IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC, and WARNER CHILCOTT (US), LLC,	)	
	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively, "Warner Chilcott" or "Plaintiffs"), by their undersigned attorneys, allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*, arises from Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 206149 with the United States Food and Drug Administration ("FDA"), through which Defendants seek approval to market a generic version of Warner Chilcott's pharmaceutical product, Enablex®, prior to the expiration of United States Patent No. 6,106,864 ("the '864 Patent"). Warner Chilcott seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

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

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

4. Upon information and belief, Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware and has a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey, 08807.

5. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC is a limited liability company organized under the laws of the State of Delaware and has a place of business at 85 Adams Avenue, Hauppauge, New York, 11788. Upon information and belief, Amneal Pharmaceuticals of New York, LLC is a wholly-owned subsidiary of Defendant Amneal Pharmaceuticals LLC.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the ’864 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1338 (action arising under any act of Congress relating to patents).

7. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals LLC because, *inter alia*, the company is a company organized and existing under the laws of the State of Delaware.

8. Upon information and belief, Amneal Pharmaceuticals LLC manufactures, imports, distributes, markets, and sells pharmaceutical drug products, including generic drug products, for sale and use throughout the United States and in this judicial district, including through its subsidiary and agent Amneal Pharmaceuticals of New York, LLC.

9. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC because, *inter alia*, the company is a company organized and existing under the laws of the State of Delaware.

10. Upon information and belief, Amneal Pharmaceuticals of New York, LLC manufactures, imports, distributes, markets, and sells pharmaceutical drug products, including generic drug products, for sale and use throughout the United States and in this judicial district, at the direction and under control of its parent company Amneal Pharmaceuticals LLC.

11. Upon information and belief, Defendant Amneal Pharmaceuticals LLC manages and controls the day-to-day operations and business of its wholly-owned subsidiary Amneal Pharmaceuticals of New York, LLC, including with respect to the development of generic drug products and the preparation and submission of ANDAs. Upon further information and belief, Amneal Pharmaceuticals of New York, LLC submitted ANDA No. 206149 to FDA at the direction and under control of its parent Amneal Pharmaceuticals LLC.

12. Upon information and belief, Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal" or "Defendants") hold themselves out as a unitary entity with respect to the regulatory approval, manufacturing, importing,

marketing, distribution, and sale of generic pharmaceutical products throughout the United States, including in this judicial district. For example, upon information and belief, Defendants worked in concert and acted as one entity with respect to the development of the products that are the subject of ANDA No. 206149, and with respect to the preparation of ANDA No. 206149 and the commission of the infringing act of submitting ANDA No. 206149 to FDA, and Defendants continue to work together in seeking FDA approval of ANDA No. 206149. In addition, upon information and belief, Defendants held themselves out as one entity with respect to sending the Notice of Paragraph IV Certification to Warner Chilcott in connection with ANDA No. 206149 (*see* ¶ 18, *infra*).

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

WARNER CHILCOTT'S PATENT AND APPROVED ENABLEX® DRUG PRODUCT

14. On August 22, 2000, the United States Patent and Trademark Office duly and lawfully issued 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.

15. 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 No. 021-513 for Enablex® tablets ("Warner Chilcott NDA"). The Enablex® 7.5 mg and 15 mg extended-release darifenacin hydrobromide tablets are indicated as a treatment for overactive bladder. FDA first granted approval of the NDA on December 22, 2004.

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

17. Upon information and belief, Amneal submitted or caused to be submitted to FDA Abbreviated New Drug Application No. 206149 (“Amneal ANDA”) under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, or sell darifenacin extended-release tablets, equivalent to 7.5 mg and 15 mg base (“the ANDA Products”), as a generic version of Enablex® prior to the expiration of the ’864 Patent.

18. Upon information and belief, on or about April 24, 2014, Amneal sent Warner Chilcott a “Notice of Paragraph IV Certification of U.S. Patent 6,106,864, Concerning ANDA 206149 for Darifenacin Hydrobromide Extended-Release Tablets, 7.5 mg and 15 mg” (“Notice Letter”). The Notice Letter represented that Amneal had submitted to FDA the Amneal ANDA and a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of the products described in the Warner Chilcott NDA before the expiration of the ’864 Patent. Hence, Amneal’s purpose in submitting the Amneal ANDA is to market the ANDA Products before the expiration of the ’864 Patent. The Notice Letter also stated that Amneal’s Paragraph IV Certification asserts that the ’864 Patent is invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the ANDA Products within the United States.

19. Upon information and belief, Amneal has assisted with, participated in, provided material support to the preparation and submission of, and intends to support the further prosecution of the Amneal ANDA.

20. Upon information and belief, if FDA approves the Amneal ANDA, Amneal will manufacture, use, offer for sale, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States.

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

COUNT I: CLAIM FOR INFRINGEMENT OF THE '864 PATENT

22. Warner Chilcott states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

23. Upon information and belief, Amneal has submitted or caused the submission of the Amneal ANDA to FDA, and continues to seek FDA approval of the Amneal ANDA.

24. Amneal has infringed the '864 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amneal ANDA with a Paragraph IV Certification and seeking FDA approval of the Amneal ANDA prior to the expiration of the '864 Patent.

25. Amneal's commercial manufacture, use, sale, offer for sale within the United States, or importation into the United States of Amneal's ANDA Products would directly infringe, and actively induce and contribute to infringement of the '864 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206149, Amneal will make, use, offer to sell, or sell Amneal's ANDA Products within the United States, or will import Amneal's ANDA Products into the United States, and thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '864 Patent.

26. Upon information and belief, Amneal will market and distribute its ANDA Products to resellers, pharmacies, health care professionals and end users of Amneal's ANDA

Products once FDA approves ANDA No. 206149. Amneal will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for administering the ANDA Products as claimed in the '864 Patent. Accordingly, Amneal will induce physicians and other health care professionals, resellers, pharmacies, and end users of Amneal's ANDA Products to directly infringe one or more claims of the '864 Patent. In addition, upon information and belief, Amneal will encourage acts of direct infringement with knowledge of the '864 Patent and knowledge that it is encouraging infringement.

27. Amneal had actual and constructive notice of the '864 Patent prior to filing the Amneal ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the '864 Patent would constitute an act of infringement. Amneal has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Amneal's ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '864 Patent. In addition, Amneal filed the Amneal ANDA with a baseless Paragraph IV Certification without adequate justification for asserting the '864 Patent to be invalid or unenforceable. Amneal's conduct in certifying invalidity and non-infringement with respect to the '864 Patent has been, and continues to be willful, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

28. Warner Chilcott will be irreparably harmed if Amneal is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '864 Patent. Warner Chilcott does not have an adequate remedy at law, and considering the balance of

hardships between Warner Chilcott and Amneal, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) The entry of judgment, in favor of Plaintiffs and against Defendants, that Defendants, through their submission of ANDA No. 206149 to FDA seeking to market the Amneal ANDA Products, have infringed the '864 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of judgment, in favor of Plaintiffs and against Defendants, declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the Amneal ANDA, or inducing or contributing to such conduct, would constitute infringement of the '864 Patent by Amneal pursuant to 35 U.S.C. § 271(a), (b), (c) and (g);

(c) The entry of a permanent injunction, enjoining Defendants and their officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with Defendants, and their successors or assigns, from infringing, inducing infringement of, and contributing to the infringement of any claims of the '864 Patent by making, using, selling, offering for sale, or importing Amneal's ANDA Products in the United States;

(d) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206149 shall 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;

(e) The entry of judgment declaring that Defendants' acts have been and are willful and that this case is an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(f) An award to Plaintiffs of their costs and expenses in this action; and

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

ASHBY & GEDDES

/s/ Andrew C. Mayo

Steven J. Balick (#2114)
Tiffany Geyer Lydon (#3950)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
tlydon@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Jeffrey B. Elikan
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
202.662.6000
gpappas@cov.com
jelikan@cov.com

Jennifer L. Robbins
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018
212.841.1000
jrobbins@cov.com

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