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Medicis Pharmaceutical Corporation*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MEDICIS PHARMACEUTICAL
CORPORATION,

Plaintiff,

v.

GLENMARK GENERICS INC., USA, and
GLENMARK GENERICS LTD.

Defendants.

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Civil Action No. _____

Document electronically filed.

COMPLAINT

For its Complaint, Plaintiff Medicis Pharmaceutical Corporation (“Medicis” or “Plaintiff”) alleges as follows:

Parties

1. Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. Medicis is the leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and podiatric conditions and aesthetics medicine. Medicis has developed and commercialized leading branded

prescription products in a number of therapeutic categories. Because of their clinical effectiveness and high quality, Medicis's products have earned wide acceptance by both physicians and patients.

2. On information and belief, Glenmark Generics Inc., USA ("Glenmark USA") has offices in the District of New Jersey, with its principal place of business at 750 Corporate Drive, Mahwah, NJ, 07430.

3. On information and belief, Glenmark Generics Ltd. ("Glenmark Ltd.") is incorporated in India, with its principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B.D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India.

4. On information and belief, Glenmark USA is a wholly-owned subsidiary and the authorized United States agent of Glenmark Ltd.

5. On information and belief, Glenmark USA is controlled and/or dominated by Glenmark Ltd.

6. On information and belief, Glenmark USA conducts operations through international subsidiaries, including Glenmark Ltd.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, Title 35, United States Code. Jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Glenmark USA because Glenmark USA resides in this judicial district and engages in continuous and systematic contacts within the District of New Jersey.

9. On information and belief, Glenmark USA acts under the direction, control, and influence of Glenmark Ltd. with respect to the acts and conduct alleged in this Complaint. Glenmark Ltd. has also assented to jurisdiction in this district on many occasions. On further information and belief, Glenmark Ltd., either directly or through its agents, is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

10. For all the reasons set forth above, this Court has personal jurisdiction over Glenmark USA and Glenmark Ltd.

11. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b), because Glenmark USA and Glenmark Ltd. employ individuals in this judicial district and have offices and facilities in this judicial district, and thus purposefully avail themselves of the privilege of conducting activities within this judicial district.

FACTUAL BACKGROUND

12. On July 20, 2004, United States Letters Patent No. 6,765,001 (the “’001 patent”), entitled “Compositions and Methods for Enhancing Corticosteroid Delivery,” duly and legally issued to inventors Eugene H. Gans and Mitchell S. Wortzman. A copy of the ‘001 is attached as Exhibit 1.

13. On May 22, 2007, United States Letters Patent No. 7,220,424 (the “’424 patent”), entitled “Compositions and Methods for Enhancing Corticosteroid Delivery,” duly and legally issued to inventors Eugene H. Gans and Mitchell S. Wortzman. A copy of the ‘424 patent is attached as Exhibit 2.

14. Medcis owns the ’001 and ’424 patents.

15. Medcis has an approved New Drug Application (“NDA”) No. 21-758 for

fluocinonide cream 0.1%, which is sold under Medicis's trademark VANOS®.

16. Medicis's VANOS® Cream is extremely successful and is widely used in the District of New Jersey, in the United States, and throughout the world to treat psoriasis, atopic dermatitis, and corticosteroid responsive dermatoses.

17. The claims of the '001 and '424 patents cover Medicis's VANOS® Cream and, therefore, Medicis submitted both the '001 and '424 patents to the United States Food and Drug Administration ("FDA") for listing in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (the "Orange Book"). The FDA has listed both the '001 and '424 patents in the Orange Book publication.

18. On information and belief, Glenmark USA, under the direction of Glenmark Ltd., has filed Abbreviated New Drug Application ("ANDA") No. 91-282 with the FDA for generic fluocinonide cream 0.1%. Glenmark USA's ANDA contains a certification of invalidity, unenforceability, and/or noninfringement of the '001 patent. Notice of that certification, but not the certification itself, was transmitted to Medicis on or after May 6, 2009, and was received by Medicis on May 8, 2009.

20. Glenmark USA had no adequate good faith basis for filing its ANDA No. 91-282 containing a certification of the alleged invalidity, unenforceability, and/or noninfringement of the claims of the '001 and '424 patents.

21. On information and belief, Glenmark USA and Glenmark Ltd. were aware of the '001 and '424 patents on or before the date Glenmark USA filed its ANDA.

22. Glenmark USA filed its ANDA for generic fluocinonide cream 0.1% because both Glenmark USA and Glenmark Ltd., through its subsidiary and authorized United States agent, seek to enter the lucrative fluocinonide cream 0.1% market that Medicis's VANOS®

Cream pharmaceutical products have created by providing very beneficial and advantageous treatments for psoriasis, atopic dermatitis, and corticosteroid responsive dermatoses.

23. Glenmark Ltd. actively and knowingly aided and abetted Glenmark USA's filing of its ANDA seeking approval to market generic copies of Medicis's VANOS® Cream pharmaceutical products.

COUNT 1

24. Each of the preceding paragraphs 1-23 is incorporated as if fully set forth herein.

25. Glenmark USA filed its ANDA No. 91-282 to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '001 patent before the expiration of the '001 patent. On information and belief, Glenmark USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

26. Glenmark USA seeks approval to market generic fluocinonide cream 0.1% under ANDA 91-282 before the expiration of the '001 patent. Glenmark USA was aware of the existence of the '001 patent prior to filing its ANDA and was aware that the submission of the ANDA constitutes an act of patent infringement.

27. Glenmark USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '001 patent.

COUNT II

28. Each of the preceding paragraphs 1-27 is incorporated as if fully set forth herein.

29. Glenmark USA filed its ANDA No. 91-282 to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '424 patent before the expiration of the '424 patent. On information and belief, Glenmark USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

30. Glenmark USA seeks approval to market generic fluocinonide cream 0.1% under ANDA 91-282 before the expiration of the '424 patent. Glenmark USA was aware of the existence of the '424 patent prior to filing its ANDA and was aware that the submission of the ANDA constitutes an act of patent infringement.

31. Glenmark USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '424 patent.

COUNT III

32. Each of the preceding paragraphs 1-31 is incorporated as if fully set forth herein.

33. When Glenmark Ltd. actively and knowingly aided and abetted Glenmark USA with the filing of its ANDA seeking approval to market generic fluocinonide cream 0.1%, Glenmark Ltd. was aware of the '001 patent and knew that Glenmark USA's submission of its ANDA constitutes an act of infringement. On information and belief, Glenmark Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(b).

34. Glenmark Ltd. acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '001 patent.

COUNT IV

35. Each of the preceding paragraphs 1-34 is incorporated as if fully set forth herein.

36. When Glenmark Ltd. actively and knowingly aided and abetted Glenmark USA with the filing of its ANDA seeking approval to market generic fluocinonide cream 0.1%, Glenmark Ltd. was aware of the '424 patent and knew that Glenmark USA's submission of its ANDA constitutes an act of infringement. On information and belief, Glenmark Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(b).

37. Glenmark Ltd. acted without a reasonable basis for a good faith belief that it

would not be liable for infringing the '424 patent.

REQUESTED RELIEF

WHEREFORE, Plaintiff Mediciis respectfully seeks the following relief:

a. That judgment be entered declaring that Defendant Glenmark USA, for Glenmark USA has infringed the '001 and '424 patents by submitting its ANDA;

b. That judgment be entered declaring that Defendant Glenmark Ltd., for Glenmark Ltd. has infringed the '001 and '424 patents by inducing Glenmark USA's infringement of the '001 and '424 patents through actively and knowingly aiding and abetting Glenmark USA's filing of its ANDA;

c. That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendants Glenmark USA and Glenmark Ltd., their officers, agents, or attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United states, of any therapeutic composition or method of use covered by the '001 and '424 patents for the full term thereof, and from inducing or contributing to such activities;

d. That an order be issued under 35. U.S.C. § 271(e)(4)(A) that the effective date of any approval of the ANDA be a date which is not earlier than the expiration of the '001 and '424 patents;

e. That this is an exceptional case under 35 U.S.C. § 285, and that judgment be entered for costs and reasonable attorneys' fees to be awarded to Mediciis; and

f. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Dated: June 19, 2009

Respectfully submitted,

s/ Sheila F. McShane

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