IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	:	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation (hereinafter "Plaintiffs"), for their Complaint herein against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., 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, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. On information and belief, Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, having a principle place of business at 5 Basel St., Petach Tikva 49131, Israel.

6. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd., and the two have common officers and directors.

7. On information and belief, the acts of Teva USA complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Teva Ltd.

8. Teva USA and Teva Ltd. are referred to hereinafter, collectively as "Teva."

JURISDICTION AND VENUE

9. 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).

10. On information and belief, Teva USA directly, or indirectly, manufactures, markets and sells drug products, including generic drug products manufactured by Teva Ltd.,

throughout the United States and in this judicial district, and is registered to do business and is incorporated in Delaware.

11. On information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Teva Ltd. directly, or through its affiliates and agents, including Teva USA, manufactures, markets and sells drug products throughout the United States and in this judicial district.

12. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the above-mentioned facts.

13. 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

14. 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 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.

15. 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.

16. 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.

17. 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.

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

19. 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.

20. 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.

21. The ‘107 patent was assigned by the inventors to Novartis AG.

22. 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.

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

24. The ‘900 patent was assigned by the inventors to Novartis AG.

25. On information and belief, Teva USA 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 (hereinafter “Teva’s Products”).

26. On information and belief, Teva 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 Teva’s Products before the expiration of the ‘391, ‘107 and ‘900 patents.

27. 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 Teva’s Products before the expiration of the ‘391, ‘107 and ‘900 patents, Teva 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 Teva’s Products for which Teva seeks approval will also infringe one or more claims of the ‘391, ‘107 and ‘900 patents.

28. Teva’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 Teva’s active behest, and with its

specific intent, knowledge and encouragement. On information and belief, Teva 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.

29. Teva 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. Teva did not allege non-infringement of any of the '391, '107, and '900 patents in its Paragraph IV certification. Teva did not allege unenforceability of any of the '391, '107 and '900 patents in its Paragraph IV certification.

30. 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 Teva's Products be a date which is not earlier than the later of the April 10, 2017 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 Teva's Products, and any act committed by Teva 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).

31. On information and belief, when Teva 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.

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

B. A permanent injunction restraining and enjoining Teva 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 Teva's Products;

C. An Order that the effective date of any approval of the aforementioned ANDA relating to Teva'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. Damages from Teva for any commercial activity constituting infringement of the '391, '107 and '900 patents;

E. 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

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

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