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

JANSSEN PRODUCTS, L.P., and PHARMA MAR, S.A. Plaintiffs, v. EVENUS PHARMACEUTICALS LABORATORIES INC., JIANGSU HENGRUI MEDICINE CO. LTD., FRESENIUS KABI USA, LLC, NATCO PHARMA LTD, SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES INC. Defendants.	Civil Action No. 3:20-cv-09369-FLW-ZNQ

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P., ("Janssen") and Pharma Mar, S.A. ("Pharma Mar") (collectively, "Plaintiffs") for their First Amended Complaint against Defendants eVenus Pharmaceuticals Laboratories Inc. ("eVenus"), Jiangsu Hengrui Medicine Co. Ltd. ("Jiangsu") (collectively, "eVenus-Jiangsu"), Fresenius Kabi USA, LLC ("Fresenius") (eVenus-Jiangsu and Fresenius collectively, "eVenus-Jiangsu-Fresenius"), Natco Pharma Limited ("Natco"), Sun

Pharmaceutical Industries Ltd. ("Sun Ltd."), and Sun Pharmaceutical Industries Inc. ("Sun Inc.") (Natco, Sun Ltd. and Sun Inc. collectively, "Natco-Sun") (eVenus-Jiangsu-Fresenius and Natco-Sun collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Defendants of U.S. Patent No. 8,895,557 (the "'557 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and for a declaratory judgment of infringement of the '557 Patent and U.S. Patent No. 7,420,051 (the "'051 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of eVenus-Jiangsu's filing of Abbreviated New Drug Application No. 214327 (the "eVenus ANDA"), supported by Drug Master File No. 33677 (the "Jiangsu DMF"), seeking approval to sell a generic copy of Plaintiffs' highly successful Yondelis® (trabectedin) 1 mg/vial (the "eVenus-Jiangsu ANDA Product") prior to the expiration of the '557 Patent and the '051 Patent (together, the "patents-in-suit").

3. This action also arises out of Natco-Sun's filing of Abbreviated New Drug Application No. 214837 (the "Natco ANDA") seeking approval to sell a generic copy of Plaintiffs' highly successful Yondelis® (trabectedin) 1 mg/vial (the "Natco-Sun ANDA Product") prior to the expiration of the '557 Patent and the '051 Patent.

THE PARTIES

4. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

5. Plaintiff Pharma Mar, S.A. is a Spanish corporation having its principal place of business at Avda. de los Reyes, 1 Pol. Ind. La Mina, 28770, Colmenar Viejo, Madrid, Spain.

6. On information and belief, Defendant eVenus is a corporation organized and existing under the laws of New Jersey, with 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, marketing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, eVenus is a wholly-owned subsidiary, alter ego and agent of Defendant Jiangsu. On information and belief, eVenus is the holder of the eVenus ANDA.

7. On information and belief, Defendant Jiangsu is a corporation organized and existing under the laws of China, having a principal place of business at 7 Kunlunshan Road, Economic and Technological Development Zone, Liangyungang, Jiangsu China 222047. On information and belief, Jiangsu is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the U.S. market. On information and belief, the acts of eVenus complained of herein were done with the cooperation, participation, and assistance of Jiangsu. On information and belief, Jiangsu is the holder of DMF No. 33677. On information and belief, Jiangsu will manufacture the API for the proposed eVenus-Jiangsu ANDA Product.

8. On information and belief, Defendant Fresenius is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. On information and belief, Fresenius is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Fresenius will financially benefit in the event FDA approves the eVenus ANDA because Fresenius is actively

involved in the use, marketing and/or sale of the proposed eVenus-Jiangsu ANDA Product in the United States, including in the State of New Jersey.

9. On information and belief, eVenus, Jiangsu and Fresenius collaborate with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the proposed eVenus-Jiangsu ANDA Product for the U.S. market, including in the State of New Jersey.

10. On information and belief, eVenus, Jiangsu, and Fresenius intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the proposed eVenus-Jiangsu ANDA Product, in the event FDA approves the eVenus ANDA.

11. On information and belief, Defendant Natco is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad – 500 034, India. On information and belief, Natco is the holder of the Natco ANDA. On information and belief, Natco is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market.

12. On information and belief, Defendant Sun Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Sun Ltd. is actively involved in the commercial manufacture, use, marketing and/or sale of the proposed Natco-Sun ANDA Product in the United States, including in the State of New Jersey.

13. On information and belief, Defendant Sun Inc. is a corporation organized and existing under the laws of Delaware having a principal place of business in New Jersey at the following business address: 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Inc. has several places of business in the State of New Jersey, including but not limited to at the following business addresses: (1) 1 Commerce Drive, Cranbury, New Jersey 08512 and (2) 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is a wholly owned subsidiary and agent of Sun Ltd.

14. On information and belief, Sun Inc. 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. On information and belief, Sun Inc. will financially benefit in the event FDA approves the Natco-Sun ANDA because Sun Inc. is actively involved in the use, marketing and/or sale of the proposed Natco-Sun ANDA Product in the United States, including in the State of New Jersey.

15. On information and belief, Natco, Sun Ltd. and Sun Inc. collaborate with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the proposed Natco-Sun ANDA Product for the U.S. market, including in the State of New Jersey.

16. On information and belief, Natco, Sun Ltd. and Sun Inc. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Natco, Sun Ltd. and Sun Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the proposed Natco-Sun ANDA Product, in the event FDA approves Natco's ANDA.

JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. On information and belief, this Court has personal jurisdiction over eVenus because eVenus has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

19. On information and belief, this Court has personal jurisdiction over eVenus, *inter alia*, because eVenus's principal place of business is in Princeton, New Jersey.

20. On information and belief, eVenus is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over eVenus.

21. 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 I.D. No. 0400276509.

22. On information and belief, eVenus is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5004028.

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

24. On information and belief and as stated in the Paragraph IV Notice Letter, eVenus intends to engage in the commercial manufacture, use, or sale of the proposed eVenus-Jiangsu ANDA Product before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of eVenus will therefore cause injury to Plaintiffs in New Jersey.

25. On information and belief, eVenus directly and/or through its parent company Jiangsu markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

26. On information and belief, eVenus derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its parent company Jiangsu.

27. On information and belief, eVenus directly and/or through its parent company Jiangsu has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

28. Venue is proper in this district for eVenus pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, eVenus is a corporation organized and existing under the laws of New Jersey, has committed and will commit acts of infringement in this judicial district and has a regular and established place of business at its headquarters in Princeton, New Jersey, located within this judicial district.

29. On July 15, 2020, counsel for eVenus-Jiangsu-Fresenius confirmed that eVenus consents to jurisdiction and venue in the District of New Jersey.

30. On information and belief, Jiangsu is subject to personal jurisdiction in New Jersey because, among other things, Jiangsu itself and through its wholly-owned subsidiary and alter ego, eVenus, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

31. On information and belief, this Court has personal jurisdiction over Jiangsu because, *inter alia,* it: (1) intends to market, sell or distribute the proposed eVenus-Jiangsu ANDA Product to residents of New Jersey; (2) has continuous and systemic contacts with the State of

New Jersey and regularly conducts business in the State of New Jersey, either directly or through one or more of its affiliates, agents, and/or alter egos; (3) exercises control over Defendant eVenus; (4) operates through its wholly owned subsidiary and alter ego eVenus, which is incorporated and maintains a principal place of business in New Jersey; (5) makes its generic pharmaceutical products available in New Jersey; (6) maintains a broad distributorship network within New Jersey; and (7) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

32. On information and belief, Jiangsu has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the Jiangsu DMF, and acting in concert with eVenus in the preparation and submission of the eVenus ANDA seeking FDA approval to market the proposed eVenus-Jiangsu ANDA Product throughout the United States, including in New Jersey, before expiration of the patents-in-suit. On information and belief, Jiangsu will manufacture the API for the proposed eVenus-Jiangsu ANDA Product.

33. On information and belief, Jiangsu and eVenus operate and act in concert as an integrated, unitary business. Jiangsu and eVenus work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey.

34. On information and belief, eVenus acts at the direction, and for the benefit, of Jiangsu, and is controlled and/or dominated by Jiangsu.

35. In the alternative, as to Jiangsu, this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 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.

36. This Court has personal jurisdiction over Jiangsu because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (1) Plaintiffs' claims arise under federal law; (2) Jiangsu is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Jiangsu has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of eVenus's ANDA, preparing and submitting the Jiangsu 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 satisfies due process.

37. Litigating in the District of New Jersey would not burden Jiangsu unduly. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Plaintiffs have a substantial interest in obtaining convenient and effective relief for violations of its property interests. In addition, the states have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

38. Venue is proper in this district for Jiangsu pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Jiangsu is a company organized and existing under the laws of China and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

39. On July 15, 2020, counsel for eVenus-Jiangsu-Fresenius confirmed that Jiangsu consents to jurisdiction and venue in the District of New Jersey.

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

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

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

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

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

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

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

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

48. On information and belief Fresenius has been and is engaging in activities directed toward infringement of the patents-in-suit, including by acting in concert with eVenus-Jiangsu with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the proposed eVenus-Jiangsu ANDA Product before expiration of the patents-in-suit. On information and belief, Fresenius intends to engage in importing, marketing, selling, distributing and/or using the proposed eVenus-Jiangsu ANDA Product before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of Fresenius will therefore cause injury to Plaintiffs in New Jersey.

49. On information and belief, Fresenius intends to take advantage of its established channels of distribution in New Jersey for the sale of the proposed eVenus-Jiangsu ANDA Product.

50. On information and belief, eVenus and Jiangsu act for the benefit, of Fresenius, with respect to the proposed eVenus-Jiangsu ANDA Product.

51. On information and belief, Fresenius knows and intends that the proposed eVenus-Jiangsu ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of Yondelis® 1 mg/vial, causing injury to Plaintiffs.

52. Fresenius has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions under the Hatch-Waxman Act. *See, e.g.*, *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 20-02892, D.I. 12 (D.N.J. June 8, 2020); *Boehringer Ingelheim Pharm., Inc. et al. v. Fresenius Kabi USA,*

LLC et al., C.A. No. 18-03244, D.I. 11 (D.N.J. Mar. 28, 2018); *Helsinn Healthcare S.A. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 15-07015, D.I. 15 (D.N.J. Oct. 26, 2015); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C.A. No. 14-08082, D.I. 11 (D.N.J. Mar. 17, 2015); *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 14-04989, D.I. 5 (D.N.J. Aug. 12, 2014); *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 14-03917, D.I. 12 (D.N.J. Aug. 4, 2014); *Novartis Pharmaceutical Corporation v Fresenius Kabi USA, LLC*, C.A. No. 13-07914, D.I. 10 (D.N.J. Feb. 13, 2014).

53. Fresenius has not contested personal jurisdiction in this judicial district. *See, e.g.*, *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 20-02892, D.I. 12 (D.N.J. June 8, 2020); *Boehringer Ingelheim Pharm., Inc. et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-03244, D.I. 11 (D.N.J. Mar. 28, 2018); *Helsinn Healthcare S.A. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 15-07015, D.I. 15 (D.N.J. Oct. 26, 2015); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C.A. No. 14-08082, D.I. 11 (D.N.J. Mar. 17, 2015); *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 14-04989, D.I. 5 (D.N.J. Aug. 12, 2014); *Merck Sharp & Dohme B.V., et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 14-03917, D.I. 12 (D.N.J. Aug. 4, 2014); *Novartis Pharmaceutical Corporation v Fresenius Kabi USA, LLC*, C.A. No. 13-07914, D.I. 10 (D.N.J. Feb. 13, 2014).

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

55. On information and belief, this Court has personal jurisdiction over Natco because, *inter alia,* Natco: (1) has continuous and systemic contacts with the State of New Jersey and regularly conducts business in the State of New Jersey, either directly or through one or more of its affiliates, agents, and/or alter egos; (2) has purposefully availed itself of the privilege of

doing business in the State of New Jersey; (3) intends to market, sell or distribute the proposed Natco-Sun ANDA Product to residents of New Jersey; (4) makes its generic pharmaceutical products available in New Jersey; and (5) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

56. On information and belief, and as stated in the Paragraph IV Notice Letter, Natco-Sun has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the Natco ANDA seeking FDA approval to commercially manufacture, use, import, sell and offer to sell the proposed Natco-Sun ANDA Product throughout the United States, including in New Jersey, before expiration of the patents-in-suit. The conduct of Natco will therefore cause injury to Plaintiffs in New Jersey.

57. On information and belief, Natco knows and intends that the proposed Natco-Sun ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of Yondelis® 1 mg/vial, causing injury to Plaintiffs.

58. Upon information and belief, Natco purposefully has conducted, intends to conduct and/or continues to conduct business in this judicial district, either directly or through one or more of its affiliates, agents, and/or alter egos. Upon information and belief, Natco works in concert with Sun Ltd. and Sun Inc. with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this judicial district.

59. Natco has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions under the Hatch-Waxman Act. *See, e.g.*, *Celgene Corp. v. Breckenridge Pharmaceuticals, Inc*., C.A. No. 20-2597, D.I. 26 (D. N.J. Apr. 23, 2020); *Shire Development LLC, et al. v. Natco Pharma Ltd*., C.A. No. 14-7053, D.I. 74 (D.N.J.

Nov. 30, 2015); *Celgene Corp. v. Natco Pharma Ltd, et al*., D.I. 7 (D.N.J. June 13, 2014); *Celgene Corp. v. Natco Pharma Ltd., et al*., C.A. 12-4571, D.I. 15 (D.N.J. Sept. 28, 2012).

60. Natco has not contested personal jurisdiction in this judicial district. *See, e.g*., *Celgene Corp. v. Breckenridge Pharmaceuticals, Inc*., C.A. No. 20-2597, D.I. 26 (D. N.J. Apr. 23, 2020); *Shire Development LLC, et al. v. Natco Pharma Ltd*., C.A. No. 14-7053, D.I. 74 (D.N.J. Nov. 30, 2015); *Celgene Corp. v. Natco Pharma Ltd, et al*., D.I. 7 (D.N.J. June 13, 2014); *Celgene Corp. v. Natco Pharma Ltd., et al*., C.A. 12-4571, D.I. 15 (D.N.J. Sept. 28, 2012).

61. In the alternative, as to Natco, this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, Natco is a foreign company organized and existing under the laws of the Republic of India, with a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad – 500 034, India.

62. This Court has personal jurisdiction over Natco because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (1) Plaintiffs' claims arise under federal law; (2) Natco is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Natco has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Natco's ANDA, 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 Natco satisfies due process.

63. Litigating in the District of New Jersey would not burden Natco unduly. Among other things, on information and belief, Natco has consented to personal jurisdiction in the District of New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Plaintiffs have a substantial interest in obtaining convenient and

effective relief for violations of its property interests. In addition, the states have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

64. Venue is proper in this district for Natco pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Natco is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

65. On information and belief, Sun Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Sun Ltd. itself and through its wholly-owned subsidiary, Sun Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

66. On information and belief, this Court has personal jurisdiction over Sun Ltd. because, *inter alia,* Sun Ltd.: (1) has continuous and systemic contacts with the State of New Jersey and regularly conducts business in the State of New Jersey, either directly or through one or more of its affiliates, agents, and/or alter egos; (2) exercises control over Defendant Sun Inc.; (3) operates through its wholly owned subsidiary Sun Inc., which maintains a principal place of business in New Jersey; (3) has purposefully availed itself of the privilege of doing business in the State of New Jersey; (4) intends to market, sell or distribute the proposed Natco-Sun ANDA Product to residents of New Jersey; (5) makes its generic pharmaceutical products available in New Jersey; (6) maintains a broad distributorship network within New Jersey; and (7) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

67. On information and belief, and as stated in the Paragraph IV Notice Letter, Natco-Sun has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the Natco ANDA seeking FDA approval to

commercially manufacture, use, import, sell and offer to sell the proposed Natco-Sun ANDA Product throughout the United States, including in New Jersey, before expiration of the patents-in-suit. The conduct of Sun Ltd. will therefore cause injury to Plaintiffs in New Jersey.

68. On information and belief, Sun Ltd. is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through affiliates, agents, and/or alter egos, throughout the United States and in this judicial district.

69. On information and belief, Sun Ltd. knows and intends that the proposed Natco-Sun ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of Yondelis® 1 mg/vial, causing injury to Plaintiffs. Sun Ltd. intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed Natco-Sun ANDA Product.

70. Upon information and belief, Sun Ltd. purposefully has conducted, intends to conduct and/or continues to conduct business in this judicial district, either directly or through one or more of its affiliates, agents, and/or alter egos. Upon information and belief, Sun Ltd. works in concert with Sun Inc. and Natco with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this judicial district.

71. Sun Ltd. has invoked the jurisdiction of the courts of this judicial district as a plaintiff or counterclaim plaintiff in patent infringement actions under the Hatch-Waxman Act. *See, e.g.*, *Sun Pharmaceutical Industries Ltd. v. Pfizer, Inc., et al*., C.A. No. 19-9330, D.I. 1 (D.N.J. Apr. 5, 2019); *Sun Pharmaceutical Industries Ltd., et al. v. VistaPharm, Inc*., D.I. 1 (D.N.J. Mar. 1, 2019); *Sun Pharmaceutical Industries Ltd. v. Novartis Pharmaceuticals Corp., et al*., D.I. 1

(D.N.J. Jan 9, 2019); *Eisai R&D Management Co. Ltd., et al. v. Sun Pharmaceutical Industries Ltd., et al*., C.A. No. 19-21857, D.I. 9 (D.N.J. Mar. 9, 2020); *Corcept Therapeutics, Inc., v. Sun Pharma Global FZA, et al*., C.A. No. 19-15678, D.I. 36 (D.N.J. Jan. 31, 2020); *Celgene Corp. v. Sun Pharma Global FZE, et al*., C.A. No. 18-11630, D.I. 10 (D.N.J. Aug. 14, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Sun Pharmaceutical Industries Ltd*., C.A. No. 17-8819, D.I. 11 (D.N.J. Dec. 26, 2017).

72. Sun Ltd. has not contested personal jurisdiction in this judicial district. *See, e.g*., *Eisai R&D Management Co. Ltd., et al. v. Sun Pharmaceutical Industries Ltd., et al*., C.A. No. 19-21857, D.I. 9 (D.N.J. Mar. 9, 2020); *Corcept Therapeutics, Inc., v. Sun Pharma Global FZA, et al*., C.A. No. 19-15678, D.I. 36 (D.N.J. Jan. 31, 2020); *Celgene Corp. v. Sun Pharma Global FZE, et al*., C.A. No. 18-11630, D.I. 10 (D.N.J. Aug. 14, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Sun Pharmaceutical Industries Ltd*., C.A. No. 17-8819, D.I. 11 (D.N.J. Dec. 26, 2017).

73. In the alternative, as to Sun Ltd., this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, Sun Ltd. is a foreign company organized and existing under the laws India, with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India.

74. This Court has personal jurisdiction over Sun Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (1) Plaintiffs' claims arise under federal law; (2) Sun Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Sun Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Natco's ANDA, 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 Sun Ltd. satisfies due process.

75. Litigating in the District of New Jersey would not burden Sun Ltd. unduly. Among other things, on information and belief, Sun Ltd. has consented to personal jurisdiction in the District of New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Plaintiffs have a substantial interest in obtaining convenient and effective relief for violations of its property interests. In addition, the states have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

76. Venue is proper in this district for Sun Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Ltd. is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

77. On information and belief, this Court has personal jurisdiction over Sun Inc., *inter alia*, because Sun Inc.'s principal place of business is in Cranbury, New Jersey.

78. On information and belief, Sun Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100954087 and 0100970132.

79. On information and belief, Sun Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003437.

80. Upon information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd., and is controlled and/or dominated by Sun Ltd.

81. On information and belief, Sun Inc. has had persistent and continuous contacts with this judicial district, including marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

82. On information and belief, and as stated in the Paragraph IV Notice Letter, Natco-Sun has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the Natco ANDA seeking FDA approval to commercially manufacture, use, import, sell and offer to sell the proposed Natco-Sun ANDA Product throughout the United States, including in New Jersey, before expiration of the patents-in-suit. The conduct of Sun Inc. will therefore cause injury to Plaintiffs in New Jersey.

83. On information and belief, Sun Inc. is in the business of marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products that Natco-Sun manufactures, either directly or through affiliates, agents, and/or alter egos, throughout the United States and in this judicial district.

84. On information and belief, Sun Inc. knows and intends that the proposed Natco-Sun ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of Yondelis® 1 mg/vial, causing injury to Plaintiffs. Sun Inc. intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed Natco-Sun ANDA Product.

85. Upon information and belief, Sun Inc. purposefully has conducted, intends to conduct and/or continues to conduct business in this judicial district, either directly or through one or more of its affiliates, agents, and/or alter egos. Upon information and belief, Sun Inc. works in concert with Sun Ltd. and Natco with respect to the regulatory approval, manufacturing,

marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this judicial district.

86. Sun Inc. has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions under the Hatch-Waxman Act. *See, e.g.*, *Eisai R&D Management Co. Ltd., et al. v. Sun Pharmaceutical Industries Ltd., et al*., C.A. No. 19-21857, D.I. 9 (D.N.J. Mar. 9, 2020); *Corcept Therapeutics, Inc., v. Sun Pharma Global FZA, et al*., C.A. No. 19-15678, D.I. 36 (D.N.J. Jan. 31, 2020); *Celgene Corp. v. Sun Pharma Global FZE, et al*., C.A. No. 18-11630, D.I. 10 (D.N.J. Aug. 14, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Sun Pharmaceutical Industries Ltd*., C.A. No. 17-8819, D.I. 11 (D.N.J. Dec. 26, 2017); *Otsuka Pharmaceutical Co. v. Sun Pharmaceutical Industries, Ltd.*, C.A. No. 14-6397, D.I. 17 (D.N.J. Dec. 11, 2014); *Otsuka Pharmaceutical Co. v. Sun Pharmaceutical Industries, Ltd., et al*., C.A. No. 14-4307, D.I. 19 (D.N.J. Nov. 19, 2014).

87. Sun Inc. has not contested personal jurisdiction in this judicial district. *See, e.g*., *Eisai R&D Management Co. Ltd., et al. v. Sun Pharmaceutical Industries Ltd., et al*., C.A. No. 19-21857, D.I. 9 (D.N.J. Mar. 9, 2020); *Corcept Therapeutics, Inc., v. Sun Pharma Global FZA, et al*., C.A. No. 19-15678, D.I. 36 (D.N.J. Jan. 31, 2020); *Celgene Corp. v. Sun Pharma Global FZE, et al*., C.A. No. 18-11630, D.I. 10 (D.N.J. Aug. 14, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Sun Pharmaceutical Industries Ltd*., C.A. No. 17-8819, D.I. 11 (D.N.J. Dec. 26, 2017); *Otsuka Pharmaceutical Co. v. Sun Pharmaceutical Industries, Ltd.*, C.A. No. 14-6397, D.I. 17 (D.N.J. Dec. 11, 2014); *Otsuka Pharmaceutical Co. v. Sun Pharmaceutical Industries, Ltd., et al*., C.A. No. 14-4307, D.I. 19 (D.N.J. Nov. 19, 2014).

88. Venue is proper in this district for Sun Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Sun Inc. has committed and will commit acts of infringement in this judicial

district and has a regular and established place of business at its headquarters in Cranbury, New Jersey, located within this judicial district.

THE ASSERTED PATENTS

89. On November 25, 2014, the U.S. Patent and Trademark Office ("PTO") issued the '557 Patent, entitled "Pharmaceutical Formulations of Ecteinascidin Compounds." A true and correct copy of the '557 Patent is attached hereto as Exhibit A.

90. Pharma Mar holds title to the '557 Patent.

91. Janssen holds an exclusive license to the '557 Patent.

92. The '557 Patent expires on January 7, 2028.

93. The FDA has awarded 6 months of pediatric exclusivity for Yondelis® (trabectedin). The period of pediatric exclusivity applicable to the '557 Patent does not expire until July 7, 2028.

94. Janssen is the holder of approved New Drug Application ("NDA") No. 207953 for Yondelis®.

95. Janssen sells Yondelis® in the United States.

96. Yondelis® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

97. The FDA's "Orange Book" also lists patents associated with approved drugs. The '557 Patent is listed in the "Orange Book" in association with Yondelis®. The claims of the '557 Patent cover Yondelis®.

98. On September 2, 2008, the PTO issued the '051 Patent, entitled "Synthetic Process for the Manufacture of an Ecteinascidin Compound." A true and correct copy of the '051 Patent is attached hereto as Exhibit B.

99. Pharma Mar holds title to the '051 Patent.

100. Janssen holds an exclusive license to the '051 Patent for the commercialization of Yondelis®.

101. The claims of the '051 Patent protect Yondelis®. Yondelis® is commercially manufactured by the processes claimed in the '051 Patent.

102. The FDA has awarded patent term extension for the '051 Patent.

103. The patent term extension for the '051 Patent expires on January 21, 2026.

104. On information and belief, eVenus-Jiangsu-Fresenius has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products containing trabectedin (also known as ecteinascidin 743 or ET-743), which are made by processes patented by the '051 Patent prior to their expiration.

105. On information and belief, eVenus-Jiangsu-Fresenius's preparations include, but are not limited to, the development of the proposed eVenus-Jiangsu ANDA Product, the filing of the eVenus ANDA with a Paragraph IV certification, and the filing of the Jiangsu DMF.

106. On information and belief, Fresenius intends to financially benefit from the eVenus ANDA by selling and distributing the proposed eVenus-Jiangsu ANDA Product upon approval.

107. On information and belief, eVenus-Jiangsu-Fresenius intends to use the processes claimed in the ’051 Patent to prepare the API, trabectedin contained in the proposed eVenus-Jiangsu ANDA Product.

108. On information and belief, trabectedin is present in the proposed eVenus-Jiangsu ANDA Product without material change from trabectedin made by use of Plaintiffs’ patented processes.

109. On information and belief, trabectedin resulting from Plaintiffs’ patented processes is the API of the proposed eVenus-Jiangsu ANDA Product and therefore essential to the proposed eVenus-Jiangsu ANDA Product.

110. On information and belief, Natco-Sun has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products containing trabectedin which are made by processes patented by the ’051 Patent prior to their expiration.

111. On information and belief, Natco-Sun’s preparations include, but are not limited to, the development of the proposed Natco-Sun ANDA Product and the filing of the Natco ANDA with a Paragraph IV certification.

112. On information and belief, Natco-Sun intends to use the processes claimed in the ’051 Patent to prepare the API, trabectedin contained in the proposed Natco-Sun ANDA Product.

113. On information and belief, trabectedin is present in the proposed Natco-Sun ANDA Product without material change from trabectedin made by use of Plaintiffs’ patented processes.

114. On information and belief, trabectedin resulting from Plaintiffs' patented processes is the API of the proposed Natco-Sun ANDA Product and therefore essential to the proposed Natco-Sun ANDA Product.

eVENUS-JIANGSU PARAGRAPH IV NOTICE LETTER AND REFUSAL TO PROVIDE REQUESTED INFORMATION

115. After receiving the eVenus-Jiangsu Paragraph IV Notice Letter, on June 17, 2020, Plaintiffs contacted eVenus-Jiangsu and asked for information documenting the process that has been and will be used to manufacture trabectedin for the proposed eVenus-Jiangsu ANDA Product so that Plaintiffs could evaluate infringement of, *inter alia*, the '051 Patent. Plaintiffs requested eVenus's ANDA, the Jiangsu DMF, executed batch records, and master batch records for the proposed eVenus-Jiangsu ANDA Product. Despite repeated requests, eVenus-Jiangsu has not provided Plaintiffs with needed information.

116. In the eVenus-Jiangsu Paragraph IV Notice Letter, eVenus-Jiangsu purported to offer confidential access to portions of the eVenus ANDA, and no other materials, on terms and conditions set forth in the eVenus-Jiangsu Offer of Confidential Access ("OCA"). The eVenus-Jiangsu OCA contained unreasonable restrictions that, among other things, would limit Plaintiffs' access to the eVenus ANDA for the sole and exclusive purpose of determining whether an action may be brought with respect to the '557 Patent and for no other purpose, and it would not allow Plaintiffs to sue on other patents that were infringed.

117. Beginning with correspondence on June 17, 2020, outside counsel for Plaintiffs negotiated in good faith with counsel for eVenus-Jiangsu in an attempt to reach agreement on reasonable terms of confidential access to the eVenus ANDA, the Jiangsu DMF, executed batch records, and master batch records for the proposed eVenus-Jiangsu ANDA Product. eVenus-Jiangsu continued to insist on unreasonable restrictions on access to these

documents that, among other things, prohibited Plaintiffs from asserting infringement of the process patent (*i.e.*, the '051 Patent) used to commercially manufacture Yondelis®. Plaintiffs repeatedly stressed that it was in the best interests of all parties for Plaintiffs to receive information important to infringement of both the Orange Book patent and process patent (*i.e.*, the eVenus ANDA, the Jiangsu DMF, executed batch records, and master batch records), and that "[i]f eVenus or Jiangsu have any basis to contest infringement of the '051 patent, they would provide the requested materials." Nonetheless, eVenus-Jiangsu refused to allow Plaintiffs access to the eVenus ANDA or any of the requested materials showing the process that has been used and will be used to manufacture the proposed eVenus-Jiangsu ANDA Product.

118. eVenus-Jiangsu refused to even produce the DMF that it submitted in support of the eVenus ANDA, which is readily accessible and can be easily produced. eVenus-Jiangsu's withholding of needed manufacturing information has impeded Plaintiffs' ability to evaluate infringement of the '051 Patent.

119. eVenus-Jiangsu's unreasonable OCA terms, which restrict Plaintiffs from asserting infringement of the '051 Patent, and eVenus-Jiangsu's refusal to produce manufacturing information for the proposed eVenus-Jiangsu ANDA Product, is consistent with the conclusion that the commercial processes invented by Pharma Mar and protected by the '051 Patent will be used to manufacture trabectedin for the proposed eVenus-Jiangsu ANDA Product. The process claimed in the '051 Patent is important for the commercial manufacture of Yondelis® (trabectedin).

120. eVenus-Jiangsu-Fresenius has not provided any basis to contest infringement of the claims of the '051 Patent, including claims that protect Yondelis® (*e.g.*, claims 7, 11 and 14).

121. On information and belief, eVenus-Jiangsu-Fresenius continues to withhold its manufacturing information because the trabectedin API of the proposed eVenus-Jiangsu ANDA Product is made using the processes claimed in the '051 Patent, and the importation, use, sale, and/or offer for sale of the proposed eVenus-Jiangsu ANDA Product, if approved by FDA, would infringe the claims of the '051 Patent.

122. On information and belief, eVenus-Jiangsu-Fresenius submitted the eVenus ANDA to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the proposed eVenus-Jiangsu ANDA Product. eVenus's ANDA has been assigned ANDA No. 214327.

123. On information and belief, eVenus, Jiangsu and Fresenius collaborated in the research, development, preparation and filing of the eVenus ANDA and the Jiangsu DMF for the proposed eVenus-Jiangsu ANDA Product.

124. The Paragraph IV Notice Letter was signed by counsel for eVenus, Jiangsu, and Fresenius and stated that the eVenus ANDA was submitted by eVenus.

125. On information and belief, Jiangsu is the holder of the Jiangsu DMF.

126. On information and belief, eVenus, Jiangsu and Fresenius have acted in concert in seeking approval of the Jiangsu DMF and the eVenus ANDA prior to expiration of the patents-in-suit.

127. On or about June 12, 2020, Janssen received the eVenus-Jiangsu Paragraph IV Notice Letter stating that eVenus has submitted ANDA No. 214327 to the FDA, seeking approval to manufacture, use, and sell the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '557 Patent.

128. The eVenus-Jiangsu Paragraph IV Notice Letter stated that eVenus's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '557 Patent are invalid as obvious.

129. eVenus-Jiangsu's obviousness theory with respect to claims of the '557 Patent has no merit. Indeed, on information and belief, due to the validity of the claims of the '557 Patent, Jiangsu tried to design around the commercial formulation for Yondelis® claimed in the patent, but despite extensive efforts, Jiangsu failed to do so.

130. In fact, Jiangsu acknowledged in public documents that trabectedin is a "complex compound" with "limited solubility in pure water" and is "a great challenge for those skilled in the art" to formulate. U.S. Patent No. 10,610,529, 1:57-67.

131. On information and belief, eVenus-Jiangsu copied the inventions of the '557 Patent since: 1) it could not meet the great challenge posed by formulating trabectedin; and 2) the claimed commercial formulation of the '557 Patent is highly successful and advantageous.

132. In the eVenus-Jiangsu Paragraph IV Notice Letter, eVenus-Jiangsu does not dispute that eVenus, Jiangsu and Fresenius infringe claims of the '557 Patent. In particular, eVenus-Jiangsu does not dispute that claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent are infringed by submission of the eVenus ANDA.

133. In the eVenus-Jiangsu Paragraph IV Notice Letter, eVenus-Jiangsu also does not dispute that the commercial manufacture, use, importation, offer for sale and sale of the proposed eVenus-Jiangsu ANDA Product, if approved by FDA, would infringe claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent.

134. On October 8, 2020, the parties held a conference pursuant to Rule 26(f) of the Federal Rules of Civil Procedure. One day later, on October 9, 2020, counsel for eVenus-

Jiangsu-Fresenius informed Plaintiffs that Fresenius and eVenus-Jiangsu had an agreement in place and that Fresenius would be responsible for selling and distributing the proposed eVenus-Jiangsu ANDA Product within the United States, and identified Fresenius as a party from whom discovery should be taken.

135. On October 10, 2020, Plaintiffs asked eVenus-Jiangsu-Fresenius to provide any agreement(s) between Fresenius and eVenus-Jiangsu concerning the proposed eVenus-Jiangsu ANDA Product. Plaintiffs repeated their request on October 11, 13, 14, 15 and 16. Despite Plaintiffs repeated requests, eVenus-Jiangsu-Fresenius, as of the date of this filing, has not produced any documents reflecting the relationship between Fresenius and eVenus-Jiangsu, impeding the ability of Plaintiffs to assess the full extent of Fresenius's role with respect to the proposed eVenus-Jiangsu ANDA Product.

136. eVenus-Jiangsu-Fresenius does not deny that Fresenius will offer to sell, sell, use, distribute, and import the proposed eVenus-Jiangsu ANDA Product in the United States and therefore infringe the '557 Patent and the '051 Patent.

137. eVenus-Jiangsu-Fresenius also does not deny that Fresenius controls this litigation.

138. On information and belief, eVenus-Jiangsu-Fresenius had actual and constructive notice of the '557 Patent and '051 Patent prior to the filing of the eVenus ANDA.

139. On information and belief, eVenus-Jiangsu-Fresenius copied the inventions of the '557 Patent and '051 Patent although there is no regulatory requirement to copy a formulation or process of manufacture in order to obtain approval for the eVenus ANDA from FDA.

140. On information and belief, eVenus-Jiangsu-Fresenius has made and continues to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the patents-in-suit.

141. On information and belief, eVenus-Jiangsu-Fresenius's actions include, but are not limited to, the development of the proposed eVenus-Jiangsu ANDA Product, the filing of the eVenus ANDA with a Paragraph IV certification, and the filing of the Jiangsu DMF.

142. On information and belief, eVenus-Jiangsu-Fresenius continues to seek FDA approval of the eVenus ANDA and intends to collaborate in the commercial manufacture, marketing and sale of the proposed eVenus-Jiangsu ANDA Product (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves the eVenus ANDA.

143. On information and belief, Fresenius intends to financially benefit from the eVenus ANDA by selling and distributing the proposed eVenus-Jiangsu ANDA Product upon approval.

144. Plaintiffs commenced this lawsuit within 45 days of the date they received eVenus-Jiangsu's notice of ANDA No. 214327 containing a Paragraph IV certification.

NATCO-SUN PARAGRAPH IV NOTICE LETTER AND REFUSAL TO PROVIDE REQUESTED INFORMATION

145. After receiving the Natco-Sun Paragraph IV Notice Letter, on July 1, 2020, Plaintiffs contacted Natco-Sun and asked for information documenting the process that has been and will be used to manufacture trabectedin for the proposed Natco-Sun ANDA Product so that Plaintiffs could evaluate infringement of, *inter alia*, the '051 Patent. Plaintiffs requested Natco's ANDA, the DMF for the proposed Natco-Sun ANDA Product, executed batch records, and master

batch records for the proposed Natco-Sun ANDA Product. Despite repeated requests, Natco-Sun had not provided Plaintiffs with the needed information prior to commencement of this action.

146. In the Natco-Sun Paragraph IV Notice Letter, Natco-Sun purported to offer confidential access to portions of the Natco ANDA, and no other materials, on terms and conditions set forth in Natco-Sun's OCA. The Natco-Sun OCA contained unreasonable restrictions that, among other things, would limit Plaintiffs' access to Natco's ANDA for the sole and exclusive purpose of determining whether an infringement action may be brought with respect to the '557 Patent and for no other purpose, and it would not allow Plaintiffs to sue on other patents that were infringed.

147. Beginning with correspondence on July 1, 2020, outside counsel for Plaintiffs negotiated in good faith with counsel for Natco-Sun in an attempt to reach agreement on reasonable terms of confidential access to the Natco ANDA, the DMF for the proposed Natco-Sun ANDA Product, executed batch records, and master batch records for the proposed Natco-Sun ANDA Product. Natco-Sun continued to insist on unreasonable restrictions on access to these documents that, among other things, prohibited Plaintiffs from asserting infringement of the process patent (*i.e.*, the '051 Patent) used to commercially manufacture Yondelis®. Plaintiffs repeatedly stressed that it was in the best interests of all parties involved for Plaintiffs to receive information important to infringement of the Orange Book patent and process patent *(i.e.*, the Natco ANDA, the DMF for the proposed Natco-Sun ANDA Product, executed batch records, and master batch records), and that if Natco-Sun has any basis to contest infringement of the '051 Patent, it would provide the requested materials. Nonetheless, Natco-Sun refused to allow Plaintiffs access to the Natco ANDA, or any of the requested materials showing the process that has been used and will be used to manufacture the proposed Natco-Sun ANDA Product.

148. Natco-Sun refused to even produce the DMF that supports the Natco ANDA, which is readily accessible and can easily be produced. Natco-Sun's withholding of needed manufacturing information has impeded Plaintiffs' ability to evaluate infringement of the '051 Patent.

149. Natco-Sun's unreasonable OCA terms, which restrict Plaintiffs from asserting infringement of the '051 Patent, and Natco-Sun's refusal to produce manufacturing information for the proposed Natco-Sun ANDA Product, is consistent with the conclusion that the commercial processes invented by Pharma Mar and protected by the '051 Patent will be used to manufacture trabectedin for the proposed Natco-Sun ANDA Product. The process claimed in the '051 Patent is important for the commercial manufacture of Yondelis® (trabectedin).

150. Natco-Sun has not provided any basis to contest infringement of the claims of the '051 Patent, including claims that protect Yondelis® (*e.g.*, claims 7, 11 and 14).

151. On information and belief, Natco-Sun continues to withhold its manufacturing information because the trabectedin API of the proposed Natco-Sun ANDA Product is made using the processes claimed in the '051 Patent and the importation, use, sale, and/or offer for sale of the proposed Natco-Sun ANDA Product, if approved by FDA, would infringe the claims of the '051 Patent.

152. On information and belief, Natco-Sun submitted the Natco ANDA to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the proposed Natco-Sun ANDA Product. Natco's ANDA has been assigned ANDA No. 214837.

153. On information and belief, Natco, Sun Ltd., and Sun Inc. collaborated in the research, development, preparation and filing of the Natco ANDA for the proposed Natco-Sun ANDA Product.

154. The Natco-Sun Paragraph IV Notice Letter was signed by counsel for Natco-Sun and stated that the Natco ANDA was submitted by Natco. Counsel for Natco-Sun also requested Plaintiffs to copy in-house counsel for Sun when serving a patent infringement complaint.

155. On information and belief, Natco, Sun Ltd. and Sun Inc. have acted in concert in seeking approval of the Natco ANDA, prior to expiration of the patents-in-suit.

156. On or about June 26, 2020, Janssen received Natco-Sun's Paragraph IV Notice Letter stating that Natco-Sun has submitted ANDA No. 214837 to the FDA, seeking approval to manufacture, use, and sell the proposed Natco-Sun ANDA Product prior to the expiration of the '557 Patent.

157. Natco-Sun's Paragraph IV Notice Letter stated that Natco's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '557 Patent are invalid as obvious.

158. Natco-Sun's obviousness theory with respect to claims of the '557 Patent has no merit.

159. On information and belief, Natco-Sun copied the inventions of the '557 Patent since: 1) it could not meet the great challenge posed by formulating trabectedin; and 2) the claimed commercial formulation of the '557 Patent is highly successful and advantageous.

160. In the Natco-Sun Paragraph IV Notice Letter, Natco-Sun does not dispute that Natco and Sun infringe claims of the '557 Patent. In particular, Natco-Sun does not dispute

that claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent are infringed by submission of the Natco ANDA.

161. In the Natco-Sun Paragraph IV Notice Letter, Natco-Sun also does not dispute that the commercial manufacture, use, importation, offer for sale, and sale of the proposed Natco-Sun ANDA Product, if approved by FDA, would infringe claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent.

162. On information and belief, Natco-Sun had actual and constructive notice of the '557 Patent and '051 Patent prior to the filing of the Natco ANDA.

163. On information and belief, Natco-Sun copied the inventions of the '557 Patent and '051 Patent although there is no regulatory requirement to copy a formulation or process of manufacture in order to obtain approval for the Natco ANDA from FDA.

164. On information and belief, Natco-Sun has made and continues to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import the proposed Natco-Sun ANDA Product prior to the expiration of the patents-in-suit.

165. On information and belief, Natco-Sun's actions include, but are not limited to, the development of the proposed Natco-Sun ANDA Product and the filing of the Natco ANDA with a Paragraph IV certification.

166. On information and belief, Natco-Sun continues to seek FDA approval of the Natco ANDA and intends to collaborate in the commercial manufacture, marketing and sale of the proposed Natco-Sun ANDA Product (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves the Natco-Sun ANDA.

167. Plaintiffs commenced this lawsuit within 45 days of the date they received Natco-Sun's notice of ANDA No. 214837 containing a Paragraph IV certification.

COUNT I

Infringement of the '557 Patent by eVenus-Jiangsu-Fresenius under 35 U.S.C. § 271(e)(2)(A)

168. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 167 hereof, as if fully set forth herein.

169. Under 35 U.S.C. § 271(e)(2)(A), eVenus-Jiangsu-Fresenius has infringed the '557 Patent by submitting ANDA No. 214327 with a Paragraph IV certification and seeking FDA approval of ANDA No. 214327 to market the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '557 Patent.

170. On information and belief, eVenus-Jiangsu-Fresenius's commercial manufacture, importation, use, sale and/or offer for sale of the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '557 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '557 Patent.

171. The eVenus-Jiangsu Paragraph IV Notice Letter does not dispute that claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent are infringed.

172. eVenus-Jiangsu-Fresenius had actual and constructive notice of the '557 Patent prior to filing ANDA No. 214327 seeking approval of the proposed eVenus-Jiangsu ANDA Product.

173. Plaintiffs have no adequate remedy at law to redress the infringement by eVenus-Jiangsu-Fresenius.

174. Plaintiffs will be irreparably harmed if eVenus-Jiangsu-Fresenius is not enjoined from infringing or actively inducing or contributing to infringement of the '557 Patent.

COUNT II

Declaratory Judgment of Infringement of the '557 Patent by eVenus-Jiangsu-Fresenius under 35 U.S.C. §§ 271(a), (b) and/or (c)

175. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 174 hereof, as if fully set forth herein.

176. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and eVenus-Jiangsu-Fresenius regarding infringement of the '557 Patent.

177. On information and belief, eVenus-Jiangsu-Fresenius has made and will continue to make substantial and meaningful preparations to import into the United States and/or to offer to sell, sell and/or use within the United States the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '557 Patent.

178. eVenus-Jiangsu-Fresenius admits that Fresenius will sell and distribute the proposed eVenus-Jiangsu ANDA Product if approved by FDA.

179. eVenus-Jiangsu-Fresenius's actions, including, but not limited to, the filing of ANDA No. 214327 with a Paragraph IV certification and eVenus-Jiangsu-Fresenius's systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 214327 indicate a refusal to change its course of action.

180. eVenus-Jiangsu-Fresenius's commercial manufacture, importation, use, sale and/or offer for sale of the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '557 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '557 Patent under §§ 271(a), (b) and/or (c).

181. The eVenus-Jiangsu Paragraph IV Notice Letter does not dispute that the proposed eVenus-Jiangsu ANDA Product would infringe claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent.

182. Plaintiffs should be granted a judicial declaration that the commercial manufacture, importation, use, offer for sale, and/or sale in the United States of the proposed eVenus-Jiangsu ANDA Product will constitute infringement of the claims of the '557 Patent under §§ 271(a), (b) and/or (c).

183. Plaintiffs have no adequate remedy at law to redress infringement by eVenus-Jiangsu-Fresenius.

184. Plaintiffs will be irreparably harmed if eVenus-Jiangsu-Fresenius is not enjoined from infringing or actively inducing or contributing to infringement of the '557 Patent.

COUNT III

Declaratory Judgment of Infringement of the '051 Patent by eVenus-Jiangsu-Fresenius under 35 U.S.C. § 271(g)

185. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 184 hereof, as if fully set forth herein.

186. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and eVenus-Jiangsu-Fresenius regarding infringement of the '051 Patent.

187. On information and belief, eVenus-Jiangsu-Fresenius has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '051 Patent prior to its expiration.

188. eVenus-Jiangsu-Fresenius admits that Fresenius will sell and distribute the proposed eVenus-Jiangsu ANDA Product if approved by FDA.

189. eVenus-Jiangsu-Fresenius's actions, including, but not limited to, the filing of ANDA No. 214327 with a Paragraph IV certification and eVenus-Jiangsu-Fresenius's systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 214327 indicate a refusal to change its course of action.

190. On June 17, 2020, Plaintiffs requested production of the eVenus ANDA, the Jiangsu DMF, executed batch records, and master batch records in order to evaluate infringement of Pharma Mar's patents protecting Yondelis®, including the '051 Patent. Plaintiffs repeated this request on at least June 25, July 1 and July 8, 2020. eVenus-Jiangsu had not produced the requested information at the commencement of this lawsuit and has not produced the Jiangsu DMF and batch records to this day. eVenus-Jiangsu also has not provided any basis to contest infringement of the claims of the '051 Patent, including the claims of the '051 Patent used to prepare Yondelis® (*e.g.*, claims 7, 11 and 14).

191. On information and belief (including eVenus-Jiangsu's failure to produce needed manufacturing information and the fact that eVenus-Jiangsu has not provided any basis to contest infringement of the claims of the '051 Patent, including claims 7, 11 and 14), eVenus-Jiangsu-Fresenius's importation, use, sale and/or offer for sale of the proposed eVenus-Jiangsu ANDA Product prior to the expiration of the '051 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '051 Patent under 35 U.S.C. § 271(g).

192. On information and belief, eVenus-Jiangsu-Fresenius had actual and constructive notice of the '051 Patent prior to the filing of ANDA No. 214327 seeking approval of the proposed eVenus-Jiangsu ANDA Product.

193. On information and belief, eVenus-Jiangsu-Fresenius's infringement of the '051 Patent is willful.

194. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of the proposed eVenus-Jiangsu ANDA Product will constitute infringement of the claims of the '051 Patent under 35 U.S.C. § 271(g).

195. Plaintiffs have no adequate remedy at law to redress infringement by eVenus-Jiangsu-Fresenius.

196. Plaintiffs will be irreparably harmed if eVenus-Jiangsu-Fresenius is not enjoined from infringing or actively inducing or contributing to infringement of the '051 Patent.

COUNT IV

Infringement of the '557 Patent by Natco-Sun under 35 U.S.C. § 271(e)(2)(A)

197. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 196 hereof, as if fully set forth herein.

198. Under 35 U.S.C. § 271(e)(2)(A), Natco-Sun has infringed the '557 Patent by submitting ANDA No. 214837 with a Paragraph IV certification and seeking FDA approval of ANDA No. 214837 to market the proposed Natco-Sun ANDA Product prior to the expiration of the '557 Patent.

199. On information and belief, Natco-Sun's commercial manufacture, importation, use, sale and/or offer for sale of the proposed Natco-Sun ANDA Product prior to the

expiration of the ’557 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’557 Patent.

200. The Natco-Sun Paragraph IV Notice Letter does not dispute that claims 1, 3-8, 11, 14-20, 22-24, and 26 of the ’557 Patent are infringed.

201. Natco-Sun had actual and constructive notice of the ’557 Patent prior to filing ANDA No. 214837 seeking approval of the proposed Natco-Sun ANDA Product.

202. Plaintiffs have no adequate remedy at law to redress the infringement by Natco-Sun.

203. Plaintiffs will be irreparably harmed if Natco-Sun is not enjoined from infringing or actively inducing or contributing to infringement of the ’557 Patent.

COUNT V

Declaratory Judgment of Infringement of the ’557 Patent by Natco-Sun under 35 U.S.C. §§ 271(a), (b) and/or (c)

204. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 203 hereof, as if fully set forth herein.

205. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Natco-Sun regarding infringement of the ’557 Patent.

206. On information and belief, Natco-Sun has made and will continue to make substantial and meaningful preparations to import into the United States and/or to offer to sell, sell and/or use within the United States the proposed Natco-Sun ANDA Product prior to the expiration of the ’557 Patent.

207. On information and belief, Natco-Sun’s actions, including, but not limited to, the filing of ANDA No. 214837 with a Paragraph IV certification and Natco-Sun’s systematic

attempts to meet the applicable regulatory requirements for approval of ANDA No. 214837 indicate a refusal to change its course of action.

208. Natco-Sun's commercial manufacture, importation, use, sale and/or offer for sale of the proposed Natco-Sun ANDA Product prior to the expiration of the '557 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '557 Patent under §§ 271(a), (b) and/or (c).

209. The Natco-Sun Paragraph IV Notice Letter does not dispute that the proposed Natco-Sun ANDA Product would infringe claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent.

210. Plaintiffs should be granted a judicial declaration that the commercial manufacture, importation, use, offer for sale, and/or sale in the United States of Natco-Sun's ANDA Product will constitute infringement of the claims of the '557 Patent under §§ 271(a), (b) and/or (c).

211. Plaintiffs have no adequate remedy at law to redress infringement by Natco-Sun.

212. Plaintiffs will be irreparably harmed if Natco-Sun is not enjoined from infringing or actively inducing or contributing to infringement of the '557 Patent.

COUNT VI

Declaratory Judgment of Infringement of the '051 Patent by Natco-Sun under 35 U.S.C. § 271(g)

213. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 212 hereof, as if fully set forth herein.

214. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Natco-Sun regarding infringement of the '051 Patent.

215. On information and belief, Natco-Sun has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '051 Patent prior to its expiration.

216. Natco-Sun's actions, including, but not limited to, the filing of ANDA No. 214837 with a Paragraph IV certification and Natco-Sun's systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 214837 indicate a refusal to change its course of action.

217. On July 1, 2020, Plaintiffs requested production of the Natco ANDA, the DMF for the proposed Natco-Sun ANDA Product, executed batch records, and master batch records in order to evaluate infringement of Pharma Mar's patents protecting Yondelis®, including the '051 Patent. Plaintiffs repeated this request on at least July 7 and July 8, 2020. Natco-Sun had not produced the requested information at the commencement of this lawsuit and has not produced the Natco-Sun DMF and batch records to this day. Natco-Sun also has not provided any basis to contest infringement of the claims of the '051 Patent, including the claims of the '051 Patent used to prepare Yondelis® (*e.g.*, claims 7, 11 and 14).

218. On information and belief (including Natco-Sun's failure to produce needed manufacturing information and the fact that Natco-Sun has not provided any basis to contest infringement of the claims of the '051 Patent, including claims 7, 11 and 14), Natco-Sun's importation, use, sale and/or offer for sale of the proposed Natco-Sun ANDA Product prior to the

expiration of the '051 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '051 Patent under 35 U.S.C. § 271(g).

219. On information and belief, Natco-Sun had actual and constructive notice of the '051 Patent prior to the filing of ANDA No. 214837 seeking approval of the proposed Natco-Sun ANDA Product.

220. On information and belief, Natco-Sun's infringement of the '051 Patent is willful.

221. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of the proposed Natco-Sun ANDA Product will constitute infringement of the claims of the '051 Patent under 35 U.S.C. § 271(g).

222. Plaintiffs have no adequate remedy at law to redress infringement by Natco-Sun.

223. Plaintiffs will be irreparably harmed if Natco-Sun is not enjoined from infringing or actively inducing or contributing to infringement of the '051 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(a) a judgment that eVenus, Jiangsu and Fresenius have infringed the '557 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of eVenus's ANDA No. 214327 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '557 Patent, including any additional exclusivity period applicable to the patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic trabectedin 1 mg/vial described in eVenus's ANDA No. 214327 would constitute infringement of the '557 Patent, or inducing or contributing to such conduct, by eVenus, Jiangsu and Fresenius pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining eVenus, Jiangsu, Fresenius and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic trabectedin 1 mg/vial described in eVenus's ANDA No. 214085, or any colorable variations thereof, until the day after the expiration of the '557 Patent, including any additional exclusivity period applicable to the '557 Patent, and from otherwise infringing one or more claims of the '557 Patent;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic trabectedin 1 mg/vial described in eVenus's ANDA No. 214085 would constitute infringement of the '051 Patent, or inducing or contributing to such conduct, by eVenus, Jiangsu and Fresenius pursuant to 35 U.S.C. § 271(g);

(f) a declaration that eVenus, Jiangsu and Fresenius have willfully infringed the '051 Patent;

(g) a judgment permanently enjoining eVenus, Jiangsu, Fresenius and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic trabectedin 1 mg/vial described in eVenus's ANDA No. 214085, or any trabectedin product that is made by any colorable variation of the processes used to make the proposed eVenus-Jiangsu ANDA

Product, until after the expiration of the '051 Patent, including any additional exclusivity period applicable to the '051 Patent, and from otherwise infringing one or more claims of the '051 Patent;

(h) a judgment that Natco, Sun Ltd. and Sun Inc. have infringed the '557 Patent under 35 U.S.C. § 271(e)(2)(A);

(i) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Natco's ANDA No. 214837 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '557 Patent, including any additional exclusivity period applicable to the patent;

(j) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic trabectedin 1 mg/vial described in Natco's ANDA No. 214837 would constitute infringement of the '557 Patent, or inducing or contributing to such conduct, by Natco, Sun Ltd. and Sun Inc. pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(k) a judgment permanently enjoining Natco, Sun Ltd., Sun Inc., and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic trabectedin 1 mg/vial described in Natco's ANDA No. 214837, or any colorable variations thereof, until the day after the expiration of the '557 Patent, including any additional exclusivity period applicable to the '557 Patent, and from otherwise infringing one or more claims of the '557 Patent;

(l) a judgment declaring that importing, selling, offering to sell, or using the generic trabectedin 1 mg/vial described in Natco's ANDA No. 214837 would constitute infringement of the '051 Patent, or inducing or contributing to such conduct, by Natco, Sun Ltd. and Sun Inc. pursuant to 35 U.S.C. § 271(g);

(m) a declaration that Natco, Sun Ltd. and Sun Inc. have willfully infringed the '051 Patent;

(n) a judgment permanently enjoining Natco, Sun Ltd., Sun Inc., and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic trabectedin 1 mg/vial described in Natco's ANDA No. 214837, or any trabectedin product that is made by any colorable variation of the processes used to make the proposed Natco-Sun ANDA Product, until after the expiration of the '051 Patent, including any additional exclusivity period applicable to the '051 Patent, and from otherwise infringing one or more claims of the '051 Patent;

(o) a declaration that this case is exceptional;

(p) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(q) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ John E. Flaherty

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Dated: October 19, 2020

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Respectfully submitted,

/s/ John E. Flaherty

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Dated: October 19, 2020

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing to be served on October 19, 2020, upon the following in the manner indicated:

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