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

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. PAR STERILE PRODUCTS, LLC; PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	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 Defendants' actions in making, using, offering to sell, selling, and/or importing in the United States generic versions of Novartis's Zometa® and Reclast® products prior to the expiration of U.S. Patent Nos. 7,932,241 ("the '241 patent"), 8,052,987 ("the '987 patent"), and 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 '241, '987, and '189 patents.

B. Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc.

4. Upon information and belief, Par Sterile Products, LLC (formerly known as JHP Pharmaceuticals, LLC) is a corporation organized under Delaware law. Its principal place of business is Parsippany, New Jersey.

5. Upon information and belief, Par Pharmaceutical Companies, Inc. is a corporation organized under Delaware law. Its principal place of business is Woodcliff Lake, New Jersey.

6. Upon information and belief, Par Sterile Products, LLC is an indirect wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. (collectively, "Par").

7. Upon information and belief, Par is the U.S. sales agent and distributor for Pharmaceutics International, Inc. ("PII") with respect to at least the zoledronic acid products that are the subject of Abbreviated New Drug Application ("ANDA") Nos. 91170 and 202163. Upon information and belief, the U.S. Food and Drug Administration ("FDA") has approved ANDA Nos. 91170 and 202163, and Par has started selling generic versions of Zometa and Reclast in the United States, including in New Jersey.

JURISDICTION AND VENUE

8. 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).

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

10. This Court has personal jurisdiction over Defendants for the following reasons, among others:

a) Defendants have sold and/or distributed generic drugs in New Jersey, including generic versions of Reclast and/or Zometa;

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

c) Defendants each have their principal place of business in New Jersey.

STATEMENT OF FACTS

A. Novartis's Branded Products

11. 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.

12. 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 "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). Unopened, Zometa has a shelf life of three years.

13. The active ingredient of Reclast is also zoledronic acid. Reclast was first approved by the FDA in 2007 and is approved to treat osteoporosis, a condition in which bones become weakened, and Paget's disease, a clinically rare genetic condition that disrupts the normal cycle of bone turnover.

14. Reclast is also administered intravenously, although the dosage of zoledronic acid in

Reclast is different than Zometa. Reclast is administered as a 5 mg dose diluted in standard buffer media. Reclast is sold only in a liquid form that is fully diluted and ready to be administered. Unopened, Reclast has a shelf life of three years.

B. The Patents-In-Suit

15. The '241 patent, entitled "Pharmaceutical products comprising bisphosphonates," was duly and legally issued on April 26, 2011 and is owned by Novartis. A copy of the '241 patent is attached as Exhibit A.

16. The '987 patent, entitled "Method of administering bisphosphonates," was duly and legally issued on November 8, 2011 and is owned by Novartis. A copy of the '987 patent is attached as Exhibit B.

17. 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 C.

18. Zometa and Reclast, their methods of use, and their process of manufacture are covered by one or more claims of the '241, '987, and '189 patents, which have been listed in connection with Zometa and Reclast in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, Defendant Par has actual or constructive knowledge of each of the patents.

C. The ANDA Process

19. The FDA regulates the manufacture, sale, and labeling of prescription drugs in the U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an Abbreviated New Drug Application (ANDA) to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of a New Drug Application ("NDA") holder to demonstrate a

drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

20. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents.

21. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's Orange Book patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

22. Under 21 U.S.C. § 355(j)(2)(A)(viii), an applicant can attempt to seek a label only for uses not covered by a branded drug's method-of-use patent(s), a so-called "Section viii carve-out." If the generic drug is ultimately approved, the FDA will require the generic drug maker to duplicate only that portion of the branded drug's label not protected by the applicable method-of-use patents, as identified in the Section viii carve-out.

D. The Generics' ANDA Products

23. As noted above, Defendant Par sells and/or distributes generic versions of Zometa and Reclast pursuant to ANDAs that have been approved by the FDA.

24. Upon information and belief, Defendant Par is the U.S. sales agent and distributor for PII with respect to at least the generic versions of Zometa and Reclast that are the subject of ANDA Nos. 91170 and 202163, respectively.

25. PII notified Novartis by letter that it had submitted to the FDA ANDA No. 91170 for a

generic version of Zometa. PII stated that ANDA No. 91170 included a Paragraph IV certification with respect to the '189 patent, alleging it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the generic Zometa products described in that ANDA.

26. PII notified Novartis by letter that it had submitted to the FDA ANDA No. 202163 for a generic version of Reclast. PII stated that ANDA No. 202163 included a Paragraph IV certification with respect to the '241 patent, alleging it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the generic Reclast products described in that ANDA. PII did not serve a Paragraph IV notice with respect to the '987 patent, but, instead, filed with the FDA a Section viii carve-out stating that it is only seeking approval for indications not covered by the '987 patent. Specifically, although the Reclast NDA is approved for the following uses: (1) osteoporosis, i.e., treatment and prevention of postmenopausal osteoporosis, treatment to increase bone mass in men with osteoporosis, and treatment and prevention of glucocorticoid-induced osteoporosis and (2) treatment of Paget's disease of bone in men and women, PII filed a Section viii carve-out stating that it is only seeking approval to market a generic version of Reclast for the treatment of Paget's disease.

27. Novartis brought suit against PII in Civil Action No. 13-1028 (SDW) (MCA) (consolidated), which is pending before the U.S. District Court for the District of New Jersey. Upon information and belief, the FDA has approved ANDA Nos. 91170 and 202163, and Par has started selling generic versions of Zometa and Reclast in the United States pursuant to those ANDAs.

28. Upon information and belief, any representation by PII and/or Par that their generic Reclast products are not and/or will not be offered for sale or sold for the treatment of

osteoporosis is knowingly incorrect. Ninety-nine and seven-tenths percent (99.7%) of patients who take Reclast each year are being treated for conditions other than Paget's disease. Only three-tenths percent (0.3%) of patients who take Reclast do so for Paget's disease. Upon information and belief, approximately 350,000 patients are currently in treatment with Reclast. Of these 350,000 patients, only about 1,000 patients have Paget's disease.

29. Despite the relatively small size of the market for treatment of Paget's patients, upon information and belief, no fewer than ten separate generic companies have submitted ANDAs for permission to sell Reclast. According to the U.S. Department of Health and Human Services, however, it typically costs generic drug makers $1 million to $2 million to bring a generic drug to market. Assuming these averages hold here, PII and/or Par would spend substantially more than the total size of the Paget's patient market in order to bring a generic Reclast product to market.

30. Upon information and belief, Doctors are free to, and frequently do, prescribe drugs for indications not identified in the drug's label. Although Par's generic Reclast products contain a label limited to Paget's disease, doctors can nonetheless prescribe Reclast for cancer patients or for patients suffering from osteoporosis.

31. Accordingly, upon information and belief, Par intends to and does manufacture, offer for sale, sell, and/or import into the United States generic Reclast in quantities that far exceed the market for treatment of Paget's disease. Upon information and belief, Par does not intend that its products be used only for treatment of Paget's disease, but in fact intends for there to be substantial use of its generic Reclast products for treatment of osteoporosis.

COUNT I (INFRINGEMENT OF THE '241 PATENT)

32. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth herein.

33. Defendant Par's generic Reclast products are covered by one or more claims of the '241 patent.

34. Defendant Par's commercial manufacture, use, offer for sale, sale, and/or importation of its generic Reclast products before the expiration of the '241 patent infringes one or more claims of the '241 patent in violation of 35 U.S.C. § 271(a).

35. There is an actual and justiciable case or controversy between Novartis and Defendant Par concerning the validity and infringement of the '241 patent. Novartis is entitled to a declaration that Defendant Par's commercial manufacture, use, sale, offer for sale, and/or importation of its generic Reclast products infringes one or more claims of the '241 patent and that the claims of the '241 patent are not invalid.

36. If Defendant Par's infringement is of the '241 patent is not enjoined, Novartis will suffer irreparable injury for which there is no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '987 PATENT)

37. Each of the preceding paragraphs 1 to 36 is incorporated as if fully set forth herein.

38. The use of Defendant Par's generic Reclast products to treat osteoporosis is covered by one or more claims of the '987 patent.

39. Upon information and belief, although the Section viii carve-out as to the '987 patent states that the products described in ANDA No. 202163 will not use the osteoporosis indication covered by the '987 patent in the labeling for the generic Reclast products and contends that the '987 patent does not cover Paget's disease, Par, in fact, intends to and does manufacture, use, offer to sell, and/or sell generic Reclast for the same use as claimed in the '987 patent. Accordingly, Par is or will be inducing infringement of the '987 patent in violation of 35 U.S.C. § 271(b), and contributing to infringement in violation of 35 U.S.C. § 271(c).

40. Upon information and belief, Defendant Par knew of the '987 patent when it first manufactured, used, offered to sell, and/or sold its generic Reclast product and knows or is willfully blind to the fact that its actions have or will induce or contribute to direct infringement of the '987 patent.

41. Defendant Par is knowingly and intentionally inducing and/or will knowingly and intentionally induce infringement of the '987 patent in violation of 35 U.S.C. § 271(b). Upon information and belief, Defendant Par knows that the vast majority of patients who are administered Reclast each year are treated for the osteoporosis indications and that only a handful of patients who are administered Reclast are treated for Paget's disease. In addition, on information and belief, Defendant Par has made substantial financial investments to bring its generic Reclast products to market, despite the fact that the market for the treatment of Paget's disease is so small that Defendant Par could never hope to recoup even its initial investment

costs, let alone turn a profit based on sales only to Paget's disease patients.

42. Defendant Par is contributing to and/or will contribute to infringement of the '987 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Reclast, which is especially made for treating osteoporosis patents and which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c). Because Paget's disease patients account for only a small percentage of Reclast uses, using generic Reclast to treat Paget's disease will not be a substantial non-infringing use. Once Paget's patients (0.3% percent of the total Reclast market) are treated with zoledronic acid, treatment of osteoporosis patients, which make up the other 99.7% of the Reclast market, using generic Reclast would constitute infringing uses. Moreover, the percentage of patients who will use Defendant Par's generic Reclast products to treat Paget's disease is even smaller than that already insubstantial number, insofar as the already small sliver of the market will be further divided among at least ten generic manufacturers. In addition, many Paget's patients will require only a single dose and be cured, and even those who experience relapse will require infrequent treatment.

43. There is an actual and justiciable case or controversy between Novartis and Defendant Par concerning the validity and infringement of the '987 patent. Novartis is entitled to a declaration that Defendant Par's manufacture, use, sale, offer for sale, and/or importation of its generic Reclast products contributes to the infringement of, and/or actively induces the infringement of one or more claims of the '987 patent, and that the claims of the '987 patent are not invalid.

44. If Defendant Par's infringement of the '987 patent is not enjoined, Novartis will suffer irreparable injury for which there is no adequate remedy at law.

COUNT III (INFRINGEMENT OF THE '189 PATENT)

45. Each of the preceding paragraphs 1 to 44 is incorporated as if fully set forth herein.

46. The use of Defendant Par's generic Zometa product is covered by one or more claims of the '189 patent.

47. Upon information and belief, Defendant Par knew of the '189 patent when it first manufactured, used, offered to sell, and/or sold its generic Zometa product, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '189 patent.

48. Use of Defendant Par's generic Zometa product in accordance with and as directed by Defendant Par's labeling for that product infringes and/or would infringe one or more claims of the '189 patent.

49. Upon information and belief, Defendant Par manufactures, uses, offers for sale, sells, and/or imports its generic Zometa product with labeling that instructs infringement of the '189 patent.

50. Upon information and belief, Defendant Par actively induces and/or will induce infringement of the '189 patent in violation of 35 U.S.C. § 271(b) by its manufacture, use, offer for sale, sale, and/or importation of its generic Zometa product.

51. Upon information and belief, Defendant Par knows that its generic Zometa product and the labeling for that product is especially made or adapted for use in infringing the '189 patent, and that its generic Zometa product and the labeling for that product is not suitable for substantial noninfringing use.

52. Upon information and belief, Defendant Par plans and intends to, and does and/or will contribute to the infringement of the '189 patent by its manufacture, use, offer for sale, sale,

and/or importation of its generic Zometa product in violation of 35 U.S.C. § 271(c).

53. There is an actual and justiciable case or controversy between Novartis and Defendant Par concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendant Par's manufacture, use, sale, offer for sale, and/or importation of its generic Zometa product contributes to the infringement of, and/or actively induces the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are not invalid.

54. If Defendant Par'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 Defendants as follows:

1. Declaring that Defendants have infringed, directly or indirectly, one or more claims of the '241, '987, and '189 patents;

2. An order permanently enjoining Defendants, and their 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, generic versions of Zometa and Reclast until after the expiration date of the '241, '987, and/or '189 patents, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

3. Damages or other monetary relief, including pre-judgment and post-judgment interest, to Novartis based on Defendants' commercial manufacture, use, offers to sell, sale, or importation into the United States of generic versions of Reclast and Zometa prior to the latest

expiration date of the '241, '987, and/or '189 patents, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that Defendants engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Reclast and Zometa have willfully infringed the claims of the '241, '987, and/or '189 patents and an award of treble damages to Novartis for Defendants' willful infringement; and

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

Dated: December 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 the following actions:

- *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. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-07914-SDW-MCA filed on December 27, 2013 in the District of New Jersey; and
- *Novartis Pharmaceuticals Corporation et al. v. Pharmaceutics International, Inc.*, Civil Action No. 2:14-cv-01347-SDW-MCA filed on March 3, 2014 in the District of New Jersey.

Dated: December 3, 2014

Respectfully Submitted,

s/William J. O'Shaughnessy

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