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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. APOTEX, INC. and APOTEX CORP., Defendants.	Civil Action No. 15-XXXX (XXX) (XXX)

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' request for approval from the U.S. Food and Drug Administration ("FDA") to manufacture, market, and sell 4 mg / 100 mL vials of zoledronic acid concentrate for intravenous infusion, which is a generic version of the 4 mg / 100 mL concentrate form of Novartis's Zometa® product, prior to the expiration of U.S. Patent No. 8,324,189 ("the '189 patent").

RELATED ACTIONS

3. Novartis has filed several other patent infringement actions currently pending before the Court involving infringement of the '189 patent, including *In re: Certain Consolidated Zoledronic Acid Cases*, Civil Action No. 2:12-cv-03967-SDW-MCA (Consolidated).

THE PARTIES

A. Novartis

4. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey.

B. Apotex, Inc. and Apotex Corp.

5. Upon information and belief, Apotex, Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business in Toronto, Canada.

6. Upon information and belief, Apotex Corp. is a corporation organized under Delaware law. Its principal place of business is in Weston, Florida.

7. Upon information and belief, Apotex, Inc. and Apotex Corp. (collectively "Apotex") are in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

8. Upon information and belief, Apotex, Inc. has submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 205405, seeking approval to market a generic version of Zometa®.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Apotex for the following reasons, among others:

a) Apotex has systematic and continuous contacts with New Jersey, in that, among other things, it sells, manufactures, imports, and/or distributes generic drugs in New Jersey;

b) Apotex's systematic and continuous contacts with New Jersey demonstrate that it has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hauled into court in this district;

c) Apotex is seeking approval to sell and/or distribute a generic version of Zometa® in New Jersey;

d) Apotex sent notification of its Paragraph IV certification to Novartis in New Jersey;

e) Novartis, which will be harmed by Apotex's actions, is domiciled in New Jersey; and

f) Apotex is already before this Court in litigation involving the '189 patent. *See In re: Certain Consolidated Zoledronic Acid Cases*, Civil Action No. 2:12-cv-03967-SDW-MCA (Consolidated).

STATEMENT OF FACTS

A. Novartis's Zometa Product

12. Novartis is the holder of New Drug Application ("NDA") No. 21-223 by which the FDA granted approval for the marketing and sale of Zometa®. The active ingredient in Zometa® is zoledronic acid. Zometa® was first approved by the FDA in 2001.

13. Zometa® is indicated for the treatment of:

- Hypercalcemia of malignancy; and

- Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy.

14. Zometa® is presently sold in two dosage forms and strengths: (i) a 4 mg / 100 mL ready to use bottle and (ii) a 4 mg / 5 mL vial of concentrate.

15. The label for Zometa® instructs that it must be administered as an intravenous infusion "over no less than 15 minutes."

B. The Patent-In-Suit

16. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012. Novartis is the owner of the '189 patent, with the right to sue for and obtain equitable relief and damages for infringement of the '189 patent. A copy of the '189 patent is attached as Exhibit A.

17. The approved method of administration for Zometa®, including the approved indication and infusion time described above, is covered by certain claims of the '189 patent. Accordingly, the '189 patent is listed in connection with Zometa® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book."

C. The FDA's Label Sameness Requirement for Generic Drugs

18. The FDA regulates the manufacture, sale, and labeling of prescription drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

19. To obtain approval to market a new drug, a manufacturer must submit an NDA to the FDA. *See* 21 U.S.C. § 355(a). Among other things, the NDA must contain scientific data and other information demonstrating that the drug is safe and effective, a statement of the composition of the drug, and labeling proposed to be used for such drug. *See* 21 U.S.C. §

355(b)(1). Once approved, the drug is "listed" by FDA along with any patents that cover the approved drug and/or methods of using the approved drug. 21 U.S.C. § 355(j)(7)

20. A drug manufacturer can seek approval to market a "generic" version of a listed drug by submitting an ANDA pursuant to Section 505(j) of the FDCA, 21 U.S.C. § 355(j). The generic drug must be "the same as" the listed drug. 21 U.S.C. § 355(j)(2)(A)(ii).

21. The FDCA requires an ANDA applicant to demonstrate that the "labeling proposed for the [generic] drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v). Use of the same label is critical because "[d]rug labeling serves as the standard under which the FDA determines whether a product is safe and effective." New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985).

22. The FDCA further requires the ANDA applicant to include with the application a comparison of the proposed labeling to the labeling of the listed drug, along with "[a] statement that the applicant's proposed labeling . . . is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section ." 21 C.F.R. 314.94(a)(8)(iii).

23. The FDA has expressly stated that it will reject ANDAs that do not meet the label sameness requirement. *See* Division of Generic Drugs, FDA, *Guidance for Industry, ANDA Submissions – Refuse-to-Receive Standards* 22 (September 2014).

24. Aside from changes to reflect that the ANDA drug product and the listed drug are produced or distributed by different manufacturers, the FDCA provides two exceptions for an ANDA applicant to deviate from the label sameness requirement: (1) when the ANDA applicant

submits a petition filed under 21 C.F.R. § 314.93 ("Suitability Petition"); and (2) when the ANDA applicant carves out from the proposed label aspects of the listed drug's labeling that are protected by patent or by exclusivity ("Carve-Out"). *See e.g.*, 21 C.F.R. 314.127(a)(7); *see also* 21 C.F.R. 314.94(a)(8)(iv); 21 U.S.C. § 355(j)(2)(C).

25. In connection with submitting an ANDA, a generic applicant must make a certification with respect to each Orange Book-listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). In particular, the ANDA applicant must provide one of four certifications with respect to each listed patent:

> (I) that no patent information has been filed in the Orange Book;
>
> (II) that the Orange Book-listed patent has expired;
>
> (III) that the generic manufacturer does not seek to market its proposed generic product before expiration of the Orange Book-listed patent; or
>
> (IV) that the Orange Book-listed patent is invalid or would not be infringed by the generic drug seeking approval.

26. A certification under subsection (IV), a so-called Paragraph IV Certification, is a statement by the applicant that the uses for which it seeks approval are the exact same uses for which a patent is listed in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

27. An ANDA Applicant cannot file both a Carve-Out and a Paragraph IV Certification. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,347 (Oct. 3, 1994). Therefore, absent a Suitability Petition, to be approved by the FDA, an ANDA containing a Paragraph IV Certification must meet the label sameness requirement, *i.e.*, the label of the proposed generic product that is the subject of the ANDA must be the same as the label of the listed drug.

D. Apotex's Proposed Generic Zometa® Product

28. By letter dated April 15, 2015, Apotex notified Novartis that it had submitted to the FDA ANDA No. 205405 pursuant to Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), seeking approval to engage in the commercial manufacture, use, and sale of 4 mg / 100 mL vials of zoledronic acid concentrate ("Apotex's Proposed Generic Zometa® Product") before expiration of the '189 patent.

29. In the notice letter, Apotex stated that its application included a Paragraph IV Certification with respect to the '189 patent, alleging that the '189 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Apotex's Proposed Generic Zometa® Product.

30. Because Apotex submitted an ANDA with a Paragraph IV Certification, absent a Suitability Petition, to be approved by FDA, the label for Apotex's Proposed Generic Zometa® Product must be the same as the label of Zometa®.

31. Upon information and belief, Apotex has not filed a Suitability Petition with the FDA for approval to deviate from the Zometa® label to include an infusion time instruction different from "no less than 15 minutes." Before filing this complaint, Novartis asked Apotex whether it had filed a Suitability Petition with the FDA for approval to deviate from the Zometa® label regarding infusion time. Apotex would not confirm. Furthermore, the FDA website does not list any Suitability Petitions for zoledronic acid. *See* FDA, OGD Suitability Tracking Report (Sorted by Drug Name), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm283497.htm (updated 04/2014).

32. Upon information and belief, because Apotex has not filed a Suitability Petition with the FDA for approval to deviate from the Zometa® label regarding infusion time, the FDA will not approve ANDA No. 205405 unless Apotex's proposed label matches that of Zometa®, including an instruction that Apotex's Proposed Generic Zometa® Product be infused for over "no less than 15 minutes." Before filing this complaint, Novartis asked Apotex to produce its correspondence with the FDA regarding the labeling for Apotex's Proposed Generic Zometa® Product, but Apotex refused.

33. Because Apotex has refused to disclose its correspondence with FDA, or whether it has a Suitability Petition with the FDA for approval to deviate from the Zometa® label regarding infusion time, Novartis resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm Novartis's good faith belief and to present to the Court evidence that, in order to obtain approval, the label of Apotex's Proposed Generic Zometa® Product will match the label of Zometa®, including an instruction that Apotex's Proposed Generic Zometa® Product be infused for over "no less than 15 minutes."

34. This action is being commenced before expiration of forty-five days from Novartis's receipt of Apotex's notice letter.

COUNT I (INFRINGEMENT OF THE '189 PATENT)

35. Each of the preceding paragraphs 1 to 34 is incorporated as if fully set forth herein.

36. Upon information and belief, Apotex knew of the '189 patent when it submitted ANDA No. 205405, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '189 patent.

37. Apotex's submission of ANDA No. 205405, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's Proposed Generic Zometa® Product before the expiration of the '189 patent constitutes an act of infringement of one or more claims of the '189 patent under 35 U.S.C. § 271(e)(2).

38. Apotex had actual and constructive knowledge of the '189 patent prior to filing ANDA No. 205405 and was aware that filing ANDA No. 205405 with the FDA constituted an act of infringement of one or more claims of the '189 patent.

39. Upon FDA approval of Apotex's ANDA No. 205405, Apotex will further infringe the '189 patent by making, using, offering to sell, and selling Apotex's Proposed Generic Zometa® Product in the United States and/or importing such product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

40. If Apotex's infringement of the '189 patent is not enjoined, Novartis will suffer irreparable injury for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against Apotex as follows:

1. A judgment that the '189 patent is valid and enforceable;

2. A judgment that one or more claims of the '189 patent are infringed by Apotex's submission of ANDA No. 205405, and that Apotex's making, using, offering to sell, or selling in the United States, or importing into the United States, Apotex's Proposed Generic Zometa® Product will infringe, directly or indirectly, one or more claims of the '189 patent;

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 205405 shall be the date which is not earlier than the expiration date

of the ’189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. An order permanently enjoining Apotex, and its affiliates, subsidiaries, officers, agents, servants, and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Apotex’s Proposed Generic Zometa® Product until after the expiration date of the ’189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

5. Damages or other monetary relief to Novartis if Apotex engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of Apotex’s Proposed Generic Zometa® Product prior to the expiration date of the ’189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: May 29, 2015

/s/ *William J. O'Shaughnessy*

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *In re: Certain Consolidated Zoledronic Acid Cases*, Civil Action No. 2:12-cv-03967-SDW-SCM (consolidated) filed on June 27, 2012 in the District of New Jersey;

- *Novartis Pharmaceuticals Corporation v. Sagent Pharmaceuticals*, Civil Action No. 2:14-cv-07556-SDW-SCM filed on December 3, 2014 in the District of New Jersey;

- *Novartis Pharmaceuticals Corporation v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:14-cv-07557-SDW-SCM filed on November 8, 2013 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation v. BPI Labs, LLC*, Civil Action No. 2:15-00950-SDW-SCM filed on February 5, 2015 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation v. Heritage Pharma Holdings, Inc.*, 15-cv-01872-SDW-SCM filed on March 12, 2015 in the District of New Jersey.

Dated: May 29, 2015

Respectfully Submitted,

s/*William J. O'Shaughnessy*

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