William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

*Attorneys for Novartis Pharmaceuticals Corporation*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

*Attorneys for Novartis Pharmaceuticals Corporation*

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

| | |
|---|---|
| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>HOSPIRA, INC.,<br><br>Defendant. | 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 Defendant's request for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Zometa® product prior to expiration of U.S. Patent No. 7,932,241 ("the '241 patent"), which is directed to certain approved presentations of zoledronic acid, and U.S. Patent No. 8,324,189 ("the '189 patent"), which is directed to oncology methods.

## THE PARTIES

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.

4. Defendant Hospira, Inc. ("Hospira") is a corporation organized under Delaware law. Its principal place of business is in Lake Forest, Illinois.

5. Upon information and belief, Hospira has systematic and continuous contacts with New Jersey, including offices in New Jersey, New Jersey distributors and significant sales in New Jersey. Upon information and belief, Hospira develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey.

6. Upon information and belief, Hospira submitted to the FDA an ANDA and a 505(b)(2) Application seeking approval for generic versions of Zometa.

## JURISDICTION AND VENUE

7. 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.

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

9. This Court has personal jurisdiction over Defendant for the following reasons, among others:

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

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

iii. Defendant 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;

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

v. Defendant has previously asserted claims in this District; and

vi. Defendant is already before this Court in litigation involving the '241 patent, C.A. No. 2:12-cv-03967-SDW-MCA.

## STATEMENT OF FACTS

### A. Novartis' Branded Products

10. 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.

11. 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 Patents-In-Suit

12. The '241 patent, entitled "Pharmaceutical products comprising bisphosphonates," was duly and legally issued on April 26, 2011 and is owned by Novartis. The '241 patent's inventors discovered that zoledronic acid could not be stored for extended periods in then-industry-standard glass vials. The acid tends to degrade the glass, resulting in particles that can contaminate the drug. Accordingly, Novartis scientists invented a novel plastic-coated vial able to hold zoledronic acid for extended periods. The '241 patent is directed to this invention. A copy of the '241 patent is attached as Exhibit 1.

13. 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. 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 2.

14. Zometa and its methods of use are covered by one or more claims of the '241 and '189 patents, which have 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, Defendant has actual or constructive knowledge of the patents.

**C. The ANDA Process**

15. 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 either an Abbreviated New Drug Application (ANDA) to the FDA**,** 21 U.S.C. § 355(j), or a so-called "§ 505(b)(2) Application," 21 U.S.C. § 355(b)(2). These processes allow 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 can rely on the original NDA submission for that purpose.

16. 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.

17. 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. Defendant's ANDA and 505(b)(2) Applications**

18. By letter dated June 21, 2013, Defendant notified Novartis that it had submitted to the FDA ANDA No. 090621 for a generic version of Zometa pre-concentrate ("Defendant's ANDA Product").

19. By a second letter dated June 21, 2013, Defendant notified Novartis that it had submitted to the FDA 505(b)(2) Application No. 204016 for a generic version of Ready-to-Use Zometa ("Defendant's 505(b)(2) Product").

20. In both of its notice letters, Defendant stated that its applications 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 Defendant's ANDA Product or Defendant's 505(b)(2) Product.

21. In its notice letter for Defendant's 505(b)(2) Product, Defendant stated that its application included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '241 patent and alleged that the '241 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of Defendant's 505(b)(2) Product.

22. 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 ’241 PATENT)**

23. Each of the preceding paragraphs 1 to 22 is incorporated as if fully set forth herein.

24. Defendant has submitted a 505(b)(2) Application with Paragraph IV notices to obtain approval to engage in the commercial manufacture, use, offering for sale, or sale of zoledronic acid solutions in a plastic-coated vial suitable to hold zoledronic acid as the active ingredient prior to the expiration of the approved-presentations patent, which constitutes an act of infringement of one or more of the claims of the ’241 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon FDA approval of its 505(b)(2) Application, Defendant will further infringe the patent relating to approved presentations by making, using, offering for sale, and selling its zoledronic acid solutions in a plastic-coated vial suitable to hold zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States in violation of 35 U.S.C. § 271(a).

26. There is an actual and justiciable case or controversy between Novartis and Defendant concerning the validity and infringement of the ’241 patent. Novartis is entitled to a declaration that Defendant’s manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug product in a plastic-coated vial suitable to hold zoledronic acid as the active ingredient will infringe or is infringing one or more claims of the ’241 patent and that the claims of the ’241 patent are valid and enforceable.

**COUNT II (INFRINGEMENT OF THE ’189 PATENT)**

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth herein.

28. Defendant's submission of ANDA No. 090621 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).

29. Defendant's submission of 505(b)(2) Application No. 204016 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).

30. Upon information and belief, upon FDA approval of their ANDA and 505(b)(2) Application, Defendant will indirectly infringe the '189 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.

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

32. Defendant 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).

33. There is an actual and justiciable case or controversy between Novartis and the Defendant concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendant's 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 the Defendant as follows:

1. Declaring that submission of ANDA No. 090621 and 505(b)(2) Application No. 204016 were acts of infringement of the '189 patent and that Defendant's manufacture, use, offer to sell, sale or importation of Defendant's ANDA Product or Defendant's 505(b)(2) Product prior to expiration of the '189 patent will infringe the '189 patent;

2. Declaring that submission of 505(b)(2) Application No. 204016 was an act of infringement of the '241 patent and that Defendant's manufacture, use, offer to sell, sale or importation of Defendant's 505(b)(2) Product prior to expiration of the '241 patent will infringe the '241 patent;

3. An order permanently enjoining Defendant, 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 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

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

DATED: August 2, 2013

s/ William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street

Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

*Attorneys for Novartis Pharmaceuticals Corporation*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

*Attorneys for Novartis Pharmaceuticals Corporation*

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

- *Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc et al.*, Civil Action No. 13-cv-02379-SDW-MCA filed on April 12, 2013 in the District of New Jersey.

Dated: August 2, 2013

Respectfully Submitted,

s/William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

*Attorneys for Novartis Pharmaceuticals Corporation*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center

250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

*Attorneys for Novartis Pharmaceuticals Corporation*