IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS CORPORATION and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C. A. No. _____

COMPLAINT

Plaintiffs Novartis Corporation and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), by their attorneys, hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 90-823 filed by Teva Parenteral Medicines, Inc. ("TPM"), Teva Pharmaceuticals, USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Israel") (collectively, "Teva") with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Novartis's Reclast® drug product.

Related Action

2. This action is related to a patent infringement action currently pending before this Court, captioned *Novartis Corp. v. Teva Parenteral Medicines, Inc. et al.*, C.A. No. 08-459-SLR (the "Pending Action"). The Pending Action involves Novartis's U.S. Patent No. 4,939,130 (the "'130 patent"), the same patent at issue in this action. The Pending Action also arises under 35 U.S.C. §§ 271 and 281, and relates to ANDAs filed by Teva with the FDA for approval to market a generic version of Novartis's Zometa® drug product.

Parties

3. Novartis Corporation is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 608 5th Avenue, New York, New York.

4. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 59 Route 10, East Hanover, New Jersey.

5. Novartis is engaged in the business of creating, developing, and bringing to market innovative pharmaceutical products to prevent and cure diseases, to ease suffering, and to enhance patients' quality of life.

6. Upon information and belief, Teva Parenteral Medicines, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 19 Hughes, Irvine, California. Upon information and belief, Teva Parenteral Medicines, Inc. is a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.

7. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of

business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

8. Upon information and belief, Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, Israel.

9. Upon information and belief, Teva is engaged in the business of manufacturing and marketing generic pharmaceuticals and TPM, Teva USA and Teva Israel acted collaboratively in the preparation and submission of Teva's ANDA No. 90-823.

Jurisdiction and Venue

10. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject-matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

11. Teva is subject to personal jurisdiction in this judicial district.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because TPM and Teva USA are incorporated in Delaware, and Teva Israel is subject to personal jurisdiction in Delaware.

Novartis's '130 Patent

13. Novartis is the owner of the '130 patent, entitled "Substituted Alkanediphosphonic Acids and Pharmaceutical Use," which the United States Patent and Trademark Office duly and legally issued to inventors Knut A. Jaeggi and Leo Widler on July 3, 1990. A true and correct copy of the '130 patent is attached hereto as Exhibit A.

14. Novartis markets commercial formulations of zoledronic acid under the trade names Zometa® and Reclast®. Novartis holds two NDAs for Zometa® (NDA Nos. 21-386 and 21-223)

and two NDAs for Reclast® (Nos. 21-817 and 22-080). The '130 patent is listed in the Orange Book with respect to both Zometa® and Reclast®.

Teva's Notice Letter and ANDA Filing

15. By letter dated November 7, 2008 (the "Teva Notice Letter"), Teva notified Novartis that pursuant to 21 U.S.C. § 355(j)(2)(B) and Section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act, Teva had submitted, and the FDA had received, ANDA No. 90-823 seeking approval to engage in the commercial manufacture, use, and sale of injections containing "Eq. 5 mg Base/100 mL" of zoledronic acid ("Teva ANDA Zoledronic Acid Injection") before the expiration date of the '130 patent. Upon information and belief, Teva intends to engage in the commercial manufacture, use, and sale of the Teva ANDA Zoledronic Acid Injection promptly upon receiving FDA approval to do so.

16. The Teva Notice Letter also informed Novartis that its ANDA filing contained a "Paragraph IV Certification" asserting that, in Teva's opinion, the claims of the '130 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's Zoledronic Acid Injection before the expiration of the '130 patent.

17. This action is being commenced before the expiration of forty-five days from the date Novartis received the Teva Notice Letter.

Count I

(Infringement of United States Patent No. 4,939,130)

18. Each of the preceding paragraphs 1 to 17 is incorporated as if fully set forth herein.

19. Teva's submission of ANDA No. 90-823 to obtain approval to engage in the commercial manufacture, use, offer for sale, or sale of the Teva ANDA Zoledronic Acid Injection prior to the expiration of the '130 patent constitutes infringement of one or more of the valid claims of the '130 patent under 35 U.S.C. § 271(e)(2)(A).

20. Teva will further infringe the '130 patent by making, using, offering to sell, and selling the Teva ANDA Zoledronic Acid Injection in the United States upon FDA approval of Teva's ANDA No. 90-823, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

21. Novartis will be substantially and irreparably damaged and harmed if Teva's infringement of the '130 patent is not enjoined. Novartis does not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Novartis prays that this Court grant the following relief:

(a) A declaration that the '130 patent is valid and enforceable;

(b) A judgment that the '130 patent is infringed by the Teva ANDA Zoledronic Acid Injection, that Teva's submission of its ANDA No. 90-823 is an act of infringement, and that Teva's making, using, offering to sell, selling, or importing the Teva ANDA Zoledronic Acid Injection will infringe the '130 patent;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Teva's ANDA No. 90-823 shall be a date which is not earlier than the expiration date of the '130 patent.

(d) An Order permanently enjoining Teva, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, or importing the Teva ANDA Zoledronic Acid Injection until after the expiration date of the '130 patent;

(e) Damages or other monetary relief to Novartis if Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of the Teva ANDA Zoledronic Acid Injection prior to the expiration date of the '130 patent;

(f) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(g) Reasonable costs of suit incurred by Novartis in this action; and

(h) Such further and other relief as this Court deems proper and just.

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