IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLENMARK GENERICS LTD. and **GLENMARK GENERICS INC., USA**	)	
Plaintiffs,	)	
v.	)	
GLAXOSMITHKLINE, PLC, **GLAXOSMITHKLINE, LLC** and **STIEFEL LABORATORIES, INC.**	)	Civil Action No. _____
Defendants.	)	

PLAINTIFFS GLENMARK GENERICS LTD. AND GLENMARK GENERICS INC., USA'S COMPLAINT FOR DECLARATORY JUDGMENTS OF PATENT NONINFRINGEMENT AND INVALIDITY

Plaintiffs Glenmark Generics Ltd. (individually, "Glenmark Ltd.") and Glenmark Generics Inc., USA (individually, "Glenmark USA") (collectively, "Glenmark") bring this action against Defendants GlaxoSmithKline, plc, GlaxoSmithKline, LLC (collectively, "GSK") and Stiefel Laboratories, Inc., also known as Stiefel, a Glaxo Company, ("Stiefel") for a declaration that Glenmark has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 6,025,389 ("the '389 patent") and 5,569,672 ("the '672 patent") (collectively, the "patents-in-suit").

THE NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code. Defendants have asserted rights under the '389 patent and the '672 patent based on Glenmark USA's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration for approval to market generic versions of Defendants' Bactroban® Cream (mupirocin calcium) drug product. As of the filing of this Complaint, the FDA has granted final approval to Glenmark USA to market generic Bactroban®, and Glenmark USA is already offering for sale or selling generic Bactroban® in the United States. In

November 2012, Defendants sent Glenmark threatening letters (i) stating there is a "growing dispute between the parties regarding a possible at-risk launch of the ANDA Product" and (ii) demanding to know why Glenmark believed its then-forthcoming generic-Bactroban® drug products did not infringe Defendants' patents. As a result, this action involves an actual case or controversy concerning the infringement and invalidity of the '389 and '672 patents. Glenmark seeks final judicial declarations that it does not infringe the '389 and '672 patents and that the '389 and '672 patents are invalid.

THE PARTIES

2. Glenmark Ltd. is an Indian company having its principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Glenmark Ltd. develops and manufactures prescription pharmaceutical drugs, including affordable, high-quality generic medicines.

3. Glenmark USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark USA develops and manufactures prescription pharmaceutical drugs, including affordable, high-quality generic medicines. Glenmark is the North American division of Glenmark Ltd.

4. On information and belief, GlaxoSmithKline, plc is a British company, with a registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England. On information and belief, GlaxoSmithKline, plc manufactures and sells pharmaceutical products throughout the United States, including within the State of Delaware.

5. According to publicly available records, GlaxoSmithKline, LLC is a Delaware corporation, with its principal place of business at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19102. On information and belief, GlaxoSmithKline, LLC manufactures and sells pharmaceutical products throughout the United States, including within the State of Delaware.

6. According to publicly available records, Stiefel Laboratories, Inc., also known as "Stiefel, a GSK company", is a Delaware corporation, with its principal place of business at 20 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709. On information and belief, Stiefel is owned by GlaxoSmithKline, plc. On information and belief, Stiefel manufactures and sells pharmaceutical products throughout the United States, including within the State of Delaware.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*) and under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) because this action involves an actual case or controversy concerning the infringement and invalidity of the '389 and '672 patents.

9. This Court has general personal jurisdiction over Defendants because they regularly conduct business in, have availed themselves of the rights and benefits of the laws of, and have regular and systematic contact with, the State of Delaware. In addition, Steifel and GlaxoSmithKline LLC are both Delaware corporations.

10. The Court has specific personal jurisdiction over Defendants because Defendants' acts that give rise to this action, namely their transmission of threatening letters to Glenmark, were directed to Glenmark Generics Inc., USA, a Delaware corporation. (See Exs. 1-3.) Although Defendants' letters were initially directed to Glenmark Ltd., Glenmark USA filed the ANDA that is the subject of Defendants' threats, and Glenmark USA has launched at-risk the now-FDA-approved generic-Bactroban® drug products that were also the subject of the Defendants' threats.

11. Furthermore, at least GlaxoSmithKline, LLC and Stiefel have previously submitted to the jurisdiction of this Court and availed themselves of the jurisdiction of this Court

by filing lawsuits in the United States District Court for the District of Delaware. *See, e.g.*, 1:12-cv-01090; 1:11-cv-00789; 1:10-cv-00592; 1:09-cv-00376.

12. Venue is appropriate in this District under 28 U.S.C. §§ 1391 because Defendants are subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

Defendants' Bactroban® Cream (Mupirocin Calcium)

13. According to publicly available records, GSK holds approved New Drug Application ("NDA") No. 50746 for Bactroban® Cream EQ 2% Base.

14. Bactroban® Cream is a 2% mupirocin calcium formulation that is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in area) due to susceptible strains of *S. aureus* and *S. pyogenes*.

15. On information and belief, GSK and Stiefel market and sell Bactroban® Cream throughout the United States, including within Delaware.

The Patents-in-Suit

16. The '389 patent issued on February 15, 2000, and is entitled "Pharmaceutical and Veterinary Compositions of Mupirocin and Methods for Their Preparation." A true and correct copy of the '389 patent as it issued is attached to this Complaint as Exhibit 4.

17. The '672 patent issued on October 29, 1996, and is entitled "Compounds." A true and correct copy of the '672 patent as it issued is attached to this Complaint as Exhibit 5.

18. On information and belief, GlaxoSmithKline, plc is the assignee or licensee of the '389 patent.

19. On information and belief, GlaxoSmithKline, plc is the assignee or licensee of the '672 patent.

20. On information and belief, GlaxoSmithKline, LLC is the assignee or licensee of the '389 patent.

21. On information and belief, GlaxoSmithKline, LLC is the assignee or licensee of the '672 patent.

22. On information and belief, Stiefel Laboratories, Inc. is the assignee or licensee of the ’389 patent.

23. On information and belief, Stiefel Laboratories, Inc. is the assignee or licensee of the ’672 patent.

24. Defendants contend that the ’389 and ’672 patents cover or protect Bactroban® Cream from generic competition. (See Exs. 1 and 3.)

Glenmark’s Generic Bactroban® Product

25. On February 22, 2010, Glenmark USA submitted ANDA No. 201587 , seeking FDA approval for a generic-Bactroban® cream.

26. GSK was legally obligated to list the ’672 patent in the FDA Orange Book by December 7, 2008 but failed to do so. The ’672 patent has never been listed in the FDA Orange Book for the Bactroban® Cream Product.

27. GSK was legally obligated to list the ’389 patent in the FDA Orange Book by December 7, 2008 but failed to do so.

28. When Glenmark filed its ANDA, there were no patents listed in the FDA Orange Book for Plaintiffs’ Bactroban® Cream.

29. As of the filing of this Complaint, on January 24, 2013, the FDA granted final approval of Glenmark USA’s ANDA No. 201587 (Ex. 6), clearing the way for Glenmark to manufacture, use, sell, offer to sell in, or import into, the United States its generic-Bactroban® product.

30. Glenmark is manufacturing, using, selling, offering to sell in, or importing into the United States its generic-Bactroban® product.

31. Glenmark’s manufacture, use, sale, offer for sale, and importation of Glenmark’s generic Bactroban® product, the subject of Glenmark USA’s ANDA, has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’389 and ’672 patents.

GSK and Stiefel's Threats To Glenmark

32. An actual case or controversy exists between Glenmark and Defendants because Defendants asserted rights under the '389 and '672 patents based on Glenmark USA's filing of ANDA No. 201587 with the FDA and based on Glenmark's launch of its generic-Bactroban® product.

33. GSK and Stiefel sent a November 7, 2012 letter, stating "Stiefel/GSK has" the '389 and '672 patents and demanding whether "Glenmark believes that its ANDA Product would not infringe the claims of these patents." A true and correct copy of that letter is attached to this Complaint as Exhibit 1. The letter demanded that Glenmark "provide a detailed explanation of the basis for any such contention by the close of business on November 13, 2012, or at least 24 hours before any launch of the ANDA product, if earlier." And the letter demanded that Glenmark provide samples of its ANDA Product by the same date. This letter was signed by outside litigation counsel for GSK and Stiefel, and in-house counsel for GSK was cc'd.

34. Glenmark responded on November 12, 2012, asking for the source of Defendants' stated knowledge of Glenmark USA's ANDA product, because such information is not publicly available and should not have been disclosed by the FDA to the NDA holder. The letter also asked Defendants for the basis of their infringement allegations. A true and correct copy of that letter is attached to this Complaint as Exhibit 2.

35. GSK and Stiefel responded on November 13, 2012. A true and correct copy of that letter is attached to this Complaint as Exhibit 3. In their responsive letter, GSK and Stiefel identified "a growing dispute between the parties regarding a possible at-risk launch of the ANDA Product…." The phrase "at-risk launch" is a term of art in the Hatch Waxman context indicating, *inter alia,* the scenario where a drug maker begins sales of a generic product at the risk of being sued for patent infringement by the NDA holder. GSK and Stiefel refused to provide the source of Defendants' stated knowledge of Glenmark USA's ANDA, stating only that "it is not important here" and that "GSK heard that Glenmark was preparing to launch an ANDA Product." GSK and Stiefel also refused to provide the basis for their allegations of

infringement but reiterated the accusation that Glenmark "does not appear to have a clear basis for contending that its product does not infringe the patents…."

36. Based on GSK and Stiefel's November 7 and November 13 letters and Glenmark's November 12 letter, subsequent at-risk launch, and current marketing of its generic Bactroban® product, there is a continuing, ripe, justiciable controversy between the parties as to non-infringement and invalidity of the '389 and '672 patents. An actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201.

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Non-Infringement of the '389 Patent)

37. Glenmark realleges and incorporates by reference paragraphs 1 through 36, inclusive, as though fully set forth in this paragraph.

38. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the non-infringement of the '389 patent.

39. The manufacture, use, sale, offer for sale, or importation of Glenmark's generic Bactroban® Cream product, which is the subject of ANDA No. 201587, has not infringed, does not infringe, and will not infringe any valid and/or enforceable claim of the '389 patent.

40. Glenmark is entitled to a declaratory judgment that it does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '389 patent, either literally or under the doctrine of equivalents.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the '389 Patent)

41. Glenmark realleges and incorporates by reference paragraphs 1 through 40, inclusive, as though fully set forth in this paragraph.

42. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the invalidity of the '389 patent.

43. The claims of the ’389 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including at least one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

44. Glenmark is entitled to a declaratory judgment that the claims of the ’389 Patent are invalid.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment of Non-Infringement of the ’672 Patent)

45. Glenmark realleges and incorporates by reference paragraphs 1 through 44, inclusive, as though fully set forth in this paragraph.

46. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the non-infringement of the ’672 patent.

47. The manufacture, use, sale, offer for sale, or importation of Glenmark’s generic Bactroban® Cream product, which is the subject of ANDA No. 201587, has not infringed, does not infringe, and will not infringe any valid and/or enforceable claim of the ’672 patent.

48. Glenmark is entitled to a declaratory judgment that it does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’672 patent, either literally or under the doctrine of equivalents.

FOURTH CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the ’672 Patent)

49. Glenmark realleges and incorporates by reference paragraphs 1 through 48, inclusive, as though fully set forth in this paragraph.

50. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the invalidity of the ’672 patent.

51. The (only) claim of the ’672 patent is invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including at least one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

52. Glenmark is entitled to a declaratory judgment that the claim of the ’672 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Glenmark asks this Court to enter judgment against GSK and Stiefel:

A. Declaring that Glenmark Generics Ltd. does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’389 patent, either literally or under the doctrine of equivalents;

B. Declaring that Glenmark Generics Inc., USA does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’389 patent, either literally or under the doctrine of equivalents;

C. Declaring that all claims of the ’389 patent are invalid;

D. Declaring that Glenmark Generics Ltd. does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’672 patent, either literally or under the doctrine of equivalents;

E. Declaring that Glenmark Generics Inc., USA does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’672 patent, either literally or under the doctrine of equivalents;

F. Declaring that the only claim of the ’672 patent is invalid; and

G. Awarding Glenmark such other relief as this Court deems just and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Adam W. Poff
Adam W. Poff (No. 3990)
James L. Higgins (No. 5021)
Rodney Square
1000 N. King Street
Wilmington, DE 19801
(302) 571-6600
apoff@ycst.com
jhiggins@ycst.com

Attorneys for Plaintiffs Glenmark Generics Ltd. and Glenmark Generics Inc., USA

Of Counsel:

H. Keeto Sabharwal
Byron L. Pickard
Nirav N. Desai
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 New York Ave., N.W., Suite 800
Washington, DC 20005-3934
(202) 371-2600

Dated: January 24, 2013