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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DURAMED PHARMACEUTICALS, INC., Plaintiff, - against - PADDOCK LABORATORIES, INC., Defendant.	Case No.: ECF Case **COMPLAINT**

Plaintiff Duramed Pharmaceuticals, Inc. ("Duramed") for its Complaint against Defendant Paddock Laboratories, Inc. ("Paddock") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, Sections 1 *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 225 Summit Avenue, Montvale, New Jersey 07645. Duramed is a proprietary pharmaceutical company that has been an innovator in the area of women's health. Duramed focuses on researching, developing, and providing patients with an array of female healthcare products, including in the area of hormone replacement therapy for women suffering from symptoms associated with menopause.

3. On information and belief, Defendant Paddock is a corporation organized under the laws of the State of Minnesota, having a principal place of business at 3940 Quebec

Avenue North, Minneapolis, Minnesota 55427-1244, and is engaged in the development, marketing, and sale of generic drug products.

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over Paddock because, *inter alia*, Paddock has purposefully availed itself of the rights and benefits of New York law. Upon information and belief, defendant Paddock engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of New York specifically, including to Walmart and Walgreens pharmacy stores in the State of New York.

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Paddock is subject to personal jurisdiction in this District.

BACKGROUND

7. On June 1, 1999, the United States Patent and Trademark Office ("USPTO") duly and legally issued U.S. Patent No. 5,908,638 ("the '638 patent"), entitled "Pharmaceutical Compositions of Conjugated Estrogens and Methods for Their Use," to Duramed. The '638 patent names Harold Eugene Huber and Mary Katherine Ryan as joint inventors. The '638 patent is valid and enforceable and does not expire until July 26, 2015. Duramed is the sole owner of the '638 patent and has the sole right to sue and to recover for any past, present or future infringement of that patent. A copy of the '638 patent is attached hereto as Exhibit A.

8. The '638 patent is directed to, *inter alia*, a pharmaceutical composition comprising conjugated estrogens for the hormonal treatment of peri-menopausal, menopausal, and post-menopausal disorders in women.

9. On March 24, 1999, the United States Food and Drug Administration ("FDA") approved Duramed's New Drug Application ("NDA") No. 02-992 for conjugated estrogens (synthetic A) tablets in 0.9 mg and 0.625 mg dosages for oral administration. Other dosages were subsequently approved under NDA No. 02-992, including 1.25 mg on March 13, 2000, 0.3mg on June 21, 2002, and 0.45 mg on February 5, 2004. Under NDA No. 02-992, Duramed sells conjugated estrogens (synthetic A) tablets for oral administration in each of these dosages under the brand name Cenestin®.

10. The '638 patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering Cenestin® conjugated estrogens (synthetic A) tablets for oral administration in each of these dosages.

ACTS GIVING RISE TO THIS ACTION

11. By letter dated January 16, 2009 (the "Notice Letter"), Paddock notified Duramed that Paddock had submitted Abbreviated New Drug Application ("ANDA") No. 91-013 to the FDA seeking approval to manufacture, sell, and distribute a generic version of Duramed's Cenestin® conjugated estrogens (synthetic A) tablets, 1.25 mg, for oral administration.

12. Pursuant to Paddock's Notice Letter, the purpose of Paddock's filing of the 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 version of Cenestin® conjugated estrogens (synthetic A) tablets, 1.25 mg, for oral administration ("the Paddock Product") prior to the expiration of the '638 patent.

13. Paddock submitted ANDA No. 91-013 to the FDA containing a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that,

in Paddock's opinion, the '638 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the Paddock product. Paddock's filing of the ANDA with the Paragraph IV certification infringed the '638 patent under 35 U.S.C. § 271(e)(2).

14. Paddock's Notice Letter indicates that in filing its ANDA, defendant Paddock intends to engage in the commercial manufacture, marketing, and sale of conjugated estrogens (synthetic A) tablets, 1.25 mg, for oral administration (including, upon information and belief, commercial marketing and sale of such a product in the State of New York) prior to the expiration of the '638 patent in the event that the FDA approves ANDA No. 91-013.

15. Upon information and belief, Paddock intends to continue to pursue approval of its ANDA by the FDA.

16. Paddock was necessarily aware of the '638 patent when it filed ANDA No. 91-013 including the Paragraph IV certification.

17. Duramed commenced this action within 45 days of the date it received the Notice Letter regarding Paddock's submission of ANDA No. 91-013 containing the Paragraph IV certification to the FDA.

COUNT I: PATENT INFRINGEMENT

(U.S. Patent No. 5,908,638)

18. Paragraphs 1 through 17 are incorporated by reference as if restated fully herein.

19. Upon information and belief, Paddock's filing of ANDA No. 91-013 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a generic version of Cenestin® conjugated estrogens (synthetic A) tablets, 1.25 mg, for oral administration prior to the expiration of the '638 patent infringed, and its maintenance of that ANDA continues to infringe, the '638 patent under 35 U.S.C. § 271(e)(2).

20. Upon information and belief, upon FDA approval of ANDA No. 91-013, Paddock intends to manufacture, offer for sale, sell and distribute the Paddock Product.

21. Upon information and belief, the commercial manufacture, use, or sale of the Paddock Product prior to the expiration of the '638 patent would infringe the '638 patent.

22. Unless Paddock is enjoined from infringing the '638 patent, Duramed will be substantially and irreparably harmed by, and will suffer damages as a result of, Paddock's actions.

23. Upon information and belief, Paddock acted without a reasonable basis for believing that it would not be liable for infringement of the '638 patent.

24. Paddock's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Duramed respectfully requests the following relief:

A. A permanent injunction barring Paddock, its officers, agents, and employees, and all persons acting in concert with Paddock, from infringing United States Patent No. 5,908,638 by making, using, selling, offering to sell, marketing, importing, or distributing any conjugated estrogen product, including the product described in Paddock's ANDA No. 91-013;

B. An order decreeing that the effective date of any approval of Paddock's ANDA No. 91-013 to be a date which is not earlier than the expiration date of United States Patent No. 5,908,638;

C. A final judgment declaring that Paddock's manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in Paddock's ANDA No. 91-013 will infringe United States Patent No. 5,908,638;

D. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285 and an award to Duramed of its attorneys' fees, costs, and expenses incurred in prosecuting this action; and

E. Such other and further relief as this Court may deem just and proper.

Dated: March 2, 2009

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