09 CV 3965

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., G. D. SEARLE LLC Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., BARR PHARMACEUTICALS, INC. Defendants.	Civil Action No. COMPLAINT

Plaintiffs Pfizer Inc. and G. D. Searle LLC (*formerly* G. D. Searle & Co.), by their attorneys, for their complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceuticals Industries Ltd. ("Teva Ltd."), and Barr Pharmaceuticals, Inc. ("Barr"), allege as follows:

PARTIES

1. Plaintiff Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 235 East 42nd Street, New York, New York 10017.

2. Plaintiff G. D. Searle LLC is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 235 East 42nd Street, New York, New York 10017. G. D. Searle LLC is a subsidiary of Pfizer.

3. On information and belief, Defendant Teva USA is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva USA is registered with the New York

Department of State, Division of Corporations, to do business in New York State and has designated Corporate Creations Network Inc, which is located at 15 North Mill Street, Nyack, New York 10960 as its agent in New York State for the receipt of service of process.

4. On information and belief, Defendant Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. On information and belief, Teva Ltd. does business in New York through its wholly-owned subsidiaries Teva USA and Barr. Teva Ltd. has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction.

5. On information and belief, Defendant Barr is a Delaware corporation with a principal place of business at 225 Summit Ave., Montvale, New Jersey, 07645. On information and belief, Barr is registered with the New York Department of State, Division of Corporations, to do business in New York State and has designated Corporate Creations Network Inc, which is located at 15 North Mill Street, Nyack, New York 10960 as its agent in New York State for the receipt of service of process.

JURISDICTION AND VENUE

6. This is an action by Plaintiffs for patent infringement arising under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

7. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

8. This Court has personal jurisdiction over Defendant Teva USA pursuant to C.P.L.R. § 302(a) because Teva USA transacts business in and is registered to do business within New York State.

9. This Court has personal jurisdiction over Defendant Teva Ltd. pursuant to C.P.L.R. § 302(a) because Teva Ltd. transacts business in New York State, including through its wholly owned subsidiaries Teva USA and Barr.

10. This Court has personal jurisdiction over Defendant Barr pursuant to C.P.L.R. § 302(a) because Barr transacts business in and is registered to do business within New York State.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

US PATENT NO. 5,601,843

12. On February 11, 1997, the United States Patent and Trademark Office issued U.S. Patent No. 5,601,843 ("the '843 patent") entitled: "Pharmaceutical Tablet Composition." A true and correct copy of the '843 Patent is attached hereto as **Exhibit A**.

13. The '843 patent was assigned to G. D. Searle & Co.

14. The '843 patent covers Plaintiffs' product Arthrotec®.

ARTHROTEC®

15. Arthrotec® is indicated for treatment of the signs and symptoms of osteoarthritis or rheumatoid arthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications.

16. Arthrotec® is covered by New Drug Application ("NDA") No. 20-607, which was approved by the FDA on December 24, 1997. The active ingredients in Arthrotec® are Diclofenac Sodium and Misoprostol.

17. The '843 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), maintained by the Food and Drug Administration ("FDA"), in connection with NDA No. 20-607 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

BARR'S ANDA

18. On information and belief, Barr filed abbreviated new drug application ("ANDA") No. 91-110 with the FDA seeking approval to market a generic copy of Pfizer's Arthrotec® product, Diclofenac Sodium Delayed Release/Misoprostol Tablets, 75 mg/200ug (the "Barr Product"), prior to expiration of the '843 patent.

19. On information and belief, with its ANDA, Barr included a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '843 Patent is invalid, unenforceable, or not infringed by the commercial manufacture, use, or sale of the Barr Product.

20. On or about March 9, 2009, Pfizer received a letter from Nicholas Tantillo, Senior Directory, Regulatory Affairs of Barr, purporting to be the notice of Barr's ANDA containing the "Paragraph IV" certification required by 21 U.S.C. § 355(j)(2)(B)(ii).

COUNT
Infringement of the '843 Patent Against Defendants Barr, Teva USA and Teva Ltd.

21. Plaintiffs incorporate and reallege paragraphs 1 through 20 above, as if set forth in full herein.

22. Barr has infringed the '843 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 91-110, by which Barr seeks FDA approval to engage in the commercial manufacture, use, or sale of the Barr Product prior to the expiration of the '843 patent.

23. If Barr commercially manufactures, uses, offers to sell, or sells the Barr Product within the United States, or imports the Barr Product into the United States, or induces or contributes to any such conduct during the term of the '843 patent, it would further infringe the '843 patent under 35 U.S.C. § 271(a), (b) and/or (c).

24. Teva USA and Teva Ltd. have infringed the '843 Patent pursuant to 35 U.S.C. § 271(e)(2)(A). On information and belief, Teva USA and Teva Ltd. own, participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 91-110 and its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) allegation to the FDA.

25. If Teva USA and/or Teva Ltd. commercially manufacture, use, offer for sale or sell the Barr Product within the United States during the term of the '843 patent, or induce or contribute to any such conduct during the term of the '843 patent, it would further infringe the '843 patent under 35 U.S.C. § 271(a), (b) and/or (c).

26. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '843 patent. Plaintiffs do not have an adequate remedy at law.

27. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

RELIEF SOUGHT

WHEREFORE, Plaintiffs pray for a judgment in its favor and against Defendants Barr, Teva USA and Teva Ltd., as follows:

A. That pursuant to 35 U.S.C. § 271, Defendants have infringed the '843 Patent;

B. That judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States of the Barr Product described in ANDA No. 91-110 will infringe the '843 Patent;

C. That the Court enter an order that the effective date of any FDA approval of the Barr Product be not earlier than the expiration date of the '843 Patent, including extensions;

D. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Barr Product described in ANDA No. 91-110, and any other product that infringes or induces or contributes to the infringement of the '843 Patent, prior to the expiration of the '843 Patent, including any extensions;

E. That Plaintiffs be awarded monetary relief if Defendants commercially use, offer for sale or sell its proposed generic version of Arthrotec®, or any other product that infringes or induces or contributes to the infringement of the '843 Patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

F. That judgment be entered that this is an exceptional case under 35 U.S.C. § 285;

G. That pursuant to 35 U.S.C. § 285, Plaintiffs recover their reasonable attorney fees incurred in connection with this action;

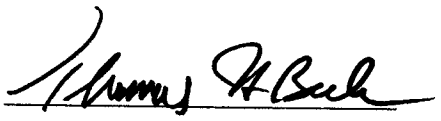
H. For an assessment of costs and expenses against Defendants; and

I. For such other and further relief as the Court may deem just and proper.

Dated: April 21, 2009

Sidley Austin LLP

Attorneys for Plaintiffs
Pfizer Inc. and G.D. Searle LLC

By: 

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