

John E. Flaherty
Cynthia Betz
MCCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, NJ 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

Of Counsel:
Irena Royzman
Christine Willgoos
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
Tel: (212) 715-9100
Fax: (212) 715-8000

Attorneys for Plaintiffs

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

JANSSEN PRODUCTS, L.P., and)
PHARMA MAR, S.A.,)

Plaintiffs,)

v.)

MSN PHARMACEUTICALS INC., and)
MSN LABORATORIES PRIVATE)
LIMITED,)

Defendants.)

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P., (“Janssen”) and Pharma Mar, S.A. (“Pharma Mar”) (collectively, “Plaintiffs”) for their Complaint against Defendants MSN Pharmaceuticals Inc. (“MSN Inc.”) and MSN Laboratories Private Limited (“MSN Labs”) (collectively, “MSN” or “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 Defendants’ filing of Abbreviated New Drug Application No. 216087 (the “MSN ANDA” or “ANDA No. 216087”), supported by Drug Master File No. 034311 (the “MSN DMF”), seeking approval to sell a generic copy of Plaintiffs’ highly successful Yondelis[®] (trabectedin) 1 mg/vial (the “MSN ANDA Product”) prior to the expiration of the ’557 Patent and the ’051 Patent (together, the “patents-in-suit”).

THE PARTIES

3. 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.

4. 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.

5. On information and belief, Defendant MSN Laboratories Private Limited is a company organized and existing under the laws of India with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India. On information and belief, MSN Labs 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, MSN Labs is the holder of the MSN ANDA and

the MSN DMF. On information and belief, MSN Labs will manufacture the proposed ANDA Product and the API used for that product. On information and belief, the acts of MSN Labs complained of here were done with the cooperation, participation, and assistance of MSN Inc.

6. On information and belief, Defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey, 08854. On information and belief, MSN 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 ID No. 0400627791. On information and belief, MSN Inc. 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, MSN Inc. is a wholly-owned subsidiary of Defendant MSN Labs and is an authorized U.S. Agent for MSN Labs, including for the MSN ANDA Product.

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

8. On information and belief, MSN Labs and MSN Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the proposed MSN ANDA Product, in the event FDA approves the MSN ANDA.

JURISDICTION AND VENUE

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

10. On information and belief, this Court has personal jurisdiction over MSN Inc. because MSN Inc. 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.

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

12. On information and belief, MSN 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. 0400627791.

13. On information and belief, MSN Inc. 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.

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

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

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

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

18. On information and belief, MSN Labs is subject to personal jurisdiction in New Jersey because, among other things, MSN Labs itself and through its wholly-owned subsidiary and alter ego, MSN 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.

19. On information and belief, this Court has personal jurisdiction over MSN Labs because, *inter alia*, it: (1) intends to market, sell or distribute the proposed MSN 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 MSN Inc.; (4) operates through its wholly owned subsidiary and alter ego MSN Inc., which 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.

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

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

22. On information and belief, MSN Inc. acts at the direction, and for the benefit, of MSN Labs, and is controlled and/or dominated by MSN Labs.

23. In the alternative, as to MSN Labs, this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, MSN Labs is a foreign company organized and existing under the laws of India, with a principal place of business in Hyderabad, Telangana, India.

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

25. Litigating in the District of New Jersey would not burden MSN Labs 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 their 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.

26. Defendants have invoked the jurisdiction of the courts of this judicial district as counterclaim plaintiffs in numerous patent infringement actions under the Hatch-Waxman Act. *See, e.g., Bausch Health Ireland Limited, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 21-10057, D.I. 10 (D.N.J. June 18, 2021); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 19-18958, D.I. 11 (D.N.J. December 6, 2019); *Chiesi USA Inc., et al., v. MSN Pharmaceuticals Inc., et al.*, C.A. No. 19-18564, D.I. 16 (D.N.J. December 23, 2019); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 19-15616, D.I. 10 (D.N.J. October 22, 2019); *BTG International Limited, et al., v. MSN Pharmaceuticals Inc., et al.*, C.A. No. 18-02372, D.I. 8 (D.N.J. June 8, 2018); *Merck Sharp & Dohme Corp. v. MSN Laboratories Private Limited, et al.*, C.A. No. 18-00675, 17 (D.N.J. March 28, 2018); *Forest Laboratories, LLC, et al., v. MSN Laboratories Private Limited, et al.*, C.A. No. 17-10140, D.I. 14 (D.N.J. December 6, 2017); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. MSN Laboratories Private Limited, et al.*, C.A. No. 17-08399, D.I. 12 (D.N.J. January 2, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. Aurobindo Pharma USA Inc., et al.*, C.A. No. 18-07887, D.I. 55 (D.N.J. June 26, 2018); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 17-05302, D.I. 47 (D.N.J. December 22, 2017); *Sumitomo Dainippon Pharma Co., Ltd., et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 17-01010, D.I. 33 (D.N.J. May 11, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. Hec Pharm Group, et al.*, C.A. No. 15-05982, D.I. 55 (D.N.J. September 3, 2015).

27. Defendants have not contested personal jurisdiction in this judicial district, including in patent infringement actions under the Hatch-Waxman Act. *See, e.g., Bausch Health Ireland Limited, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 21-10057, D.I. 10 (D.N.J.

June 18, 2021); *Actelion Pharmaceuticals Ltd., et al., v. MSN Pharmaceuticals Inc., et al.*, C.A. No. 20-03859, D.I. 16 (D.N.J. June 3, 2020); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 19-18958, D.I. 11 (D.N.J. December 6, 2019); *Chiesi USA Inc., et al., v. MSN Pharmaceuticals Inc., et al.*, C.A. No. 19-18564, D.I. 16 (D.N.J. December 23, 2019); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 19-15616, D.I. 10 (D.N.J. October 22, 2019); *BTG International Limited, et al., v. MSN Pharmaceuticals Inc., et al.*, C.A. No. 18-02372, D.I. 8 (D.N.J. June 8, 2018); *Merck Sharp & Dohme Corp. v. MSN Laboratories Private Limited, et al.*, C.A. No. 18-00675, 17 (D.N.J. March 28, 2018); *Forest Laboratories, LLC, et al., v. MSN Laboratories Private Limited, et al.*, C.A. No. 17-10140, D.I. 14 (D.N.J. December 6, 2017); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. MSN Laboratories Private Limited, et al.*, C.A. No. 17-08399, D.I. 12 (D.N.J. January 2, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. Aurobindo Pharma USA Inc., et al.*, C.A. No. 18-07887, D.I. 55 (D.N.J. June 26, 2018); *Mitsubishi Tanabe Pharma Corporation, et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 17-05302, D.I. 47 (D.N.J. December 22, 2017); *Sumitomo Dainippon Pharma Co., Ltd., et al., v. MSN Laboratories Private Ltd., et al.*, C.A. No. 17-01010, D.I. 33 (D.N.J. May 11, 2018); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. Hec Pharm Group, et al.*, C.A. No. 15-05982, D.I. 55 (D.N.J. September 3, 2015).

28. Venue is proper in this district for MSN Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, MSN 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 Piscataway, New Jersey, located within this judicial district.

29. Venue is proper in this district for MSN Labs pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MSN Labs 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).

30. On July 14, 2021, counsel for Defendants confirmed that Defendants do not contest jurisdiction and venue in the District of New Jersey.

THE ASSERTED PATENTS

31. 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.

32. Pharma Mar holds title to the ’557 Patent.

33. Janssen holds an exclusive license to the ’557 Patent.

34. The ’557 Patent expires on January 7, 2028.

35. 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.

36. Janssen is the holder of approved New Drug Application (“NDA”) No. 207953 for Yondelis[®].

37. Janssen sells Yondelis[®] in the United States.

38. 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).

39. 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[®].

40. 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.

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

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

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

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

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

46. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States and/or sell, offer to 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 its expiration.

47. On information and belief, Defendants' preparations include, but are not limited to, the development of the proposed MSN ANDA Product, the filing of the MSN ANDA with a Paragraph IV certification, and the filing of the MSN DMF.

48. On information and belief, Defendants intend to use the processes claimed in the '051 Patent to prepare the API, trabectedin, contained in the proposed MSN ANDA Product.

49. The processes claimed in the '051 Patent are important for the commercial-scale manufacture of trabectedin. Prior art processes for manufacturing trabectedin were not commercially feasible. The inventive processes claimed in the '051 Patent have been adopted by third parties, including generic drug companies, for the manufacture of trabectedin. Natco Pharma Limited, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc. have stipulated to infringement of this important patent. *See* Stipulation and Order Regarding Infringement of U.S. Patent No. 7,420,051 (Dkt. 104), *Janssen Products, L.P., et al. v. eVenus Pharmaceuticals Laboratories Inc., et al.*, 3:20-cv-09369 (D.N.J. June 2, 2021).

50. On information and belief, trabectedin is present in the proposed MSN ANDA Product without material change from trabectedin made by use of Plaintiffs' patented processes.

51. On information and belief, trabectedin resulting from Plaintiffs' patented processes is the API of the proposed MSN ANDA Product, and is therefore essential to the proposed MSN ANDA Product.

**MSN PARAGRAPH IV NOTICE LETTER, MSN ANDA,
AND REQUESTED DOCUMENTS**

52. On or about June 28, 2021, Plaintiffs received MSN's Paragraph IV Notice Letter dated June 24, 2021 ("PIV Letter") stating that Defendants submitted ANDA No. 216087 to the FDA, seeking approval to manufacture, use, and sell the proposed MSN ANDA Product prior to the expiration of the '557 Patent.

53. On information and belief, Defendants submitted the MSN 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 MSN ANDA Product. The MSN ANDA has been assigned ANDA No. 216087.

54. On information and belief, MSN Labs is the holder of the MSN ANDA and MSN DMF.

55. On information and belief, MSN Inc. is the U.S. agent for the MSN ANDA.

56. On information and belief, Defendants have acted in concert in seeking approval of the MSN DMF and the MSN ANDA prior to expiration of the patents-in-suit.

57. On information and belief, Defendants collaborated in the research, development, preparation and filing of the MSN ANDA and the MSN DMF for the proposed MSN ANDA Product.

58. On information and belief, Defendants have made and continue to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import the proposed MSN ANDA Product prior to the expiration of the patents-in-suit.

59. On information and belief, Defendants' actions include, but are not limited to, the development of the proposed MSN ANDA Product, the filing of the MSN ANDA with a Paragraph IV certification, and the filing of the MSN DMF.

60. On information and belief, Defendants continue to seek FDA approval of the MSN ANDA and intend to collaborate in the commercial manufacture, marketing and sale of the proposed MSN 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 MSN ANDA.

61. After receiving the PIV Letter on June 28, Plaintiffs contacted Defendants on June 29, 2021 and asked for information describing the proposed MSN ANDA Product and documents reflecting the process that has been and will be used to manufacture trabectedin for the proposed MSN ANDA Product so that Plaintiffs could evaluate infringement of the '557 Patent and the '051 Patent. Specifically, Plaintiffs requested the MSN ANDA, MSN DMF, samples of

the proposed MSN ANDA Product, and master and executed batch records reflecting the manufacture of trabectedin.

62. On July 8, 2021, Defendants provided Plaintiffs with the MSN ANDA and portions of the MSN DMF.

63. On July 14, 2021, Plaintiffs repeated their request that Defendants produce all master and executed batch records concerning the manufacture of trabectedin so that Plaintiffs could evaluate infringement. Defendants produced certain batch records.

64. On information and belief, the batch records Defendants produced contain anomalous features indicative of not being prepared in the ordinary course of business, and are scientifically implausible on their face.

65. On July 16, 2021 and again on July 20, Plaintiffs repeated their request for all executed batch records, as well as for the complete MSN DMF.

66. On July 21, 2021, Defendants produced another portion of the MSN DMF. Plaintiffs again repeated their request for all executed batch records, including all those referred to in the DMF. On July 22, July 23, July 26, July 29, July 30, August 2, and August 3, 2021, Plaintiffs repeated their requests for all executed batch records. On July 22, July 23, July 26, July 29, and August 3, 2021, Plaintiffs also informed counsel for MSN that “[t]he documents that MSN provided were not prepared in the ordinary course” and that “[t]he process depicted there is not what is being practiced.” Plaintiffs asked that if MSN contends that it does not infringe the MSN ’051 Patent, that it provide any documents prepared in the ordinary course to that effect. Plaintiffs

also requested the MSN process development report and analytical data for its executed batch records. Plaintiffs noted that it is in MSN's interest to produce such documents.

67. To date Defendants have not produced the requested documents, impeding Plaintiffs ability to fully evaluate infringement of the '051 Patent.

68. The information provided by the documents that Defendants have produced to date, and Defendants' failure to produce the requested executed batch records, is consistent with the conclusion that the processes used by Defendants to manufacture trabectedin for the proposed MSN ANDA Product is the same as the commercial processes invented by Pharma Mar and protected by the '051 Patent. Not only has MSN failed to produce the requested executed batch records, but the ones MSN produced are scientifically implausible. MSN has also failed to produce any other documents prepared in the ordinary course of business reflecting the preparation of trabectedin. If MSN had a good faith basis to contend that it did not infringe the '051 Patent, it would have provided such documents. But MSN did not do so. Further, as set forth above, the processes claimed in the '051 Patent are important for the commercial manufacture of trabectedin. Prior art processes were not usable on a commercial scale. The claimed processes have been used by other parties and other generic companies have admitted to infringement of the claims of the '051 Patent for the commercial manufacture of trabectedin for their proposed generic copies of Plaintiffs' Yondelis[®]. On information and belief, MSN uses the claimed processes of the '051 Patent to manufacture trabectedin for the proposed MSN ANDA Product.

69. The MSN PIV Letter stated that the MSN ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(B), that claims of the '557 Patent are invalid as obvious. The obviousness theory Defendants set forth in the PIV Letter with respect to the claims of the '557 Patent has no merit.

70. In the PIV Letter, Defendants do not dispute that MSN Labs and MSN Inc. infringe the claims of the '557 Patent. Defendants do not dispute that the claims of the '557 Patent are infringed by submission of the MSN ANDA.

71. In the PIV Letter, Defendants do not dispute that the commercial manufacture, use, importation, offer for sale and sale of the proposed MSN ANDA Product, if approved by FDA, would infringe claims 1, 3-8, 11, 14-20, 22-24, and 26 of the '557 Patent.

72. On information and belief, Defendants had actual and constructive notice of the '557 Patent and '051 Patent prior to the filing of the MSN ANDA.

73. On information and belief, Defendants 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 MSN ANDA from FDA.

74. Plaintiffs commenced this lawsuit within 45 days of the date they received Defendants' notice of ANDA No. 216087 containing a Paragraph IV certification.

COUNT I

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

75. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 74 hereof, as if fully set forth herein.

76. Under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '557 Patent by submitting ANDA No. 216087 with a Paragraph IV certification and seeking FDA approval of ANDA No. 216087 to market the proposed MSN ANDA Product prior to the expiration of the '557 Patent.

77. On information and belief, Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the proposed MSN 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.

78. The MSN 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.

79. Defendants had actual and constructive notice of the '557 Patent prior to filing ANDA No. 216087 seeking approval of the proposed MSN ANDA Product.

80. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants.

81. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants under 35 U.S.C. §§ 271(a), (b) and/or (c)

82. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 81 hereof, as if fully set forth herein.

83. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '557 Patent.

84. On information and belief, Defendants have 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 MSN ANDA Product prior to the expiration of the '557 Patent.

85. Defendants admit that they will sell and distribute the proposed MSN ANDA Product if approved by FDA.

86. Defendants' actions, including, but not limited to, the filing of ANDA No. 216087 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 216087 indicate a refusal to change their course of action.

87. Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the proposed MSN 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).

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

89. 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 MSN ANDA Product will constitute infringement of the claims of the '557 Patent under §§ 271(a), (b) and/or (c).

90. Plaintiffs have no adequate remedy at law to redress infringement by Defendants.

91. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants under 35 U.S.C. § 271(g)

92. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 91 hereof, as if fully set forth herein.

93. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '051 Patent.

94. On information and belief, Defendants have 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.

95. Defendants' actions, including, but not limited to, the filing of ANDA No. 216087 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 216087 indicate a refusal to change their course of action.

96. On information and belief, Defendants' importation, use, sale and/or offer for sale of the proposed MSN 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 (*e.g.*, claims 11 and 14) under 35 U.S.C. § 271(g).

97. On information and belief, Defendants had actual and constructive notice of the '051 Patent prior to the filing of ANDA No. 216087 seeking approval of the proposed MSN ANDA Product.

98. On information and belief, Defendants' infringement of the '051 Patent is willful.

99. 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 MSN

ANDA Product will constitute infringement of the claims of the '051 Patent under 35 U.S.C. § 271(g).

100. Plaintiffs have no adequate remedy at law to redress infringement by Defendants.

101. Plaintiffs will be irreparably harmed if Defendants are 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 MSN Labs and MSN Inc. 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 ANDA No. 216087 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 ANDA No. 216087 would constitute infringement of the '557 Patent, or inducing or contributing to such conduct, by MSN Labs and MSN Inc. pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining MSN Labs and MSN 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 ANDA No. 216087, 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 ANDA No. 216087 would constitute infringement of the '051 Patent, or inducing or contributing to such conduct, by MSN Labs and MSN Inc. pursuant to 35 U.S.C. § 271(g);

(f) a declaration that MSN Labs and MSN Inc. have willfully infringed the '051 Patent; and

(g) a judgment permanently enjoining MSN Labs and MSN 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 ANDA No. 216087, or any trabectedin product that is made by any colorable variation of the processes used to make the proposed MSN 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 declaration that this case is exceptional;

(i) an award of Plaintiffs' costs, expenses, reasonable attorney's 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

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

Respectfully submitted,

Of Counsel:

Irena Royzman
Christine Willgoos
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
Tel: (212) 715-9100
Fax: (212) 715-8000

Daniel Williams
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
990 March Road
Menlo Park, CA 94025
Tel: (650) 752-1700
Fax: (650) 752-1800

/s/ John E. Flaherty

John E. Flaherty
Cynthia Betz
MCCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, New Jersey 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

*Attorneys for Plaintiffs Janssen Products, L.P.
and Pharma Mar, S.A.*

Dated: August 5, 2021

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. However, the matter in controversy involves the validity and infringement of patents currently asserted in this Court against different generic manufacturers in the following action presided over by the Honorable Zahid N. Quraishi: *Janssen Products, L.P., et al., v. eVenus Pharmaceuticals Laboratories Inc., et al.*, 3:20-cv-09369-ZNQ-LHG (D.N.J.).

Respectfully submitted,

/s/ John E. Flaherty

John E. Flaherty
Cynthia Betz
McCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, New Jersey 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

*Attorneys for Plaintiffs Janssen Products,
L.P. and Pharma Mar, S.A.*

Of Counsel:

Irena Royzman
Christine Willgoos
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
Tel: (212) 715-9100
Fax: (212) 715-8000

Daniel Williams
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
990 March Road
Menlo Park, CA 94025
Tel: (650) 752-1700
Fax: (650) 752-1800

Dated: August 5, 2021