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
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

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

Amanda L. Major
Tracey C. Allen
Rachel Weiner Cohen
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
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, Plaintiff, v. AMNEAL PHARMACEUTICALS, LLC; AMNEAL-AGILA, LLC; MYLAN INC.; MYLAN INSTITUTIONAL 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 a generic version 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. The Generic Defendants

Amneal Pharmaceuticals, LLC and Amneal-Agila, LLC

4. Upon information and belief, Amneal Pharmaceuticals, LLC is a corporation organized under Delaware law. Its principal place of business is in Bridgewater, New Jersey.

5. Upon information and belief, Amneal-Agila, LLC is a corporation organized under Delaware law. Its principal place of business is in Bridgewater, New Jersey.

6. Upon information and belief, Amneal-Agila, LLC is a wholly-owned subsidiary of Amneal Pharmaceuticals, LLC (collectively, "Amneal").

7. Upon information and belief, Amneal, is 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, Amneal is a U.S. sales agent and distributor for Strides, Inc. and Agila Specialties Private Ltd. (collectively, "Strides") with respect to at least the generic version of Zometa that is the subject of Abbreviated New Drug Application ("ANDA") No. 202650. Upon information and belief, the U.S. Food and Drug Administration ("FDA") has approved ANDA No. 202650, and Amneal has started selling a generic version of Zometa in the United States, including in New Jersey.

Mylan Inc. and Mylan Institutional, Inc.

9. Upon information and belief, Mylan Inc. is a corporation organized under Pennsylvania law. Its principal place of business is Canonsburg, Pennsylvania.

10. Upon information and belief, Mylan Institutional Inc. is a corporation organized under Illinois law. Its principal place of business is Rockford, Illinois.

11. Upon information and belief, Mylan Institutional Inc. is a wholly-owned subsidiary of Mylan Inc. (collectively, "Mylan").

12. Upon information and belief, Mylan is a U.S. sales agent and distributor for Strides, with respect to at least the generic version of Zometa that is the subject of ANDA No. 202650. Upon information and belief, the FDA has approved ANDA No. 202650, and Mylan has started selling a generic version of Zometa in the United States, including in New Jersey.

JURISDICTION AND VENUE

13. 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).

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

15. 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 a generic version of Zometa;

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

c) Defendant Amneal has its principal place of business in New Jersey; and

d) Defendant Mylan 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.

STATEMENT OF FACTS

A. Novartis's Branded Products

16. 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.

17. 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.

B. The Patents-In-Suit

18. 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.

19. 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 each of the patents.

C. The ANDA Process

20. 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.

21. 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.

22. 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.

D. The Generics' ANDA Products

23. As noted above, Defendants sell and/or distribute a generic version of Zometa pursuant to an ANDA that has been approved by the FDA.

24. Upon information and belief, Defendants Amneal and Mylan are U.S. sales agents and distributors for Strides with respect to at least the generic version of Zometa that is the subject of ANDA No. 202650.

25. Strides notified Novartis by letter that it had submitted to the FDA ANDA No. 202650 for a generic version of Zometa. Strides stated that ANDA No. 202650 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. Novartis brought suit against Strides 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 No. 202650, and Amneal and Mylan have started selling generic versions of Zometa in the United States pursuant to that ANDA.

COUNT I (INFRINGEMENT OF THE '189 PATENT)

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

28. The use of Defendants Amneal's and Mylans's generic Zometa products is covered by one or more claims of the '189 patent.

29. Upon information and belief, Defendants Amneal and Mylan knew of the '189 patent when they first manufactured, used, offered to sell, and/or sold their respective generic Zometa products, and know or are willfully blind to the fact that their actions will induce or contribute to direct infringement of the '189 patent.

30. Use of Defendants Amneal's and Mylan's generic Zometa products in accordance with and as directed by Defendants Amneal's and Mylan's labeling for those products infringes and/or would infringe one or more claims of the '189 patent.

31. Upon information and belief, Defendants Amneal and Mylan manufacture, use, offer for sale, sell, and/or import their respective generic Zometa products with labeling that instructs infringement of the '189 patent.

32. Upon information and belief, Defendants Amneal and Mylan actively induce and/or will induce infringement of the '189 patent in violation of 35 U.S.C. § 271(b) by their manufacture, use, offer for sale, sale, and/or importation of their respective generic Zometa products.

33. Upon information and belief, Defendants Amneal and Mylan know that their generic Zometa products and the labeling for those products are especially made or adapted for use in infringing the '189 patent, and that their generic Zometa products and the respective labeling for those products are not suitable for substantial noninfringing use.

34. Upon information and belief, Defendants Amneal and Mylan plan and intend to, and do and/or will contribute to the infringement of the '189 patent in violation of 35 U.S.C. § 271(c) by their manufacture, use, offer for sale, sale, and/or importation of their respective generic Zometa products.

35. There is an actual and justiciable case or controversy between Novartis and Defendants Amneal and Mylan concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendants Amneal's and Mylan's manufacture, use, sale, offer for sale, and/or importation of their generic Zometa products 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.

36. If Defendants Amneal and Mylan infringement of the '189 patent is not enjoined Novartis will suffer irreparable injury for which there 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 '189 patent;

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 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;

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 Zometa 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;

4. Declaring that Defendants engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Zometa have willfully infringed the claims of the '189 patent nd 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
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, Novartis Corporation, and Novartis AG

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street

New York, NY 10007
(212) 230-8800

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

Amanda L. Major
Tracey C. Allen
Rachel Weiner Cohen
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
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 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
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
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HALE AND DORR LLP

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Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
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Washington, DC 20006
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