IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. APOTEX INC. AND APOTEX CORP., Defendant.	C.A. No. 23-153-CFC **ANDA CASE** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) brings this First Amended Complaint for patent infringement of U.S. Patent No. 11,285,129 (the '129 patent) against Defendants Apotex Inc. and Apotex Corp. (together, Apotex, unless otherwise specified) related to Apotex's filing of Abbreviated New Drug Application No. 211607 (Apotex's ANDA or ANDA No. 211607) 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. 211607. 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 defendant Apotex Inc. has stated in court filings, Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. *E.g.*, Compl., *Apotex Inc. and Apotex Corp. v. Eli Lilly & Co.*, Case No. 22-cv-2342 (S.D.Ind.) (filed Dec. 6, 2022); Answer of Defs. Apotex Inc. & Apotex Corp., Affirmative Defs.

And Counterclaims for Declaratory Judgment, *In re Jublia*, No. 18-13635 (D.N.J.) (consolidated), ECF No. 50.

3. As defendant Apotex Corp. has recently represented in at least one court filing. Apotex Corp. is a corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. *E.g.*, Compl., *Apotex Inc. and Apotex Corp. v. Eli Lilly & Co.*, Case No. 22-cv-2342 (S.D.Ind.) (filed Dec. 6, 2022); Answer of Defs. Apotex Inc. & Apotex Corp., Affirmative Defs. And Counterclaims for Declaratory Judgment, *In re Jublia*, No. 18-13635 (D.N.J.) (consolidated), ECF No. 50.

4. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

5. On information and belief Apotex Corp. is the designated U.S. agent for Apotex Inc. in accordance with 21 C.F.R. § 314.50(a) in connection with Apotex's ANDA.

6. On information and belief, Apotex Corp. is a generic pharmaceutical company that distributes and sells generic pharmaceutical products in the State of New Jersey and throughout the United States that are manufactured by Apotex Inc.

JURISDICTION AND VENUE

7. 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).

8. Given its extensive presence in this District, this Court has personal jurisdiction over Apotex.

9. Apotex, among other things, develops, manufactures, markets, imports, and/or sells pharmaceutical products, including generic drug products. Apotex 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 Apotex's generic products. Apotex purposefully has conducted and continues to conduct business in this judicial district. Moreover, Apotex has previously submitted to the jurisdiction of this Court in other cases, and also availed itself of this Court by moving to transfer the present action to this Court from the United States District Court for the District of New Jersey. *E.g.*, *Apotex Inc. et al v. Allergan Inc.*, C.A. No. 12-cv-00196-SLR (D. Del.), ECF No. 1; *Senju Pharmaceutical Co. Ltd. et al v. Apotex Inc. et al*, C.A. No. 12-cv-00159-SLR (D. Del.), ECF No. 9; *see Vanda Pharms. Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 2:22-cv-07529-CCC-JSA (D.N.J.), ECF No. 18.

10. Apotex took the costly, significant step of applying to the U.S. Food and Drug Administration (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, Delaware and elsewhere. Apotex's submission of its ANDA constitutes a formal act that reliably indicates plans to engage in marketing of the proposed generic drugs. On information and belief, Apotex intends to direct sales of its drugs into Delaware, among other places.

11. On information and belief, Apotex will engage in marketing of its ANDA product in Delaware and will, through its actions, induce or contribute to the use of its products within this District.

12. This Court has personal jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because Apotex Inc. has extensive contacts with the United States, including but not limited to the above-described commercial contract, is not subject to jurisdiction

in any particular state, and exercising jurisdiction over Apotex Inc. is consistent with the laws of the United States and the United States Constitution.

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

14. Venue is proper as to Apotex because, among other things, it has previously consented to venue in this jurisdiction. *E.g.*, *Senju Pharmaceutical Co. Ltd. et al v. Apotex Inc. et al*, C.A. No. 12-cv-00159-SLR (D. Del.), ECF No. 9. Apotex likely will also commit acts of infringement in this judicial district.

15. Venue is further proper as to Apotex Inc., a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

16. On information and belief, Apotex 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

17. 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).[1] A copy of the ’129 patent is attached as Exhibit A.

18. 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).

[1] The date the ’129 patent issued—March 29, 2022—was the second day of trial in the prior litigation. *See infra* ¶¶ 62-63.

19. The ’129 patent covers a method of administering tasimelteon to a patient where it is first determined whether the patient is taking a beta-adrenergic receptor antagonist. If the patient is not taking a beta-adrenergic receptor antagonist, 20 mg of tasimelteon is administered once daily before bedtime. If the patient is taking a beta-adrenergic receptor antagonist, the patient is instructed to stop taking the beta-adrenergic receptor antagonist, and 20 mg of tasimelteon is administered once daily before bedtime. *See* Exhibit A.

20. 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)).

21. Based on at least the scientific literature, a person of skill in the art at the time of the invention would have believed that tasimelteon would be able to overcome any lowering of melatonin potentially caused by a beta blocker. But surprisingly this is not so. Therefore, the negative interaction between beta blockers and tasimelteon as described and claimed in the ’129

patent would have been unexpected and surprising to a person of skill in the art at the time of the invention.

22. 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.

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

24. 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

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

A. Vanda and HETLIOZ®

26. 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.

27. 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.

28. 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.

29. Specifically, 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. 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.

30. A copy of the HETLIOZ® prescribing information is attached as Exhibit D ("HETLIOZ® Label").

31. 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.

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

33. 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."

34. 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."

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

B. Apotex's ANDA

36. Based on publicly available documentation from the FDA's website, Apotex filed ANDA No. 211607 on January 31, 2018 to obtain approval to manufacture and sell a generic version of HETLIOZ® (Apotex's ANDA Product).

37. Based on Apotex's public statements and other publicly available information, Apotex's ANDA seeks permission to market Apotex's ANDA Product for at least Non-24.

38. Apotex 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.

39. On or around June 15, 2022, Vanda received written notice of Apotex's Paragraph IV Certification relating to the '129 patent (Notice Letter), along with an enclosed statement of Apotex'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 Apotex's ANDA Product (Detailed Statement). Notably, Apotex did not claim that the '129 patent was unenforceable by virtue of the doctrine of equitable estoppel or any other theory claiming that Vanda had foregone its patent rights.

C. Apotex's infringement of the '129 patent

40. On February 2, 2020, the FDA issued a tentative approval of Apotex's ANDA to market a generic version of tasimelteon. *See* Exhibit B (Apotex Tentative Approval Letter).

41. The FDA issued final approval of Apotex's ANDA to market a generic equivalent of Hetlioz® on December 20, 2022 (Apotex Final Approval Letter). A copy of the Final Approval Letter is attached as Exhibit C.

42. A copy of Apotex's proposed ANDA product prescribing information is attached as Exhibit E ("Apotex Proposed Label"). The proposed label for Apotex's ANDA Product includes language substantially like that in the currently approved HETLIOZ® prescribing information relating to the treatment of Non-24.

43. The Apotex Proposed Label includes the Non-24 Indication. Exhibit E at 1.

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

Per FDA labeling guidelines, labeling for prescription medicines is the primary method of communicating drug information to healthcare professionals, patients, and the patients' caregivers. U.S. Food & Drug Administration, *Frequently Asked Questions about Labeling for Prescription Medicines*, https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines (last visited May 12, 2023).

45. On information and belief, Apotex's ANDA product will be sold and/or distributed to healthcare professionals, patients, and the patients' caregivers along with the final Apotex Label's prescribing information.

46. The language in Section 7.3 of Apotex's Proposed Label ("Apotex's Section 7.3") is substantially similar to that in Section 7.3 of the currently approved HETLIOZ® Label ("HETLIOZ® Section 7.3"). *Compare* Exhibit D at 5 *with* Exhibit E at 4. HETLIOZ® Section 7.3 states

> **7.3 Beta-Adrenergic Receptor Antagonists (e.g., acebutolol, metoprolol)**
>
> 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 tasimelteon.

Apotex's Section 7.3 states

> **7.3 Beta-Adrenergic Receptor Agonists (e.g., acebutolol, metoprolol)**
>
> 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 tasimelteon.

47. On information and belief, in selling and/or distributing Apotex's FDA-approved ANDA Product, Apotex will include a final label which will likely include language identical or substantively identical to HETLIOZ® Section 7.3 as described above.

48. Accordingly, on information and belief, a reader of Apotex's Section 7.3 and in particular a physician, reading Apotex's Section 7.3 would understand Apotex's Section 7.3 to instruct the reader to avoid the use of beta blockers.

49. Before a physician prescribes a therapy, the physician must determine the patient's problem, determine whether (and what kind of) treatment is warranted, select a therapy that will treat the problem, write a prescription if a prescription drug is selected, inform the patient about the drug and provide any instructions or warnings, and monitor the treatment.

50. In selecting a therapy—and later informing the patient about the therapy—a physician must familiarize himself or herself with the label and the instructions and warnings contained therein, including whether the drug will treat the patient's problem, how the drug is effective, how much to prescribe, how often to take the drug, and when to take the drug, any risks of taking the drug, and other substances to avoid. Thus, prescription drug labels are essential tools for physicians to guide a treatment.

51. As respects drug-drug interactions, some, if not all, physicians would thoroughly check for potential contraindications and for interactions if the patient is taking another medication.

52. According to the FDA, Section 7 of a prescription drug label "[d]escribes clinically important interactions which may lead to an increased frequency or severity of an adverse reaction or decrease the effectiveness of a drug, and practical instructions to mitigate the risks of these interactions." FDA, *How Do I Use Prescription Drug Labeling* (as of May 11, 2023),

perma.cc/H2S9-C4C3. Further, "[i]nformation under the Drug Interactions heading must include a concise summary of those drugs (or classes of drugs) or foods that interact or are predicted to interact in clinically significant ways with the subject drug, and practical instructions for preventing or managing the interaction (§ 201.57(a)(12))." FDA, *Guidance for Industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements* (Feb. 2013), perma.cc/Q8X8-RFGG.

53. Physicians as a general matter endeavor to prescribe—and patients expect—treatment that is optimized to be efficacious in treating their problem and to avoid adverse consequences. The information contained in Section 7 of a label is crucial to identifying for physicians any drug-drug interactions that are clinically significant and offering practical instructions for preventing or mitigating the interaction.

54. 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).

55. A physician would read and understand that Section 7.3 of the label encourages discontinuation of beta blockers by instructing that there may be a reduced efficacy of Apotex's ANDA Product when a beta-blocker is co-administered with its ANDA Product.

56. On information and belief, 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 Apotex's ANDA Product to avoid the reduced efficacy of tasimelteon described in Section 7.3.

57. Indeed, some of the conditions that beta blockers treat may also be treated by alternative therapeutics. Thus, at least some doctors would prescribe a different class of medicines (other than beta blockers) to facilitate treatment of the underlying disease and avoid the reduced efficacy of co-administration with Apotex's ANDA Product.

58. There is a well-known risk of hypertension at night, and many doctors would ensure that patients are adequately treated during the nighttime. As a result, many (if not all) doctors would conclude that changing the time of administration of the beta blocker will not suffice for adequate treatment. Instead, many (if not all) doctors would conclude that, when treating a patient with tasimelteon as directed, the preferred course of action is ceasing beta blocker administration and substituting with a drug of a different class.

59. On information and belief, doctors have in fact directed patients, at the time they prescribe tasimelteon, to discontinue use of beta blockers. On information and belief, doctors direct this course of action based on the tasimelteon label language describing the drug-drug interaction.

D. Apotex's imminent launch

60. Based on at least publicly available documentation from the FDA's website, the FDA tentatively approved Apotex's ANDA on February 2, 2020. The same documentation stated that, based on at least Apotex's patent certifications, "final approval of [Apotex'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."

61. Based on publicly available information, including Apotex's public statements and information available on FDA's website, Apotex currently has final approval to market Apotex's ANDA Product.

E. Prior Litigation

62. Vanda previously brought an action against Apotex on different patents relating to Vanda's HETLIOZ® product. *Vanda Pharm. Inc. v. Apotex Pharm. USA Inc*., Case No. 1:18-cv-00651-CFC (D. Del.) (the "prior litigation"). In that case, a four-day bench trial was conducted from March 28 to March 31, 2022. The court entered an opinion on December 13, 2022, with final judgment on December 14, 2022. The court held, *inter alia*, that claim 3 of U.S. Patent No. RE46,604 ("the RE604 patent") and claim 14 of U.S. Patent No. 10,149,829 ("the '829 patent"), were obvious. *Id.* at D.I. 336–388.

63. 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.

64. The Federal Circuit holds that the validity of different patents are presumed by law to present different issues. *See Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995).

65. Claim 1 of the '129 patent covers an improved method of administering tasimelteon to a patient that requires a novel two-path therapy regime: after determining whether the patient is taking a beta-adrenergic receptor antagonist (the "determining step") (1) if the patient is not taking a beta-adrenergic receptor antagonist, administering 20 mg of tasimelteon once daily before bedtime; or (2) if the patient is taking a beta-adrenergic receptor antagonist, instructing the patient to stop taking the beta-adrenergic receptor antagonist and then administering 20 mg of tasimelteon once daily before bedtime. Exhibit A. Claim 2 requires the beta-adrenergic receptor antagonist to be alprenolol, altenolol, carvedilol, metoprolol, or propranolol. *Id.* Claim 3 further requires that the patient be suffering from Non-24. *Id.*

66. The claims of the ’129 patent are materially different and present materially different questions of patentability from the patent claims that were adjudicated in the prior litigation, including the claims of the RE604 and the ’829 patent. For example, the claims of the RE604 and the ’829 patent do not relate in any way to the beta blocker drug-drug interaction described and claimed in the ’129 patent.

67. In order to prove invalidity of the ’129 patent, both pathways ((1) and (2)) in the two-path therapy regime must be shown to be invalid. *See, e.g.*, *Lincoln Nat’l Life Ins. Co. v. Transamerica Life Ins. Co.*, 609 F.3d 1364 (Fed. Cir. 2010).

68. Because the ’129 patent was not asserted in the prior litigation, none of its claim terms (such as, *e.g.*, the claim term “determining,” which serves as a modifier/gateway for the two conditional options in Claim 1, or the claim term “or”) were construed in the prior litigation.

69. All claimed steps and limitations in the ’129 patent have patentable weight. This includes the determining step, which modifies how the claim is practiced and so is functionally related to the other claim limitations which encompass the structural elements of the claimed invention.

70. Because the ’129 patent was not asserted in the prior litigation, the patentable weight and/or patentability of the determining step were not evaluated in the prior litigation.

71. Because the ’129 patent was not asserted in the prior litigation, the patentable weight and/or patentability of other limitations of the claims, including those in the dependent claims, were not evaluated in the prior litigation.

72. The limitations of the claims of the ’129 patent, including the assessment of whether a patient is on beta blockers to avoid interfering with tasimelteon, constitute non-obvious, novel, and otherwise patentable inventions. The prior art actually taught away from the claimed

invention because literature both before and after the priority date of the '129 patent suggested that beta blockers could be useful in the treatment of circadian rhythm disorders.

F. Imminent irreparable harm to Vanda

73. Were Apotex to launch its ANDA Product, Vanda would suffer immediate, severe, irreparable harm.

74. HETLIOZ® is one of Vanda's two approved products and accounted for roughly 65% of Vanda's revenue in 2022.

75. 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.

76. 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.

77. Were Apotex to launch its ANDA Product, Vanda will experience irreparable harm, such as and including, *e.g.*, price erosion associated with its Hetlioz® product and/or other

irreparable harm such as and including, *e.g.*, marketplace losses associated with the presence of one or more generic competitor(s) in the market.

CLAIMS FOR RELIEF

COUNT I
(Infringement of the '129 Patent – 35 U.S.C. § 271(e))

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

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

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

81. Upon information and belief, Apotex has actual knowledge of the '129 patent.

82. If Apotex's marketing and sale of Apotex'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)

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

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

85. 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.

86. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Apotex's ANDA Product before the expiration date of the '129 patent, including Apotex's filing of its ANDA No. 211607.

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

88. Vanda is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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 Apotex 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), Apotex has infringed at least one claim of the '129 patent by submitting or causing to be submitted ANDA No. 211607 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Apotex ANDA Product before the expiration of the '129 patent;

b. enter a declaration that Apotex 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 Apotex'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 Apotex 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 consistent with 35 U.S.C. § 271(e)(4)(A);

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

e. enjoin Apotex and all persons acting in concert with Apotex from the commercial manufacture, use, import, offer for sale, and/or sale of the Apotex 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 Apotex and all persons acting in concert with Apotex 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 Apotex 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 Apotex, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

j. determine that Apotex'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.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, plaintiff demands a trial by jury on all issues so triable.

Dated: May 12, 2023

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
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