IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC. and DR. FALK PHARMA GmbH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Inc. ("Salix") and Dr. Falk Pharma GmbH ("Falk") (collectively "Plaintiffs") bring this action against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") and, in support thereof, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement against Teva. This action arises under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively.

2. This action arises from Teva's submission of Abbreviated New Drug Application ("ANDA") No. 209970 to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Salix's drug product, Apriso® prior to the expiration of United States Patent Number 8,865,688 ("the '688 patent").

THE PARTIES

3. Plaintiff Salix is a California corporation having its corporate offices and principal place of business at 8510 Colonnade Center Drive, Raleigh. North Carolina 27615.

4. Salix is a wholly owned subsidiary of Salix Pharmaceuticals Ltd. On April 1, 2015, Valeant Pharmaceuticals International, an indirect, wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc., acquired Salix Pharmaceuticals Ltd.

5. Plaintiff Falk is a German corporation having its corporate offices and principal place of business at Leinenweberstr. 5, 79108 Freiburg im Breisgau, Germany.

6. On information and belief, Defendant Teva is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Teva.

9. On information and belief, Teva has extensive contacts with the State of Delaware. Teva is a Delaware corporation, has appointed an agent in Delaware to receive service of process, and previously has submitted to jurisdiction in this District.

10. On information and belief, Teva has continuous and systematic contacts with this District, at least because Teva is registered with the Delaware Board of Pharmacy as a Pharmacy-Wholesale and Distributor/Manufacturer CSR to distribute drugs in Delaware, has substantial marketing and sales activities in this District, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products in this District.

11. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

SALIX'S APRISO® NDA

12. Salix is the original holder of approved New Drug Application ("NDA") No. 22-301 for Apriso® (mesalamine) Extended Release Capsules.

13. On October 31, 2008, the FDA approved NDA No. 22-301 for the manufacture, marketing and sale of Apriso® in a 0.375 g dosage strength with a single indication for the maintenance of remission of ulcerative colitis in adults.

14. Salix has sold Apriso® under NDA No. 22-301 since its approval by the FDA.

15. Valeant Pharmaceuticals International is the current holder of NDA No.22-301.

THE '688 PATENT

16. On October 21, 2014, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '688 patent, which bears the title "Compositions and Methods for Treatment of Bowel Diseases with Granulated Mesalamine." Exhibit A is a true and correct copy of the '688 patent.

17. Falk is the owner by assignment of the '688 patent, and Salix is the exclusive licensee of the '688 patent.

18. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '688 patent was listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering Apriso®.

19. The Orange Book states that the '688 patent expires May 1, 2030.

TEVA'S NOTICE LETTER

20. Teva sent a letter dated February 13, 2017 (the "Notice Letter") notifying Plaintiffs that Teva had filed ANDA No. 209970 ("Teva's ANDA") seeking FDA approval to commercially manufacture, use, or sell a generic version of 375 mg mesalamine oral extended

release capsules ("Teva's ANDA product") prior to the expiration of the '688 patent. The Notice Letter stated that Teva was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") and 21 C.F.R. § 314.95.

21. Plaintiffs received the letter not earlier than February 14, 2017.

22. As stated in the Notice Letter, Teva's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A), alleging that, "in Teva's opinion and to the best of its knowledge, U.S. Patent No. 8,865,688 is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Teva's ANDA" ("Paragraph IV Certification").

23. Teva also attached to the Notice Letter "Teva Pharmaceuticals USA, Inc.'s Detailed Factual and Legal Basis for Its Paragraph IV Certification that U.S. Patent No. 8,896,688 is Invalid, Unenforceable and/or Not Infringed by the Mesalamine Extended-release Capsules USP, 375 mg Product Described in Teva Pharmaceuticals USA, Inc.'s ANDA No. 209970" (the "Detailed Statement"). The Detailed Statement alleges invalidity of the '688 patent.

24. Plaintiffs commenced this action within forty-five (45) days of receiving the Notice Letter.

COUNT I

(Infringement of the '688 patent)

25. Paragraphs 1 to 25 are incorporated herein as set forth above.

26. Teva's submission of Teva's ANDA No. 209970 to the FDA under § 505(j) of the Food, Drug, and Cosmetic Act to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of Teva's ANDA product prior to expiration of the '688 patent was an act of infringement of one or more claims of the '688 patent under 35 U.S.C. § 271(e)(2).

27. Upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '688 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

28. On information and belief, after the FDA has approved Teva's ANDA No. 209970, Teva intends to manufacture, market, sell, and offer to sell Teva's product with an FDA-approved product insert that will direct physicians and patients in the use of Teva's ANDA product.

29. On information and belief, Teva will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Teva knows will directly infringe one or more claims of the '688 Patent, by marketing Teva's ANDA product with the FDA-approved product insert.

30. On information and belief, Teva has knowledge of the '688 patent and knows that the use of Teva's ANDA product in accordance with the FDA-approved product will directly infringe one or more claims of the '688 patent, either literally or under the doctrine of equivalents.

31. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court.

32. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH request entry of judgment in their favor and against Teva as follows:

A. A declaration that the claims of United States Patent Number 8,865,688 are valid and enforceable;

B. A declaration that Teva's submission to the FDA of Teva's ANDA No. 209970 to obtain approval for the commercial manufacture, use, offer for sale, sale in, and/or importation

into the United States of Teva's ANDA product before the expiration of United States Patent Number 8,865,688 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

C. A declaration that Teva's manufacture, use, offer to sell, sale in, and/or importation into the United States of Teva's ANDA product prior to the expiration of United States Patent Number 8,865,688 will infringe one or more claims of United States Patent Number 8,865,688 under 35 U.S.C. § 271(b);

D. An order that the effective date of the approval of Teva's ANDA No. 209970 be a date that is not earlier than the expiration of the term of United States Patent Number 8,865,688, including any extensions(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Teva and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 8,865,688 prior to the expiration date of United States Patent Number 8,865,688, and any additional dates of exclusivity;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interested, if Teva engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of its ANDA Product before the expiration of United States Patent Number 8,865,688 and any additional dates of exclusivity;

G. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs, and expenses; and

H. Any and all other and further relief as this Court deems just and proper.

Dated: March 27, 2017

Respectfully submitted,

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