IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. ___ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) brings this Complaint for Patent Infringement of U.S. Patent No. 11,918,556 (the '556 Patent) against Defendant Teva Pharmaceuticals USA, Inc. (Teva) related to Teva's filing of Abbreviated New Drug Application No. 211601 (Teva's ANDA) for approval of a generic version of Vanda's HETLIOZ® (tasimelteon) 20 mg oral capsules (Teva's ANDA Product), as well as Teva's present and continuing engagement in the commercial manufacture, use, importation, offer for sale, or sale of Teva's ANDA Product. Vanda alleges as follows:

THE PARTIES

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

2. On information and belief, Teva is a pharmaceutical company incorporated in Delaware that maintains its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Teva because, among other things, Teva has committed, aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement by, *inter alia*, filing an ANDA, receiving final approval to market Teva's ANDA Product that is the subject of Teva's ANDA, and/or making, using, importing, offering for sale, and selling Teva's ANDA Product, which has led and will lead to foreseeable harm and injury to Vanda.

5. This Court also has personal jurisdiction over Teva by virtue of Teva's incorporation in the State of Delaware.

6. The Court also has personal jurisdiction over Teva because, *inter alia*, Teva has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Teva regularly and continuously transacts business within Delaware, including by selling pharmaceutical products including Teva's ANDA Product in Delaware, either on its own or through its affiliates. Upon information and belief, Teva derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

7. This Court also has personal jurisdiction over Teva because Teva has frequently availed itself of the legal protections of the State of Delaware, by, among other things, admitting jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Bayer Pharma AG et al. v. Teva Pharms. USA, Inc.*, C.A. No.

23-551-RGA (D. Del.), D.I. 14; *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 18-651-CFC (D. Del.), D.I. 9.

8. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

9. Teva has litigated multiple cases relating to Teva's ANDA Product in the United States District Court for the District of Delaware, and Teva has not challenged the venue of this District as improper in any of those cases. *See, e.g.*, *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 18-651 (D. Del.), D.I. 9 at ¶ 21.

10. Venue is proper because, *inter alia*, Teva is incorporated in Delaware and thus resides in this District. On information and belief, Teva has also committed and/or will commit further acts of infringement in this District.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

12. On March 5, 2024, the '556 Patent, titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the United States Patent & Trademark Office. A copy of the '556 Patent is attached as **Exhibit A**.

13. The '556 Patent generally claims methods of treating a patient for a circadian rhythm disorder or a sleep disorder wherein the patient is being treated with a beta-adrenergic receptor antagonist (commonly called beta blockers). The methods covered by the '556 Patent involve the administering of tasimelteon, an exogenous melatonin agonist, and are intended to avoid a decrease in the efficacy of tasimelteon caused by coadministration with beta blockers.

14. The '556 Patent will expire no earlier than April 7, 2033.

15. The ’556 Patent names Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors.

16. Vanda is the assignee of the ’556 Patent and owns all rights, title, and interest in the ’556 patent.

ACTS GIVING RISE TO THIS ACTION

17. This is an action arising under the patent laws of the United States (35 U.S.C. § 100 *et seq.*) based on Teva’s present and continuing infringement of one or more claims of the ’556 Patent.

A. Vanda and HETLIOZ®

18. Vanda is an innovative pharmaceutical company that acquired HETLIOZ® (tasimelteon) from a large pharmaceutical company that tried, but failed, to develop it into a useful FDA-approvable therapy.

19. Under Vanda’s stewardship, and after devoting years and many millions of dollars to research, development, and regulatory processes, HETLIOZ® became the first and only FDA-approved therapy to treat two rare and orphan disorders: Non-24-Hour Sleep-Wake Disorder (Non-24) and nighttime sleep disturbances in Smith-Magenis Syndrome in patients 16 years or older.

20. Vanda holds approved New Drug Application (NDA) No. 205677 for HETLIOZ® (tasimelteon) capsules, 20 mg, approved by the FDA on January 31, 2014, for the treatment of Non-24.

21. A copy of the HETLIOZ® Prescribing Information, Revised January 2024 is attached as **Exhibit B** (HETLIOZ® Label).

22. HETLIOZ® contains the active compound tasimelteon and is available in a 20 mg strength.

23. The HETLIOZ® Label states that HETLIOZ® is indicated for the treatment of Non-24, which is a circadian rhythm disorder.

24. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ capsules in adults is 20 mg one hour before bedtime, at the same time every night."

25. Section 7.3 of the HETLIOZ® Label states that "[b]eta-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."

26. HETLIOZ® is covered by one or more claims of the '556 patent.

27. The '556 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) in connection with NDA No. 205677 as covering HETLIOZ®.

B. Teva's ANDA

28. Teva filed Teva's ANDA no later than January 31, 2018 to obtain approval to manufacture and sell Teva's ANDA Product.

29. By a letter that Vanda received on or around September 12, 2022 (Teva's 2022 Notice Letter), Teva notified Vanda that it had submitted to the FDA Teva's ANDA. On information and belief, the purpose of Teva's submission of Teva's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to April 7, 2033.

30. In Teva's 2022 Notice Letter, Teva notified Vanda that, as a part of Teva's ANDA, Teva had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to U.S. Patent No. 11,285,129, which is listed in the Orange Book in connection with HETLIOZ®, asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Teva's ANDA Product.

C. Teva's Launch of Teva's ANDA Product and Teva's Infringement of the '556 Patent

31. On September 27, 2021, the FDA issued a tentative approval of Teva's ANDA to market a generic version of tasimelteon.

32. The FDA issued final approval of Teva's ANDA to market a generic version of tasimelteon on December 12, 2022 (Teva Final Approval Letter). A copy of the Teva Final Approval Letter is attached as **Exhibit C**.

33. On December 27, 2022, Vanda brought suit against Teva, asserting U.S. Patent No. 11,285,129. *See Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 23-152 (D. Del.), D.I. 1.

34. Teva commercially launched Teva's ANDA Product on or around December 29, 2022.

35. Teva's Package Insert, revised May 2022, ("Teva's Label") was submitted to the FDA. Teva's Package Insert, Revised May 2022 (attached as **Exhibit D**, available at https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=ce5a2fa3-ed54-422d-96c2-1821496eb32f&type=pdf). Teva's Label is available on the government website DailyMed.nlm.nih.gov, which is operated by the National Library of Medicine, National Institutes of Health. S*ee* **Exhibit E** (available at https://dailymed.nlm.nih.gov/dailymed/about-dailymed.cfm).

The DailyMed website explains that "[t]he labeling on DailyMed is the most recent submitted labeling to the FDA by companies and currently in use." *See id.*

36. Teva's Label, as submitted to the FDA, reports the "Marketing Start Date" for Teva's ANDA Product as December 29, 2022. **Exhibit D** (Teva's Label) at 14.

37. On information and belief, Teva has actively promoted its ANDA Product, including by advertising its ANDA Product on its website. *E.g.*, Teva, *Tasimelteon Capsules* (visited December 9, 2024), https://www.tevausa.com/our-products/tevagenerics/teva-generics-catalog/vision-product-page/tasimelteoncapsules (attached as **Exhibit F**). Teva's website also provides a link labeled "Full Prescribing Information" that directs visitors to Teva's Label on DailyMed. *See id.* Additionally, upon information and belief, in accordance with applicable federal law, Teva distributes Teva's ANDA Product with Teva's Label.

38. Teva has admitted that the intended audience for its Label includes patients and physicians and that prescribers would treat patients according to "what's listed in the labeling." *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 18-651 (D. Del.), D.I. 347 at 304:3-16 (attached as **Exhibit G**). Teva also admitted that it expects prescribers of its ANDA Product to "follow what's in the labeling." *Id.* at 304:3-21.

39. Teva's Label instructs prescribers to administer Teva's ANDA Product to treat patients with Non-24, which is a circadian rhythm disorder, because Teva's Label indicates Teva's ANDA Product to treat this disorder. **Exhibit D** (Teva's Label) at 1, 3.

40. "[B]eta-adrenergic receptor antagonists are widely prescribed for various clinical indications, including for the treatment of cardiovascular diseases and other conditions." *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 23-152 (D. Del.), D.I. 7, Attach. 2, at ¶ 51

(Declaration of Dr. Daniel Combs) (attached as **Exhibit H**). Thus, at least some patients may be using beta-adrenergic receptor antagonists when their physician is considering prescribing Teva's ANDA Product. Teva's Label contemplates that patients who could be prescribed Teva's ANDA Product may be taking beta blockers because Teva's Label contains a section titled "7.3 Beta-Adrenergic Receptor Antagonists (e.g., acebutolol, metoprolol)" in Section 7, which is the "Drug Interactions" section of Teva's Label. **Exhibit D** (Teva's Label) at 4.

41. Teva's ANDA Product includes tasimelteon as its active ingredient. **Exhibit D** (Teva's Label) at 1, 3. The "Dosage and Administration" section in Teva's Label describes the recommended dosage for tasimelteon capsules and "Important Administration Information." **Exhibit D** (Teva's Label) at 3.

42. When prescribers consider prescribing Teva's ANDA Product to a patient who is taking beta-adrenergic receptor antagonists, on information and belief, at least some prescribers would be concerned with the beta-adrenergic receptor antagonist interaction with tasimelteon described in Teva's Label. **Exhibit D** (Teva's Label) at 4. Section 7.3 of Teva's Label, which is part of Section 7 that is titled "Drug Interactions," explains that "[n]ighttime administration of beta-adrenergic receptor antagonists may reduce the efficacy of tasimelteon." **Exhibit D** (Teva's Label) at 4. On information and belief, the negative interaction described in Teva's Label would encourage at least some prescribers to have the patient discontinue treatment with beta-adrenergic receptor antagonists before prescribing or continuing therapy with Teva's ANDA Product.

43. After having a patient discontinue treatment with beta-adrenergic receptor antagonists and thereby addressing that potential interaction, on information and belief, at least some

prescribers would understand, based on Teva's Label, that Teva's ANDA Product may be prescribed to the patient, and at least some prescribers would prescribe Teva's ANDA Product to the patient. **Exhibit D** (Teva's Label) at 4. In this scenario, the prescriber accordingly would follow the recommended dosage information in Section 2.2 of Teva's Label, which instructs prescribers that "[t]he recommended dosage of tasimelteon capsules in adults is 20 mg one hour before bedtime, at the same time every night." **Exhibit D** (Teva's Label) at 3. Teva's Label thus instructs the prescriber to administer 20 mg of tasimelteon to the patient once daily. Teva's Label also instructs that the patient be administered tasimelteon "one hour before bedtime," which is within the range of about one-half hour to about one-and-one-half hours recited in Claim 1 of the '556 Patent. Teva's Label's instructions requiring that the tasimelteon be administered "one hour before bedtime, at the same time every night" also directs prescribers to administer tasimelteon an hour before the patient's target bedtime.

44. On information and belief, at least some prescribers would have their patients discontinue treatment with beta blockers to avoid decreased efficacy caused by coadministration of tasimelteon with beta blockers.

D. Prior Litigation

45. On December 27, 2022, Vanda brought suit against Teva, asserting U.S. Patent No. 11,285,129 (the '129 Case). *See Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 23-152 (D. Del.), D.I. 1. At the time of Vanda's suit, the '129 Patent had been timely listed in the Orange Book for HETLIOZ®. Litigation in the '129 Case between Vanda and Teva is ongoing.

46. Vanda did not assert the '556 Patent in the '129 Case because, *inter alia*, the

'129 Case was filed prior to the issuance of the '556 Patent.

CLAIMS FOR RELIEF
COUNT I
(Infringement of the '556 Patent – 35 U.S.C. § 271(e))

47. Vanda incorporates by reference and realleges paragraphs 1 through 46 above as though fully restated herein.

48. No later than January 31, 2018, Teva submitted to the FDA Teva's ANDA for Teva's ANDA Product seeking authorization to commercially manufacture, use, import, offer to sell, or sell Teva's ANDA Product in the United States.

49. Teva's submission of Teva's ANDA seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Teva's ANDA Product, prior to the expiration of the '556 Patent, constitutes infringement of at least one or more claims of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, Teva knows and intends that physicians, healthcare professionals, and/or patients prescribe or will prescribe, administer or will administer, and/or use or will use Teva's ANDA Product according to Teva's instructions and/or Teva's Label in an infringing manner, and therefore induce or will induce infringement of at least one or more claims of the '556 Patent with the requisite intent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

51. On information and belief, Teva is selling and offering to sell or will sell and offer to sell Teva's ANDA Product with provided instructions and/or Teva's Label in an infringing manner, wherein Teva's ANDA Product is a material part of the claimed invention, wherein Teva

knows that physicians prescribe or will prescribe, healthcare providers administer or will administer, and/or patients use or will use Teva's ANDA Product in accordance with Teva's provided instructions and/or Teva's Label, wherein such use directly infringes or will directly infringe at least one or more claims of the '556 Patent, and wherein generic tasimelteon capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Teva is thus contributing to or will contribute to the infringement of at least one or more claims of the '556 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(c).

52. On information and belief, Teva's actions relating to Teva's ANDA were done by and for the benefit of Teva.

53. On information and belief, Teva had knowledge of the '556 Patent on or around its issue date of March 5, 2024 or obtained such knowledge shortly thereafter. In the alternative, Teva will have knowledge of the '556 Patent at least as of the filing of the Complaint in this action.

54. Unless Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '556 Patent and all other relevant activities are enjoined by the Court, Vanda will be substantially and irreparably harmed for which, Vanda does not have an adequate remedy at law.

COUNT II
(Infringement of the '556 Patent – 35 U.S.C. § 271(b-c))

55. Vanda incorporates by reference and realleges paragraphs 1 through 54 above as though fully restated herein.

56. On or around December 29, 2022, Teva commercially launched Teva's ANDA Product, and Teva continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '556 Patent.

57. On information and belief, Teva possesses the specific intent to encourage direct infringement of the ’556 Patent by others. On information and belief, Teva had knowledge of the ’556 Patent on or around its issue date of March 5, 2024 or obtained such knowledge shortly thereafter. In the alternative, Teva will have knowledge of the ’556 Patent at least as of the filing of the Complaint in this action.

58. Alternatively, Teva subjectively believed that there was a high probability that the use of Teva’s ANDA product was protected by a valid patent, and Teva’s encouraging, recommending, or promoting the use of Teva’s ANDA Product would actively induce or contribute to the infringement of the patent, but took deliberate steps to avoid confirming those facts, and therefore willfully blinded itself to the infringing nature of the use of Teva’s ANDA Product.

59. On information and belief, Teva knows and intends that physicians, healthcare professionals, and/or patients prescribe, administer, and/or use Teva’s ANDA Product according to Teva’s instructions and/or Teva’s Label in an infringing manner, and therefore induce infringement of at least one or more claims of the ’556 Patent with the requisite intent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

60. On information and belief, Teva is selling and offering to sell Teva’s ANDA Product with provided instructions and/or Teva’s Label in an infringing manner, wherein Teva’s ANDA Product is a material part of the claimed invention, wherein Teva knows that physicians prescribe, healthcare providers administer, and/or patients use Teva’s ANDA Product in accordance with Teva’s provided instructions and/or Teva’s Label, wherein such use directly infringes at least one or more claims of the ’556 Patent, and wherein generic tasimelteon capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information

and belief, Teva is thus contributing to the infringement of at least one or more claims of the '556 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(c).

61. On information and belief, Teva knew that the administration or use of Teva's ANDA product would result in one or more act(s) of direct infringement of the '556 Patent, and that Teva's encouraging, recommending, or promoting would actively induce or contribute to direct infringement of the '556 Patent. On information and belief, despite such knowledge, Teva has been and is actively inducing or contributing to the infringement of the '556 Patent by others and is doing so willfully and deliberately.

62. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Teva's ANDA Product before the expiration of the '556 Patent will cause and has caused damage to Vanda, entitling Vanda to damages or monetary relief.

63. Unless Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '556 Patent and all other relevant activities are enjoined by the Court, Vanda will be substantially and irreparably harmed for which, Vanda does not have an adequate remedy at law.

64. Vanda has suffered lost profits and will continue to suffer lost profits for its HETLIOZ® product because of Teva's infringing acts with respect to Teva's ANDA Product, including sales that would have been made by Vanda that were either lost as a result of Teva's infringement or were made at eroded prices because of Teva's infringement. These lost profits have caused and will cause a loss in revenue available to Vanda for reinvestment, including, *inter alia*, in research and development opportunities, resulting in long term damage to Vanda's product pipeline and future profits. But for Teva's infringement, Vanda would not have suffered injury, entitling Vanda to damages in the form of lost profits resulting from at least diverted sales and price erosion, future

lost profits due to the curtailment of Vanda's research and development programs, and, in no event, less than a reasonable royalty under 35 U.S.C. § 284.

JURY DEMAND

65. Vanda respectfully requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Vanda prays for a judgment in its favor and against Teva, and respectfully requests the following relief

a. A judgment that Teva's submission and maintenance of Teva's ANDA constituted an act of infringement of the '556 Patent;

b. A judgment that Teva induces infringement of the '556 Patent;

c. A judgment that Teva contributes to the infringement of the '556 Patent;

d. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Teva, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Teva's ANDA Product until the expiration of the '556 Patent, including any extensions and/or periods of exclusivity to which Vanda and/or the '556 Patent are or become entitled;

e. An order pursuant to 35 U.S.C. § 271(e)(4)(A) directing FDA to rescind the final approval of the Teva ANDA and that the effective date of any approval of the Teva ANDA be a date not earlier than midnight on April 7, 2033 corresponding to the expiration of the '556 Patent, including any extensions and/or other periods of exclusivity to which Vanda and/or the '556 Patent are or become entitled;

f. An order requiring Teva to take reasonable steps to recall Teva's ANDA Product from the market;

g. An award of damages pursuant to 35 U.S.C. §§ 271(e)(4)(c) and/or 284 plus pre-judgment and post-judgment interest, including a trebling of damages for Teva's willful infringement;

h. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, costs, expenses, and disbursements of this action; and

i. Such other and further relief as the Court may deem just and proper.

Dated: December 9, 2024

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

Of Counsel:

Paul W. Hughes
Sarah P. Hogarth
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com
shogarth@mwe.com

Jason Leonard
MCDERMOTT WILL & EMERY LLP
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5400
jleonard@mwe.com