

49. 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 and ’336 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the eVenus ANDA Products.

50. In the eVenus Notice Letters, eVenus stated that the eVenus ANDA Products contain bupivacaine as an active ingredient.

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

52. 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 Products within the United States, or will import the eVenus ANDA Products 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 Products in or into the United States.

53. Pacira brings this action within forty-five days of receipt of the December 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 BY THE EVENUS 10 ML ANDA PRODUCT

54. Pacira incorporates each of the preceding paragraphs 1–53 as if fully set forth herein.

55. On information and belief, Defendants submitted or caused submission of eVenus's ANDA to obtain FDA approval for the eVenus 10 mL ANDA Product in the United States before expiration of the '495 patent.

56. The eVenus 10 mL ANDA Product, and the use of the eVenus 10 mL ANDA Product, are covered by one or more claims of the '495 patent.

57. 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 10 mL 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).

58. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 10 mL 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).

59. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 10 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus’s ANDA.

60. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in or into the United States would infringe one or more claims of the ’495 patent.

61. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’495 patent.

62. 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 10 mL 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 10 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 10 mL 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 10 mL 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.

63. 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.

64. On information and belief, Defendants know that the eVenus 10 mL ANDA Product and proposed labeling are especially made or adapted for use in

infringing the ’495 patent, that the eVenus 10 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 10 mL 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.

65. 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 10 mL 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.

66. 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.

67. 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 10 mL ANDA

Product.

68. 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.

69. 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 BY THE EVENUS 10 ML ANDA PRODUCT

70. Pacira incorporates each of the preceding paragraphs 1–69 as if fully set forth herein.

71. These claims arise under the Declaratory Judgment Act, 28 U.S.C.

§§ 2201 and 2202.

72. 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.

73. On information and belief, Defendants submitted or caused submission of eVenus's ANDA to obtain FDA approval for the eVenus 10 mL ANDA Product in the United States before expiration of the '495 patent.

74. The eVenus 10 mL ANDA Product, and the use of the eVenus 10 mL ANDA Product, are covered by one or more claims of the '495 patent.

75. 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 the eVenus 10 mL ANDA Product before the expiration date of the '495 patent, including eVenus's filing of ANDA No. 214348.

76. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 10 mL 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).

77. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 10 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus's ANDA.

78. The commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in or into the United States will infringe one or more claims of the '495 patent.

79. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in accordance with, and as directed by, its proposed product labeling will infringe one or more claims of the '495 patent.

80. 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 10 mL 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 10 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 10 mL 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 10 mL 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.

81. 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.

82. On information and belief, Defendants know that the eVenus 10 mL ANDA Product and proposed labeling are especially made or adapted for use in infringing the ’495 patent, that the eVenus 10 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 10 mL 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.

83. 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 10 mL ANDA Product with its Products labeling in or into the United States following FDA approval of eVenus's ANDA prior to the expiration of the '495 patent.

84. 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.

85. 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 10 mL 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.

86. 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.

87. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the eVenus 10 mL ANDA Product will constitute infringement of one or more claims of the '495 patent.

COUNT III – INFRINGEMENT OF THE '336 PATENT BY THE EVENUS 10 ML ANDA PRODUCT

88. Pacira incorporates each of the preceding paragraphs 1–87 as if fully set forth herein.

89. On information and belief, Defendants submitted or caused submission of eVenus's ANDA to obtain FDA approval for the eVenus 10 mL ANDA Product in the United States before expiration of the '336 patent.

90. The eVenus 10 mL ANDA Product, and the use of the eVenus 10 mL ANDA Product, are covered by one or more claims of the '336 patent.

91. 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 10 mL ANDA Product in or into the United States before the expiration of the '336 patent is an act of infringement of the '336 patent under 35 U.S.C. § 271(e)(2)(A).

92. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 10 mL 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 '336 patent under 35 U.S.C. § 271(a)-(c).

93. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 10 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus's ANDA.

94. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in or into the United States would infringe one or more claims of the '336 patent.

95. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in accordance with,

and as directed by, its proposed product labeling would infringe one or more claims of the ’336 patent.

96. 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 10 mL 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 10 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 10 mL 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 ’336 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus 10 mL ANDA Product to directly infringe the ’336 patent. On information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’336 patent and knowledge that Defendants are encouraging infringement.

97. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’336 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 '336 patent and specific intent to infringe that patent.

98. On information and belief, Defendants know that the eVenus 10 mL ANDA Product and proposed labeling are especially made or adapted for use in infringing the '336 patent, that the eVenus 10 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 10 mL 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 '336 patent immediately and imminently upon approval of eVenus's ANDA.

99. Notwithstanding Defendants' knowledge of the claims of the '336 patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus 10 mL 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 '336 patent.

100. The foregoing actions by Defendants constitute and/or will constitute direct infringement of the '336 patent; active inducement of infringement by others of the '336 patent; and contribution to the infringement by others of the '336 patent.

101. 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 '336 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 10 mL ANDA Product.

102. On information and belief, Defendants have acted with full knowledge of the '336 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '336 patent; active inducement of infringement by others of the '336 patent; and/or contribution to the infringement by others of the '336 patent. On information and belief, the direct and indirect infringement by Defendants of the '336 patent was and is willful. Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

103. Pacira will be substantially and irreparably damaged by infringement of the '336 patent. Unless Defendants are enjoined from directly infringing the '336 patent, actively inducing infringement of the '336 patent, and contributing to the infringement of the '336 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 IV – DECLARATORY JUDGMENT OF INFRINGEMENT

OF THE ’336 PATENT BY THE EVENUS 10 ML ANDA PRODUCT

104. Pacira incorporates each of the preceding paragraphs 1–103 as if fully set forth herein.

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

106. 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.

107. On information and belief, Defendants submitted or caused submission of eVenus’s ANDA to obtain FDA approval for the eVenus 10 mL ANDA Product in the United States before expiration of the ’336 patent.

108. The eVenus 10 mL ANDA Product, and the use of the eVenus 10 mL ANDA Product, are covered by one or more claims of the ’336 patent.

109. 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 the eVenus 10 mL ANDA Product before the expiration date of the ’336 patent, including eVenus’s filing of ANDA No. 214348.

110. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 10 mL 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 ’336 patent under 35 U.S.C. § 271(a)-(c).

111. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 10 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus’s ANDA.

112. The commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in or into the United States will infringe one or more claims of the ’336 patent.

113. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 10 mL ANDA Product in accordance with, and as directed by, its proposed product labeling will infringe one or more claims of the ’336 patent.

114. 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 10 mL 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 10 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 10 mL ANDA Product, which are substantially similar to the instructions in the prescribing information for EXPAREL®, (Exhibit B), and which, if followed, will infringe the ’336 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus 10 mL ANDA Product to directly infringe the ’336 patent. On information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’336 patent and knowledge that Defendants are encouraging infringement.

115. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’336 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 ’336 patent and specific intent to infringe that patent.

116. On information and belief, Defendants know that the eVenus 10 mL ANDA Product and proposed labeling are especially made or adapted for use in infringing the ’336 patent, that the eVenus 10 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 10 mL 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 ’336 patent immediately and imminently upon approval of eVenus’s ANDA.

117. Notwithstanding Defendants’ knowledge of the claims of the ’336 patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus 10 mL ANDA Product with its Products labeling in or into the United States following FDA approval of eVenus’s ANDA prior to the expiration of the ’336 patent.

118. The foregoing actions by Defendants will constitute direct infringement of the ’336 patent; active inducement of infringement by others of the ’336 patent; and contribution to the infringement by others of the ’336 patent.

119. 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 ’336 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 10 mL ANDA Product. On information and belief, Defendants have acted with full knowledge of the ’336 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the ’336 patent; active inducement of infringement

by others of the ’336 patent; and/or contribution to the infringement by others of the ’336 patent. On information and belief, the direct and indirect infringement by Defendants of the ’336 patent was and is willful. Defendants’ conduct renders this case “exceptional” under 35 U.S.C. § 285.

120. Pacira will be substantially and irreparably damaged by infringement of the ’336 patent. Unless Defendants are enjoined from directly infringing the ’336 patent, actively inducing infringement of the ’336 patent, and contributing to the infringement of the ’336 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.

121. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the eVenus 10 mL ANDA Product will constitute infringement of one or more claims of the ’336 patent.

COUNT V – INFRINGEMENT OF THE ’336 PATENT BY THE EVENUS 20 ML ANDA PRODUCT

122. Pacira each of the preceding paragraphs 1–121 as if fully set forth herein.

123. On information and belief, Defendants submitted or caused submission of eVenus's ANDA to obtain FDA approval for the eVenus 20 mL ANDA Product in the United States before expiration of the '336 patent.

124. The eVenus 20 mL ANDA Product, and the use of the eVenus 20 mL ANDA Product, are covered by one or more claims of the '336 patent.

125. 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 20 mL ANDA Product in or into the United States before the expiration of the '336 patent is an act of infringement of the '336 patent under 35 U.S.C. § 271(e)(2)(A).

126. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 20 mL 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 '336 patent under 35 U.S.C. § 271(a)-(c).

127. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 20 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus's ANDA.

128. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 20 mL ANDA Product in or into the United States would infringe one or more claims of the ’336 patent.

129. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 20 mL ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’336 patent.

130. 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 20 mL 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 20 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 20 mL 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 ’336 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus 20 mL ANDA Product to directly infringe the ’336 patent. On information

and belief, Defendants will encourage acts of direct infringement with knowledge of the ’336 patent and knowledge that Defendants are encouraging infringement.

131. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’336 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 ’336 patent and specific intent to infringe that patent.

132. On information and belief, Defendants know that the eVenus 20 mL ANDA Product and proposed labeling are especially made or adapted for use in infringing the ’336 patent, that the eVenus 20 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 20 mL 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 ’336 patent immediately and imminently upon approval of eVenus’s ANDA.

133. Notwithstanding Defendants’ knowledge of the claims of the ’336 patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus 20 mL 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 ’336 patent.

134. The foregoing actions by Defendants constitute and/or will constitute direct infringement of the ’336 patent; active inducement of infringement by others of the ’336 patent; and contribution to the infringement by others of the ’336 patent.

135. 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 ’336 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 20 mL ANDA Product.

136. On information and belief, Defendants have acted with full knowledge of the ’336 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the ’336 patent; active inducement of infringement by others of the ’336 patent; and/or contribution to the infringement by others of the ’336 patent. On information and belief, the direct and indirect infringement by Defendants of the ’336 patent was and is willful. Defendants’ conduct renders this case “exceptional” under 35 U.S.C. § 285.

137. Pacira will be substantially and irreparably damaged by infringement of the ’336 patent. Unless Defendants are enjoined from directly infringing the ’336

patent, actively inducing infringement of the ’336 patent, and contributing to the infringement of the ’336 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 VI– DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’336 PATENT BY THE EVENUS 20 ML ANDA PRODUCT

138. Pacira incorporates each of the preceding paragraphs 1–137 as if fully set forth herein.

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

140. 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.

141. On information and belief, Defendants submitted or caused submission of eVenus’s ANDA to obtain FDA approval for the eVenus 20 mL ANDA Product in the United States before expiration of the ’336 patent.

142. The eVenus 20 mL ANDA Product, and the use of the eVenus 20 mL ANDA Product, are covered by one or more claims of the ’336 patent.

143. 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 the eVenus 20 mL ANDA Product before the expiration date of the ’336 patent, including eVenus’s filing of ANDA No. 214348.

144. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of the eVenus 20 mL 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 ’336 patent under 35 U.S.C. § 271(a)-(c).

145. On information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the eVenus 20 mL ANDA Product in or into the United States immediately and imminently upon approval of eVenus’s ANDA.

146. The commercial manufacture, use, sale, offer for sale, or importation of the eVenus 20 mL ANDA Product in or into the United States will infringe one or more claims of the ’336 patent.

147. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the eVenus 20 mL ANDA Product in accordance with,

and as directed by, its proposed product labeling will infringe one or more claims of the ’336 patent.

148. 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 20 mL 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 20 mL ANDA Product with a product label or product insert that will include instructions for using or administering the eVenus 20 mL ANDA Product, which are substantially similar to the instructions in the prescribing information for EXPAREL®, (Exhibit B), and which, if followed, will infringe the ’336 patent. Accordingly, Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the eVenus 20 mL ANDA Product to directly infringe the ’336 patent. On information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’336 patent and knowledge that Defendants are encouraging infringement.

149. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’336 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 '336 patent and specific intent to infringe that patent.

150. On information and belief, Defendants know that the eVenus 20 mL ANDA Product and proposed labeling are especially made or adapted for use in infringing the '336 patent, that the eVenus 20 mL ANDA Product is not a staple article or commodity of commerce, and that the eVenus 20 mL 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 '336 patent immediately and imminently upon approval of eVenus's ANDA.

151. Notwithstanding Defendants' knowledge of the claims of the '336 patent, Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the eVenus 20 mL ANDA Product with its Products labeling in or into the United States following FDA approval of eVenus's ANDA prior to the expiration of the '336 patent.

152. The foregoing actions by Defendants will constitute direct infringement of the '336 patent; active inducement of infringement by others of the '336 patent; and contribution to the infringement by others of the '336 patent.

153. 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 '336 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 20 mL ANDA Product. On information and belief, Defendants have acted with full knowledge of the '336 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '336 patent; active inducement of infringement by others of the '336 patent; and/or contribution to the infringement by others of the '336 patent. On information and belief, the direct and indirect infringement by Defendants of the '336 patent was and is willful. Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

154. Pacira will be substantially and irreparably damaged by infringement of the '336 patent. Unless Defendants are enjoined from directly infringing the '336 patent, actively inducing infringement of the '336 patent, and contributing to the infringement of the '336 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.

155. Plaintiffs are entitled to a declaratory judgment that future commercial

manufacture, use, offer for sale, sale, and/or importation of the eVenus 20 mL ANDA Product will constitute infringement of one or more claims of the ’336 patent.

PRAYER FOR RELIEF

WHEREFORE, Pacira requests the following relief:

(a) A judgment that the ’495 and ’336 patents have 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 Products, or any other drug product that infringes or the use of which infringes the ’495 and ’336 patents, be not earlier than the expiration date of the ’495 and ’336 patents, 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 Products, or any other drug product covered by or whose use is covered by the ’495 and ’336 patents, prior to the expiration of the ’495 and ’336 patents, 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 Products, or any other drug product that is covered by or whose use is covered by the ’495 and ’336 patents, prior to the expiration of the ’495 and ’336 patents, 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 Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the ’495 and ’336 patents 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 Products, or any product that infringes the ’495 and ’336 patents, or induces or contributes to such conduct, prior to the expiration of the ’495 and ’336 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Defendants willfully and deliberately infringed the ’495 and ’336 patents;

(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: February 10, 2022

Respectfully submitted,

/s/ *John E. Flaherty*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 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: February 10, 2022

/s/ *John E. Flaherty*
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