

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

WARNER CHILCOTT COMPANY, LLC and  
WARNER CHILCOTT (US), LLC,

Plaintiffs,

v.

TORRENT PHARMACEUTICALS LIMITED  
and TORRENT PHARMA INC.,

Defendants.

C. A. No. \_\_\_\_\_

**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. Upon information and belief, Defendant Torrent Pharmaceuticals Limited (“Torrent Limited”) is a company organized and existing under the laws of India, having its principal place of business at Torrent House, Off Ashram Road, Ahmedabad-380 009, India.

4. Upon information and belief, Defendant Torrent Pharma Inc. (“Torrent Inc.”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan, 49009.

5. On information and belief, Torrent Inc. sells numerous generic drugs, manufactured and supplied by Torrent Limited, throughout the United States, including in this judicial district.

6. On information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Limited (Torrent Inc. and Torrent Limited collectively referred to herein as “Torrent” or “Defendants”).

7. On information and belief, the acts of Torrent Limited complained of herein were 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, Torrent Inc.

8. On information and belief, the acts of Torrent Inc. complained of herein were 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, Torrent Limited.

#### **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, Torrent Inc. and Torrent Limited, has individually and jointly committed, or aided, abetted, contributed to and/or participated 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.

11. On information and belief, Torrent Limited is in the business of formulating, manufacturing, and commercializing pharmaceutical products and either directly or through one or more of its wholly-owned subsidiaries, agents, or distributors, including but not limited to Torrent Inc., marketing, selling, and/or distributing pharmaceutical products throughout the United States, including in this judicial district.

12. On information and belief, Torrent Inc., is a wholly-owned subsidiary of Torrent Limited and is in the business of marketing and selling Torrent generic drugs throughout the United States, including in this judicial district.

13. On information and belief, Torrent Limited and Torrent Inc. collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

14. On information and belief, Torrent Limited and Torrent Inc. acted in concert to develop Torrent's generic copies of Plaintiffs' Enablex® tablets as set forth and described in Abbreviated New Drug Application ("ANDA") No. 205209 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.

15. On information and belief, Torrent Limited through its authorized agent Torrent Inc. submitted ANDA No. 205209 to the United States Food and Drug Administration ("FDA"). On information and belief, Torrent Inc. participated in the preparation and filing of Torrent Limited's ANDA No. 205209 in its own capacity and as Torrent Limited's "U.S. Agent."

16. This Court has personal jurisdiction over Torrent Inc. 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.

17. In addition, Torrent Limited and Torrent Inc. 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**

18. 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.

19. 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®.”

20. 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.

21. Upon information and belief, Torrent submitted to the FDA ANDA No. 205209, 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.

22. By letter purportedly dated October 28, 2013 (“the Notice Letter”), Torrent notified Warner Chilcott that it had submitted ANDA No. 205209 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.

23. 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.

24. The Notice Letter asserted that Torrent Limited 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**

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

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

27. Upon information and belief, when Torrent filed ANDA No. 205209, it was aware of the ‘864 patent and that the filing of its ANDA with the request for approval prior to the expiration of the ‘864 patent was an act of infringement. Torrent was aware of the existence of the ‘864 patent at least as of the date it sent the Notice Letter.

28. Torrent's submission of ANDA No. 205209 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. 205209, Torrent will make, use, offer to sell, sell and/or import Torrent's 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.

29. Upon information and belief, upon FDA approval of ANDA No. 205209, Torrent will encourage acts of direct infringement with knowledge of the '864 patent and knowledge that its acts are encouraging infringement. Upon further information and belief, Torrent will induce direct infringement of one or more claims of the '864 patent at least by resellers, pharmacies, health care professionals and end users of Torrent's ANDA Products.

30. Torrent has been aware of the existence of the '864 patent and has no reasonable basis for believing that the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Torrent's 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.

31. The acts of infringement by Torrent 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 their submission of ANDA No. 205209 with the FDA seeking to market the Torrent 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 Torrent's 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. 205209 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 wilful 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: December 18, 2013

/s/ Steven J. Fineman

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