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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC and MAYNE PHARMA INTERNATIONAL PTY. LTD., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No.: **COMPLAINT AND LOCAL RULE 11.2 CERTIFICATION**

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, LLC, and Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively "Plaintiffs"), by their respective undersigned attorneys, bring this action against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. and hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

THE PARTIES

2. Plaintiff Warner Chilcott Laboratories Ireland Limited ("WCLI") is a company organized and existing under the laws of the Republic of Ireland, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

3. Plaintiff Warner Chilcott Company, LLC ("WCCL") is a limited liability company established under the laws of the Commonwealth of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

4. 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. WCLI, WCCL, and WCUS hereinafter are referred to collectively as "Warner Chilcott".

5. Plaintiff Mayne Pharma International Pty. Ltd. ("Mayne") is a corporation organized and existing under the laws of Australia, having a principal place of business at Level 21-390 St. Kilda Road, Melbourne, Australia 3004.

6. Mayne was formerly known as F. H. Faulding & Co., Ltd.

7. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a corporation organized under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

9. On information and belief, Mylan Pharma is a wholly owned subsidiary of Mylan Inc., and the acts of Mylan Pharma complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Mylan Inc. On information and belief, Mylan Pharma and Mylan Inc. have officers or directors in common.

10. Mylan Pharma and Mylan Inc. hereinafter are referred to collectively as "Mylan."

JURISDICTION AND VENUE

11. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

12. Mylan Pharma is registered to do business in the State of New Jersey. Its agent for service of process in New Jersey is Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

13. Mylan has submitted to jurisdiction in this judicial district in numerous patent cases in the last five years, including in a pending proceeding that involves the same

patent that is at issue here: *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc. et al.*, Civ. Docket No. 2:08-cv-06304-WJM-MF. Mylan has maintained continuous and systematic contacts in New Jersey, and sells various products and does business throughout the United States, including in this judicial district.

14. On information and belief, this Court has personal jurisdiction over Mylan by virtue of, *inter alia*, the above-mentioned facts.

15. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF -- PATENT INFRINGEMENT

Plaintiffs' NDA And U.S. Patent No. 6,958,161

16. Mayne is the holder of New Drug Application ("NDA") No. 50-795 which relates to delayed-release tablets containing 75 mg base, 100 mg base and 150 mg base of doxycycline hyclate.

17. The United States Food and Drug Administration ("FDA") has approved the use of the tablets described in NDA No. 50-795 for the treatment of a variety of bacterial infections as described in the product labeling. The 75 mg base and 100 mg base tablets were approved by the FDA on or about May 6, 2005, and the 150 mg base tablets were approved on or about June 20, 2008. These tablets are prescribed and sold in the United States under the trademark Doryx®.

18. Mayne is the owner of United States Patent No. 6,958,161 ("the '161 Patent," copy attached as Exhibit A), entitled "Modified Release Coated Drug Preparation."

19. The '161 Patent was duly and legally issued by the United States Patent and Trademark Office on October 25, 2005. The '161 Patent claims, *inter alia*, modified release preparations of doxycycline hyclate, and is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Doryx Delayed-Release Tablets ("Doryx®").

20. The '161 Patent originally was assigned by the inventors to F. H. Faulding & Co. Limited, and subsequently assigned to Mayne.

21. Warner Chilcott has exclusive rights to market and sell product covered by the '161 Patent in the United States, including Doryx®.

Mylan's Prior Infringement And Prior ANDA No. 90-431

22. On information and belief, prior to December 5, 2008, Mylan submitted to the FDA a separate Abbreviated New Drug Application ("ANDA"), ANDA No. 90-431, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg base, which are covered by one or more claims of the '161 Patent.

Mylan's Infringement And ANDA No. 91-052

23. On information and belief, after December 5, 2008, Mylan submitted to the FDA ANDA No. 91-052 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Extended Release Tablets 150 mg ("Mylan's Proposed Drug Product"), which is covered by one or more claims of the '161 Patent.

24. On information and belief, Mylan submitted ANDA No. 91-052 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use,

offer for sale, sale, and/or importation of Mylan's Proposed Drug Product before the expiration of the '161 Patent.

25. On information and belief, Mylan made, and included in ANDA No. 91-052, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale, of Mylan's Proposed Drug Product.

26. By filing ANDA No. 91-052 under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Mylan's Proposed Drug Product before the expiration of the '161 Patent, and Paragraph IV Certification, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's Proposed Drug Product for which Mylan seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

27. Mylan's Proposed Drug Product, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Mylan's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Mylan will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

28. On information and belief, Mylan did not allege in its Paragraph IV Certification that the '161 Patent is invalid under any of 35 U.S.C. § 101 *et seq*.

29. On information and belief, Mylan did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

30. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 91-052 relating to Mylan's Proposed Drug Product be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Mylan's Proposed Drug Product, and any act committed by Mylan with respect to the subject matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

31. On information and belief, Mylan lacked a good faith basis for its Paragraph IV Certification when ANDA No. 91-052 was filed. Mylan's ANDA No. 91-052 and Paragraph IV Certification is a wholly unjustified infringement of the '161 Patent.

32. Mylan has violated its duty of due care to avoid the known patent rights of the '161 Patent.

33. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Mylan as follows:

(a) Judgment that the '161 Patent remains valid and enforceable;

(b) Judgment that Mylan has infringed one or more claims of the '161 Patent by filing ANDA No. 91-052 and Paragraph IV Certification relating to Mylan's Proposed Drug Product;

(c) An Order that the effective date of any approval of Mylan's ANDA No. 91-052 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and § 505(j)(2)(A)(vii)(IV) of the Act be a date which is not earlier than the expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A permanent injunction restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mylan's Proposed Drug Product;

(e) Judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(f) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the '161 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem proper.

Dated: May 1, 2009

Respectfully submitted,

By: s/William J. Heller

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