

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
APOTEX INC. and APOTEX CORP.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) for its Complaint against Defendants Apotex Inc. and Apotex Corp. (“Apotex”) 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, Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, Apotex Corp. is a 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 Abbreviated New Drug Application No. 211607 (the “Apotex ANDA”).

6. On information and belief, Apotex Corp. is a generic pharmaceutical company that distributes and sells generic pharmaceutical products in the State of Delaware and throughout the United States that are manufactured by Apotex Inc. (Apotex Inc. and Apotex Corp. are collectively referred to herein as “Apotex” unless otherwise specified).

II. NATURE OF THE ACTION

7. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Apotex’s infringement of one or more claims of Vanda’s U.S. Patent No. 10,829,465 (“the ’465 patent”), which, in relevant part, generally relates to compositions comprising purified tasimelteon.

8. Vanda is the holder of approved New Drug Application No. 205677 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 a circadian rhythm sleep disorder.

9. Tasimelteon is the active ingredient in Hetlioz®.

10. On information and belief, Apotex filed its 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 (“Apotex’s ANDA Product”).

11. On information and belief, 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, the '465 patent is invalid, unenforceable, and/or that certain claims will not be infringed by Apotex's ANDA Product.

12. Vanda received written notice of Apotex's ANDA and Paragraph IV Certification as to the '465 patent on January 14, 2021 ("Notice Letter"), along with an enclosed statement of Apotex's alleged factual and legal bases for stating that the '465 patent is invalid, unenforceable, and/or will not be infringed by Apotex's ANDA Product ("Detailed Statement").

13. Apotex's Detailed Statement does not provide any factual bases or other statements alleging that the '465 patent is unenforceable.

14. This action is being commenced within 45 days of receipt of Apotex's Notice Letter.

15. Apotex has infringed one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex ANDA with a Paragraph IV Certification and seeking FDA approval of the Apotex ANDA prior to the expiration of the '465 patent or any extensions thereof.

16. Apotex has infringed one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex 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 '465 patent or any extensions thereof.

III. JURISDICTION

17. 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.

18. This Court has personal jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in the State of Delaware.

19. On information and belief, Apotex'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.

20. This Court has personal jurisdiction over Apotex Inc. under Fed. R. Civ. P. 4(k) because, on information and belief, Apotex Inc. is organized under the laws of Canada.

21. This Court has personal jurisdiction over Apotex Inc. because at least one of the provisions under Del. Code Ann. tit. 10, § 3104, is satisfied. On information and belief, Apotex satisfies at least § 3104(c)(1) (“[t]ransacts any business or performs any character of work or service in the State”), § 3104(c)(2) (“[c]ontracts to supply services or things in this State”), § 3104(c)(3) (“[c]auses tortious injury in the State by an act or omission in this State), and § 3104(c)(4) (“[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State”).

22. This Court also has personal jurisdiction over Apotex Inc. because this suit arises out of and relates to Apotex Inc.'s activities, in concert with Apotex Corp., that are, and will be, directed to Delaware. On information and belief, following any FDA approval of the Apotex ANDA, Apotex Inc., in concert with Apotex Corp., will market and sell Apotex's ANDA Product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, including in this Judicial District.

23. On information and belief, Apotex Inc., directly and through its subsidiaries, affiliates, or agents, including Apotex Corp., is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

24. Apotex Inc. and Apotex Corp., acting in concert, have 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, Apotex prepared and filed ANDA No. 211607 with the intention of seeking to market generic tasimelteon nationwide, including within this Judicial District.

25. On information and belief, Apotex 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 Apotex's ANDA Product in the State of Delaware, either directly or through one or more of Apotex's wholly owned subsidiaries, agents, and/or alter egos.

26. On information and belief, Apotex 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. Apotex intends to take advantage of its established channels of distribution in Delaware for the sale of Apotex's ANDA Product.

IV. VENUE

27. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) with regard to Apotex Corp., because, upon information and belief, Apotex Corp. resides in the State of Delaware and therefore Apotex's ANDA submission is sufficiently related to this District.

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