

Jurisdiction and Venue

4. 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.

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

6. This Court has personal jurisdiction over Sandoz because its principal place of business is in, and it has continuous and systematic contacts with, the State of New Jersey.

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

Count 1: Patent Infringement

8. OMJPI incorporates by reference the allegations contained in paragraphs 1 to 7 above.

9. 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.

10. 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.

11. OMJPI is the holder of an approved New Drug Application (“NDA”) covering ORTHO TRI-CYCLEN LO®.

12. Upon information and belief, Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 91-232 (“Sandoz 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.

13. As part of its ANDA filing, Sandoz has purportedly provided written certification to the FDA that the claims of the ‘815 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sandoz’s generic version of ORTHO TRI-CYCLEN LO®.

14. By letter dated April 30, 2009, Sandoz 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 OMJPI that Sandoz 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.

15. Sandoz has infringed the ‘815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 91-232 with a Paragraph IV certification and seeking FDA approval of ANDA No. 91-232 prior to the expiration of the ‘815 Patent.

16. This case is an exceptional one, and OMJPI is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

17. OMJPI will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the ‘815 Patent. OMJPI does not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, OMJPI seeks the following relief:

A. A judgment that Sandoz has 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. 91-232 is not earlier than the expiration date of the '815 Patent, or any later expiration of exclusivity for the '815 Patent to which OMJPI is or becomes entitled;

C. A permanent injunction restraining and enjoining Sandoz and its 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. 91-232;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 91-232 would constitute infringement of the '815 Patent, or inducing or contributing to such conduct, by Sandoz 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: June 4, 2009</p>	<p>McCarter & English, LLP</p> <p>By: <u>/s/ Andrew T. Berry</u> Andrew T. Berry</p> <p>Four Gateway Center 100 Mulberry Street Newark, New Jersey 07102 T (973) 622.4444 F (973) 624.7070 <i>Attorneys for Plaintiff</i></p>
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action alleges infringement of the same patent at issue in the matters *Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al. v. Barr Laboratories*, Docket No. 03-4678 (SRC) and *Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al. v. Watson Laboratories*, Docket No. 08-5103 (SRC).

/s/ Andrew T. Berry
Andrew T. Berry
MCCARTER & ENGLISH, LLP