IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	C. A. No. 14-_____

COMPLAINT FOR PATENT INFRINGEMENT

For their complaint herein, Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively, "Warner Chilcott" or "Plaintiffs") allege as follows:

PARTIES

1. Plaintiff Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of Puerto Rico, having a place of business at Union Street, Road 195 KM 1.1, Fajardo, Puerto Rico, 00738.

2. Plaintiff Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 100 Enterprise Drive, Rockaway, New Jersey, 07866.

3. On information and belief, Defendant Apotex Inc. is incorporated under the laws of Canada with a principal place of business at 150 Signet Dr., Toronto, Ontario M9L IT9, Canada.

4. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

5. On information and belief, Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants") sell numerous generic drugs throughout the United States, including in this judicial district.

6. On information and belief, Apotex Inc. and Apotex Corp. acted in concert to perform the acts complained of herein.

7. On information and belief, to the extent any act complained of herein was done only by Apotex Inc., it was done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Corp.

8. On information and belief, to the extent any act complained of herein was done only by Apotex Corp., it was done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Inc.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

10. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each of the Defendants has individually and jointly committed, or aided, abetted, contributed to, participated in, and/or acted in concert in the commission of the tortious act of patent infringement as set forth herein. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. On information and belief, Defendants are in the business of formulating, manufacturing, and commercializing pharmaceutical products and, either directly or through one or more of their wholly-owned subsidiaries, agents, distributors, or affiliated companies,

marketing, selling, and/or distributing pharmaceutical products throughout the United States, including in this judicial district.

12. On information and belief, Defendants collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

13. On information and belief, Defendants acted in concert to develop Apotex Inc.'s generic copies of Plaintiffs' Enablex® tablets as set forth and described in Abbreviated New Drug Application ("ANDA") No. 206313 at issue in this litigation, and to seek approval from the FDA to sell said products throughout the United States including in this judicial district.

14. On information and belief, Defendants acted in concert to submit ANDA No. 206313 to the United States Food and Drug Administration ("FDA"). On information and belief, Defendants acted in concert in the preparation and filing of Apotex Inc.'s ANDA No. 206313.

15. This Court has personal jurisdiction over Apotex Corp. also by virtue of, *inter alia*, the fact that it is a corporation organized and existing under the laws of Delaware, and has systematic and continuous contacts with the State of Delaware, including sales in this judicial district and being registered to do business in the State of Delaware.

16. In addition, Defendants have previously submitted to the jurisdiction of this Court and, *inter alia*, asserted counterclaims in other civil actions initiated in this jurisdiction, without challenging personal jurisdiction.

ACTS GIVING RISE TO THIS ACTION

17. On August 22, 2000, the United States Patent and Trademark Office duly and lawfully issued United States Patent No. 6,106,864 ("the '864 patent"), entitled "Pharmaceutical Formulations Containing Darifenacin." The named inventors of the '864 patent are Thomas Dolan, Michael Humphrey, and Donald Nichols. Warner Chilcott Company, LLC is the owner

of all right, title, and interest in and to the ’864 patent. A true and correct copy of the ’864 patent is attached as Exhibit A.

18. Warner Chilcott Company, LLC is the holder of, and Warner Chilcott (US), LLC is the United States correspondent and regulatory affairs agent regarding, New Drug Application (“NDA”) No. 021-513 for Enablex® tablets. The Enablex® 7.5mg and 15mg extended release darifenacin hydrobromide tablets are indicated as a treatment for overactive bladder. The FDA first granted approval of the NDA on December 22, 2004. Warner Chilcott markets these tablets in the United States under the tradename “Enablex®.”

19. The ’864 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the “Orange Book”) for Enablex® tablets, 7.5mg and 15mg equivalent to darifenacin base dosage forms.

20. Upon information and belief, Defendants acted in concert to submit to the FDA ANDA No. 206313, which included a certification with respect to the ’864 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to manufacture, use, offer to sell, sell and/or import darifenacin hydrobromide, tablet, extended release 7.5mg, 15mg equivalent to darifenacin base (“the ANDA Products”), as a generic version of Enablex® prior to the expiration of the ’864 patent.

21. By letter purportedly dated June 19, 2014 (“the Notice Letter”), Apotex Inc. notified Warner Chilcott that it had submitted ANDA No. 206313 to the FDA, which included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’864 patent, seeking approval to engage in the commercial manufacture, offer to sell, sale, and/or import of the ANDA products prior to the expiration of the ’864 patent.

22. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Warner Chilcott's receipt of the Notice Letter.

23. The Notice Letter asserted that Apotex Inc. submitted a Paragraph IV Certification pursuant to Sections 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and that such Certification asserted that the '864 patent is invalid and/or unenforceable and/or contains no claims that would be infringed by the manufacture of the ANDA products.

COUNT I

24. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

25. Upon information and belief, the ANDA Products and their use are the subject of one or more claims of the '864 patent.

26. Upon information and belief, when Defendants acted in concert to file ANDA No. 206313, they were aware of the '864 patent and that the filing of ANDA No. 206313 with the request for approval prior to the expiration of the '864 patent was an act of infringement. Defendants were, individually and jointly, aware of the existence of the '864 patent at least as of the date on which Apotex Inc. sent the Notice Letter.

27. The submission of ANDA No. 206313 for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Products prior to the expiration of the '864 patent, is an act of infringement of the '864 patent pursuant to 35 U.S.C. § 271(e)(2)(A). Upon information and belief, unless enjoined by this Court, upon FDA approval of ANDA No. 206313, Defendants will act in concert to make, use, offer to sell, sell and/or import the ANDA Products in the United States, which would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '864 patent.

28. Upon information and belief, upon FDA approval of ANDA No. 206313, Defendants will act in concert to encourage acts of direct infringement with knowledge of the

’864 patent and knowledge that their acts are encouraging infringement. Upon further information and belief, Defendants will act in concert to induce direct infringement of one or more claims of the ’864 patent at least by resellers, pharmacies, health care professionals and end users of the ANDA Products.

29. Defendants, individually or jointly, have been aware of the existence of the ’864 patent and have no reasonable basis for believing that the commercial manufacture, use, offer for sale, sale and/or importation into the United States of the ANDA Products will not infringe, contribute to the infringement thereof, and/or induce the infringement of the ’864 patent, thus rendering this case “exceptional,” as that term is set forth in 35 U.S.C. § 285.

30. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that judgment be entered in favor of Plaintiffs and against Defendants as follows:

a. Finding that Defendants, through the submission of ANDA No. 206313 with the FDA seeking to market the ANDA products, infringed and/or will infringe the ’864 patent under 35 U.S.C. § 271(e)(2)(A);

b. Restraining and enjoining, preliminarily and permanently, Defendants and their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from infringing, inducing infringement of, and/or contributing to the infringement of any claims of the ’864 patent by making, using, selling, offering for sale and/or importing the ANDA Products in the United States;

c. Ordering pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206313 be a date that is not earlier than the expiration date of the '864 patent, or any later expiration of exclusivity for the '864 patent to which Plaintiffs are or become entitled;

d. Finding that Defendants acts have been and are willful and that this is an exceptional case, and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

e. Awarding such other and further relief as the Court deems just and proper.

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Dated: July 30, 2014

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