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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, INC., Plaintiff, v. WATSON PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC., Defendants.	CIVIL ACTION NO.

COMPLAINT

Plaintiff Warner Chilcott Company, Inc. (Warner Chilcott), by and through its attorneys, St. John & Wayne, L.L.C., brings this action for patent infringement against Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. Warner Chilcott alleges as follows:

THE PARTIES

1. Warner Chilcott is a Puerto Rico corporation, having its principal place of business at Union Street KM1-1, Fajardo, Puerto Rico 00738. Warner Chilcott is engaged in the business of development, manufacture, and sale of pharmaceutical drug products, particularly for use in the therapeutic areas of women's health care and dermatology.

2. On information and belief, Defendant Watson Pharmaceuticals, Inc. is a Nevada corporation having its corporate headquarters at 311 Bonnie Circle, Corona, California 92880 and its commercial headquarters at 360 Mt. Kemble Avenue, Morristown, New Jersey 07962. On information and belief, Defendant Watson Pharmaceuticals, Inc. is engaged in the business of manufacturing and selling generic versions of pharmaceutical drug products.

3. On information and belief, Defendant Watson Laboratories, Inc. is a Nevada corporation having its corporate headquarters at 311 Bonnie Circle, Corona, California 92880 and its commercial headquarters at 360 Mt. Kemble Avenue, Morristown, New Jersey 07962. On information and belief, Defendant Watson Laboratories, Inc. is engaged in the business of manufacturing generic versions of pharmaceutical drug products.

4. On information and belief, Defendant Watson Laboratories, Inc. is a wholly owned subsidiary of Defendant Watson Pharmaceuticals, Inc. and the two have common officers and directors. Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. are referred to hereinafter, collectively, as "Watson."

NATURE OF THE ACTION

5. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to an Abbreviated New Drug Application ("ANDA") filed by Watson with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Warner Chilcott's highly successful Loestrin® 24 Fe pharmaceutical product sold in the United States.

JURISDICTION

6. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, both Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. are Nevada corporations with their commercial headquarters in Morristown, New Jersey.

8. On information and belief, this Court has personal jurisdiction over both Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. because both corporations conduct business in New Jersey related to the subject matter of this lawsuit and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here, having invoked the benefits and protections of New Jersey's laws.

COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,552,394

9. United States Patent No. 5,552,394 ("the '394 patent"), entitled Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy, was duly and legally issued by the United States Patent and Trademark Office on September 3, 1996. A true copy of the '394 patent is attached as Exhibit A.

10. Since August 1, 2004, Warner Chilcott has owned the entire right, title, and interest in the '394 patent.

11. The '394 patent relates to a method of female contraception, which comprises *inter alia* monophasicly administering a combination comprising 20 micrograms of ethinyl estradiol and 1 mg of norethindrone acetate for 24 days of a 28 day cycle.

12. On February 17, 2006, the United States Food and Drug Administration (FDA) approved Warner Chilcott's New Drug Application (NDA) No. 021871 for a female contraceptive product, which is now sold under the trademark Loestrin® 24 Fe.

13. Loestrin® 24 Fe provides a dosage regimen consisting of 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate

and four placebo tablets containing iron. The '394 patent covers the use of Loestrin® 24 Fe in accordance with the labeling approved by the FDA and is listed under the Patent and Exclusivity Information for this product in the twenty-sixth edition of the FDA's Approved Drug Products (the "Orange Book").

14. On or about June 19, 2006, Watson mailed a letter to Warner Chilcott indicating that Watson had filed ANDA No. 78-267 in order to obtain approval to market an oral contraceptive product comprising 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets ("Watson's Product") in the United States as the generic equivalent of Loestrin® 24 Fe before the expiration of the '394 patent. *See* Exhibit B. In its letter, Watson also stated that it had filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '394 patent are invalid, unenforceable, and/or not infringed. Watson's Detailed Statement of the Factual and Legal Bases for Its Opinion That U.S. Patent No. 5,552,394 Is Invalid, Unenforceable or Not Infringed only alleges, however, that the '394 patent is obvious over unspecified prior art.

15. Under 35 U.S.C. § 271(e)(2)(A), Watson's submission to the FDA of ANDA No. 78-267 to obtain approval for the commercial manufacture, use, or sale of Watson's Product before the expiration date of the '394 patent constitutes patent infringement of one or more claims of the '394 patent.

16. Upon FDA approval of Watson's ANDA No. 78-267, Watson will actively induce infringement by others of the '394 patent, unless this Court orders that the effective date of any FDA approval of Watson's ANDA shall be no earlier than the expiration date of the '394 patent.

17. By way of example, on information and belief, women using Watson's Product for the indication and in the manner approved by the FDA will be actively induced to directly infringe one or more claims of the '394 patent.

18. On information and belief, the use of Watson's Product constitutes a material part of at least one of the claims of the '394 patent; Watson knows that its Product is especially made or adapted for use in infringing at least one of the claims of the '394 patent; and Watson's Product is not a staple article of commerce or a commodity of commerce suitable for substantial noninfringing use.

19. Upon FDA approval of Watson's ANDA No. 78-267, Watson will contribute to the infringement by others of the '394 patent, unless this Court orders that the effective date of any FDA approval of Watson's ANDA shall be no earlier than the expiration date of the '394 patent..

20. On information and belief, Watson had knowledge of the '394 patent and, by its promotional activities and package insert for its Product, will know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '394 patent.

21. On information and belief, by filing ANDA No. 78-267, Watson intentionally and willfully infringed the '394 patent.

22. Warner Chilcott will be substantially and irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court. Warner Chilcott has no adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiff Warner Chilcott demands judgment against Defendants Watson Pharmaceuticals , Inc. and Watson Laboratories, Inc. and respectfully requests that this Court enter Orders:

A. declaring that, under 35 U.S.C. § 271(e)(2)(A), Watson's submission to the FDA of an ANDA to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of an oral contraceptive product comprising 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets before the expiration of the '394 patent was an act of infringement of the '394 patent;

B. declaring that, if approved, Watson's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of an oral contraceptive product comprising 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets would constitute infringement of the '394 patent;

C. ordering that the effective date of any FDA approval of Watson's oral contraceptive product comprising 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets shall be no earlier than the expiration date of the '394 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. enjoining Watson, and all persons acting in concert with Watson, from commercially manufacturing, using, offering for sale, or selling an oral contraceptive product comprising 24 tablets each containing twenty micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets within the United States or importing into the United States an oral contraceptive product comprising 24 tablets each containing twenty

micrograms of ethinyl estradiol and one milligram of norethindrone acetate and four placebo tablets, until the expiration of the '394 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

E. enjoining Watson, and all persons acting in concert with Watson, from seeking, obtaining, or maintaining approval of Watson's ANDA No. 78-267 until the expiration of the '394 patent;

F. declaring this to be an exceptional case and awarding Warner Chilcott its attorney fees under 35 U.S.C. § 285;

G. awarding Warner Chilcott its costs and expenses in this action; and

H. awarding Warner Chilcott any further and additional relief as this Court deems just and proper.

Dated: July 28, 2006

ST. JOHN & WAYNE, L.L.C. ,
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