IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

'09 CIV 8100

ASTELLAS PHARMA INC.,
and ASTELLAS PHARMA US, INC.

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,
and TEVA PHARMACEUTICALS
INDUSTRIES, LTD.

Defendants.

CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc. and Astellas Pharma US, Inc. for their complaint herein against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., hereby allege as follows:

THE PARTIES

1. Astellas Pharma Inc. ("Astellas Pharma") is a corporation organized and existing under the laws of Japan, having a principal place of business at 3-11, Nihonbashi-Honcho 2 Chome, Chuo-ku, Tokyo 103-8411, Japan.

2. Astellas Pharma US, Inc. ("Astellas US") is a corporation organized and existing under the laws of Delaware, having its principal place of business at Three Parkway North, Deerfield, IL 60015.

3. Astellas Pharma and Astellas US are referred to hereinafter, collectively, as "Astellas."

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, P.O. Box 1090, North Wales, PA 19454-1090.

5. On information and belief, defendant Teva Pharmaceutical Industries, Ltd. ("Teva Industries") is an Israeli corporation having its principal place of business at 5 Basel St., P.O. Box 3190, Petach Tivka 49131, Israel.

6. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries, and these two companies 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, assistance of, and at least in part the benefit of, Teva Industries.

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

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.

10. Jurisdiction is predicated upon 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, this Court has personal jurisdiction over Teva USA and Teva Industries.

12. On information and belief, Teva USA derives substantial revenue from selling various products and doing business through the United States, including in New York and this District.

13. On information and belief, Teva USA is registered to do business with the New York State Division of Corporations, and Corporate Creations Network Inc., 15 North Mill Street, Nyack, NY 10960, is authorized to accept service on behalf of Teva USA.

14. On information and belief, Teva Industries is the holder of Drug Master File #22173, submitted to the United States Food & Drug Administration ("FDA"), for "Solifenacin as manufactured in Netanya, Israel for Teva Pharmaceuticals Industries, Ltd."

15. On information and belief, Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold, including sold by Teva USA, throughout the United States, including in this District.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF

17. Astellas US is the owner of approved New Drug Application 21-518, by which the FDA granted approval for the drug solifenacin succinate in a 5 mg and 10 mg strength tablet dosage form. Astellas sells solifenacin succinate tablets under the trademark "VESIcare®." VESIcare® has been approved for use in the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

18. Astellas Pharma is the owner of United States Patent No. 6,017,927 ("the '927 patent"). The '927 patent was duly and legally issued on January 25, 2000.

19. Astellas Pharma was formed as a result of the merger of Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") of Tokyo, Japan and Fujisawa Pharmaceutical Co., Ltd. of Osaka, Japan. The '927 patent was initially assigned to Yamanouchi, which subsequently became Astellas Pharma following the merger.

20. The '927 patent claims, *inter alia*, solifenacin succinate and pharmaceutical compositions containing it. A copy of the '927 patent is attached as Exhibit A.

21. 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, and sale of 5 mg and 10 mg tablets of solifenacin succinate.

22. On information and belief, Teva USA submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its solifenacin succinate 5 mg and 10 mg tablets prior to the expiration of the '927 patent.

23. On information and belief, Teva USA made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") that, in Teva USA's opinion and to the best of its knowledge, the '927 patent was invalid for obviousness.

24. On information and belief, on or about August 11, 2009, Teva USA sent a notice letter to Plaintiffs Astellas in which Teva USA represented that it had filed an ANDA with FDA for solifenacin succinate tablets, and sought approval of its ANDA prior to the expiration of the '927 patent. Plaintiff Astellas US received a copy of Teva's notice letter on August 12, 2009.

25. Solifenacin and its salts are claimed in each of claims 1-7 of the '927 Patent.

26. By seeking approval of its ANDA to engage in the commercial manufacture, use, and sale of 5 mg and 10 mg tablet dosage forms of solifenacin succinate, before the expiration of the '927 patent, Teva USA has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. Further, the commercial manufacture, use, offer for sale, sale, or importation of Teva USA's proposed 5 mg and 10 mg tablet dosage forms of solifenacin succinate, for which Teva USA seeks approval in its ANDA No. 91-464, would infringe the '927 patent.

28. Plaintiffs Astellas are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court specifying that the effective date of approval for ANDA No. 91-464 for the commercial manufacture, use, importation or sale of the 5 mg and 10 mg tablet dosage form of solifenacin succinate, shall be a date which is not earlier than the expiration date of the '927 patent or any later date of exclusivity to which Astellas is or becomes entitled.

29. On information and belief, when Teva USA filed its ANDA, it was aware of the '927 patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '927 patent was an act of infringement of this patent. On information and belief, Teva USA was aware that it had the obligations to make a good faith evaluation and have a reasonable belief that the patent for which it is seeking approval is invalid, before submitting its Paragraph IV certification to the FDA representing that the '927 patent was invalid, and to provide detailed reasons supporting that assertion in its Notice Letter, but Teva USA failed to make that evaluation or provide the required detailed factual and legal bases in its

Notice Letter.

30. This is an exceptional case and Astellas is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs respectfully request the following relief:

a. A judgment that Teva infringed one or more claims of the '927 patent by submitting its ANDA relating to generic solifenacin succinate;

b. A permanent injunction restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, sale or importation of solifenacin succinate claimed by the '927 patent;

c. An order, as authorized by 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Teva's ANDA No. 91-464 shall not be earlier than the expiration date of the '927 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

d. Damages from Teva for any commercial activity constituting infringement of the '927 patent;

e. An award to Plaintiff of the costs and a reasonable attorney fee in this action; and

f. Such other and further relief as the Court may deem appropriate under the circumstances.

Dated: September 22, 2009

Robert L. Baechtold (RB 6866)
Nicholas M. Cannella (NC 9543)
Simon D. Roberts (SR 3944)
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Attorneys for Plaintiffs Astellas Pharma Inc. and Astellas Pharma US, Inc.

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