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

| | |
|---|---|
| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>ACCORD HEALTHCARE INC.; FRESENIUS KABI USA, LLC; and HIKMA FARMACEUTICA S.A.,<br><br>Defendants. | Civil Action No. 13-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, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendants' request for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis' Zometa® product prior to expiration of U.S. Patent No. 8,324,189 ("the '189 patent"), which is directed to oncology methods.

## 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. Accord Healthcare Inc.

4. Accord Healthcare Inc. ("Accord") is a corporation organized under North Carolina law. Its principal place of business is 1009 Slater Road, Suite 210-B, Durham, North Carolina, 27703. Upon information and belief, Defendant Accord 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, Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District.

5. Upon information and belief, Defendant Accord has submitted to the FDA ANDA No. 205279, seeking approval to market a generic version of Zometa.[1]

[1] Although ANDA No. 205279 was purportedly submitted by a company called "Accord Healthcare, Inc. USA," no such corporate entity appears to exist.

**C. Hikma Farmaceutica S.A.**

6. Hikma Farmaceutica S.A. ("Hikma") is a corporation chartered under the laws of the Republic of Portugal. Its principal place of business is Estrada Rio Da Mo No. 8, 8[a] & 8b-Fervenca, 2705-906 Terrugem SNT, Portugal. Upon information and belief, Defendant Hikma 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, Defendant Hikma's agent and subsidiary, West-Ward Pharmaceutical Corp., through which, upon information and belief, Defendant Hikma conducts its U.S. operations, is located in this District. Defendant Hikma has also previously asserted claims in this District.

7. Upon information and belief, Defendant Hikma has submitted to the FDA ANDA No. 202182, seeking approval to market a generic version of Zometa.

**D. Fresenius Kabi USA, LLC**

8. Fresenius Kabi USA, LLC ("Fresenius" and, together with Defendants Accord and Hikma, "Defendants") is a Delaware limited liability company. Its principal place of business is 1501 East Woodfield Road, Suite 300 East Schaumburg, Illinois 60173-5837. Upon information and belief, Defendant Fresenius has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey.

9. Upon information and belief, Defendant Fresenius has submitted to the FDA ANDA No. 091516, seeking approval to market a generic version of Zometa.

## JURISDICTION AND VENUE

10. 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.

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

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

i. Defendants have sold generic drugs in New Jersey, and are seeking approval and/or have obtained tentative approval to sell and/or distribute a generic version of Zometa in New Jersey;

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

iii. Defendants have systematic and continuous contacts with New Jersey, in that, among other things, they sell, manufacture, import and/or distribute generic drugs in New Jersey;

iv. Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District; and

v. Defendant Hikma has previously asserted claims in this District.

## STATEMENT OF FACTS

### A. Novartis' Branded Products

13. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is used 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.

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

**B. The Patent-In-Suit**

15. The '189 patent, entitled "Use of zoledronate 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. During clinical trials of Zometa, Novartis scientists learned that cancer patients could suffer renal toxicity—*i.e.*, kidney damage—if the drug were administered too quickly. After extensive clinical experimentation, however, Novartis scientists discovered that renal toxicity could be controlled if Zometa were administered as a 4 mg dose over a 15 minute period. The '189 patent is directed to this method of treatment. A copy of the '189 patent is attached as Exhibit 1.

16. Zometa and its methods of use are covered by one or more claims of the '189 patent, which has been 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, Defendants have actual or constructive knowledge of the patent.

**C. The ANDA Process**

17. 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 an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

18. 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.

19. In particular, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's 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.

**D. Defendants' ANDA Applications**

20. By letter dated March 14, 2013, Defendant Accord notified Novartis that it had submitted to the FDA ANDA No. 205279 for a generic version of Zometa ("Accord's ANDA Product").

21. By letter dated March 25, 2013, Defendant Fresenius notified Novartis that it had submitted to the FDA ANDA No. 091516 for a generic version of Zometa ("Fresenius' ANDA Product").

22. By letter dated April 3, 2013, Defendant Hikma notified Novartis that it had submitted to the FDA ANDA No. 202182 for a generic version of Zometa ("Hikma's ANDA Product" and, together with Accord's ANDA Product and Fresenius' ANDA Production,

"Defendants' ANDA Products").

23. In their respective notice letters, Defendants stated that their ANDAs included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '189 patent and alleged that the '189 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendants' ANDA Products.

24. This action is being commenced before expiration of forty-five days from Novartis' receipt of each of the notice letters.

**COUNT I (INFRINGEMENT OF THE '189 PATENT)**

25. Each of the preceding paragraphs 1 to 24 is incorporated as if fully set forth herein.

26. Defendant Accord's submission of ANDA No. 205279 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Accord had knowledge of the '189 patent when it submitted its ANDA to the FDA.

27. Defendant Fresenius' submission of ANDA No. 091516 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Fresenius had knowledge of the '189 patent when it submitted its ANDA to the FDA.

28. Defendant Hikma's submission of ANDA No. 202182 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Hikma had knowledge of the '189 patent

when it submitted its ANDA to the FDA.

29. Upon information and belief, upon FDA approval of their respective ANDAs, Defendants will indirectly infringe the Zometa patent by making, using, offering to sell, and selling its zoledronic acid solution containing 4 mg zoledronic acid as the active ingredient in the United States and/or importing such a solution into the United States.

30. Specifically, Defendants will knowingly and intentionally induce patients to infringe the '189 patent in violation of 35 U.S.C. § 271(b).

31. Defendants will also contribute to infringement of the '189 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Zometa, which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c).

32. There is an actual and justiciable case or controversy between Novartis and each of the Defendants concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendants' manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug product will contribute to the infringement of and/or actively will induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are valid.

**PRAYER FOR RELIEF**

WHEREFORE, Novartis requests entry of judgment in its favor and against each of the Defendants as follows:

1. Declaring that submission of ANDA Nos. 205279, 091516, 202182 were acts of infringement of the '189 patent and that Defendants' manufacture, use, offer to sell, sale or importation of Defendants ANDA Products prior to expiration of the '189 patent will infringe the

'189 patent;

2. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their 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 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

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

DATED: April 12, 2013

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; and

- *Novartis Pharmaceuticals Corporation v. Actavis LLC et al.*, Civil Action No. 13-cv-1028-SDW-MCA filed on February 20, 2013 in the District of New Jersey.

Dated: April 12, 2013

Respectfully Submitted,

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