IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. GLENMARK PHARMACEUTICALS, LTD., GLENMARK GENERICS LTD., and GLENMARK GENERICS INC., USA, Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation, for their Complaint herein against Defendants Glenmark Pharmaceuticals, Ltd. Glenmark Generics Ltd. and Glenmark Generics Inc., USA allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

3. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

4. On information and belief, Defendant Glenmark Pharmaceuticals, Ltd. ("Glenmark Pharma") is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO - Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai, 400099, India. On information and belief, Glenmark Pharma, itself and through its subsidiaries and agents, sells various drug products in the United States, including in this judicial district.

5. On information and belief, Defendant Glenmark Generics Ltd. ("Glenmark Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India. On information and belief, Glenmark Ltd. is owned by Glenmark Pharma. On information and belief, Glenmark Ltd., itself and through its subsidiaries and agents, sells various drug products in the United States, including in this judicial district.

6. On information and belief, Defendant Glenmark Generics Inc., USA ("Glenmark USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. On information and belief, Glenmark USA is a wholly owned subsidiary of Glenmark Ltd. On information and belief, Glenmark USA sells various drug products in the United States, including in this judicial district.

7. Glenmark Pharma, Glenmark Ltd. and Glenmark USA are referred to collectively herein as "Glenmark."

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Glenmark USA, Glenmark Ltd. and Glenmark Pharma, by virtue of, *inter alia,* the incorporation of Glenmark USA in the state of Delaware and the fact that they have availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

11. Plaintiff NPC holds an approved new drug application ("NDA") NDA No. 50-791 for Myfortic® delayed-release tablets (180 mg and 360 mg), which tablets contain the active ingredient mycophenolic acid in its sodium salt form, mycophenolate sodium. Myfortic® tablets were approved by the United States Food And Drug Administration ("FDA") in 2004 for the prophylaxis (or prevention) of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids. NPC markets Myfortic® delayed-release tablets (180 mg and 360 mg) in the United States.

12. Myfortic® delayed-release tablets are an enteric formulation of mycophenolate sodium that delivers the active moiety mycophenolic acid. Mycophenolic acid is an immunosuppressant agent. As the sodium salt, mycophenolic acid can be chemically

designated as (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoic acid sodium salt.

13. Novartis AG is the owner of United States Letters Patent No. 6,025,391 ("the '391 patent"). The '391 patent was duly and legally issued on February 15, 2000. A true copy of the '391 patent is attached hereto as Exhibit A.

14. The '391 patent claims, *inter alia*, pharmaceutical compositions containing a mycophenolate salt, adapted to prevent release of the mycophenolic salt in the stomach and to release the mycophenolate salt in the upper part of the intestinal tract. It also claims, *inter alia*, pharmaceutical compositions containing an enteric coated pharmaceutically acceptable mycophenolate salt. The '391 patent also claims, *inter alia*, methods of immunosuppressing a subject in need of immunosuppression by administering a therapeutically effective amount of enteric coated pharmaceutically acceptable mycophenolate salt.

15. The '391 patent was assigned by the inventors to Novartis AG.

16. Novartis AG is the owner of United States Letters Patent No. 6,172,107 ("the '107 patent"). The '107 patent was duly and legally issued on January 9, 2001. A true copy of the '107 patent is attached hereto as Exhibit B.

17. The '107 patent claims, *inter alia*, pharmaceutical compositions containing a mycophenolate salt formulated to disintegrate selectively in the intestinal tract to release mycophenolate there. It also claims, *inter* alia, pharmaceutical compositions containing an enteric coating that are suitable as an immunosuppressant medicament. The '107 patent also claims, *inter alia*, methods of immunosuppressing a subject in need of immunosuppression by administering a

therapeutically effective amount of a composition formulated to disintegrate selectively in the intestinal tract to release mycophenolate there.

18. The '107 patent was assigned by the inventors to Novartis AG.

19. Novartis AG is the owner of United States Letters Patent No. 6,306,900 ("the '900 patent"). The '900 patent was duly and legally issued on October 23, 2001. A true copy of the '900 patent is attached hereto as Exhibit C.

20. The '900 patent claims, *inter alia*, pharmaceutical compositions containing a mycophenolate salt adapted to prevent release of mycophenolate in the stomach.

21. The '900 patent was assigned by the inventors to Novartis AG.

22. On information and belief, Glenmark USA, on behalf of Glenmark Ltd. and/or Glenmark Pharma, submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic Myfortic® delayed-release tablets (180 mg and 360 mg) ("Glenmark's Products").

23. On information and belief, Glenmark submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's Products before the expiration of the '391, '107 and '900 patents.

24. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's Products before the expiration of the '391, '107 and '900 patents, Glenmark has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial

manufacture, use, offer for sale, sale and/or importation of Glenmark's Products for which Glenmark seeks approval will also infringe one or more claims of the '391, '107 and '900 patents.

25. Glenmark 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 '391, '107 and '900 patents are invalid. Glenmark did not allege non-infringement of any of the '391, '107, and '900 patents in its Paragraph IV certification. Glenmark did not allege unenforceability of any of the '391, '107 and '900 patents in its Paragraph IV certification.

26. On information and belief, when Glenmark filed its ANDA, it was aware of the '391, '107 and '900 patents, and that the filing of its ANDA with the request for its approval prior to the expiration of that patent was an act of infringement.

27. Glenmark's Products, if approved, will be administered to human patients in an amount effective to immunosuppress those patients, which administration constitutes direct infringement of the '391 and '107 patents. This will occur at Glenmark's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Glenmark will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '391 and '107 patents.

28. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Glenmark's Products be a date which is not earlier than the later of the expiration dates of the '391, '107 and '900 patents or any later date of exclusivity to which Plaintiffs are or become entitled. Further, Plaintiffs are entitled to an award of damages for any

commercial sale or use of Glenmark's Products, and any act committed by Glenmark with respect to the subject matter claimed in the '391, '107 and '900 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

29. On information and belief, Glenmark has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's ANDA Product, including seeking approval of that product under Glenmark's ANDA.

30. There is a substantial and immediate controversy between Plaintiffs and Glenmark concerning the '391, '107 and '900 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Glenmark will infringe and/or induce infringement of one or more claims of the '391, '107 and '900 patents.

31. This is an exceptional case, and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Glenmark has infringed one or more claims of the '391, '107 and '900 patents by filing the aforesaid ANDA relating to Glenmark's Products;

B. A permanent injunction restraining and enjoining Glenmark and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Glenmark's Products;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Glenmark's Products be a date which is not earlier than the later of the expiration of the right of exclusivity under the '391, '107 and '900 patents, or any later right of exclusivity to which Plaintiffs are or become entitled;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's Products will infringe one or more claims of the '391, '107 and '900 patents, and that Glenmark will induce infringement of one or more claims of the '391 and '107 patents;

E. Damages from Glenmark for any commercial activity constituting infringement of the '391, '107 and '900 patents;

F. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs are entitled to the costs and reasonable attorney fees in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: June 18, 2014

McCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

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