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

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WARNER CHILCOTT COMPANY, LLC and )  
WARNER CHILCOTT (US), LLC )  
 )  
Plaintiffs, )  
 )  
v. )  
 )  
WATSON LABORATORIES, INC. – FLORIDA )  
 )  
Defendant. )  

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Civil Action No. 11-5989 (FSH/PS)

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC, by their undersigned attorneys, bring this action against Defendant Watson Laboratories, Inc. – Florida, 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”) is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314.

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

5. Warner Chilcott filed this action against Watson Pharmaceuticals, Inc., Watson Pharma, Inc. and Watson on October 12, 2011. (D.I. 1). Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. agreed, *inter alia*, to be bound by any judgment, order or decision rendered in this action as to Watson as if they were named defendants in the stipulated dismissal ordered by the Court on December 21, 2011. (D.I. 13).

### **JURISDICTION AND VENUE**

6. 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).

7. Upon information and belief, this Court has personal jurisdiction over Watson because, *inter alia*, it has 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.

8. Upon information and belief, this Court has personal jurisdiction over Watson because, *inter alia*, it has purposefully availed itself of the benefits and protections of New Jersey’s laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Watson has 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.

9. 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.

10. Watson has consented to personal jurisdiction in this action. (D.I. 13).

11. Accordingly, this Court has personal jurisdiction over the Defendant because it, either directly or through an agent, regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and derives substantial revenue from services, or things used or consumed in New Jersey.

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

### **BACKGROUND**

13. 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<sup>®</sup> and are indicated for the treatment of osteoporosis in post-menopausal women.

14. 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.

15. 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.

16. U.S. Patent No. 8,246,989 (“the ’989 patent”) entitled “Dosage Forms of Bisphosphonates” lawfully issued from the United States Patent and Trademark Office (“PTO”) on August 21, 2012. A copy of the ’989 patent is attached as Exhibit C.

17. Warner Chilcott Company, LLC owns the ’459, ’460 and ’989 patents.

18. The ’459, ’460 and ’989 patents cover the use of Atelvia<sup>®</sup> 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.

19. Upon information and belief, Watson 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<sup>®</sup> prior to the expiration of the '459, '460 and '989 patents.

**COUNT I**  
**CLAIM FOR INFRINGEMENT OF THE '459 PATENT**

20. Paragraphs 1 through 19 are repeated.

21. 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.

22. Upon information and belief, Watson 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.

23. 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 has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

24. 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 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.

25. 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.

26. 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**

27. Paragraphs 1 through 19 are repeated.

28. 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.

29. Upon information and belief, Watson 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.

30. 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 has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

31. 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 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.

32. 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.

33. 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.

**COUNT III**  
**CLAIM FOR INFRINGEMENT OF THE '989 PATENT**

34. Paragraphs 1 through 19 are repeated.

35. Upon information and belief, 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 '989 patent before its expiration, and therefore Watson has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

36. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '989 patent will infringe one or more claims of the '989 patent. Upon approval of Watson's ANDA, Watson will be involved in the marketing and sales of the Watson ANDA product and will actively induce and/or contribute to infringement of the '989 patent.

37. 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 '989 patent, or any later expiration of exclusivity for the '989 patent to which Warner Chilcott is or becomes entitled.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) Judgment that the Defendant 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 Defendant, its 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 the Defendant 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 Defendant, its 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) Judgment that the Defendant has infringed one or more claims of the '989 patent by submitting ANDA No. 20-3090.

(f) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendant, its 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 '989 patent;

(g) 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, '460 and '989 patents, or any later expiration of exclusivity for the '459, '460 and '989 patents to which Plaintiffs are or become entitled; and

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

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

Dated: September 11, 2012

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 the subject of WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC v. TEVA PHARMACEUTICALS USA, INC., Civil Action 2:11-CV-06936-FSH-PS (D.N.J.) (the “Teva case”) and WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC v. RANBAXY, INC. and RANBAXY LABORATORIES LTD., Civil Action 2:12-CV-02474-FSH-PS (D.N.J.) (the “Ranbaxy case”). The Teva case and the Ranbaxy case involve the same patents and the same product as the matter in controversy and have been consolidated for pre-trial purposes.

Dated: September 11, 2012

Respectfully submitted,

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