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

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. PHARMACEUTICS INTERNATIONAL, INC., Defendant.	)	Civil Action No.

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, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendant's requests for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Zometa® product prior to the expiration of U.S. Patent No. 8,324,189 ("the '189 patent").

THE PARTIES

A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '189 patent.

B. Pharmaceutics International, Inc.

4. Defendant Pharmaceutics International, Inc. ("Pii") is a corporation organized under Maryland law. Its principal place of business is in Hunt Valley, Maryland.

5. Upon information and belief, Pii has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey. In addition, Pii has previously acquiesced to personal jurisdiction and asserted counterclaims in this District.

JURISDICTION AND VENUE

6. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

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

8. This Court has personal jurisdiction over the defendant for the following reasons, among others:

a) The defendant has sold generic drugs in New Jersey, and is seeking approval to sell and/or distribute a generic version of Zometa in New Jersey;

b) Novartis, which will be harmed by the defendant's actions, is domiciled in New Jersey;

c) Defendant Pii 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; and

d) Defendant Pii has previously acquiesced to personal jurisdiction and asserted counterclaims in this jurisdiction, including in related matter *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated).

STATEMENT OF FACTS

A. Novartis's Zometa Product

9. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is approved to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

10. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4

mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003).

B. The Patent-In-Suit

11. 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, and is owned by Novartis. A copy of the '189 patent is attached as Exhibit A.

12. 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." Accordingly, the defendant has actual or constructive knowledge of the patent.

C. Pii's Proposed Generic Product

13. By letter dated January 17, 2014, Pii notified Novartis that it had submitted to the FDA New Drug Application No. 205627 pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act seeking approval to a market generic version of Zometa ("Pii's 505(b)(2) Product").

14. In the notice letter, Defendant Pii stated that its application included certifications pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) with respect to the '189 patent, alleging that it is invalid and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of Pii's 505(b)(2) Product.

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

COUNT I (INFRINGEMENT OF THE '189 PATENT)

16. Each of the preceding paragraphs 1 to 15 is incorporated as if fully set forth herein.

17. The use of Defendant Pii's 505(b)(2) Product is covered by one or more claims of the '189 patent.

18. Upon information and belief, Defendant Pii knew of the '189 patent when it submitted 505(b)(2) Application No. 205627, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '189 patent.

19. Defendant Pii's submission of 505(b)(2) Application No. 205627, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its Zometa products before the expiration of the '189 patent is an act of infringement of the '189 patent under 35 U.S.C. § 271(e)(2).

20. Use of Defendant Pii's 505(b)(2) Product in accordance with and as directed by Defendant Pii's proposed labeling would infringe one or more claims of the '189 patent.

21. Upon information and belief, upon FDA approval of its 505(b)(2) Application, Defendant Pii will indirectly infringe the Zometa patent by making, using, offering to sell, and selling Pii's 505(b)(2) Product in the United States and/or importing this product into the United States.

22. Upon information and belief, upon FDA approval of its 505(b)(2) Application, Defendant Pii will actively induce infringement of the '189 patent in violation of 35 U.S.C. § 271(b) by making, using, offering to sell, and selling Pii's 505(b)(2) Product in the United States.

23. Upon information and belief, Defendant Pii knows that its 505(b)(2) Product and its proposed labeling are especially made or adapted for use in infringing the '189 patent, and that

its 505(b)(2) Product is not suitable for substantial noninfringing use.

24. Upon information and belief, Defendant Pii plans and intends to, and will, contribute to the infringement of the '189 patent immediately and imminently upon approval of its 505(b)(2) Product in violation of 35 U.S.C. § 271(c).

25. There is an actual and justiciable case or controversy between Novartis and Defendant Pii concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendant Pii's manufacture, use, sale, offer for sale, and/or importation of its 505(b)(2) Product will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are not invalid.

26. Unless Defendant Pii is enjoined from infringing the '189 patent, actively inducing infringement of the '189 patent, and/or contributing to the infringement by others of the '189 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

PRAYER FOR RELIEF

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

1. Declaring that the '189 patent is not invalid;

2. Declaring that the Defendant has infringed, directly or indirectly, one or more claims of the '189 patent;

3. Damages or other monetary relief to Novartis if defendant engages or continues to engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of Pii's 505(b)(2) Product prior to the latest expiration date of the '189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that the Defendant by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Pii's 505(b)(2) Product has willfully infringed the claims of the '189 patent;

5. An order permanently enjoining Defendant, 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 Pii's 505(b)(2) Product until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled; and

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

Dated: March 3, 2014

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:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Accord Healthcare Inc.*, Civil Action No. 2:13-cv-07178-SDW-MCA filed on November 26, 2013 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-07914-SDW-MCA filed on December 27, 2013 in the District of New Jersey.

Dated: March 3, 2014

s/William J. O'Shaughnessy

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