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.	Civil Action No. _____

COMPLAINT

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

Nature of the Action

1. In this action, Novartis seeks to block Teva Parenteral Medicines, Inc. ("TPM"), Teva Pharmaceuticals USA, Inc.'s ("Teva USA") and Teva Pharmaceutical Industries Ltd's. ("Teva Israel") (collectively, "Teva") improper triggering of the litigation process that Congress has carefully constructed for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug by filing an Abbreviated New Drug Application ("ANDA").

2. Upon information and belief, as of June 10, 2008, Teva did not have an ANDA with respect to any zoledronic acid product that had been received by the United States Food and Drug Administration ("FDA"). The receipt of an ANDA by the FDA is a prerequisite that must

be satisfied before Teva can send Novartis proper notification of the ANDA and a "Paragraph IV certification." Such a notice letter, if it were valid, would start a time period in which Novartis must sue for patent infringement in order to obtain a 30-month statutory delay during which the FDA cannot approve Teva's ANDA. However, since, upon information and belief, no Teva ANDA had been received by the FDA as of June 10, 2008, Teva could not send a valid notice letter to Novartis, and therefore, could not trigger Novartis's statutory right to sue for infringement or commence the 30-month stay.

3. Nonetheless, on June 10, 2008, Teva sent two purported Paragraph IV Notices (the "Teva Notice Letters") to Novartis regarding Teva's purported ANDA submissions (ANDA Nos. 78-576 and 78-580) to the FDA under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, and stating that Novartis's U.S. Patent No. 4,939,130 (the "'130 patent") is either invalid, unenforceable, or will not be infringed by Teva's generic zoledronic acid products. Since, upon information and belief, Teva's ANDA submissions had not been received by the FDA as of June 10, 2008, the Teva Notice Letters are not lawful, and cannot trigger Novartis's right or obligation to sue Teva or begin the 30-month stay of ANDA approval under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3).

4. Since Teva's premature attempt to trigger the ANDA patent litigation process is in violation of federal law, this Court should declare the Teva Notice Letters improper and without legal effect.

5. In addition, because Teva's proposed generic product(s) would infringe Novartis's '130 patent, the filing of a proper ANDA which is received by the FDA is an act of infringement under 35 U.S.C. § 271(e)(2). Accordingly, in the alternative, if the Teva Notice Letters are deemed sufficient by the Court to trigger the deadline for Novartis to sue Teva under 21 U.S.C. §

355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), Novartis hereby seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and other applicable laws for Teva's infringement of the '130 patent.

Parties

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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 purported submission of Teva's ANDA Nos. 78-576 and 78-580.

Jurisdiction and Venue

13. 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.

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

15. 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.

FACTUAL BACKGROUND

16. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to the FDA, and the FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

17. A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on and take advantage of the innovator company's data and the FDA's prior finding

of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously-approved drug (the "listed" or "branded" drug).

18. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This certification is known as a "Paragraph IV Certification."

19. When an applicant submits an ANDA to the FDA, the FDA has 60 days to preliminarily review the application to ensure that it is sufficiently complete to permit substantive review. *See* 21 C.F.R. § 314.101. Only after the FDA notifies the applicant that its ANDA is substantially complete is the ANDA deemed to have been "received" or filed by the FDA.

20. The sponsor of an ANDA which is accepted for review by the FDA that contains a Paragraph IV Certification must provide notice to both the owner of the listed patent and the holder of the NDA for the reference listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95. The federal regulations specifically govern the timing of such Paragraph IV Notifications by directing that the sending of such notices must occur after the FDA has

officially received the ANDA as "sufficiently complete" for review. *See* 21 U.S.C. § 355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

21. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies, such as Novartis, because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. The innovator company is thus assured of a 30-month period during which it may enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. There are powerful incentives for generic companies to obtain the earliest possible filing date by jumping the gun with incomplete ANDA filings. The earliest ANDA filer may be entitled to 180 days of market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). By filing prematurely or notifying the NDA or patent-holder prematurely, the first ANDA filer may also be able to manipulate the rules surrounding the 30-month stay to its advantage and reach the market sooner than would otherwise be permitted.

23. Therefore, one of the important protections built into the ANDA process is that a generic applicant may not even send a Paragraph IV Notice until it "receives from the FDA an acknowledgement letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b). The generic applicant must also include

in its Paragraph IV Notice a "statement that the FDA has received" the ANDA filings. *See* 21 C.F.R. § 314.95(c)(1).

24. These safeguards make simple common sense. Incomplete ANDAs risk burdening the judicial system with premature, and perhaps entirely unnecessary, patent infringement litigation. If the incomplete ANDA is never completed, the parties will be forced to conduct unnecessary and costly infringement litigation. Even if the incomplete ANDA is eventually completed, the premature filing would prejudice not only the innovator company, but also other ANDA filers. Accordingly, the ANDA applicant may not trigger the litigation process by serving a Paragraph IV Notice unless and until it has an ANDA on file that the FDA has accepted for substantive review.

Novartis's '130 Patent

25. 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 Wilder on July 3, 1990. A true and correct copy of the patent is attached hereto as Exhibit A.

26. 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 approved 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 Letters and ANDA Filings

27. In the Teva Notice Letters dated June 10, 2008, 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 was amending ANDA Nos. 78-576 and 78-580, which purportedly were previously submitted to the FDA, to seek approval to engage in the commercial manufacture, use, and sale

of injections containing "Eq. 4 mg Base/Vial" of zoledronic acid ("Teva ANDA Zoledronic Acid Injection") before the expiration date of the '130 patent.

28. Teva also notified Novartis in the Teva Notice Letters that each of its amended ANDA filings 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."

29. The Teva Notice Letters do not contain the required "statement that the FDA has received" the ANDA filings. *See* 21 C.F.R. § 314.95(c)(1). The Teva Notice Letters state only that Teva is "submitting" an amendment to ANDA Nos. 78-576 and 78-580. Moreover, the FDA's online listing of reference drugs for which Paragraph IV ANDAs have been filed (http://www.fda.gov/cder/ogd/ppiv.htm), as updated on July 21, 2008, does not indicate that the FDA has received or accepted any Paragraph IV ANDAs for any form of zoledronic acid.

30. The current formulation of Zometa® is a liquid concentrate of zoledronic acid. The original (and discontinued) formulation of Zometa® was a lyophilized powder form of zoledronic acid, Eq. 4 mg Base/Vial. Accordingly, because the Teva Notice Letters refer only to Eq. 4 mg Base/Vial of zoledronic acid, upon information and belief, Teva is seeking approval of one or more generic versions of the discontinued formulation of Zometa®. As such, Teva was required, pursuant to 21 C.F.R. § 314.122, to submit a petition seeking the FDA's determination as to whether the discontinued version of Zometa® was withdrawn from the market for safety or efficacy reasons. Upon information and belief, Teva has not done so.

31. Accordingly, upon information and belief, the Teva Notice Letters were submitted prematurely, in violation of 21 U.S.C. § 355(j)(2)(B)(ii).

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

Count I

(A Declaration that Teva's Notice Letters Are Null, Void and Without Legal Effect)

33. Each of the preceding paragraphs 1-32 is incorporated as if fully set forth herein.

34. The Teva Notice Letters did not include a "statement that the FDA has received" the ANDA filings. Upon information and belief, at the time Teva sent the Teva Notice Letters, the FDA had not received an ANDA from Teva for the Teva ANDA Zoledronic Acid Injection. Therefore, Teva has no legitimate basis to trigger the ANDA patent litigation process.

35. Upon information and belief, Teva is seeking approval of one or more generic versions of the discontinued formulation of Zometa®. Teva did not, as it is required to do, submit a petition seeking the FDA's determination as to whether the discontinued version of Zometa® was withdrawn from the market for safety or efficacy reasons.

36. As a consequence, Teva's Notice Letters are improper, null, void, and without legal effect, and Teva has improperly triggered the ANDA litigation process.

37. The controversy concerning the validity and effectiveness of the Teva Notice Letters will cause Novartis to suffer substantial prejudice and unnecessary legal fees and costs unless the controversy and the surrounding cloud of uncertainty is resolved by the Court.

38. Accordingly, Novartis is entitled to a declaration that: (1) the Teva Notice Letters are improper, null, void, and without legal effect and that Teva was not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Novartis's claims regarding the '130 patent because the Teva Notice Letters are null, void, and without legal effect; (3) the Teva Notice Letters did not commence the 45 day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA receives and accepts Teva's

ANDA Nos. 78-576 and/or 78-580, Teva must serve new Paragraph IV Notice Letters on Novartis pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay will not commence until Teva has sent valid Paragraph IV Notice Letters to Novartis following the FDA's receipt of each of Teva's ANDA Nos. 78-576 and 78-580.

Count II

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

39. Each of the preceding paragraphs 1 to 38 is incorporated as if fully set forth herein.

40. Teva's submission of amended ANDA Nos. 78-576 and 78-580 to obtain approval to engage in the commercial manufacture, use, offer to sell 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).

41. Upon FDA approval of Teva's amended ANDA Nos. 78-576 and 78-580, 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, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

42. 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) An Order to preliminarily and permanently enjoin Teva (1) to withdraw its improper and ineffective Notice Letters; and (2) to refrain from sending any new Notice Letters to Novartis unless and until the FDA has notified Teva that its ANDAs have been received for review;

(b) A declaration that (1) the Teva Notice Letters are improper, null, void, and without legal effect and that Teva was not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Novartis's claims regarding the '130 patent because the Teva Notice Letters are null, void, and without legal effect; (3) the Teva Notice Letters did not commence the 45 day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA receives Teva's ANDA Nos. 78-576 and 78-580, Teva must serve new Paragraph IV Notice Letters on Novartis pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay will not begin until Teva has sent valid Paragraph IV Notice Letters to Novartis following the FDA's receipt and acceptance of Teva's ANDA Nos. 78-576 and 78-580;

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

(d) A judgment that a claim or claims of the '130 patent are infringed by the Teva ANDA Zoledronic Acid Injection, that Teva's submission of its amended ANDA Nos. 78-576 and 78-580 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;

(e) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Teva's amended ANDA No. 78-576 shall be a date which is not earlier than the expiration date of the '130 patent;

(f) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Teva's amended ANDA No. 78-580 shall be a date which is not earlier than the expiration date of the '130 patent;

(g) 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;

(h) 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;

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

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

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

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Dated: July 24, 2008