Justin T. Quinn
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761

Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VANDA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 22- ____ *Document Electronically Filed* **JURY TRIAL DEMANDED**

VERIFIED COMPLAINT

This is a patent infringement action brought by plaintiff Vanda Pharmaceuticals Inc. (Vanda) for infringement of U.S. Patent No. 11,285,129 (the '129 patent) against Defendant Teva Pharmaceuticals USA, Inc. (Teva) related to Teva's filing of Abbreviated New Drug Application No. 211601 (Teva's ANDA or ANDA No. 211601) for approval of a generic version of Vanda's HETLIOZ® (tasimelteon) 20mg oral capsules, and the anticipated future marketing and sales of products under ANDA No. 211601. 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. As reflected on Teva's website, Teva is a pharmaceutical company that maintains its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201–02, at least because this action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq. E.g.*, *Vanda Pharm. Inc. et al. v. West-Ward Pharm. Int'l Ltd. et al.*, 887 F.3d 1117 (Fed. Cir. 2018) (subject matter jurisdiction for a claim under 35 U.S.C. § 271(e)(2)(A) is established under § 1338 by the filing of an ANDA).

4. Given its extensive presence in this District, this Court has personal jurisdiction over Teva.

5. Teva, among other things, develops, manufactures, markets, imports, and/or sells pharmaceutical products, including generic drug products. Teva directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for sales of Teva's generic products. Teva purposefully has conducted and continues to conduct business in this judicial district. Moreover, based on publicly available court records, Teva has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *E.g.*, Teva Pharmaceuticals, Inc, Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defs., and Counterclaims to Plaintiff's Compl. for Patent Infringement, *Evoke Pharma, Inc. v. Teva Pharms, Inc. & Teva Pharms USA, Inc.*, No. 22-02019 (D.N.J.), ECF No. 19; Teva Pharmaceuticals USA, Inc.'s Answer to Compl., Affirmative Defs., and Counterclaims, *Merck Sharp & Dohme B.V. & Organon USA Inc. v. Teva Pharms. USA, Inc.*, No. 20-18972 (D.N.J.), ECF No. 12.

6. Teva has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, New Jersey and elsewhere. Teva's submission of its ANDA constitutes a formal act that reliably indicate plans to engage in marketing of the proposed generic drugs. On information and belief, Teva intends to direct sales of its drugs into New Jersey, among other places.

7. On information and belief, Teva will engage in marketing of its proposed ANDA product in New Jersey and will, through its actions, induce or contribute to the use of its products within this District.

8. Teva represents on its website that it maintains a regular and established place of business as its North America-U.S. headquarters at 400 Interpace Parkway, #3, Parsippany, NJ 07054, which lies within this district.

9. Venue is proper in this district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

10. Venue is proper as to Teva because, among other things, it maintains a regular and established place of business in this judicial district, and it has previously consented to venue in this jurisdiction.

11. On information and belief, Teva submitted ANDA No. 211601 from within this District.

12. On information and belief, Teva is preparing to market and sell its ANDA product within this District and will, through its actions, induce or contribute to the use of its products within this District.

THE PATENT-IN-SUIT

The '129 Patent

13. On March 29, 2022, the '129 patent, titled "Treatment of Circadian Rhythm Disorders," was duly and legally issued by the United States Patent & Trademark Office (USPTO). A copy of the '129 patent is attached as Exhibit A.

14. The '129 patent generally relates to a method of administering tasimelteon to a patient and the interaction between tasimelteon and beta-adrenergic receptor antagonists (beta blockers). As a broad matter, the Federal Circuit has specifically confirmed the validity of such drug-drug-interaction patents. *See Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1382–83 (Fed. Cir. 2021).

15. The negative interaction of beta blockers and tasimelteon would not have been expected in light of literature, including literature both before and after the priority date of the '129 patent, suggesting that beta blockers could be useful in the treatment of circadian rhythm disorders. *E.g.*, H. De Leersnyder *et al.*, *β_1-adrenergic antagonists improve sleep and behavioural disturbances in a circadian disorder, Smith-Magenis syndrome,* 38 J. MED. GENET. 586 (2001); P.Gehrman *et al.*, *Treatment of a patient with a circadian sleep-wake disorder using a combination of melatonin and metoprolol*, 17 J.CLIN. SL. MED. 10 (Oct. 21, 2021) (discussing the use of a combination of a beta blocker and the administration of exogenous melatonin in treating a patient with a circadian rhythm disorder). The prior art thus taught away from the claimed invention. *See Cephalon, Inc. v. Slayback Pharma Ltd. Liab. Co.*, 456 F. Supp. 3d 594, 602 (D.Del. 2002) ("And the court must also be mindful that 'when the prior art teaches away from comb[ining] certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.'" (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007)).

16. The '129 patent names Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors.

17. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (called the Orange Book) lists the expiration date of the '129 patent as January 25, 2033.

18. Vanda is the assignee of the '129 patent and owns all rights, title, and interest in the '129 patent.

ACTS GIVING RISE TO THIS ACTION

19. This is an action arising under the patent laws of the United States (35 U.S.C. § 100 *et seq.*) based on Teva's current and likely future infringement of one or more claims of the '129 Patent.

A. Vanda and HETLIOZ®

20. Vanda is a small pharmaceutical company whose business model largely consists of acquiring compounds that other companies failed to develop into a useful treatment, identifying potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them.

21. Vanda acquired tasimelteon, now marketed as HETLIOZ®, from a large pharmaceutical company that tried, but failed, to develop it into a useful FDA-approvable therapy.

22. 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 later nighttime sleep disturbances in Smith-Magenis Syndrome in patients 16 years or older.

23. Specifically, Vanda holds approved New Drug Application (NDA) No. 205677 for HETLIOZ® (tasimelteon) capsules, 20 mg, approved by the United States Food & Drug

Administration (FDA) on January 31, 2014, for the treatment of Non-24. On December 1, 2020, the FDA approved supplemental New Drug Application (sNDA) 205677/S-007 allowing the marketing of HETLIOZ® to treat nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.

24. Vanda's currently approved HETLIOZ® label instructs on the treatment of a circadian rhythm disorder, *i.e.*, Non-24, when administering HETLIOZ® to a patient.

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

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

27. Section 7.3 of the currently approved HETLIOZ® 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."

28. On or around April 15, 2022, Vanda submitted patent information to list the '129 patent in the Orange Book for HETLIOZ®.

B. Teva's ANDA

29. Based on publicly available documentation from the FDA's website, Teva filed ANDA No. 211601 on January 31, 2018 to obtain approval to manufacture and sell a generic version of HETLIOZ® (Teva's ANDA Product).

30. Based on Teva's public statements, Teva's ANDA seeks permission to market Teva's ANDA Product for at least Non-24.

31. Teva made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Paragraph IV Certification) that, in its opinion and to the best of its knowledge, its ANDA does not seek approval to market a product, or the use of which, that would infringe the '129 patent, and/or that claims of the '129 patent are invalid and/or unenforceable.

32. On or around September 12, 2022, Vanda received written notice of Teva's Paragraph IV Certification relating to the '129 patent (Notice Letter), along with an enclosed statement of Teva's alleged factual and legal bases for stating that the claims of the '129 patent are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product (Detailed Statement).

C. Teva's infringement of the '129 patent

33. On information and belief, based on at least Teva's filing of an ANDA, the requirements of applicable law, and other publicly available information, the proposed and/or final prescribing information for Teva's ANDA Product will include language substantially like that in the currently approved HETLIOZ® prescribing information relating to the treatment of Non-24.

34. On information and belief, if Teva commences marketing and sale of its ANDA Product, it will market and sell its product at least to patients suffering from Non-24.

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

36. Accordingly, on information and belief, a reader of Teva's Section 7.3 of the prescribing information for Teva's ANDA Product would understand this section of the prescribing information to instruct the reader to avoid the use of beta blockers.

37. 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. *E.g.*, M. Reiter, *Cardiovascular drug class specificity: beta-blockers*, 47 PROG. CARDIOVASC. DIS. 1, 11 (Jul-Aug. 2004). Moreover, some of the conditions that beta blockers may also be treated by alternative therapeutics. Therefore, on information and belief, based on at least the prescribing information associated with Teva's ANDA Product, including Teva's Section 7.3, in administering tasimelteon to a patient, at least some patients would be undergoing treatment with beta blockers when they are prescribed tasimelteon, and at least some doctors would counsel some patients taking certain beta blockers to cease their use of those beta blockers when taking Teva's ANDA Product, at least in order to avoid the reduced efficacy of tasimelteon described in Teva's Section 7.3. Additionally, on information and belief, at least some doctors would prescribe a different class of medicines (other than beta blockers) to facilitate treatment of the underlying disease and co-administration with Teva's ANDA Product.

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

D. Teva's imminent launch

39. Based on at least publicly available documentation from the FDA's website, the FDA tentatively approved Teva's ANDA on September 27, 2021. The same documentation stated that, based on at least Teva's patent certifications, "final approval of [Teva's] ANDA may not be

granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until [U.S. Patent No. 5,856,529] patent has expired, currently December 9, 2022."

40. Based on information available on FDA's website, Teva currently has final approval to market Teva's ANDA Product.

41. Vanda previously brought an action against Teva on different patents relating to its HETLIOZ® product. *Vanda Pharm. Inc. v. Teva Pharm. USA Inc*., Case No. 1:18-cv-00651-CFC (D.Del.). In that case, a four-day bench trial was conducted on March 28 to March 31, 2022. The court entered an opinion on December 13, 2022, with final judgment on December 14, 2022. *Id.* at ECF Nos. 336–388. This case is currently on appeal to the Federal Circuit. *Vanda Pharm. Inc. v. Teva Pharm. USA Inc*., No. 23-1247 (Fed. Cir.). The '129 patent could not have been included in the previous action because it issued on March 29, 2022, *i.e*., in the middle of the four-day bench trial.

42. In a December 19, 2022 court filing in the Federal Circuit, Teva has stated that it has "FDA final approval and the ability to immediately launch a generic tasimelteon product." Teva Pharmaceuticals USA, Inc.'s Non-Confidential Emergency Mot. for Review, Reconsideration, or Modification of Temporary Injunction at 2, *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 23-1247 (Fed. Cir. filed Dec. 19, 2022), ECF No. 9.

E. Imminent irreparable harm to Vanda

43. Were Teva to launch its ANDA Product, Vanda would suffer immediate, severe, irreparable harm.

44. HETLIOZ® is one of Vanda's two approved products and accounted for nearly 65% of Vanda's revenue in 2021.

45. Vanda depends on this revenue for the substantial research & development efforts it is currently conducting, including

- HETLIOZ® (tasimelteon) as a treatment for insomnia, jet-lag disorder, delayed sleep-phase disorder, and sleep disturbances in patients with autism spectrum disorder.
- FANAPT® (iloperidone) as a treatment for bipolar disorder and for Parkinson's disease psychosis, as well as developing a long-acting injectable formulation of iloperidone.
- A third drug, tradipitant, as a treatment for gastroparesis, motion sickness, atopic dermatitis, and COVID-19 pneumonia.
- Four early-stage compounds: one for treatment of several cancers; one as a treatment for dry eye and ocular inflammation; one as a treatment secretory diarrhea disorder; and one as a treatment for psychiatric disorders.

46. In 2021, Hetlioz® net sales reached $173.5 million globally; the vast majority of those sales (over $165 million) are in the United States. Between its initial launch in 2014 and the third quarter of this year (that is, Q3 2022), cumulative net U.S. sales of Hetlioz® totaled approximately $900 million.

47. In the first 9 months of 2022, Vanda reinvested approximately 90% of its total revenue into research and development and company operations, as reflected in public filings.

CLAIMS FOR RELIEF

COUNT I
(Infringement of the '129 Patent)

48. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs.

49. Upon information and belief, Teva has infringed at least one claim of the '129 patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting Teva's ANDA, by which Teva 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 the Teva ANDA Product prior to the expiration of the '129 patent.

50. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of the Teva ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '129 patent.

51. Upon information and belief, Teva has actual knowledge of the '129 patent.

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

COUNT II
(Declaratory Judgment of Infringement of the '129 Patent)

53. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs.

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

55. There is an actual case or controversy such that the Court may entertain Vanda's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

56. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva's ANDA Product before the expiration date of the '129 patent, including Teva's filing of its ANDA No. 211601.

57. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '129 patent.

58. Vanda is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product will constitute infringement of at least one claim of the '129 patent.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that the Court enter judgment in its favor against Teva 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), Teva has infringed at least one claim of the '129 patent by submitting or causing to be submitted ANDA No. 211601 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Teva ANDA Product before the expiration of the '129 patent;

b. enter a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the '129 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon in accordance with Teva's proposed label before the expiration of the '129 patent;

c. order that that the effective date of any approval by the FDA of the Teva ANDA Product be a date that is not earlier than the expiration of the '129 patent, or such later date as the Court may determine;

d. enjoin Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of the Teva ANDA, or contributing to or inducing anyone to do the same, until expiration of the '129 patent;

e. enjoin Teva and all persons acting in concert with Teva from the commercial manufacture, use, import, offer for sale, and/or sale of the Teva ANDA Product, or contributing to or inducing anyone to do the same, until expiration of the '129 patent, or such later date as the Court may determine;

f. enjoin Teva and all persons acting in concert with Teva from infringing the '129 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

g. award monetary damages under 35 U.S.C. §§ 271(e)(4)(C) and 284,

h. 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;

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

j. determine that Teva's infringement has been willful, wanton, and deliberate and that the damages against it be increased up to three times under 35 U.S.C. § 284 on this basis; and

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

Dated: December 27, 2022
Newark, New Jersey

/s/ *Justin T. Quinn*

Justin T. Quinn
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761

Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

OF COUNSEL:

Paul W. Hughes (*pro hac vice* to be submitted)
April E. Weisbruch (*pro hac vice* to be submitted)
Christopher M. Bruno (*pro hac vice* to be submitted)
Sarah P. Hogarth (*pro hac vice* to be submitted)
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street N.W.
Washington, D.C. 20001
Tel: (202) 756-8000
Fax: (202) 756-8087
phughes@mwe.com
aweisbruch@mwe.com
cbruno@mwe.com
shogarth@mwe.com

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: December 27, 2022
Newark, New Jersey

/s/ *Justin T. Quinn*

Justin T. Quinn
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761

Attorneys for Plaintiff
Vanda Pharmaceuticals, Inc.

VERIFICATION

I, Mihael H. Polymeropoulos, MD, state as follows:

I am the Chief Executive Officer of plaintiff Vanda Pharmaceuticals Inc. I have read the foregoing verified complaint and know the contents thereof. The verified complaint is true to the best of my knowledge and understanding, except as to matters therein stated to be alleged upon information and belief and, as to those matters, I believe them to be true.

Dated: December 27, 2022

Mihael H. Polymeropoulos, MD

STATE OF Virginia §
§
COUNTY OF Virginia Beach §

Before me, the undersigned Notary Public, on this day, December 27, 2022, personally appeared Mihael H. Polymeropoulos, MD, and, after being duly sworn, he subscribed to the above statement.

Reginald Renard Barnes

NOTARY PUBLIC

Notarized online using audio-video communication

COMMONWEALTH OF VIRGINIA · ELECTRONIC NOTARY PUBLIC · N

Reginald Renard Barnes

REGISTRATION NUMBER
7950517
COMMISSION EXPIRES
August 31, 2025