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. 24-___

COMPLAINT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") alleges as follows against Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (together, "MSN"):

NATURE OF THE ACTION

1. This patent infringement action arises out of MSN's submission of Abbreviated New Drug Application ("ANDA") No. 219541 ("MSN's ANDA") seeking approval from the United States Food & Drug Administration ("FDA") to market a generic version of Vanda's Hetlioz LQ® tasimelteon (4mg/mL) oral suspension ("MSN's ANDA Product").

THE PARTIES

2. Plaintiff Vanda is a pharmaceutical company incorporated in Delaware with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC, 20037.

3. Defendant MSN Pharmaceuticals is a Delaware corporation with its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs. *See, e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No.

23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10.

4. Defendant MSN Labs is an Indian private limited company having a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana, 500018, India. *See, e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10.

5. Upon information and belief, MSN Pharmaceuticals and MSN Labs acted in conjunction and coordination to prepare and submit MSN's ANDA. Upon information and belief, MSN Pharmaceuticals is the designated U.S. agent, in accordance with 21 C.F.R. § 314.50(a), for MSN Labs for MSN's ANDA.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) at least because this action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including at least 35 U.S.C. § 271(e)(2)(A). *E.g.*, *Vanda Pharms. Inc. v. West-Ward Pharm. Int'l Ltd*, 887 F.3d 1117 (Fed. Cir. 2018).

7. This Court has personal jurisdiction over MSN Pharmaceuticals, at least because MSN Pharmaceuticals: (1) is incorporated in Delaware; (2) directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this district; (3) by the filing of MSN's ANDA, has sought approval to market and sell a generic version of Vanda's Hetlioz LQ® in this district; (4) has previously consented to this Court's jurisdiction, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10; and (5) has previously availed itself of this Court's jurisdiction by

asserting counterclaims in this Court, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

8. This Court has personal jurisdiction over MSN Labs, at least because MSN Labs: (1) is an Indian entity over which jurisdiction under Rule 4(k)(2) of the Federal Rules of Civil Procedure may be exercised; (2) directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this district; (3) by the filing of MSN's ANDA, has sought approval to market and sell a generic version of Vanda's Hetlioz LQ® in this district; (4) has previously consented to jurisdiction in this district, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10; and (5) has previously availed itself of this Court's jurisdiction by asserting counterclaims in this Court, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

9. Venue is appropriate in this district with regard to Vanda's claims against MSN Pharmaceuticals under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b), at least because MSN Pharmaceuticals: (1) is incorporated in Delaware; (2) has previously consented to venue in this district, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10; (3) on information and belief, directly or indirectly submitted MSN's ANDA in Delaware; and (4) on information and belief, is preparing to market and sell its ANDA product in this district.

10. Venue is appropriate in this district with regard to Vanda's claims against MSN Labs under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b), at least because MSN Labs: (1) on information and belief, is an Indian entity that may be sued in any judicial district; (2) has previously consented to venue in this district, *e.g.*, *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, No. 23-1420 (D. Del.), D.I. 21; *Astellas Pharma Inc. v. MSN Pharms. Inc.*, No. 23-689 (D. Del.), D.I. 12; *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 20-1334 (D. Del.), D.I. 10; (3) on information and belief, directly or indirectly submitted MSN's ANDA in Delaware; and (4) on information and belief, is preparing to directly or indirectly, market and sell MSN's ANDA Product in this district.

BACKGROUND

A. Vanda and Hetlioz LQ®

11. Vanda is a pharmaceutical company focused on the development and commercialization of innovative therapies to address high-priority unmet medical needs and improve the lives of patients.

12. Vanda acquired tasimelteon, a melatonin-receptor agonist, from a large pharmaceutical company that tried but failed to develop it into a marketable therapy.

13. Vanda's extensive and costly research with tasimelteon yielded life-changing results for patients, often children, suffering from certain rare, debilitating diseases.

14. On December 1, 2020, the FDA approved Vanda's supplemental new drug application to market Hetlioz® capsules for treating nighttime sleep disturbances associated with another rare disease, Smith-Magenis Syndrome ("SMS"), in patients 16 years or older.

15. For children between the ages of 3 and 15 suffering from sleep disturbances associated with SMS, Vanda offers a different product: a drinkable suspension containing 4 mg/mL of tasimelteon.

16. The FDA approved Vanda's new drug application, NDA 214517, to market Hetlioz LQ® (tasimelteon suspension, 4 mg/mL) to treat nighttime sleep disturbances in SMS in patients 3 years to 15 years of age on December 1, 2020. This suspension is marketed as Hetlioz LQ®. By submitting MSN's ANDA, MSN has sought FDA approval to market a generic version of Hetlioz LQ® (tasimelteon suspension, 4 mg/mL).

17. The current version of the Hetlioz®/Hetlioz LQ® prescribing information (i.e., label) is attached as Ex. 1.

18. The Dosing and Administration Section of the Highlights of Prescribing Information in the currently approved Hetlioz®/Hetlioz LQ® label provides a matrix specifying doses and dosage forms of tasimelteon to be administered in treating nighttime sleep disturbances in SMS patients based on the weight and age of the patients being treated:

Nighttime sleep disturbances in SMS (2.3)			
Patients 16 years of age and older	Capsules	Not applicable	20 mg one hour prior to bedtime
Pediatric Patients 3 to 15 years of age	Oral Suspension	≤ 28 kg	0.7 mg/kg one hour before bedtime
		>28 kg	20 mg one hour before bedtime

19. Section 2.4 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information states, "Shake HETLIOZ LQ oral suspension well for at least 30 seconds before every administration."

20. Section 7.1 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information states, "Avoid use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

21. Section 7.3 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information states, "Beta-adrenergic receptor antagonists have been shown to reduce the production of melatonin via specific inhibition of beta-1 adrenergic receptors. Nighttime administration of beta-adrenergic receptor antagonists may reduce the efficacy of HETLIOZ."

22. Section 8.7 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information states, "Smoking 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."

23. As of the date of this Complaint, the following 24 patents are listed as covering Hetlioz LQ® in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"): U.S. Patent No. 9,539,234; U.S. Patent No. 9,730,910; U.S. Patent No. 10,071,977; U.S. Patent No. 10,149,829; U.S. Patent No. 10,179,119; U.S. Patent No. 10,376,487; U.S. Patent No. 10,610,510; U.S. Patent No. 10,610,511; U.S. Patent No. 10,829,465; U.S. Patent No. 10,980,770; U.S. Patent No. 11,141,400; U.S. Patent No. 11,202,770; U.S. Patent No. 11,266,622; U.S. Patent No. 11,285,129; U.S. Patent No. 11,566,011; U.S. Patent No. 11,633,377; U.S. Patent No. 11,759,446; U.S. Patent No. 11,760,740; U.S. Patent No. 11,786,502; U.S. Patent No. 11,826,339; U.S. Patent No. 11,833,130; U.S. Patent No. 11,850,229; U.S. Patent No. 11,918,556; and U.S. Patent No. 11,918,557 ("the OB-Listed LQ Patents").

B. MSN's ANDA and Notice Letter

24. On or around June 3, 2024, Vanda received a letter sent on behalf of MSN informing Vanda that the FDA received MSN's ANDA along with a paragraph IV certification for all the OB-Listed LQ Patents (the "Notice Letter").

25. MSN attached to the Notice Letter what it purports to be a statement of detailed factual and legal bases for its paragraph IV certification that the OB-Listed LQ Patents are invalid, unenforceable, and/or not infringed ("MSN's Statement").

26. Upon information and belief, MSN submitted MSN's ANDA to obtain FDA approval to market MSN's ANDA Product, a tasimelteon (4 mg/mL) oral suspension, for treatment of nighttime sleep disturbances caused by SMS in children from 3 years of age up to and including 15 years of age.

27. Upon information and belief, MSN has represented to the FDA that MSN's ANDA Product is bioequivalent to Hetlioz LQ®.

THE ASSERTED PATENTS AND MSN'S INFRINGEMENT

A. The SMS Patents

28. On January 15, 2019, U.S. Patent No. 10,179,119 (the "'119 patent"), titled "Method of Treatment," was duly and legally issued by the United States Patent & Trademark Office ("USPTO"). A copy of the '119 patent is attached as Exhibit 2.

29. On March 8, 2022, U.S. Patent No. 11,266,622 (the "'622 patent"), titled "Method of Treatment," was duly and legally issued by the USPTO. A copy of the '622 patent is attached as Exhibit 3.

30. Vanda is the assignee of, and owns all rights, title, and interest in, the '119 patent and the '622 patent (together, the "SMS Patents").

31. The SMS Patents name Christian Lavedan and Mihael H. Polymeropoulos as inventors.

32. The Orange Book lists the expiration dates of the SMS Patents as August 29, 2035.

33. The SMS Patents generally relate to methods of treating SMS and sleep disturbances associated with SMS by administering tasimelteon daily in effective amounts, including, for example, 20 mg.

34. Hetlioz LQ® is an FDA-approved suspension containing tasimelteon that a patient may take orally once daily before bedtime to treat sleep disturbances associated with SMS.

35. When taken as recommended in the Dosing and Administration Section of the FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® attached as Exhibit 1, at least some patients, such as those weighing more than 28 kg, will ingest a dose of Hetlioz LQ® containing 20 mg of tasimelteon one hour before bedtime to treat sleep disturbances associated with SMS.

36. On information and belief, based on at least MSN's filing of an ANDA, the requirements of applicable law, and other publicly available information, the proposed and/or final prescribing information for MSN's ANDA Product includes, in its Dosing and Administration Section ("MSN's Dosing and Administration Section"), language identical to that in the Dosing and Administration Section of the currently approved Hetlioz®/Hetlioz LQ® prescribing information.

37. Accordingly, on information and belief, prescribers of MSN's ANDA Product would understand MSN's Dosing and Administration Section of MSN's label to instruct the prescriber to administer MSN's ANDA product once daily in an amount effective to treat a patient suffering from sleep disturbances associated with SMS.

38. On information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including MSN's Dosing and Administration Section, in accordance with their prescriber's instruction, at least some patients would take MSN's ANDA Product

once daily in an amount effective for the treatment of the patients' sleep disturbances associated with SMS, including, for example, a 20 mg dose of tasimelteon. On information and belief, at least some prescribers would prescribe MSN's ANDA Product once daily in an amount effective for the treatment of the patients' sleep disturbances associated with SMS, including, for example, a 20 mg dose of tasimelteon.

39. On information and belief, in marketing and selling MSN's ANDA Product, MSN will include the proposed and/or final prescribing information identical to the Dosing and Administration Section of the currently approved Hetlioz®/Hetlioz LQ® prescribing information as described above.

B. The Beta Blocker Interaction Patents

40. On March 29, 2022, U.S. Patent No. 11,285,129 (the "'129 patent"), titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the USPTO. A copy of the '129 patent is attached as Exhibit 4.

41. On December 26, 2023, U.S. Patent No. 11,850,229 (the "'229 patent"), titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the USPTO. A copy of the '229 patent is attached as Exhibit 5.

42. Vanda is the assignee of, and owns all rights, title, and interest in, the '129 patent and the '229 patent (together, the "Beta Blocker Interaction Patents").

43. The Beta Blocker Interaction Patents name Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors.

44. The Orange Book lists the expiration dates of the Beta Blocker Interaction Patents as January 25, 2033.

45. The Beta Blocker Interaction Patents generally relate to methods of administering tasimelteon to a patient and the interaction between tasimelteon and beta-adrenergic receptor antagonists ("beta blockers").

46. As reflected in the Beta Blocker Interaction Patents, Vanda's studies demonstrated that patients receiving beta blocker therapy were less likely to become entrained to tasimelteon therapy than patients not receiving beta blocker therapy.

47. Prior to the disclosure in the Beta Blocker Interaction Patents, no publicly available information supported by scientific studies described the relationship between administration of beta blockers and administration of tasimelteon.

48. The FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® attached as Exhibit 1 warns patients that taking beta blockers at nighttime may reduce the efficacy of tasimelteon and reduce the production of melatonin.

49. On information and belief, based on at least MSN's filing of an ANDA, the requirements of applicable law, and other publicly available information, the proposed and/or final prescribing information for MSN's ANDA Product includes, in its Section 7.3 ("MSN's Section 7.3"), language identical to that in Section 7.3 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information.

50. Accordingly, on information and belief, at least some prescribers of MSN's ANDA Product would understand Section 7.3 of MSN's prescribing information to instruct the prescriber to determine whether his or her patient is taking a beta blocker prior to administering MSN's ANDA Product, and, in the case that the patient is not taking a beta blocker, the prescriber would understand that Section 7.3 instructs that MSN's ANDA Product may be administered. Alternatively, if the prescriber determines that the patient is taking a beta blocker, the prescriber

would understand Section 7.3 to instruct that the prescriber must have the patient cease or discontinue the use of beta blockers before administering MSN's ANDA Product to the patient.

51. Beta blockers are a broad and widely prescribed class of medications used for various clinical benefits, including the treatment of cardiovascular diseases and other conditions. Moreover, some of the conditions that beta blockers treat may also be treated by alternative therapeutics. Therefore, on information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including MSN's Section 7.3, in administering tasimelteon to a patient, at least some prescribers would determine whether their patients are taking beta blockers before administering MSN's ANDA Product, and if the prescribers determined that their patients were not taking beta blockers, the prescribers would understand that Section 7.3 instructs that MSN's ANDA product may be administered to such patients. Alternatively, on information and belief, if the prescribers determined that the patients were taking beta blockers, at least some prescribers would counsel some patients taking certain beta blockers to cease or discontinue use of those beta blockers when taking MSN's ANDA Product, at least in order to avoid the reduced efficacy of tasimelteon described in Section 7.3 of MSN's prescribing information. Additionally, on information and belief, at least some prescribers would prescribe a different class of medicines (other than beta blockers) to facilitate treatment of the underlying disease and co-administration with MSN's ANDA Product.

52. On information and belief, in marketing and selling MSN's ANDA Product, MSN will include the proposed and/or final prescribing information identical to Section 7.3 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information as described above.

C. The Smoker Method of Treatment Patents

53. On April 7, 2020, U.S. Patent No. 10,610,510 (the "'510 patent"), titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the USPTO. A copy of the '510 patent is attached as Exhibit 6.

54. On April 20, 2021, U.S. Patent No. 10,980,770 (the "'770 patent"), titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the USPTO. A copy of the '770 patent is attached as Exhibit 7.

55. Vanda is the assignee of, and owns all rights, title, and interest in, the '510 patent and the '770 patent (together, the "Smoker MOT Patents").

56. The Smoker MOT Patents name Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors.

57. The Orange Book lists the expiration dates of the Smoker MOT Patents as January 25, 2033.

58. The Smoker MOT Patents generally relate to methods of administration to avoid the harmful impact smoking has on the metabolism of tasimelteon. The '770 patent is also directed to methods of treatment devised to avoid the harmful effects caused by coadministration of tasimelteon with a CYP1A2 inhibitor.

59. As reflected in the Smoker MOT Patents, data from Vanda's clinical studies showed that smoking and/or coadministration with a CYP1A2 inhibitor affects patient exposure to tasimelteon.

60. Prior to the disclosure of the Smoker MOT Patents, no publicly available information supported by scientific studies described the effect of smoking on the administration of tasimelteon. Similarly, no publicly available information supported by scientific studies described

the effect that coadministration with a CYP1A2 inhibitor would have on an oral tasimelteon therapy.

61. Section 8.7 of the FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® attached as Exhibit 1 warns patients that the efficacy of, and a patient's exposure to, tasimelteon may be reduced by smoking.

62. Section 7.1 of the FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® attached as Exhibit 1 warns patients that strong CYP1A2 inhibitors should not be administered in combination with Hetlioz LQ®, which contains tasimelteon, because of potentially large increases in tasimelteon exposure and greater risk of adverse events.

63. On information and belief, based on at least MSN's filing of an ANDA, the requirements of applicable law, and other publicly available information, the proposed and/or final prescribing information for MSN's ANDA Product includes, in its Section 8.7 ("MSN's Section 8.7") and its Section 7.1 ("MSN's Section 7.1"), language identical to that in Section 8.7 and Section 7.1 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information.

64. Accordingly, on information and belief, at least some prescribers of MSN's ANDA Product would understand Section 8.7 of MSN's prescribing information to instruct the prescriber to determine whether his or her patient is a smoker prior to administering MSN's ANDA Product, and, in the case that the patient is a non-smoker, the prescriber would understand that Section 8.7 instructs that MSN's ANDA product may be administered. Alternatively, if the prescriber determines that the patient is a smoker, the prescriber would understand Section 8.7 to instruct that the prescriber must have his or her patient cease or reduce smoking before using MSN's ANDA product, which contains tasimelteon. Further, on information and belief, at least

some prescribers of MSN's ANDA Product would understand Section 7.1 of MSN's prescribing information to instruct the prescriber to determine whether his or her patient is taking a CYP1A2 inhibitor before administering MSN's ANDA Product, and, in the case that the patient is not taking a CYP1A2 inhibitor, the prescriber would understand that Section 7.1 instructs that MSN's ANDA Product may be administered. Alternatively, if the prescriber determines that the patient is taking a CYP1A2 inhibitor, the prescriber would understand Section 7.1 to instruct that the prescriber must have his or her patient discontinue use of the CYP1A2 inhibitor before using MSN's ANDA product, which contains tasimelteon.

65. On information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including Section 8.7 of MSN's prescribing information, in administering tasimelteon to a patient, at least some prescribers would determine whether their patients are smokers before administering MSN's ANDA product, and if the prescribers determined that their patients were non-smokers, the prescribers would understand that Section 8.7 instructs that MSN's ANDA product may be administered to such patients. Alternatively, on information and belief, if the prescribers determined that the patients were smokers, at least some prescribers would counsel some patients to cease or reduce smoking when taking MSN's ANDA Product, at least in order to avoid the reduced exposure to and reduced efficacy of tasimelteon described in MSN's Section 8.7. On information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including Section 7.1 of MSN's prescribing information, in administering tasimelteon to a patient, at least some prescribers would determine whether their patients are taking CYP1A2 inhibitors before administering MSN's ANDA product, and if the prescribers determined that their patients were not taking CYP1A2 inhibitors, the

prescribers would understand that Section 7.1 instructs that MSN's ANDA product may be administered to such patients. Alternatively, on information and belief, if the prescribers determined that the patients were using CYP1A2 inhibitors, at least some prescribers would counsel some patients to discontinue use of such CYP1A2 inhibitors when taking MSN's ANDA Product, at least in order to avoid large increases in exposure to tasimelteon and greater risk of adverse events caused by coadministration of tasimelteon with CYP1A2 inhibitors as described in MSN's Section 7.1.

66. On information and belief, in marketing and selling MSN's ANDA Product, MSN will include the proposed and/or final prescribing information identical to Sections 8.7 and 7.1 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information as described above.

D. Suspension SMS Method of Treatment Patent

67. On September 19, 2023, U.S. Patent No. 11,759,446 (the "'446 patent"), titled "Liquid Tasimelteon Formulations and Methods of Use Thereof," was duly and legally issued by the USPTO. A copy of the '446 patent is attached as Exhibit 8.

68. Vanda is the assignee of, and owns all rights, title, and interest in, the '446 patent (the "Suspension SMS Method of Treatment Patent").

69. The '446 patent names Deepak Phadke and Mihael H. Polymeropoulos as inventors.

70. The Orange Book lists the expiration date of the '446 patent as February 21, 2041.

71. The '446 patent generally relates to methods of treating SMS using tasimelteon in a liquid dosage form and different dosage amounts depending on a patient's weight.

72. The '446 patent discloses the characteristics of a liquid formulation of tasimelteon and dosing considerations in treating SMS.

73. Prior to the disclosure of the ’446 patent, no publicly available information described dosing regimens for liquid formulations in the treatment of SMS, nor was a liquid formulation of tasimelteon disclosed.

74. The FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® attached as Exhibit 1 indicates Hetlioz LQ® for the treatment of nighttime sleep disturbances in SMS. The FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® further instructs dosage types and dosage forms in which tasimelteon is recommended to be administered in the treatment of nighttime sleep disturbances in SMS. The FDA-approved prescribing information accompanying Hetlioz®/Hetlioz LQ® further instructs to shake Hetlioz LQ® before administration.

75. On information and belief, based on at least MSN’s filing of an ANDA, the requirements of applicable law, and other publicly available information, the proposed and/or final prescribing information for MSN’s ANDA Product includes, in its Dosing and Administration Section and its Section 2.4 (“MSN’s Section 2.4”), language identical to that in the Dosing and Administration Section and Section 2.4 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information.

76. Accordingly, on information and belief, at least some prescribers of MSN’s ANDA product would understand MSN’s Dosing and Administration Section to instruct the prescriber to administer tasimelteon liquid suspension in different dosage amounts depending on the patient’s weight, as claimed in the ’446 patent. On information and belief, at least some prescribers of MSN’s ANDA product would understand MSN’s Section 2.4 to instruct the prescriber to counsel the patient or caregiver to shake the liquid formulation of tasimelteon before administering, as claimed in the ’446 patent.

77. On information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including MSN's Dosing and Administration Section, in administering tasimelteon to a patient, at least some prescribers would counsel some patients to take MSN's ANDA Product to treat SMS through administering tasimelteon liquid suspension in a dosage amount determined by the patient's weight as claimed in the '446 patent. On information and belief, based on at least the prescribing information associated with MSN's ANDA Product, including MSN's Section 2.4, in administering tasimelteon to a patient, at least some prescribers would counsel some patients or caregivers to shake MSN's ANDA Product before administration as claimed in the '446 patent.

78. On information and belief, in marketing and selling MSN's ANDA Product, MSN will include the proposed and/or final prescribing information identical to the Dosing and Administration Section and Section 2.4 of the currently approved Hetlioz®/Hetlioz LQ® prescribing information as described above.

CLAIMS FOR RELIEF
COUNT I
INFRINGEMENT OF U.S. PATENT NO. 10,179,119

79. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

80. Upon information and belief, MSN has infringed the '119 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '119 patent. Upon information and belief, prescribers of MSN's ANDA Product would understand MSN's prescribing information to instruct that MSN's ANDA Product, which comprises tasimelteon, should be administered in an amount effective to treat sleep

disturbances associated with SMS and would counsel patients to take MSN's ANDA Product in accordance with such instructions.

81. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '119 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

82. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '119 patent, under 35 U.S.C. § 271.

83. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

84. On information and belief, the proposed prescribing information for MSN's ANDA Product ("MSN's Label") will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

85. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '119 patent.

86. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '119 patent with the requisite intent under 35 U.S.C. § 271(b).

87. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral

suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '119 patent. Moreover, tasimelteon oral suspension is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '119 patent under 35 U.S.C. § 271(c).

88. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '119 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 11,266,622

89. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

90. Upon information and belief, MSN has infringed the '622 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '622 patent. Upon information and belief, prescribers of MSN's ANDA Product would understand MSN's ANDA Product Label to instruct that at least some SMS patients should be administered 20 mg of tasimelteon daily and would prescribe patients such dosages of MSN's ANDA Product.

91. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '622 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

92. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '622 patent, under 35 U.S.C. § 271.

93. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

94. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

95. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '622 patent.

96. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '622 patent with the requisite intent under 35 U.S.C. § 271(b).

97. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians

will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '622 patent. Moreover, tasimelteon oral suspension is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '622 patent under 35 U.S.C. § 271(c).

98. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '622 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 11,285,129

99. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

100. Upon information and belief, MSN has infringed the '129 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '129 patent. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Section 7.3 of its prescribing information to instruct that use of beta blockers should be ceased when using MSN's ANDA Product and would counsel patients to follow such instructions when using MSN's ANDA Product.

101. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '129 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

102. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '129 patent, under 35 U.S.C. § 271.

103. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

104. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

105. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '129 patent.

106. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '129 patent with the requisite intent under 35 U.S.C. § 271(b).

107. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '129 patent. Moreover, tasimelteon oral suspension is

not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '129 patent under 35 U.S.C. § 271(c).

108. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '129 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 11,850,229

109. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

110. Upon information and belief, MSN has infringed the '229 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '229 patent. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Section 7.3 of its prescribing information to instruct that use of beta blockers should be discontinued when using MSN's ANDA Product and would counsel patients to follow such instructions when using MSN's ANDA Product.

111. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '229 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

112. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '229 patent, under 35 U.S.C. § 271.

113. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

114. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

115. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '229 patent.

116. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '229 patent with the requisite intent under 35 U.S.C. § 271(b).

117. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '229 patent. Moreover, tasimelteon oral suspension is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '229 patent under 35 U.S.C. § 271(c).

118. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 10,610,510

119. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

120. Upon information and belief, MSN has infringed the '510 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '510 patent. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Section 8.7 of its prescribing information to instruct that patients should cease or reduce smoking when using tasimelteon and would counsel patients to take MSN's ANDA Product in accordance with such instructions.

121. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '510 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

122. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '510 patent, under 35 U.S.C. § 271.

123. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

124. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

125. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '510 patent.

126. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '510 patent with the requisite intent under 35 U.S.C. § 271(b).

127. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '510 patent. Moreover, tasimelteon oral suspension is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(c).

128. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '510 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 10,980,770

129. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

130. Upon information and belief, MSN has infringed the '770 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '770 patent. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Section 8.7 of its prescribing information to instruct that patients should cease or reduce smoking when using tasimelteon and would counsel patients to take MSN's ANDA Product in accordance with such instructions. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Section 7.1 of its prescribing information to instruct that patients should discontinue treatment with a CYP1A2 inhibitor before using tasimelteon and would counsel patients to take MSN's ANDA Product in accordance with such instructions.

131. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '770 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

132. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '770 patent, under 35 U.S.C. § 271.

133. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

134. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

135. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '770 patent.

136. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '770 patent with the requisite intent under 35 U.S.C. § 271(b).

137. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '770 patent. Moreover, tasimelteon oral suspension is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '770 patent under 35 U.S.C. § 271(c).

138. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '770 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 11,759,446

139. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

140. Upon information and belief, MSN has infringed the '446 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting MSN's ANDA, by which MSN seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of MSN's ANDA Product prior to the expiration of the '446 patent. Upon information and belief, at least some prescribers of MSN's ANDA Product would understand MSN's Dosing and Administration Section to instruct the prescriber to administer tasimelteon in different dosage amounts depending on the patient's weight, as claimed in the '446 patent. Upon information and belief, at least some prescribers of MSN's ANDA product would understand MSN's Section 2.4 to instruct the prescriber to counsel the patient or caregiver to shake the liquid formulation of tasimelteon before administering as claimed in the '446 patent. Upon information and belief, a prescriber would counsel patients to take MSN's ANDA Product in accordance with the foregoing instructions.

141. Upon information and belief, under at least 35 U.S.C. §§ 271(b) and/or (c), MSN will infringe at least one claim of the '446 patent, either literally or under the doctrine of equivalents, if it markets MSN's ANDA Product.

142. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '446 patent, under 35 U.S.C. § 271.

143. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of MSN's ANDA Product is required to substantively copy that of Hetlioz®/Hetlioz LQ®.

144. On information and belief, the proposed prescribing information for MSN's Label will be substantially identical to that of Hetlioz®/Hetlioz LQ®.

145. On information and belief, MSN's Label will instruct and encourage prescribers to practice the claimed methods of the '446 patent.

146. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use MSN's ANDA Product according to MSN's instructions and/or MSN's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '446 patent with the requisite intent under 35 U.S.C. § 271(b).

147. On information and belief, if MSN's ANDA Products are sold, marketed, distributed, and/or imported in the United States, MSN will sell or offer to sell generic tasimelteon oral suspension with accompanying instructions and/or MSN's Label in an infringing manner because MSN's ANDA Product is a material part of the claimed invention, and MSN knows that physicians will prescribe, healthcare providers will administer, and/or patients will use MSN's ANDA Products in accordance with the accompanying instructions and/or MSN's Label, and such use will directly infringe one or more claims of the '446 patent. Moreover, tasimelteon oral suspension is

not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, MSN will thus contribute to the infringement of one or more claims of the '446 patent under 35 U.S.C. § 271(c).

148. If MSN's marketing and sale of the MSN ANDA Product prior to the expiration of the '446 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that the Court enter judgment in its favor against MSN on the patent infringement claims set forth above and respectfully requests that this Court:

a. enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of each of the '119, '622, '129, '229, '510, '770, and '446 patents (the "Asserted Patents") by submitting or causing to be submitted MSN's ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the MSN ANDA Product before the expiration of each of the Asserted Patents;

b. enter judgment that, under 35 U.S.C. § 271(a), the use of MSN's ANDA Product in the United States before the expiration of each of the Asserted Patents will directly infringe at least one claim of each of the Asserted Patents;

c. enter judgment that, under 35 U.S.C. § 271(b) MSN has induced or will induce the infringement of at least one claim of each of the Asserted Patents by promoting MSN's ANDA Product for others' use, offer to sell, or sale in the United States before the expiration of each of the Asserted Patents;

d. enter judgment that, under 35 U.S.C. § 271(c) MSN has contributed to or will contribute to the infringement of at least one claim of each of the Asserted Patents by promoting MSN's ANDA Product for others' use, offer to sell, or sale in the United States before the expiration of each of the Asserted Patents;

e. order that that the effective date of any approval by the FDA of the MSN ANDA Product be a date that is not earlier than the expiration of the last expiring Asserted Patent(s), or such later date as the Court may determine consistent with 35 U.S.C. § 271(e)(4)(A);

f. enjoin MSN and all persons acting in concert with MSN from maintaining approval of the MSN ANDA, or contributing to or inducing anyone to do the same, until expiration of each of the Asserted Patents;

g. enjoin MSN and all persons acting in concert with MSN from the commercial manufacture, use, import, offer for sale, and/or sale of the MSN ANDA Product, or contributing to or inducing anyone to do the same, until expiration of each of the Asserted Patents, or such later date as the Court may determine;

h. enjoin MSN and all persons acting in concert with MSN from infringing each of the Asserted Patents, 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 while the litigation is pending;

i. award monetary damages under 35 U.S.C. §§ 271(e)(4)(C) and 284, to the extent applicable,

j. declare this to be an exceptional case under 35 U.S.C. § 285 and award Vanda costs, expenses, and disbursements in this action, including reasonable attorney's fees;

k. assess 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; and

l. award Vanda such further and additional relief as this Court deems just and proper.

Dated: July 12, 2024

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