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

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, and NOVARTIS AG Plaintiffs, v. WOCKHARDT USA LLC and WOCKHARDT LIMITED Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis Corporation, and Novartis AG (collectively, "Novartis"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Application ("ANDA") Nos. 203070 and 203989 filed by Wockhardt USA LLC with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of Novartis's Reclast® (ANDA No. 203070) and Zometa® (ANDA No. 203989) drug products, prior to expiration of U.S. Patent Nos. 7,932,241 ("the '241 patent") and 8,052,987 ("the '987 patent").

PARTIES

2. Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey.

3. Novartis Corporation is a corporation existing under the laws of the State of New York, with its principal place of business at 608 5th Avenue, New York, New York.

4. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Upon information and belief, Wockhardt USA LLC is a corporation organized and existing under the laws of Delaware, having its principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey.

6. Upon information and belief, Wockhardt USA LLC is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district.

7. Upon information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Limited and is controlled and/or dominated by Wockhardt Limited at

the direction, under the control, and for the benefit of Wockhardt Limited. Upon information and belief, Wockhardt Limited established Wockhardt USA LLC for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

8. Upon information and belief, Wockhardt Limited is a corporation organized and existing under the laws of India, having its principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, India.

9. Upon information and belief, Wockhardt Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district, through various directly or indirectly owned operating subsidiaries, including Wockhardt USA LLC.

10. Upon information and belief, Wockhardt USA LLC and Wockhardt Limited act in concert with one another and hold themselves out as an integrated unit for purposes of developing, manufacturing, distributing, marketing, and selling generic drug products throughout the United States, including in this judicial district. For example, in Wockhardt Limited's 2010-11 Annual Report, Wockhardt Limited lists Wockhardt USA LLC as one of its "International Offices." (*See* Annual Report, available at http://www.wockhardt.com/pdf/Annual-Report-2010-11-53a4d.pdf (last accessed June 14, 2012).

11. Upon information and belief, Wockhardt USA LLC and Wockhardt Limited acted collaboratively and in concert in the preparation and submission of ANDA Nos. 203070 and 203989.

12. Upon information and belief, and consistent with past practices, Wockhardt Limited's preparation and submission of ANDA No. 203070 was done with the assistance of, and in concert with, Wockhardt USA LLC.

13. Upon information and belief, Wockhardt USA LLC's preparation and submission of ANDA Nos. 203070 and 203989 was done at the direction, under the control, and for the direct benefit of, and in concert with, Wockhardt Limited.

14. Upon information and belief, following any FDA approval of ANDA Nos. 203070 and 203989, Wockhardt Limited and Wockhardt USA LLC will act in concert with one another, and with other Wockhardt Limited subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA Nos. 203070 and 203989 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

15. Wockhardt USA LLC and Wockhardt Limited are collectively referred to hereafter as "Wockhardt."

JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

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

18. This Court has personal jurisdiction over Wockhardt USA LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in Piscataway, New Jersey.

19. This Court also has personal jurisdiction over Wockhardt USA LLC because, among other things, it has committed, or aided, abetted, contributed to, or participated

in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

20. This Court also has personal jurisdiction over Wockhardt USA LLC because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt USA LLC derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt USA LLC has persistent, systematic and continuous contacts with New Jersey and has therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

21. This Court also has personal jurisdiction over Wockhardt USA LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (*e.g.*, *Aventis Pharms. Inc. v. Wockhardt Limited*., C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis U.S. LLC v. Wockhardt Limited*., C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*,C.A. No. 11-1997, Defendants Wockhardt USA LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

22. This Court has personal jurisdiction over Wockhardt Limited because, among other things, it has committed, or aided, abetted, contributed to, or participated in the

commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

23. This Court also has personal jurisdiction over Wockhardt Limited because, among other things, as described above it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt Limited derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt Limited has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

24. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal places of business in New Jersey (*i.e.*, Wockhardt USA LLC).

25. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (*e.g.*, *Aventis Pharms. Inc. v. Wockhardt Limited*., C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis U.S. LLC v. Wockhardt Limited*., C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*,C.A. No. 11-1997, Defendants Wockhardt USA LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

26. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over both Wockhardt USA LLC and Wockhardt Limited.

PATENT IN SUIT

27. On April 26, 2011, the U.S. Patent and Trademark Office duly and legally issued the '241 patent, entitled "Pharmaceutical Products Comprising Bisphosphonates." A true and correct copy of the '241 patent is attached hereto as **Exhibit 1**. Novartis is the owner of the '241 patent by assignment, with the right to sue for and obtain equitable relief and damages for infringement of the '241 patent.

28. On November 8, 2011, the U.S. Patent and Trademark Office duly and legally issued the '987 patent, entitled "Method of Administering Bisphosphonates." A true and correct copy of the '987 patent is attached hereto as **Exhibit 2**. Novartis is the owner of the '987 patent by assignment, with the right to sue for and obtain equitable relief and damages for infringement of the '987 patent.

29. NPC is the holder of New Drug Application ("NDA") Nos. 21-817 and 22-080 by which the FDA granted approval for the marketing and sale of the equivalent of a 5 mg/ 100 mL dosage strength of zoledronic acid, which NPC markets in the United States under the trade name "Reclast®." Reclast® is covered by claims of the '241 and '987 patent. The FDA's official publication of approved drugs (the "Orange Book") includes Reclast® together with the '241 patent and the '987 patent.

30. NPC is the holder of NDA Nos. 21-223 and 21-386 by which the FDA granted approval for the marketing and sale of the equivalent of a 4 mg/ 100 mL dosage strength of zoledronic acid, which NPC markets in the United States under the trade name "Zometa®."

Zometa® is covered by claims of the '241 patent. The FDA's official publication of approved drugs (the "Orange Book") includes Zometa® together with the '241 patent.

INFRINGEMENT BY WOCKHARDT

ANDA No. 203070

31. By letter dated July 25, 2011, ("the First Notice Letter"), Wockhardt notified Novartis that Wockhardt had submitted ANDA No. 203070 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of a zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient before the expiration of the '241 patent. Upon information and belief, Wockhardt intends to engage in the commercial manufacture, use, and sale of its zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient promptly upon receiving FDA approval to do so.

32. By filing ANDA No. 203070, Wockhardt has necessarily represented to the FDA that its zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid has the same active ingredient as Reclast®, has the same method of administration, dosage form, and strengths as Reclast®, and is bioequivalent to Reclast®.

33. In the First Notice Letter, Wockhardt notified Novartis that its ANDA No. 203070 contained a "Paragraph IV certification" asserting that the '241 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Wockhardt's zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid (generic Reclast®).

34. By letter dated January 13, 2012, ("the Second Notice Letter"), Wockhardt notified Novartis that its ANDA No. 203070 contained a "Paragraph IV certification" asserting

that the '987 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Wockhardt's zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid (generic Reclast®).

ANDA No. 203989

35. By letter dated May 14, 2012, ("the Third Notice Letter"), Wockhardt notified Novartis that Wockhardt had submitted ANDA No. 203989 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of a zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient before the expiration of the '241 patent. Upon information and belief, Wockhardt intends to engage in the commercial manufacture, use, and sale of its zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient promptly upon receiving FDA approval to do so.

36. By filing ANDA No. 203989, Wockhardt has necessarily represented to the FDA that its zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid has the same active ingredient as Zometa®, has the same method of administration, dosage form, and strengths as Zometa®, and is bioequivalent to Zometa®.

37. In the Notice Letter, Wockhardt notified Novartis that its ANDA contained a "Paragraph IV certification" asserting that the '241 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Wockhardt's zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid.

38. This Complaint is being filed before the expiration of the forty-five days from the date Novartis received the Third Notice Letter.

COUNT I (INFRINGEMENT OF THE '241 PATENT)

39. Each of the preceding paragraphs 1 to 38 is incorporated as if fully set forth herein.

40. Wockhardt's submissions of ANDA Nos. 203070 and 203989 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100mL of zoledronic acid as the active ingredient prior to the expiration of the '241 patent constitutes infringement of one or more of the claims of the '241 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon FDA approval of Wockhardt's ANDA Nos. 203070 and 203989, and unless enjoined by the Court, Wockhardt will further infringe the '241 patent by making, using, offering to sell, and selling its zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100 mL of zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

42. Upon information and belief, Wockhardt had actual and constructive knowledge of the '241 patent prior to filing ANDA Nos. 203070 and 203989 and was aware that filing of these ANDAs, with the aforementioned Paragraph IV certifications, constituted an act of infringement of the '241 patent.

43. If Wockhardt's infringement of the '241 patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '987 PATENT)

44. Each of the preceding paragraphs 1 to 43 is incorporated as if fully set forth.

45. Wockhardt's submission of ANDA No. 203070 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of a zoledronic acid solution containing the equivalent of 5 mg/ 100mL of zoledronic acid as the active ingredient prior to the expiration of the '987 patent constitutes infringement of one or more of the claims of the '987 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon FDA approval of Wockhardt's ANDA No. 203070, and unless enjoined by the Court, Wockhardt will further infringe the '987 patent by making, using, offering to sell, and selling its zoledronic acid solutions containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

47. Upon information and belief, Wockhardt had actual and constructive knowledge of the '987 patent prior to filing ANDA No. 203070 and was aware that filing of this ANDA, with the aforementioned Paragraph IV certification, constituted an act of infringement of the '987 patent.

48. If Wockhardt's infringement of the '987 patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more valid, enforceable claims of the '241 patent are infringed by Wockhardt's submissions of ANDA Nos. 203070 and 203989, and that Wockhardt's making, using, offering to sell, or selling in the United States, or importing into the United States Wockhardt's zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100 mL of zoledronic acid as the active ingredient will infringe the '241 patent.

2. A judgment that one or more valid, enforceable claims of the ’987 patent are valid, enforceable and infringed by Wockhardt’s submission of ANDA No. 203070, and that Wockhardt’s making, using, offering to sell, or selling in the United States, or importing into the United States Wockhardt’s zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient will infringe the ‘987 patent.

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA Nos. 203070 or 203989 shall be a date which is not earlier than the latest expiration date of the ‘241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 203070 shall be a date which is not earlier than the latest expiration date of the ‘987 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. An order permanently enjoining Wockhardt, its affiliates, subsidiaries, and each of its 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 Wockhardt’s zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient until after the latest expiration date of the ‘241 patent and/or the ‘987 patent (whichever is latest), including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

6. An order permanently enjoining Wockhardt, its affiliates, subsidiaries, and each of its 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 Wockhardt's zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient until after the latest expiration date of the '241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

7. Damages or other monetary relief to Novartis if Wockhardt engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Wockhardt's zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient prior to the latest expiration date of the '241 patent and/or the '987 patent (whichever is latest), including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

8. Damages or other monetary relief to Novartis if Wockhardt engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Wockhardt's zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient prior to the latest expiration date of the '241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

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

DATED: June 27, 2012

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 not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

Dated: June 27, 2012

Respectfully Submitted,

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