

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

ORTHO-MCNEIL-JANSSEN)	
PHARMACEUTICALS, INC.)	
)	
and)	
)	
JOHNSON & JOHNSON)	
PHARMACEUTICAL RESEARCH)	
& DEVELOPMENT, LLC)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. _____
)	
WATSON LABORATORIES, INC., and)	
WATSON PHARMACEUTICALS, INC.)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMJPI”) and Johnson & Johnson Pharmaceutical Research & Development, LLC (“J&J Research”) (collectively “Plaintiffs”), by their attorneys, for their complaint against Watson Laboratories, Inc. (“Watson Labs”), and Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) (collectively, “Watson” or “Defendants”) allege as follows:

The Parties

1. Plaintiff OMJPI is a corporation organized and existing under the laws of Pennsylvania and having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

2. Plaintiff J&J Research is a limited liability company organized and existing under the laws of New Jersey and having its principal place of business at 920 U.S. Route 202, Raritan, New Jersey.

3. Upon information and belief, Defendant Watson Labs is a corporation organized and existing under the laws of Nevada, with places of business at 311 Bonnie Circle, Corona, California 92880, and 360 Mt. Kemble Avenue, Morristown, New Jersey 07962. 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 pharmaceutical products.

4. Upon information and belief, Defendant Watson Pharmaceuticals is a corporation organized and existing under the laws of Nevada, with a place of business at 360 Mt. Kemble Avenue, Morristown, New Jersey 07692. Watson Pharmaceuticals is a pharmaceutical company that develops, manufactures, markets and distributes both branded and generic pharmaceutical products.

5. Watson Labs is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two have common officers and directors. Upon information and belief, Watson Pharmaceuticals participated in, directed, authorized, caused, and/or collaborated in the acts complained of herein, knowing that these actions would lead to and cause infringement of the patent at issue in this lawsuit.

Jurisdiction and Venue

6. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355.

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

8. This Court has personal jurisdiction over Watson Labs and Watson Pharmaceuticals because each has continuous and systematic contacts with the State of New Jersey.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count 1: Patent Infringement

10. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 9 above.

11. United States Patent No. 6,214,815 (“the ‘815 Patent”) entitled “TRIPHASIC ORAL CONTRACEPTIVE” duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on April 10, 2001. OMJPI is the owner of the ‘815 Patent. A copy of the ‘815 Patent is attached hereto as Exhibit A.

12. OMJPI currently markets a prescription oral contraceptive product under the trademark ORTHO TRI-CYCLEN LO®. ORTHO TRI-CYCLEN LO® is covered by the claims of the ‘815 Patent.

13. J&J Research is the holder of an approved New Drug Application (“NDA”) covering ORTHO TRI-CYCLEN LO®.

14. Upon information and belief, Watson submitted Abbreviated New Drug Application (“ANDA”) No. 90-479 (“Watson ANDA”) to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of ORTHO TRI-CYCLEN LO® before the expiration of the ‘815 patent.

15. As part of its ANDA filing, Watson has purportedly provided written certification to the FDA that the claims of the '815 patent are invalid, unenforceable, and/or will not be infringed.

16. By letter dated September 4, 2008, Watson gave written notice of its certification of invalidity, unenforceability, and/or noninfringement of the '815 patent, alleging that the '815 Patent is anticipated, obvious, and invalid, and informing Plaintiffs that Watson seeks approval to engage in the commercial manufacture, use and sale of a product bioequivalent to ORTHO TRI-CYCLEN LO® prior to the expiration of the '815 Patent.

17. Upon information and belief, Watson Pharmaceuticals and Watson Labs have collaborated in the research and development of Watson's proposed bioequivalent generic version of ORTHO TRI-CYCLEN LO® before the expiration of the '815 patent, continue to collaborate in seeking approval of ANDA No. 90-479 from the FDA, and intend to collaborate in the commercial manufacture, marketing and sale of a generic version of ORTHO TRI-CYCLEN LO® in the event that FDA approves the Watson ANDA.

18. Watson has infringed the '815 Patent under 35 U.S.C. §271(e)(2)(A) by virtue of submitting ANDA No. 90-479 with a Paragraph IV certification and seeking FDA approval of ANDA No. 90-479 prior to the expiration of the '815 Patent.

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

20. Plaintiffs will be irreparably harmed if Watson Labs and Watson Pharmaceuticals are not enjoined from infringing or actively inducing or contributing to infringement of the '815 patent. Plaintiffs do not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Watson Labs and Watson Pharmaceuticals have infringed the '815 patent under 35 U.S.C. §271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 90-479 is not earlier than the expiration date of the '815 patent, or any later expiration of exclusivity for the '815 patent to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Watson Labs and Watson Pharmaceuticals and their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 90-479;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 90-479 would constitute infringement of the '815 patent, or inducing or contributing to such conduct, by Watson Labs and Watson Pharmaceuticals pursuant to 35 U.S.C. §§ 271 (a), (b) and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

<p>Of Counsel:</p> <p>George F. Pappas Jeffrey B. Elikan Eric R. Sonnenschein COVINGTON & BURLING LLP 1201 Pennsylvania Avenue, N.W. Washington, D.C. 20004 Tel: 202-662-6000</p> <p>Dated: October 16, 2008</p>	<p>McCarter & English, LLP</p> <p><u> /s/ Andrew T. Berry</u> Andrew T. Berry McCarter & English LLP Four Gateway Center 100 Mulberry Street Newark, New Jersey 07102 T (973) 639 2097 F (973) 297 3952</p>
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