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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT (US), LLC and MAYNE PHARMA INTERNATIONAL PTY. LTD.,	Civil Action No.:
Plaintiffs,	
v.	
SANDOZ INC.,	

: **COMPLAINT**
:
Defendant. :
----------X

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., and Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively "Plaintiffs"), by their respective undersigned attorneys, bring this action against Defendant Sandoz 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, Inc. ("WCCI") is a 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, WCCI, 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 Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado and having a principal place of business at 506 Carnegie Center, Ste. 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

8. 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).

9. Sandoz is subject to personal jurisdiction in New Jersey because it regularly and systematically conducts business within New Jersey, has an office within New Jersey, sells various products throughout the United States, including within New Jersey, and has previously submitted to the jurisdiction of this Court.

10. 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

11. 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.

12. On or about May 6, 2005, the United States Food and Drug Administration ("FDA") 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. These tablets are prescribed and sold in the United States under the trademark Doryx®.

13. 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."

14. 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®").

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

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

Sandoz's Infringement and ANDA No. 90-192

17. On information and belief, Sandoz submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 90-192 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 Delayed-Release Tablets 75 mg and 100 mg ("Sandoz's Proposed Drug Products"), which are covered by one or more claims of the '161 Patent.

18. On information and belief, Sandoz submitted its ANDA No. 90-192 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Drug Products before the expiration of the '161 Patent.

19. On information and belief, Sandoz made, and included in its ANDA, 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 Sandoz's Proposed Drug Products.

20. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Sandoz's Proposed Drug Products before the expiration of the '161 Patent, and Paragraph IV Certification, Sandoz 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 Sandoz's Proposed Drug Products for which Sandoz seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

21. Sandoz's Proposed Drug Products, 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 Sandoz's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Sandoz will actively induce,

encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

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

23. 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 the aforementioned ANDA relating to Sandoz's Proposed Drug Products 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 Sandoz's Proposed Drug Products, and any act committed by Sandoz 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).

24. On information and belief, Sandoz lacked a good faith basis for its Paragraph IV Certification when ANDA No. 90-192 was filed. Sandoz's ANDA and Paragraph IV Certification is a wholly unjustified infringement of the '161 Patent.

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

26. 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 Sandoz as follows:

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

(b) Judgment that Sandoz has infringed one or more claims of the '161 Patent by filing the aforesaid ANDA and Paragraph IV Certification relating to Sandoz's Proposed Drug Products;

(c) An Order that the effective date of any approval of Sandoz's ANDA No. 90-192 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 Sandoz 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 Sandoz's Proposed Drug Products;

(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 Sandoz 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: January 15, 2009

By: /s William J. Heller

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

I hereby certify that the patent in suit here is the subject of the following related action pending in this Court before the Honorable William J. Martini: *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc. et al.*, Civ. Docket No. 2:08-cv-06304-WJM-MF.

McCARTER & ENGLISH, LLP

Dated: January 15, 2009

By: /s William J. Heller
William J. Heller, Esq.
A Member of the Firm

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