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Warner Chilcott Company, LLC
and Warner Chilcott (US), LLC.

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

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. – FLORIDA, and WATSON PHARMA, INC. Defendants.	CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC, by their undersigned attorneys, bring this action against Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. – Florida, and Watson Pharma, Inc. (collectively "Watson"), and hereby allege as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("WCCL"), is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union Street, Road 195, Km. 1.1, Fajardo, Puerto Rico.

2. Plaintiff Warner Chilcott (US), LLC ("WCUS") is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866. WCCL and WCUS hereinafter are referred to collectively as "Warner Chilcott."

3. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida ("Watson Labs") is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314.

4. Upon information and belief, Watson Labs is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

5. Upon information and belief, Defendant Watson Pharma, Inc. ("Watson Pharma") is a Delaware corporation having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, Watson Pharma is in the business of, among other things, distributing and selling generic copies of branded pharmaceutical products for the U.S. market, including on behalf of Watson Labs.

7. Upon information and belief, Defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a Nevada corporation having it headquarters at 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. Upon information and belief, Watson Pharmaceuticals develops, manufactures and/or markets pharmaceutical products throughout the United States, including in this judicial district, through its own actions and through the actions of its agents and operating subsidiaries, including Watson Labs and Watson Pharma.

9. Upon information and belief, Watson Labs was formerly known as Andrx Pharmaceuticals, Inc. Watson Labs is a wholly-owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly-owned subsidiary of Watson Pharmaceuticals.

10. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

JURISDICTION AND VENUE

11. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Upon information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Labs and Watson Pharma because, *inter alia,* they have committed, aided, abetted, actively induced, contributed to or participated in the commission of a tortious act of patent infringement leading to foreseeable harm and injury to Warner Chilcott, namely, the

submission to the U.S. Food and Drug Administration ("FDA") of the Abbreviated New Drug Application ("ANDA") at issue in this case.

13. Upon information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Labs and Watson Pharma because, *inter alia,* they have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma have had persistent, continuous and systematic contacts with this judicial district, including, *inter alia,* maintaining executive offices in New Jersey and, either directly or through an agent, deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey.

14. Upon information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma share certain common employees, officers and directors.

15. Upon information and belief, each of Watson Pharmaceuticals, Watson Labs and Watson Pharma operates in whole or in part from a shared location at 400 Interpace Parkway, Parsippany, New Jersey 07054.

16. Upon information and belief, Watson Pharmaceuticals organizes its operations by division, including at least the Generic, Brand and Distribution divisions, and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions.

17. Upon information and belief, Watson's Generic division, which develops, manufactures, markets and sells generic copies of branded pharmaceutical products for the U.S. market, relies on the respective coordinated contributions of at least Watson Pharmaceuticals, Watson Labs and Watson Pharma.

18. Upon information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic division.

19. Upon information and belief, Watson Pharmaceuticals has consolidated its activities and financial results, including revenue earned, with, *inter alia,* Watson Labs and Watson Pharma in its most recent SEC filings and Annual Report.

20. Upon information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and Watson Labs, distributes and sells in New Jersey and elsewhere in the United States, various generic pharmaceutical products that are manufactured by Watson Labs or for which Watson Labs is the named applicant on approved ANDAs. Upon information and belief, Watson Pharma and Watson Labs are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products.

21. Watson Pharmaceuticals, Watson Labs and Watson Pharma are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products, including the generic risedronate sodium delayed release tablets described in ANDA No. 20-3090 ("Watson's ANDA product"). The Defendants, as part of Watson Pharmaceutical's Generic division, will collaborate in the manufacture, marketing, and/or sale of Watson's ANDA product, including in the state of New Jersey, should FDA approval be granted.

22. If ANDA No. 20-3090 is approved, Watson's ANDA product which is charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey.

23. Accordingly, this Court has personal jurisdiction over the Defendants because they, either directly or through an agent, including each other, regularly do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and derive substantial revenue from services, or things used or consumed in New Jersey.

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

BACKGROUND

25. Warner Chilcott is the holder of New Drug Application ("NDA") No. 22-560, which relates to delayed release oral tablets with 35 mg of the active ingredient risedronate sodium. These tablets were approved by the FDA on October 8, 2010. The tablets are sold under the trademark Atelvia™ and are indicated for the treatment of osteoporosis in post-menopausal women.

26. U. S. Patent No. 7,645,459 ("the '459 patent") entitled "Dosage Forms of Bisphosphonates" lawfully issued from the United States Patent and Trademark Office ("PTO") on January 12, 2010. A copy of the '459 patent is attached as Exhibit A.

27. U. S. Patent No. 7,645,460 ("the '460 patent") entitled "Dosage Forms of Risedronate" lawfully issued from the United States Patent and Trademark Office ("PTO") on January 12, 2010. A copy of the '460 patent is attached as Exhibit B.

28. Warner Chilcott Company, LLC owns the '459 and '460 patents.

29. The '459 and the '460 patents cover the use of Atelvia™ in accordance with the labeling approved by the FDA and have been listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

30. Upon information and belief, Watson Labs, jointly with, and/or as the agent of, Watson Pharmaceuticals and Watson Pharma, submitted Watson's ANDA to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of a generic version of Atelvia™ prior to the expiration of the '459 and '460 patents.

COUNT I
CLAIM FOR INFRINGEMENT OF THE '459 PATENT

31. Paragraphs 1 through 30 are repeated.

32. Upon information and belief, Watson's ANDA No. 20-3090 included a certification with respect to the '459 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '459 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Watson's ANDA product.

33. Upon information and belief, Watson Labs sent notice of that certification to Warner Chilcott on or about August 29, 2011. Warner Chilcott received that notification on or about August 30, 2011.

34. Because Watson's ANDA was submitted under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '459 patent before its expiration, Watson Labs, jointly with, and/or as the agent of Watson Pharmaceuticals and Watson Pharma, has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, Watson Pharmaceuticals and Watson Pharma will be involved in the manufacturing, marketing, distribution, and sale of Watson's ANDA product, should Watson's ANDA be approved, and thus are considered to have submitted the ANDA with Watson Labs.

36. Watson Labs was acting jointly with its co-defendants and/or acting as the agent of its co-defendants when it submitted Watson's ANDA to the FDA. By acting jointly with Watson Labs to submit the application, and/or causing their agent to submit the application, Watson Pharmaceuticals and Watson Pharma committed an act of infringement with respect to the '459 patent under 35 U.S.C. § 271(e)(2)(A).

37. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '459 patent will infringe one or more claims of the '459 patent. Upon approval of Watson's ANDA, Watson Pharmaceuticals and Watson Pharma will be involved in the marketing and sales of the Watson ANDA product and will actively induce and/or contribute to infringement of the '459 patent.

38. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration date of the '459 patent, or any later expiration of exclusivity for the '459 patent to which Warner Chilcott is or becomes entitled.

39. Watson's certification to the FDA that the '459 patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285. Warner Chilcott is entitled to its costs and reasonable attorney fees.

COUNT II
CLAIM FOR INFRINGEMENT OF THE '460 PATENT

40. Paragraphs 1 through 30 are repeated.

41. Upon information and belief, Watson's ANDA No. 20-3090 included a certification with respect to the '460 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '460 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Watson's ANDA product.

42. Upon information and belief, Watson Labs sent notice of that certification to Warner Chilcott on or about August 29, 2011. Warner Chilcott received that notification on or about August 30, 2011.

43. Because Watson's ANDA was submitted under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '460 patent before its expiration, Watson Labs, jointly with, and/or as the agent of Watson Pharmaceuticals and Watson Pharma, has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, Watson Pharmaceuticals and Watson Pharma will be involved in the manufacturing, marketing, distribution, and sale of Watson's ANDA product, should Watson's ANDA be approved, and thus are considered to have submitted the ANDA with Watson Labs.

45. Watson Labs was acting jointly with its co-defendants and/or acting as the agent of its co-defendants when it submitted Watson's ANDA to the FDA. By acting jointly with Watson Labs to submit the application, and/or causing their agent to submit the application, Watson Pharmaceuticals and Watson Pharma committed an act of infringement with respect to the '460 patent under 35 U.S.C. § 271(e)(2)(A).

46. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '460 patent will infringe one or more claims of the '460 patent. Upon approval of Watson's ANDA, Watson Pharmaceuticals and Watson Pharma will be involved in the marketing and sales of the Watson ANDA product and will actively induce and/or contribute to infringement of the '460 patent.

47. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration date of the '460 patent, or any later expiration of exclusivity for the '460 patent to which Warner Chilcott is or becomes entitled.

48. Watson's certification to the FDA that the '460 patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285. Warner Chilcott is entitled to its costs and reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) Judgment that each of the Defendants has infringed one or more claims of the '459 patent by submitting ANDA No. 20-3090.

(b) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '459 patent;

(c) Judgment that each of the Defendants has infringed one or more claims of the '460 patent by submitting ANDA No. 20-3090.

(d) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in

the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '460 Patent;

(e) An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 20-3090 be a date that is not earlier than the expiration of the '459 and '460 patents, or any later expiration of exclusivity for the '459 and '460 patents to which Plaintiffs are or become entitled; and

(f) Declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285.

(g) Such other and further relief as the Court may deem just and proper.

Dated: October 12, 2011

Respectfully submitted,

s/ William J. O'Shaughnessy
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that 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: October 12, 2011

Respectfully submitted,

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