IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION
One Health Plaza
East Hanover, New Jersey 07936,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857;

MARGARET HAMBURG
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, MD 20857; and

KATHLEEN SEBELIUS
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20204.

Defendants.

COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") for its Complaint against the Food and Drug Administration ("FDA"), Kathleen Sebelius, Secretary of Health and Human Services and Margaret Hamburg, Commissioner of Food and Drugs, by its undersigned attorneys, alleges as follows:

1. This is an action for a declaratory judgment and mandatory injunctive relief requiring the FDA to withdraw its September 14, 2010 approval of Abbreviated New Drug Application ("ANDA") No. 78-278, filed by Watson Laboratories, Inc. ("Watson"), with respect to generic famciclovir tablets.

2. Famciclovir is a pharmaceutical sold for treatment of herpes. Novartis is the holder of NDA No. 20-363 for famciclovir tablets, which Novartis sells under the brand name

FAMVIR®. Novartis is the assignee of U.S. Patent No. 5,246,937 (the "'937 Patent") which includes compound claims and method of use claims directed to famciclovir.

3. The FDA approved Watson's ANDA improperly in violation of the Food Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.*, because (i) Watson's ANDA No. 78-278 did not satisfy a statutory precondition to FDA approval in that it failed to include a certification, pursuant to 21 U.S.C. Section 355(j)(2)(A)(vii), with respect to the compound claims in the '937 patent directed to famciclovir; and (ii) as reflected in the FDA's Orange Book, Novartis is entitled to marketing exclusivity with respect to those tablets until March 21, 2011.

THE PARTIES

4. Plaintiff Novartis is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

5. Defendant FDA is an agency of the United States Government within the Department of Health and Human Services, with offices at 200 C Street, S.W., Washington, D.C. 20201, and 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the FDCA.

6. Defendant Margaret A. Hamburg, M.D., is Commissioner of Food and Drugs and is the senior official of the FDA. She is sued in her official capacity. Dr. Hamburg maintains offices at 200 C Street, S.W., Washington, D.C. 20201, and 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

7. Defendant Kathleen Sebelius is Secretary of Health and Human Services and the official charged by law with administering the FDCA. She is sued in her official capacity. Secretary Sebelius maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

JURISDICTION AND VENUE

8. This action arises under the APA, 5 U.S.C. § 551 *et seq.*, and the FDCA, 21 U.S.C. § 301, *et seq.* This court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361, and 2201-2202.

9. There exists an actual and justiciable controversy between Novartis and defendants requiring resolution by this Court. Novartis has no adequate remedy at law.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

BACKGROUND

11. Plaintiff Novartis is the holder of NDA No. 20-363 covering sales of 125 mg, 250 mg and 500 mg famciclovir tablets. Novartis markets such tablets under the brand name FAMVIR®.

12. Novartis is the assignee of the '937 Patent which contains both compound claims directed to famciclovir and method of use claims directed to the use of famciclovir. A copy of the '937 patent is annexed as Exhibit A.

13. The only famciclovir tablets currently marketed in the United States are sold by Novartis or under license from Novartis.

14. Pursuant to section 505(b)(1) of the FDCA, 21 U.S.C. § 355(b)(1), Novartis submitted information about the '937 patent for listing in the FDA's Orange Book as a patent claiming famciclovir and/or a method of using famciclovir 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 famciclovir.

15. The original expiration date of the '937 patent was September 21, 2010. However, pursuant to 21 U.S.C. § 355a(c), the FDA granted a 180 day pediatric extension of Novartis's exclusivity under the '937 patent until March 21, 2011, and the Orange Book identifies March 21, 2011 as the expiration date for the '937 patent.

16. Prior to the expiration of the '937 patent, Watson filed an abbreviated new drug application, ANDA No. 78-278, pursuant to section 505(j) of the FDA Act, 21 U.S.C. § 355(j), seeking to market famciclovir tablets that were generic versions of Novartis's FAMVIR® tablets.

17. Watson's failure to include a certification to the '937 patent or to serve Novartis with notice of that certification deprived Novartis of its rights under the FDCA to protect its rights under the '937 patent, including its right to enforce the patent, as extended by the FDA, prior to FDA approval.

18. On September 14, 2010, the FDA approved Watson's ANDA No. 78-278, notwithstanding the FDA's extension of Novartis's exclusivity rights under the '937 patent until March 21, 2011. A copy of the FDA's approval letter to Watson is annexed as Exhibit B.

19. Pursuant to the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii), an ANDA applicant generally must submit to the FDA a certification stating with respect to each patent which claims the drug for which the applicant seeks approval,

(I) that such patent information has not been filed;

(II) that such patent has expired;

(III) of the date on which such patent will expire; or

(IV) that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

20. On information and belief, Watson filed no such certification with ANDA No. 78-278. Instead, Watson filed only a statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) statement (a "section viii statement"), that it was not seeking approval for a method of use claimed by the '937 patent. Pursuant to section 505(j)(2)(A)(viii) of the FDCA and implementing FDA regulations, 21 C.F.R. 314.94(a)(12)(iii), Watson's section viii statement was potentially sufficient only with respect to method of use claims in the '937 patent, but was insufficient with respect to the drug product claims in the '937 patent. Where a patent has been submitted for Orange Book listing that claims both the drug product and a method of using the drug, FDA has repeatedly ruled that "the ANDA applicant must address all claims for which the patent was submitted." A recent example of FDA's ruling on this issue is contained in a March 15, 2010 letter from Janet Woodcock, M.D., Director of FDA's Center for Drug Evaluation and Research in FDA Docket 2009-P-0411, attached as Exhibit C.

CLAIM FOR DECLARATORY AND INJUNCTIVE RELIEF

21. Paragraphs 1 through 20 are incorporated herein by reference.

22. Watson's failure to include in ANDA No. 78-278 a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) with respect to the drug product claims in the '937 patent rendered its ANDA ineligible for FDA approval.

23. The FDA violated the FDCA by approving ANDA No. 78-278 without requiring that Watson file a certification under 21 U.S.C. § 355(j)(2)(A)(vii).

24. The FDA violated the FDCA by approving ANDA No. 78-278 prior to the expiration of Novartis's patent exclusivity as extended by the FDA pursuant to section 505a(c) of the FDCA, 21 U.S.C. § 355a(c).

25. The FDA's approval of ANDA No.78-278 was inconsistent with the FDA's own precedent as set forth in the FDA's March 15, 2010 decision granting Sandoz's citizen petition with respect to Actos and Actoplus Met tablets.

26. The FDA's approval of ANDA No. 78-278 was final agency action for which Novartis has no other adequate remedy without the meaning of 5 U.S.C. § 704.

27. The FDA's approval of ANDA No. 78-278 was arbitrary, capricious and not in accordance with law.

28. Novartis will be irreparably harmed if Watson is permitted to launch its generic version of Novartis's FAMVIR® product prior to March 21, 2011.

29. Novartis has no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, Novartis requests that this court issue judgment in its favor and against defendants and issue the following relief:

1. A declaratory judgment that defendants acted unlawfully in approving ANDA No. 78-278.

2. A temporary restraining order and a preliminary injunction requiring that the FDA withdraw its approval of ANDA No. 78-278 until March 21, 2011.

3. Such other and further relief as this court may deem just and proper.

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