

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
TEVA PHARMACEUTICALS USA, INC.,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) for its Complaint against Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including HETLIOZ® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder (“Non-24”).

2. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

II. NATURE OF THE ACTION

3. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Teva’s infringement of one or more claims of Vanda’s U.S. Patent No. 10,449,176 (“the ’176 patent”), which, in relevant part, generally relates to the use of tasimelteon in the treatment of circadian rhythm disorders or sleep disorders.

4. Vanda is the holder of approved New Drug Application No. 205,677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration (“FDA”) on January 31, 2014, for the treatment of Non-24 (“HETLIOZ® NDA”), a circadian rhythm sleep disorder.

5. Tasimelteon is the active ingredient in HETLIOZ®.

6. On information and belief, Teva filed Abbreviated New Drug Application No. 211601 (the “ANDA”) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the “FFDCA”), to obtain approval to commercially manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 (“Teva’s ANDA Product”).

7. On information and belief, 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, the ’176 patent is invalid, unenforceable, and/or that certain claims will not be infringed by Teva’s ANDA Product.

8. Vanda received written notice of Teva’s ANDA and Paragraph IV Certification as to the ’176 patent on December 20, 2019 (“Notice Letter”), along with an enclosed statement of Teva’s alleged factual and legal bases for stating that the ’176 patent is invalid, unenforceable, and/or will not be infringed by Teva’s ANDA Product (“Detailed Statement”).

9. Teva’s Detailed Statement does not provide any factual bases or other statements alleging that the ’176 patent is unenforceable.

10. This action is being commenced within 45 days of receipt of Teva’s Notice Letter.

11. Teva has infringed one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA with a Paragraph IV Certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '176 patent or any extensions thereof.

12. Teva has infringed one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon for the treatment of Non-24 prior to the expiration of the '176 patent or any extensions thereof.

III. JURISDICTION

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over Teva because Teva is incorporated in the State of Delaware.

15. On information and belief, Teva's registered agent for service of process is Corporate Creations Network Inc., with an address at 3411 Silverside Road #104, Tatnall Building, Wilmington, Delaware 19810.

16. On information and belief, Teva is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

17. Teva has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures HETLIOZ® for sale and use throughout the United States, including

in this Judicial District. On information and belief, and as indicated by the Notice Letter and Supplemental Notice Letter, Teva prepared and filed ANDA No. 211601 with the intention of seeking to market generic tasimelteon nationwide, including within this Judicial District.

18. On information and belief, Teva plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursement for sales of the Teva ANDA Product in the State of Delaware, either directly or through one or more of Teva's wholly owned subsidiaries, agents, and/or alter egos.

19. On information and belief, Teva knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of HETLIOZ®, causing injury to Vanda. Teva intends to take advantage of its established channels of distribution in Delaware for the sale of the Teva ANDA Product.

IV. VENUE

20. Venue is proper in this judicial District under 28 U.S.C. § 1400(b) because Teva is incorporated in the State of Delaware.

V. THE PATENT-IN-SUIT

(U.S. PATENT NO. 10,449,176)

21. The allegations above are incorporated herein by reference.

22. The '176 patent covers, generally, a method of preventing or treating disorders associated with a desynchronous melatonin or cortisol circadian rhythm.

23. As explained in the '176 patent, "this invention provides a method of preventing or treating disorders associated with a desynchronous melatonin or cortisol circadian rhythm, i.e., a circadian rhythm that is not synchronized with the natural day/night cycle." The '176 patent further explains "[s]uch method comprises internally administering to a patient

having a desynchronous melatonin or cortisol circadian rhythm an effective amount of a melatonin agonist, in particular, tasimelteon or an active metabolite thereof, as described in this specification.”

24. Vanda is the owner of all rights, title, and interest in the '176 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the '176 patent on October 22, 2019, to Marlene Michelle Dressman, Louis William Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '176 patent is attached to this Complaint as Exhibit A.

25. The '176 patent generally claims a method of preventing or treating disorders associated with a desynchronous melatonin or cortisol circadian rhythm. As an example, claim 1 of the '176 patent claims, “A method of treating a disorder associated with a desynchronous cortisol circadian rhythm in an individual having a desynchronous cortisol circadian rhythm, said method comprising internally administering to the individual an effective amount of tasimelteon, wherein the disorder associated with a desynchronous cortisol circadian rhythm is selected from a group consisting of: obesity, depression, and neurological impairment.”

VI. COUNT I

(INFRINGEMENT OF THE '176 PATENT)

26. The allegations above are incorporated herein by reference.

27. Teva filed the Teva ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '176 patent and any extensions thereof.

28. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment

of Non-24 before the expiration of the '176 patent. The Notice Letter represents that an Amendment to Teva's ANDA was submitted with a Paragraph IV Certification that the '176 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

29. Teva thus has actual knowledge of the '176 patent.

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

31. 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.”

32. The HETLIOZ® Label also states “HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).” Non-24 is a neurological impairment associated with a desynchronous cortisol circadian rhythm as set forth in Claims 1–9.

33. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24.

34. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '176 patent, and Vanda has the right to enforce the '176 patent and sue for infringement thereof.

35. The '176 patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) for HETLIOZ® in its 20 mg strength.

36. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe claims 1–9 of the '176 patent.

37. On information and belief, if Teva's ANDA is approved, prescribers and patients will follow the instructions in the proposed label for Teva's ANDA Product and administer Teva's ANDA Product in a manner that would infringe claims 1–9 of the '176 patent.

38. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 1–9 of the '176 patent.

39. Teva has infringed the '176 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength, to be taken without food, for the treatment of Non-24, which is covered by one or more claims of the '176 patent, prior to the expiration of the '176 patent.

40. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '176 patent, including claim 1–20 under 35 U.S.C. § 271(a), (b), and/or (c).

41. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III Certification”) as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

42. Vanda seeks entry of an order declaring that Teva has infringed the '176 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

43. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date

that is not earlier than the expiration of the '176 patent or any later expiration of exclusivity for the '176 patent to which Vanda becomes entitled.

44. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '176 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

45. On information and belief, Teva's statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the '176 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

46. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Teva and grant the following relief:

A. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '176 patent;

B. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the '176 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 for the treatment of Non-24 before the expiration of the '176 patent;

C. an order requiring that Teva amend its Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '176 patent or any later period of exclusivity to which Vanda is or may become entitled;

E. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '176 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;

F. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '176 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;

G. an assessment of 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;

H. an award to Vanda of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. such other and further relief as this Court may deem just and proper.

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/s/ Karen Jacobs

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