IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	C.A. No. 18-651-CFC (Cons.)
	)	
v.	)	Relates to C.A. No. 20-1334-CFC
	)	
MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LIMITED,	)	
	)	
Defendants.	)	

DEFENDANTS MSN PHARMACEUTICALS INC. AND MSN LABORATORIES PRIVATE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF VANDA'S AMENDED COMPLAINT

Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "MSN"), by and through the undersigned attorneys, submit their answer, affirmative defenses, and counterclaims to the Amended Complaint for patent infringement filed by Plaintiff Vanda Pharmaceuticals Inc. ("Vanda"). MSN denies all allegations in Vanda's Amended Complaint except those admitted specifically below. This pleading is based upon MSN's knowledge of its own activities, and upon information and belief as to the activities of others.

I. THE PARTIES

1. MSN admits, upon information and belief, that Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite

300E, Washington, DC 20037. MSN further admits, upon information and belief, that Vanda is a pharmaceutical company that markets HETLIOZ® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24"). MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

2. MSN admits that MSN Pharmaceuticals is a Delaware corporation. MSN admits that MSN Pharmaceuticals has a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies any remaining allegations of this paragraph.

3. MSN admits that 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. MSN denies any remaining allegations of this paragraph.

4. MSN admits that MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs. MSN denies any remaining allegations of this paragraph.

5. MSN admits that 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"). MSN denies any remaining allegations of this paragraph.

6. MSN admits that MSN Pharmaceuticals is a pharmaceutical company that manufactures and distributes generic pharmaceutical products for sale in the United States, including in Delaware, in conjunction and coordination with MSN Labs. MSN denies any remaining allegations of this paragraph.

7. MSN admits that MSN Pharmaceuticals and MSN Labs acted in conjunction and coordination to prepare and submit the MSN ANDA. MSN denies any remaining allegations of this paragraph.

II. NATURE OF THE ACTION

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that the Amended Complaint purports to bring an action for infringement arising under the patent laws of 35 U.S.C. §§ 100, *et seq*., relating to U.S. Patent Nos. 10,610,510 ("the '510 patent") and 10,610,511 ("the '511 patent"). MSN further admits that this Amended Complaint suggests that these patents, in relevant part, generally relate to the use of tasimelteon in the treatment of circadian rhythm disorders or sleep disorders. MSN denies any remaining allegations of this paragraph.

9. Upon information and belief based on information available from the Food and Drug Administration ("FDA"), MSN admits that Vanda is the holder of approved New Drug Application No. 205,677 for HETLIOZ® (tasimelteon) capsules, 20 mg. MSN further admits, upon information and belief, that HETLIOZ®

was approved by the FDA on January 31, 2014 and that the approved indication for HETLIOZ® in its current label is treatment of Non-24. MSN denies any remaining allegations of this paragraph.

10. Upon information and belief, MSN admits that Tasimelteon is the active ingredient in HETLIOZ®.

11. Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it filed the MSN ANDA No. 211654 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"). MSN denies any remaining allegations of this paragraph.

12. MSN admits that it made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). MSN admits that its Paragraph IV Certification speaks for itself. MSN denies any remaining allegations of this paragraph.

13. Upon information and belief, Vanda received written notice of MSN's ANDA and Paragraph IV Certification as to the '510 and '511 patents on or about March 24, 2021 ("Notice Letter"). MSN admits that its ANDA, Paragraph IV Certification, Notice Letter and Detailed Statement speak for themselves. MSN denies any remaining allegations of this paragraph.

14. MSN admits that its Detailed Statement speaks for itself. MSN denies any remaining allegations of this paragraph.

15. Upon information and belief, MSN admits that the first complaint Vanda filed against MSN concerning the '510 and '511 patents was filed prior to receipt by Vanda of the Notice Letter, and that this Amended Complaint was filed within 45 days of Vanda's receipt of MSN's Notice Letter. MSN denies any remaining allegations of this paragraph.

16. MSN denies the allegations of this paragraph.

III. JURISDICTION

17. Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that this action arises under the patent laws of the United States generally. MSN does not contest that this Court has subject matter jurisdiction of this action against MSN for the purposes of this action only. MSN denies any remaining allegations of this paragraph.

18. Paragraph 18 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals is a Delaware corporation. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest

personal jurisdiction in this judicial district. MSN denies any remaining allegations of this paragraph.

19. MSN admits that MSN Pharmaceuticals is registered to conduct business within the State of Delaware. MSN denies any remaining allegations of this paragraph.

20. MSN admits that MSN Pharmaceuticals maintains as a registered agent for service of process United States Corporation Agents, Inc., with an address at 300 Delaware Ave., Suite 210-A, Wilmington, DE 19801. MSN denies any remaining allegations of this paragraph.

21. Paragraph 21 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that MSN Labs is organized under the laws of India. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest personal jurisdiction in this judicial district. MSN denies any remaining allegations of this paragraph.

22. Paragraph 22 contains conclusions of law for which no response is required. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest personal jurisdiction in this judicial district. MSN denies any remaining allegations of this paragraph.

23. Paragraph 23 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it seeks FDA approval of the MSN ANDA. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest personal jurisdiction in this judicial district. MSN denies the remaining allegations of this paragraph.

24. MSN admits that MSN Labs manufactures and distributes generic pharmaceuticals in the United States, including in Delaware, directly and/or through its subsidiaries, affiliates, or agents, including MSN Pharmaceuticals. MSN denies any remaining allegations of this paragraph.

25. Paragraph 25 contains conclusions of law for which no response is required. To the extent a response is required, MSN denies the allegations of this paragraph.

26. MSN admits that it filed ANDA No. 211654 with the intention of seeking approval to market generic tasimelteon nationwide, including within this Judicial District. MSN denies the remaining allegations of this paragraph.

27. MSN admits that it seeks FDA approval for the commercial marketing and sale of generic tasimelteon in the United States, including in Delaware. MSN denies the remaining allegations of this paragraph.

28. Paragraph 28 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it seeks FDA approval for the commercial marketing and sale of generic tasimelteon in the United States, including in Delaware. MSN denies the remaining allegations of this paragraph.

29. Paragraph 29 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it seeks FDA approval for the commercial marketing and sale of generic tasimelteon in the United States, including in Delaware. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest personal jurisdiction in this judicial district. MSN denies the remaining allegations of this paragraph.

30. Paragraph 30 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals manufactures, markets, and sells FDA-approved generic pharmaceutical drugs in the United States, including in Delaware. For the purposes of this action only and solely to conserve the resources of the parties and the Court, MSN does not contest personal jurisdiction in this judicial district. MSN denies the remaining allegations of this paragraph.

31. Paragraph 31 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that MSN Labs is that parent company of its subsidiary, MSN Pharmaceuticals, and that MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware and the United States. MSN denies the remaining allegations of this paragraph.

32. Paragraph 32 contains conclusion of law for which no response is required. To the extent a response is required, MSN admits that records of prior actions speak for themselves. MSN denies the remaining allegations of this paragraph.

IV. VENUE

33. Paragraph 33 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest that venue is proper in this Court for the purposes of this action only. MSN denies the remaining allegations of this paragraph.

V. THE PATENT-IN-SUIT

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

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

34. MSN incorporates its answers to each of the preceding paragraphs herein by reference.

35. MSN admits that '510 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

36. MSN admits that the '510 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

37. Paragraph 37 contains conclusions of law for which no response is required. To the extent a response is required, MSN denies that that the '510 patent was duly and legally issued. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

38. Paragraph 38 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that '510 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

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

39. MSN incorporates its answers to each of the preceding paragraphs herein by reference.

40. MSN admits that '511 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

41. MSN admits that the '511 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

42. Paragraph 42 contains conclusions of law for which no response is required. To the extent a response is required, MSN denies that that the '511 patent was duly and legally issued. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

43. Paragraph 43 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that '511 patent speaks for itself. MSN denies any remaining allegations of this paragraph.

VI. COUNT I

(INFRINGEMENT OF THE '510 PATENT)

44. MSN incorporates its answers to each of the preceding paragraphs herein by reference.

45. MSN admits that it filed the MSN ANDA under § 505(j) of the FFDCA, seeking 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. MSN denies the remaining allegations of this paragraph.

46. MSN admits that its Notice Letter speaks for itself. MSN denies any remaining allegations of this paragraph.

47. Paragraph 47 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it is aware of the

existence of the '510 patent. MSN denies the remaining allegations of this paragraph.

48. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

49. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

50. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

51. MSN admits that the MSN ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24. MSN denies the remaining allegations of this paragraph.

52. Paragraph 52 contains conclusions of law for which no response is required. To the extent a response is required, MSN denies the allegations of this paragraph.

53. Upon information and belief, MSN admits that the '510 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for HETLIOZ® in its 20 mg strength. MSN denies the remaining allegations of this paragraph.

54. MSN denies the allegations of this paragraph.

55. MSN denies the allegations of this paragraph.

56. MSN denies the allegations of this paragraph.

57. MSN denies the allegations of this paragraph.

58. MSN denies the allegations of this paragraph.

59. MSN denies that Vanda is entitled to an entry of an order requiring that MSN amend its Paragraph IV Certification in the MSN ANDA in this or any other way. MSN denies the remaining allegations of this paragraph.

60. MSN denies that Vanda is entitled to an 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). MSN denies the remaining allegations of this paragraph.

61. MSN denies that Vanda is entitled to an entry of an order 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. MSN denies the remaining allegations of this paragraph.

62. MSN denies the allegations of this paragraph.

63. MSN denies the allegations of this paragraph.

64. MSN denies the allegations of this paragraph.

VII. COUNT II

(INFRINGEMENT OF THE '511 PATENT)

65. MSN incorporates its answers to each of the preceding paragraphs herein by reference.

66. MSN admits that it filed the MSN ANDA under § 505(j) of the FFDCA, seeking approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '511 patent and any extensions thereof. MSN denies the remaining allegations of this paragraph.

67. MSN admits that its Notice Letter speaks for itself. MSN denies the remaining allegations of this paragraph.

68. Paragraph 68 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that it is aware of the existence of the '511 patent. MSN denies the remaining allegations of this paragraph.

69. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

70. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

71. MSN admits that the quoted language appears in the HETLIOZ® Label. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies them.

72. MSN admits that the MSN ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24. MSN denies the remaining allegations of this paragraph.

73. Paragraph 73 contains conclusions of law for which no response is required. To the extent a response is required, MSN denies the allegations of this paragraph.

74. Upon information and belief, MSN admits that the '511 patent is listed in the FDA's Orange Book for HETLIOZ® in its 20 mg strength. MSN denies the remaining allegations of this paragraph.

75. MSN denies the allegations of this paragraph.

76. MSN denies the allegations of this paragraph.

77. MSN denies the allegations of this paragraph.

78. MSN denies the allegations of this paragraph.

79. MSN denies the allegations of this paragraph.

80. MSN denies that Vanda is entitled to an entry of an order requiring MSN to amend its Paragraph IV Certification in this or any other way. MSN denies the remaining allegations of this paragraph.

81. MSN denies that Vanda is entitled to an 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). MSN denies the remaining allegations of this paragraph.

82. MSN denies that Vanda is entitled to an entry of an order 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. MSN denies the remaining allegations of this paragraph.

83. MSN denies the allegations of this paragraph.

84. MSN denies the allegations of this paragraph.

85. MSN denies the allegations of this paragraph.

PRAYER FOR RELIEF

The remainder of Vanda's Amended Complaint is a prayer for relief, and does not require a response. To the extent any response is required, MSN denies that Vanda is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "MSN"), hereby assert the following defenses without undertaking or otherwise shifting any applicable burdens of proof. MSN reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The filing of MSN's Abbreviated New Drug Application ("ANDA") No. 211654 has not infringed and does not infringe any valid and enforceable claim of United States Patent Nos. 10,610,510 ("the '510 patent") or 10,610,511 ("the '511 patent") either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

The manufacture, use, sale, or offer for sale of MSN's proposed generic product that is the subject of ANDA No. 211654 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claims of the '510 patent or '511 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Affirmative Defense

Claims of the '510 patent and '511 patent are invalid under one or more provisions of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Fourth Affirmative Defense

The Amended Complaint fails to state a claim upon which relief can be granted.

Fifth Affirmative Defense

MSN's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

MSN has not willfully infringed any claim of the '510 patent or '511 patent.

Seventh Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For their Counterclaims against Plaintiff/Counterclaim-Defendant Vanda Pharmaceuticals Inc. ("Vanda"), MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "MSN") state as follows:

PARTIES

1. MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

2. MSN Laboratories Private Limited is an Indian private limited company, having a place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

3. Upon information and belief, Vanda Pharmaceuticals Inc. is a Delaware corporation having a principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037.

JURISDICTION AND VENUE

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

5. These counterclaims arise under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Vanda because, among other reasons, Vanda subjected itself to the jurisdiction of this Court by filing its original Complaint and Amended Complaint here.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1400(a).

8. There is an actual and justiciable controversy between the parties as to the infringement of United States Patent Nos. 10,610,510 ("the '510 patent") and 10,610,510 ("the '511 patent").

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

13. The FDA's duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

C. MSN's ANDA

16. MSN submitted its ANDA No. 211654 ("MSN's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of a capsule product containing 20 mg of tasimelteon as the active ingredient ("MSN's Proposed Product"), before the '510 patent and '511 patent expire.

17. On information and belief, the FDA lists Vanda as the holder of NDA No. 205,677.

18. On information and belief, NDA No. 205,677 relates to Vanda's Hetlioz® capsule product.

19. On information and belief, Vanda lists the '510 patent and '511 patent in the Orange Book in connection with NDA No. 205,677.

20. Vanda initiated the present litigation by filing a Complaint.

21. Vanda has alleged in the present action that MSN has infringed and will infringe the '510 patent and '511 patent by filing ANDA No. 211654 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

22. As a consequence of the foregoing, there is an actual and justiciable controversy between MSN, on the one hand, and Vanda, on the other hand, as to whether the claims of the '510 patent and '511 patent are invalid and/or

unenforceable, and whether those claims are being infringed or will be infringed by MSN's ANDA No. 211654 or by the manufacture, use, or sale of the products described therein.

COUNT I
(Declaration of Non-Infringement of the '510 Patent)

23. MSN re-alleges and incorporates the allegations of paragraphs 1-22 as if fully set forth herein.

24. Vanda alleges ownership, title, and/or interest to the '510 patent and has brought claims against MSN alleging infringement of the '510 patent.

25. The manufacture, use, or sale of MSN's Proposed Product would not infringe any valid or enforceable claim of the '510 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

26. A present, genuine, and justiciable controversy exists between MSN, on the one hand, and Vanda, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, or sale of MSN's Proposed Product would infringe any valid or enforceable claim of the '510 patent.

27. MSN is entitled to a declaration that the manufacture, use, or sale of MSN's Proposed Product would not infringe any valid or enforceable claim of the '510 patent.

28. This case is an exceptional one, and MSN is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Invalidity of the '510 Patent)

29. MSN re-alleges and incorporates the allegations of paragraphs 1-28 as if fully set forth herein.

30. Vanda alleges ownership of the '510 patent and has brought claims against MSN alleging infringement of the '510 patent.

31. One or more of the claims of the '510 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

32. One or more claims of the '510 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of prior art to the '510 patent.

33. Moreover, one or more claims of the '510 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

34. A present, genuine, and justiciable controversy exists between MSN and Vanda regarding, inter alia, the validity of claims of the ’510 patent.

35. MSN is entitled to a declaration that claims of the ’510 patent are invalid.

36. This case is an exceptional one, and MSN is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Non-Infringement of the ’511 Patent)

37. MSN re-alleges and incorporates the allegations of paragraphs 1-36 as if fully set forth herein.

38. Vanda alleges ownership, title, and/or interest to the ’511 patent and has brought claims against MSN alleging infringement of the ’511 patent.

39. The manufacture, use, or sale of MSN’s Proposed Product would not infringe any valid or enforceable claim of the ’511 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

40. A present, genuine, and justiciable controversy exists between MSN, on the one hand, and Vanda, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, or sale of MSN’s Proposed Product would infringe any valid or enforceable claim of the ’511 patent.

41. MSN is entitled to a declaration that the manufacture, use, or sale of MSN's Proposed Product would not infringe any valid or enforceable claim of the '511 patent.

42. This case is an exceptional one, and MSN is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Invalidity of the '511 Patent)

43. MSN re-alleges and incorporates the allegations of paragraphs 1-42 as if fully set forth herein.

44. Vanda alleges ownership of the '511 patent and has brought claims against MSN alleging infringement of the '511 patent.

45. One or more of the claims of the '511 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

46. One or more claims of the '511 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of prior art to the '511 patent.

47. Moreover, one or more claims of the '511 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without

undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

48. A present, genuine, and justiciable controversy exists between MSN and Vanda regarding, inter alia, the validity of claims of the '511 patent.

49. MSN is entitled to a declaration that claims of the '511 patent are invalid.

50. This case is an exceptional one, and MSN is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE Defendants MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited respectfully request that this Court enter a Judgment and Order in their favor and against Plaintiff/Counterclaim-Defendant Vanda Pharmaceuticals Inc. as follows:

a. declaring that MSN has not infringed any valid and enforceable claim of U.S. Patent No. 10,610,510;

b. declaring that MSN has not infringed any valid and enforceable claim of U.S. Patent No. 10,610,511;

c. declaring that the claims of U.S. Patent No. 10,610,510 are invalid;

d. declaring that the claims of U.S. Patent No. 10,610,511 are invalid;

e. declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding MSN its costs, expenses, and reasonable attorneys' fees in this action; and

f. awarding MSN any further and additional relief as the Court deems just and proper.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (No. 110)
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