

David E. De Lorenzi
Sheila F. McShane
Gibbons P.C.
Attorneys for Plaintiff
One Gateway Center
Newark, NJ 07102-5496
(973) 596-4637
Fax (973) 639-6482
SMcShane@gibbonslaw.com

*Counsel For Plaintiff
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

Medicis Pharmaceutical Corporation (“Medicis” or “Plaintiff”) alleges:

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. *See, e.g., Medicis Pharmaceutical Corporation v. Glenmark Generics, Inc., USA, et al.*, Case No. 2:09-cv-03010 (PGS)(ES) (D.N.J. June 19, 2009). 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 March 28, 2006, United States Patent No. 7,018,656 (the “‘656 patent”), entitled “Antimycotic Gel With High Active Substance Release,” duly and legally issued to inventors Manfred Bohn, Karl Theodor Kraemer, and Astrid Markus. A copy of the ‘656 patent is attached as Exhibit A.

13. Medicis owns the ‘656 patent.

14. Medicis has an approved New Drug Application (“NDA”) No. 20-519 for Ciclopirox Gel 0.77%, which is sold under Medicis’s trademark LOPROX®.

15. Medicis’s LOPROX® Gel is extremely successful and is widely used in the District of New Jersey and throughout the United States as a synthetic antifungal agent.

16. The claims of the '656 patent cover Medicis's LOPROX® Gel and, therefore, Medicis submitted the '656 patent to the United States Food and Drug Administration for listing in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (the "Orange Book"). The FDA has listed the '656 patent in the Orange Book publication.

17. On information and belief, Glenmark USA, under the direction of Glenmark Ltd., has filed Abbreviated New Drug Application ("ANDA") No. 91-595 with the FDA for generic ciclopirox gel 0.77%. 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 September 16, 2009, and was received by Medicis on September 21, 2009.

18. Glenmark USA has no adequate good faith basis for filing its ANDA No. 91-595 containing a certification of the alleged invalidity, unenforceability, and/or noninfringement of the claims of the '656 patent.

19. On information and belief, Glenmark USA and Glenmark Ltd. were aware of the '656 patent on or before the date Glenmark USA filed its ANDA.

20. Glenmark USA filed its ANDA for generic ciclopirox gel 0.77% because both Glenmark USA and Glenmark Ltd., through its subsidiary and authorized United States agent, seek to enter the lucrative ciclopirox gel 0.77% market that Medicis's LOPROX® Gel products have created by providing very beneficial and advantageous treatments for fungal skin infections.

21. Glenmark Ltd. actively and knowingly aided and abetted Glenmark USA's filing of its ANDA seeking approval to market generic copies of Medicis's LOPROX® Gel products.

Count I

22. Each of the preceding paragraphs 1-21 is incorporated as if fully set forth herein.

23. Glenmark USA filed its ANDA No. 91-595 to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '656 patent before the expiration of the '656 patent. On information and belief, Glenmark USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

24. Glenmark USA seeks approval to market generic ciclopirox gel 0.77% under ANDA No. 91-595 before the expiration of the '656 patent. Glenmark USA was aware of the existence of the '656 patent prior to filing its ANDA and was aware that submission of the ANDA constitutes an act of patent infringement.

25. Glenmark USA acted without a reasonable basis or a good faith belief that it would not be liable for infringing the '656 patent.

Count II

26. Each of the preceding paragraphs 1-26 is incorporated as if fully set forth herein.

27. When Glenmark Ltd. actively and knowingly aided and abetted Glenmark USA with the filing of its ANDA seeking approval to market generic ciclopirox gel 0.77%, Glenmark Ltd. was aware of the '656 patent and knew that Glenmark USA's submission of its ANDA constitutes an act of patent infringement. On information and belief, Glenmark Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(b).

28. Glenmark Ltd. acted without a reasonable basis or good faith belief that it would not be liable for infringing the '656 patent.

Requested Relief

WHEREFORE, Medicis respectfully seeks the following relief:

- a. That judgment be entered declaring that Defendant Glenmark USA has infringed the '656 patent by submitting its ANDA;
- b. That judgment be entered declaring that Defendant Glenmark Ltd. has infringed the '656 patent by inducing Glenmark USA's infringement of the '656 patent 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 '656 patent for the full term thereof, and from inducing or contributing to such activities;
- d. That an order be issued under 25 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 '656 patent;
- 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 Medicis; and
- f. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Dated: October 30, 2009

Respectfully submitted,

s/Sheila F. McShane

Sheila F. McShane
Gibbons P.C.
Attorneys for Plaintiff
One Gateway Center
Newark, NJ 07102-5496
(973) 596-4637
Fax (973) 639-6482
SMcShane@gibbonslaw.com

Of Counsel:
Matthew D. Powers
WEIL, GOTSHAL & MANGES, LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000
Matthew.Powers@weil.com

Nicolas G. Barzoukas
Jason C. Abair
Audrey L. Maness
WEIL, GOTSHAL & MANGES, LLP
700 Louisiana Street, Suite 1600
Houston, TX 77002
(713) 546-5000
Fax (713) 546-9511
Nicolas.Barzoukas@weil.com
Jason.Abair@weil.com
Audrey.Maness@weil.com

**ATTORNEYS FOR PLAINTIFF
MEDICIS PHARMACEUTICAL
CORPORATION**