IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LIMITED, Defendants.	)))))))))))	C.A. No. 18-651-CFC (Consolidated) Relates to *MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited*, C.A. No. 20-1334-CFC

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Amended Complaint against Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "MSN") alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including Hetlioz® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24").

2. On information and belief, MSN Pharmaceuticals is a Delaware corporation, with its principal place of business 20 Duke Road, Piscataway, New Jersey 08854.

3. On information and belief, MSN Labs is an Indian private limited company, having a place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

4. On information and belief, MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs.

5. On information and belief MSN Pharmaceuticals is the designated U.S. agent for MSN Labs in accordance with 21 C.F.R. § 314.50(a) in connection with Abbreviated New Drug Application No. 211654 (the "MSN ANDA").

6. On information and belief, MSN Pharmaceuticals is a generic pharmaceutical company that manufactures and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States in concert with MSN Labs.

7. On information and belief, MSN Pharmaceuticals and MSN Labs acted in concert to prepare and submit the MSN ANDA.

II. NATURE OF THE ACTION

8. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq*.) based upon MSN's infringement of one or more claims of Vanda's U.S. Patent Nos. 10,610,510 ("the '510 patent") and 10,610,511 ("the '511 patent"), which, in relevant part, generally relate to the use of tasimelteon in the treatment of circadian rhythm disorders or sleep disorders.

9. Vanda is the holder of approved New Drug Application No. 205677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration ("FDA") on January 31, 2014, for the treatment of Non-24, a circadian rhythm sleep disorder.

10. Tasimelteon is the active ingredient in Hetlioz®.

11. On information and belief, MSN filed the MSN ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially

manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("MSN's ANDA Product").

12. On information and belief, MSN made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that in its opinion the '510 and '511 patents are invalid, unenforceable, and/or that certain claims will not be infringed by MSN's ANDA Product.

13. Vanda received written notice of MSN's ANDA and Paragraph IV Certification as to the '510 and '511 patents on March 24, 2021 ("Notice Letter"), along with an enclosed statement of MSN's alleged factual and legal bases for stating that the '510 and '511 patents are invalid, unenforceable, and/or will not be infringed by MSN's ANDA Product ("Detailed Statement").

14. MSN's Detailed Statement does not provide any factual bases or other statements alleging that the '510 and '511 patents are unenforceable.

15. This action was filed prior to receipt of MSN's notice letter; and the Amended Complaint, which includes a request for relief under the FFCA, was filed within 45 days of receipt of MSN's Notice Letter.

16. MSN has infringed one or more claims of each of the '510 and '511 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the MSN ANDA with a Paragraph IV Certification and seeking FDA approval of the MSN ANDA, including one or more amendments thereto, prior to the expiration of the '510 and '511 patents or any extensions thereof. MSN has infringed one or more claims of each of the '510 and '511 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the MSN ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States

generic tasimelteon for the treatment of Non-24 prior to the expiration of the '510 and '511 patents or any extensions thereof.

III. JURISDICTION

17. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. This Court has personal jurisdiction over MSN Pharmaceuticals because MSN Pharmaceuticals is organized under the laws of the State of Delaware.

19. On information and belief, MSN Pharmaceuticals is registered to conduct business within the State of Delaware (File No. 5454849). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx (accessed on Sept. 23, 2020).

20. On information and belief, MSN Pharmaceuticals maintains as a registered agent for service of process United States Corporation Agents, Inc., with an address at 221 North Broad Street, Suite 3A, Middletown, Delaware 19709.

21. This Court has personal jurisdiction over MSN Labs under Fed. R. Civ. P. 4(k) because, on information and belief, MSN Labs is organized under the laws of India.

22. This Court has personal jurisdiction over MSN Labs because at least one of the provisions under Del. Code Ann. tit. 10, § 3104, is satisfied. On information and belief, MSN Labs satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), and § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or

omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

23. This Court also has personal jurisdiction over MSN Labs because this suit arises out of and relates to MSN Labs's activities, in concert with MSN Pharmaceuticals, that are, and will be, directed to Delaware. On information and belief, following any FDA approval of the MSN ANDA, MSN Labs, in concert with MSN Pharmaceuticals, will market and sell MSN's ANDA Product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, including in this Judicial District.

24. On information and belief, MSN Labs, directly and through its subsidiaries, affiliates, or agents, including MSN Pharmaceuticals, is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

25. MSN Pharmaceuticals and MSN Labs, acting in concert, have committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures Hetlioz® for sale and use throughout the United States, including in this Judicial District.

26. On information and belief, and as indicated by the Notice Letter, MSN Pharmaceuticals and MSN Labs, acting in concert, prepared and filed ANDA No. 211654 with the intention of seeking to market generic tasimelteon nationwide, including within this Judicial District.

27. On information and belief, MSN plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's

prescription drug formulary, and seek Medicaid reimbursement for sales of MSN's ANDA Product in the State of Delaware, either directly or through one or more of MSN's subsidiaries, agents, and/or alter egos.

28. On information and belief, MSN knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of Hetlioz®, causing injury to Vanda. MSN intends to take advantage of its established channels of distribution in Delaware for the sale of MSN's ANDA Product.

29. This Court also has personal jurisdiction over MSN Labs by virtue of, *inter alia*, its activities, in concert with MSN Pharmaceuticals (*e.g.*, filing the MSN ANDA seeking approval to market generic tasimelteon prior to the expiration of the '510 and '511 patents), which were purposefully directed to the State of Delaware. Vanda is incorporated in Delaware, and thus the consequences of MSN Labs's actions were (and will be) suffered in Delaware. MSN Labs knew or should have known that Vanda is a Delaware corporation and thus MSN Labs knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

30. This Court also has personal jurisdiction over MSN Labs because MSN Labs's contacts within this Judicial District are continuous and systematic. On information and belief, MSN Labs, in concert with MSN Pharmaceuticals, develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and throughout the United States. Thus, on information and belief, MSN Labs does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. These continuous and

systematic contacts, including, but not limited to, those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over MSN Labs.

31. On information and belief, MSN Labs maintains continuous and systematic contacts with Delaware through its U.S. subsidiary MSN Pharmaceuticals, which is organized under the laws of the State of Delaware.

32. Furthermore, on information and belief, MSN Pharmaceuticals and MSN Labs have admitted or consented to, or not contested, the jurisdiction of this Court and/or have availed themselves of the rights, benefits, and privileges of this Court by asserting claims and counterclaims in prior District of Delaware actions.

IV. VENUE

33. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b) and (c) and § 1400(b) because MSN Pharmaceuticals is incorporated in the State of Delaware and MSN Labs is incorporated in India and may be sued in any judicial district in the United States in which MSN Labs is subject to the Court's personal jurisdiction.

V. THE PATENTS-IN-SUIT

(U.S. PATENT NOS. 10,610,510 and 10,610,511)

U.S. Patent No. 10,610,510

34. The allegations above are incorporated herein by reference.

35. The '510 patent covers, generally, a method of treating circadian rhythm disorders by administration of tasimelteon to patients who may be smokers.

36. As explained in the '510 patent, smoking "has been found to increase the clearance of tasimelteon, thereby reducing patient exposure" to the drug, and therefore, administration of tasimelteon to patient who is a smoker may require, in some cases, "reducing

or eliminating the individual's smoking." The '510 patent further explains that aspects of the invention, as they relate to the effects of smoking on tasimelteon exposure include, without limitation: "treating a patient with tasimelteon wherein the patient is a smoker" with a method comprising "instructing the patient to reduce or eliminate smoking."

37. Vanda is the owner of all rights, title, and interest in the '510 patent, entitled "Treatment Of Circadian Rhythm Disorders." The USPTO duly and legally issued the '510 patent on April 7, 2020, to Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '510 patent is attached to this Amended Complaint as Exhibit A.

38. The '510 patent generally claims methods of treating circadian rhythm disorders using tasimelteon based on whether the patient is a smoker.

U.S. Patent No. 10,610,511

39. The allegations above are incorporated herein by reference.

40. The '511 patent covers, generally, the administration of an effective dose of tasimelteon without food or under fasted conditions to treat patients suffering from a circadian rhythm disorder or sleep disorder.

41. As explained in the '511 patent, one embodiment of the invention "provides a method for administering tasimelteon to a human patient that comprises orally administering an effective dose of tasimelteon under fasted conditions." The '511 patent further explains, "[t]asimelteon may be administered where, for example, the patient is being treated for a circadian rhythm disorder or for a sleep disorder, including, for example, Non-24 Disorder."

42. Vanda is the owner of all rights, title, and interest in the '511 patent, entitled "Method of Treatment." The USPTO duly and legally issued the '511 patent on April 7,

2020, to Marlene Michelle Dressman, Mihael H. Polymeropoulos, and Paolo Baroldi as inventors, which was assigned to Vanda. A true and correct copy of the '511 patent is attached to this Amended Complaint as Exhibit B.

43. The '511 patent generally claims methods of treating circadian rhythm disorders or sleep disorders using tasimelteon based on instructing the patient to take tasimelteon without food or under fasted conditions.

VI. COUNT I

(INFRINGEMENT OF THE '510 PATENT)

44. The allegations above are incorporated herein by reference.

45. MSN filed the MSN ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '510 patent and any extensions thereof.

46. MSN's Notice Letter states that MSN filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '510 patent. The Notice Letter represents that an Amendment to MSN's ANDA was submitted with a Paragraph IV Certification that the '510 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Product.

47. MSN thus has actual knowledge of the '510 patent. *See also* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/211654Orig1s000TAltr.pdf (accessed on Sept. 23, 2020).

48. The FDA-approved Hetlioz® Label instructs prescribers that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

49. The Hetlioz® Label further instructs prescribers that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

50. The Hetlioz® Label also teaches prescribers that "[s]moking causes induction of CYP1A2 levels. The exposure of tasimelteon in smokers was lower than in non-smokers and therefore the efficacy of HETLIOZ may be reduced in smokers [*see Clinical pharmacology (12.3)*]." The Hetlioz® Label further teaches prescribers: "[t]asimelteon exposure decreased by approximately 40% in smokers, compared to nonsmokers [*see Use in Specific Populations (8.7)*]."

51. On information and belief, the MSN ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24.

52. Thus, the use of Hetlioz® and any generic tasimelteon for the treatment of Non-24 is covered by the '510 patent and Vanda has the right to enforce the '510 patent and sue for infringement thereof.

53. The '510 patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Hetlioz® in its 20 mg strength.

54. On information and belief, the MSN ANDA essentially copies the Hetlioz® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, teaches, and/or suggests that prescribers infringe claims 1–13 of the '510 patent.

55. On information and belief, if MSN's ANDA is approved, prescribers and patients will follow the instructions in the proposed label for MSN's ANDA Product and administer MSN's ANDA Product in a manner that would infringe claims 1–13 of the '510 patent.

56. On information and belief, MSN's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claims 1–13 of the '510 patent.

57. MSN has infringed the '510 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the MSN ANDA, including one or more amendments, to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by one or more claims of the '510 patent, prior to the expiration of the '510 patent.

58. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the MSN ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '510 patent, including claims 1–13 under 35 U.S.C. § 271(a), (b), and/or (c).

59. Vanda seeks entry of an order requiring that MSN amend its Paragraph IV Certification in the MSN ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

60. Vanda seeks entry of an order declaring that MSN has infringed the '510 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

61. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the MSN ANDA be a date that is not earlier than the expiration of the '510 patent or any later expiration of exclusivity for the '510 patent to which Vanda becomes entitled.

62. Vanda will be irreparably harmed if MSN is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '510 patent.

Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

63. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

64. To the extent MSN commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

VII. COUNT II

(INFRINGEMENT OF THE '511 PATENT)

65. The allegations above are incorporated herein by reference.

66. MSN filed the MSN ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon to be taken under fasted conditions or without food for the treatment of Non-24 before the expiration of the '511 patent and any extensions thereof.

67. MSN's Notice Letter states that MSN filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '511 patent. The Notice Letter represents that an Amendment to MSN's ANDA was submitted with a Paragraph IV Certification that the '511 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Product.

68. MSN thus has actual knowledge of the '511 patent. *See also* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/211654Orig1s000TAltr.pdf (accessed on Sept. 23, 2020).

69. The FDA-approved Hetlioz® Label instructs prescribers that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

70. The Hetlioz® Label further instructs prescribers that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

71. The Hetlioz® Label also instructs prescribers that "HETLIOZ should be taken without food *[see Clinical Pharmacology (12.3)]*."

72. On information and belief, the MSN ANDA seeks approval for a 20 mg tasimelteon oral capsule to be taken under fasted conditions or without food for the treatment of Non-24.

73. Thus, the use of Hetlioz® and any generic tasimelteon for the treatment of Non-24 is covered by the '511 patent and Vanda has the right to enforce the '511 patent and sue for infringement thereof.

74. The '511 patent is listed in the FDA's Orange Book for Hetlioz® in its 20 mg strength.

75. On information and belief, the MSN ANDA essentially copies the Hetlioz® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, teaches, and/or suggests that prescribers infringe claims 1–2 and 4–19 of the '511 patent.

76. On information and belief, if MSN's ANDA is approved, prescribers and patients will follow the instructions in the proposed label for MSN's ANDA Product and administer MSN's ANDA Product in a manner that would infringe claims 1–2 and 4–19 of the '511 patent.

77. On information and belief, MSN's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claims 1–2 and 4–19 of the '511 patent.

78. MSN has infringed the '511 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the MSN ANDA, including one or more amendments, to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength to be taken without food or under fasted conditions for the treatment of Non-24, which is covered by one or more claims of the '511 patent, prior to the expiration of the '511 patent.

79. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the MSN ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '511 patent, including claims 1–2 and 4–19 under 35 U.S.C. § 271(a), (b), and/or (c).

80. Vanda seeks entry of an order requiring that MSN amend its Paragraph IV Certification in the MSN ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

81. Vanda seeks entry of an order declaring that MSN has infringed the '511 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

82. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the MSN ANDA be a date that is not earlier than the expiration of the '511 patent or any later expiration of exclusivity for the '511 patent to which Vanda becomes entitled.

83. Vanda will be irreparably harmed if MSN is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '511 patent.

Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

84. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

85. To the extent MSN commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against MSN and grant the following relief:

A. an adjudication that MSN has infringed directly, contributed to, or induced the infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the MSN ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '510 patent;

B. an adjudication that MSN has infringed directly, contributed to, or induced the infringement of one or more claims of the '511 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the MSN ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '511 patent;

C. a declaration that MSN will infringe directly, contribute to, or induce the infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '510 patent;

D. a declaration that MSN will infringe directly, contribute to, or induce the infringement of one or more claims of the '511 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '511 patent;

E. an order requiring that MSN amend its Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

F. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the MSN ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '510 patent or any later period of exclusivity to which Vanda is or may become entitled;

G. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the MSN ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '511 patent or any later period of exclusivity to which Vanda is or may become entitled;

H. a permanent injunction enjoining MSN, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '510 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the MSN ANDA;

I. a permanent injunction enjoining MSN, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '511 patent, or contributing to or inducing

anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the MSN ANDA;

J. an order enjoining MSN, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '510 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the MSN ANDA;

K. an order enjoining MSN, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '511 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the MSN ANDA;

L. an assessment of pre-judgment and post-judgment interest and costs against MSN, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

M. an award to Vanda of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

N. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Karen Jacobs (#2881)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
kjacobs@morrisnichols.com
dfahnestock@morrisnichols.com

Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

OF COUNSEL:

Nicholas Groombridge
Eric Alan Stone
Josephine Young
Daniel J. Klein
Jennifer Rea Deneault
Michael F. Milea
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

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