William J. O'Shaughnessy
Ravin R. Patel
McCarter & English LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444
Facsimile: (973) 624-7070

Attorneys for Plaintiffs
Warner Chilcott Company, LLC
and Warner Chilcott (US), LLC.

OF COUNSEL:
Dominick A. Conde
Steven C. Kline
Gregory B. Sephton
Joshua A. Davis
Fitzpatrick, Cella,
Harper & Scinto
1290 Avenue of the Americas
New York, New York 10104
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

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

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, Plaintiffs, v. IMPAX LABORATORIES, INC. Defendant.	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 Defendant Impax Laboratories, Inc. ("Impax"), 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 Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

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

JURISDICTION AND VENUE

5. 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).

6. Upon information and belief, this Court has personal jurisdiction over Impax 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.

7. Upon information and belief, this Court has personal jurisdiction over Impax 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, Impax has had persistent, continuous and systematic contacts with this judicial district, 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. In fact, Impax has filed at least one complaint in this Court, Civil Action No. 10-6554, and Impax has consented to personal jurisdiction in this Court in other patent cases, Civil Action Nos. 09-1233; 10-4270; 11-3130; and 12-2154. Thus, Impax is subject to general jurisdiction in New Jersey.

8. Upon information and belief, Impax is registered with the New Jersey Department of Health and Senior Services as a "Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business" pursuant to N.J.S.A. 24:6B.

9. If ANDA No. 205066 is approved, Impax'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. 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.

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

BACKGROUND

12. 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.

13. 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.

14. 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.

15. 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.

16. Warner Chilcott Company, LLC owns the '459, '460 and '989 patents.

17. The '459, '460 and '989 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.

18. Upon information and belief, Impax submitted Impax'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, '460 and '989 patents.

COUNT I
CLAIM FOR INFRINGEMENT OF THE '459 PATENT

19. Paragraphs 1 through 18 are repeated.

20. Upon information and belief, Impax's ANDA No. 205066 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 Impax's ANDA product.

21. Upon information and belief, Impax sent notice of that certification to Warner Chilcott on or about September 10, 2013. Warner Chilcott received that notification on or about September 11, 2013.

22. Because Impax'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, Impax has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

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

24. 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 Impax'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.

25. Impax’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

26. Paragraphs 1 through 18 are repeated.

27. Upon information and belief, Impax’s ANDA No. 205066 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 Impax’s ANDA product.

28. Upon information and belief, Impax sent notice of that certification to Warner Chilcott on or about September 10, 2013. Warner Chilcott received that notification on or about September 11, 2013.

29. Because Impax’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, Impax has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

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

31. 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 Impax'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.

32. Impax'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

33. Paragraphs 1 through 18 are repeated.

34. Upon information and belief, Impax's ANDA No. 205066 included a certification with respect to the '989 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '989 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Impax's ANDA product.

35. Upon information and belief, Impax sent notice of that certification to Warner Chilcott on or about September 10, 2013. Warner Chilcott received that notification on or about September 11, 2013.

36. Because Impax'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, Impax has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

37. The commercial manufacture, use, offer for sale, sale and/or importation of Impax's ANDA product before the expiration of the '989 patent will infringe one or more claims of the '989 patent. Upon approval of Impax's ANDA, Impax will be involved in the marketing

and sales of the Impax ANDA product and will actively induce and/or contribute to infringement of the ’989 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 Impax’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.

39. Impax’s certification to the FDA that the ’989 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 the Defendant has infringed one or more claims of the ’459 patent by submitting ANDA No. 205066;

(b) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendant, 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 the Defendant has infringed one or more claims of the ’460 patent by submitting ANDA No. 205066;

(d) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendant, 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) Judgment that the Defendant has infringed one or more claims of the '989 patent by submitting ANDA No. 205066;

(f) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendant, 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 '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. 205066 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;

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

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

Dated: October 23, 2013

Respectfully submitted,

s/ William J. O'Shaughnessy

William J. O'Shaughnessy
Ravin R. Patel
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444

Dominick A. Conde
Steven C. Kline
Gregory B. Sephton
Joshua A. Davis
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas

New York, New York 10104
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Facsimile: (973) 624-7070

Attorneys for Plaintiffs
Warner Chilcott Company, LLC
and Warner Chilcott (US), LLC

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. WATSON LABORATORIES, INC. – FLORIDA, Civil Action 2:11−CV−05989−FSH−JBC (D.N.J.) (the "Watson case"), WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC v. TEVA PHARMACEUTICALS USA, INC., Civil Action 2:11−CV−06936−FSH−JBC (D.N.J.) (the "Teva case"), and WARNER CHILCOTT COMPANY, INC. and WARNER CHILCOTT (US), LLC v. RANBAXY, INC. and RANBAXY LABORATORIES LTD., Civil Action 2:12-CV-02474-FSH-JBC (D.N.J.) (the "Ranbaxy case"). The Watson 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: October 23, 2013

Respectfully submitted,

s/ William J. O'Shaughnessy

William J. O'Shaughnessy
Ravin R. Patel
McCarter & English LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444
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Dominick A. Conde
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Joshua A. Davis
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue of the Americas
New York, New York 10104
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC