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Duramed Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

DURAMED PHARMACEUTICALS, INC., Plaintiff, v. WATSON LABORATORIES, INC., Defendants.	CASE NO. 3:08-cv-116-LRH-RAM **AMENDED COMPLAINT** **[JURY DEMAND]**

Plaintiff Duramed Pharmaceuticals, Inc. ('Duramed") for its Complaint against Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 et seq.

THE PARTIES

2. Plaintiff Duramed is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Rd,

Woodcliff Lake, NJ 07677. Duramed is a proprietary pharmaceutical company that has been an innovator in the area of women's health. Duramed focuses on providing patients with an array of female healthcare products, with particular emphasis on developing and marketing products that serve the reproductive and menopausal needs of women. After this lawsuit was filed, Duramed changed its name to Teva Women's Health, Inc.

3. On information and belief, Watson Laboratories, Inc ("Watson Labs") is a corporation organized and existing under the laws of the State of Nevada, having a registered agent located at 6100 Neil Road, Ste 500, Reno, Nevada 89511. Watson Labs is the holder of various Abbreviated New Drug Applications on file with the U.S. Food and Drug Administration ("FDA"), pursuant to which Watson manufactures, sells and distributes generic copies of innovative pharmaceutical products.

4. Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having its commercial headquarters at 360 Mt. Kemble Avenue, Morristown, New Jersey.

5. Watson Labs is a wholly owned subsidiary of Watson Pharmaceuticals and, upon information and belief, the two companies have common officers and directors. Upon information and belief, Watson Labs has at all times relevant to this Complaint acted with the authorization, cooperation, participation, direction and assistance of Watson Pharmaceuticals. Watson Labs and Watson Pharmaceuticals are referred to hereinafter, collectively, as "Watson."

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 1338(a).

7. Watson is subject to personal jurisdiction in Nevada because, among other things, it conducts business in Nevada related to the subject matter of this lawsuit, maintains a regular place of business in Nevada, and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court here, having invoked the benefits and protections of Nevada's laws.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and (c), and 1400(b).

BACKGROUND

9. As part of its commitment to developing new products for women, Duramed developed and obtained approval from the U.S. Food and Drug Administration ("FDA") to sell under the trade name Seasonique® an extended-cycle oral contraceptive available in the United States. Seasonique® is the first such extended-cycle oral contraceptive to combine administration of estrogen and progestin for a period of 84 days with administration of estrogen for a period of 7 days in order to diminish premenstrual symptomatology.

10. United States Patent No. 7,320,969 ("the '969 Patent"), entitled "Oral Contraceptives to Prevent Pregnancy and Diminish Premenstrual Symptomatology," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 22, 2008. The '969 Patent will expire on January 30, 2024. Duramed is the owner by assignment of all right, title and interest in and to the '969 Patent. A copy of the '969 Patent is attached to this Complaint as Exhibit A.

11. The '969 Patent claims, *inter alia*, a method of female contraception, which comprises administering a combination of specified dosages of estrogen and progestin for 84 consecutive days, followed by administering specified dosages of estrogen for a period of 7 days.

12. Duramed sells one or more drug products under the trade name Seasonique® in the United States pursuant to an approved New Drug Application (No. 21-840). The approved use of such products is claimed by the '969 Patent.

ACTS GIVING RISE TO THIS ACTION

13. By letter dated January 22,2008 (the "Notice Letter"), Watson notified Duramed that Watson had submitted an Abbreviated New Drug Application ("ANDA") (No. 78-834) to the FDA seeking approval to manufacture, sell, and distribute a generic copy of Duramed's Seasonique® extended-cycle contraceptive product. The purpose of the Watson ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial

manufacture, use, and sale of a generic copy of Seasonique® that combines 84 progestin and estrogen tablets and 7 estrogen tablets packaged together ("the Watson Product") prior to the expiration of the '969 patent.

14. Upon information and belief, Watson submitted ANDA No. 78-834 to the FDA containing a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '969 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the Watson Product. Such certification constituted an act of infringement of the '969 Patent pursuant to 35 U.S.C. § 271(e)(2).

15. The Notice Letter provided to Duramed by Watson reflects that, as part of ANDA No. 78-834 and pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Watson certified to the FDA that the '969 Patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the Watson Product.

16. Watson had knowledge of the '969 patent prior to filing its ANDA.

17. On July 28, 2011, Watson announced that it had launched Amethia™, its generic copy of Seasonique®, and that it had begun shipping that product despite the pendency of this lawsuit.

COUNT I: PATENT INFRINGEMENT

(U.S. Patent No. 7,320,969)

18. Duramed incorporates by reference the allegations contained in paragraphs 9-17, above.

19. Watson's filing of ANDA No. 78-834 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Watson Product prior to the expiration of the '969 Patent is an act of infringement of the '969 Patent.

20. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringement of the '969 Patent.

21. The use of the Watson Product in accordance with and as directed by the proposed product labeling infringes the '969 Patent. Watson has stipulated that "its filing of ANDA No. 78-834 ('ANDA') and the use of products made pursuant to the ANDA would

infringe claims 1-9, 15, and 17-19 of United States Patent No. 7,320,969 to the extent those claims are found valid and enforceable," and the Court entered that stipulation as an order on March 17, 2009.

22. Upon FDA approval of ANDA No. 78-834, Watson intended to manufacture, offer for sale, sell and distribute the Watson Product with its product labeling. On July 28, 2011, Watson announced that it had launched Amethia™, Watson's generic copy of Seasonique®, and that it had begun shipping that product. It did so despite the fact that it has stipulated that use of that product infringes the '969 patent, and despite the pendency of this lawsuit.

23. Watson knows that the Watson Product and its product labeling are especially made or adapted for use in infringing the '969 Patent and that the Watson Product and its product labeling are not suitable for substantial noninfringing use.

24. The foregoing actions by Watson constitute infringement, and active inducement of infringement, of the '969 Patent and seek to contribute to the infringement by others of the '969 Patent, under at least 35 U.S.C. § 271(a)-(c) and (e).

25. Unless Watson is enjoined from infringing, inducing infringement and contributing to the infringement of, the '969 Patent, Duramed will be substantially and irreparably harmed by, and will suffer damages as a result of, Watson's actions.

26. Duramed does not have an adequate remedy at law.

WHEREFORE, plaintiff Duramed respectfully requests the following relief:

(a) A final judgment permanently enjoining Watson, and all persons acting in concert with Watson, from making, using, selling, offering to sell, marketing, distributing, or importing any oral contraceptive product, including but not limited to the Watson Product, the use of which infringes the '969 Patent;

(b) A final judgment ordering that the effective date of any approval of any ANDA filed by Watson for an oral contraceptive product, the use of which infringes the '969 Patent, including but not limited to ANDA No. 78-834, be not earlier than the expiration date of United States Patent No. 7,320,969;

(c) A final judgment declaring that Watson's manufacture, sale, offers for sale, marketing and distribution in, or importation into, the United States of the Watson Product will induce and contribute to infringement of United States Patent No. 7,320,969;

(d) A final judgment awarding Duramed damages resulting from Watson's infringement, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(e) A declaration that this is an exceptional case and an award to Duramed of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Duramed's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

GREENBERG TRAURIG, LLP

By: /s/ Nicholas A. Brown

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Watson Pharmaceuticals

Press Release

Watson Launches Generic Seasonique(R)

PARSIPPANY, N.J., July 28, 2011 /PRNewswire via COMTEX/ --

Watson Pharmaceuticals, Inc. (NYSE: WPI) today announced that its subsidiary, Watson Laboratories, Inc., has launched Amethia(TM) (levonorgestrel/ethinyl estradiol (0.15 mg/0.03 mg) and ethinyl estradiol (0.01 mg)), the generic equivalent of Duramed Pharmaceuticals Inc.'s Seasonique(R). Watson began shipping the product today, following a denial by the United States Court of Appeals for the Federal Circuit of a request for a temporary injunction. Duramed's lawsuit alleging that Watson's product infringes Duramed's U.S. Patent No. 7,320,969 remains pending.

For the most recent twelve months ending April 30, 2011, Seasonique had sales of approximately $110 million, according to IMS Health data. Watson's Amethia(TM) tablets are indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.

About Watson Pharmaceuticals, Inc.

Watson Pharmaceuticals, Inc. is an integrated global specialty pharmaceutical company. The Company is engaged in the development, manufacturing, marketing and distribution of generic pharmaceuticals and specialized branded pharmaceutical products focused on Urology and Women's Health. Watson has operations in many of the world's established and growing international markets.

For press release and other company information, visit Watson Pharmaceuticals' Web site at http://www.watson.com.

Forward-Looking Statement

Statements contained in this press release that refer to non-historical facts are forward-looking statements that reflect Watson's current perspective of existing information as of the date of this release. It is important to note that Watson's goals and expectations are not predictions of actual performance. Actual results may differ materially from Watson's current expectations depending upon a number of factors, risks and uncertainties affecting Watson's business. These factors include, among others, the difficulty of predicting the timing and outcome of the pending patent litigation and risks that an adverse outcome in such litigation could render Watson liable for substantial damages; the impact of competitive products and pricing; the timing and success of product launches; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to Watson and its third party manufacturers' facilities, products and/or businesses; changes in the laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products; and such other risks and uncertainties detailed in Watson's periodic public filings with the Securities and Exchange Commission, including but not limited to Watson's quarterly report on form 10-Q for the quarter ended June 30, 2011 and Watson's annual report on Form 10-K for the year ended December 31, 2010. Except as expressly required by law, Watson disclaims any intent or obligation to update these forward-looking statements.

Seasonique(R) is a registered trademark of Teva Women's Health, Inc.

(Logo: http://photos.prnewswire.com/prnh/20100121/LA41294LOGO)

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SOURCE Watson Pharmaceuticals, Inc.