

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

JANSSEN PHARMACEUTICALS,)
INC.)

Plaintiff,)

v.)

Civil Action No. _____

GLENMARK GENERICS LTD.)
and GLENMARK GENERICS INC.,)
USA)

Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Janssen Pharmaceuticals, Inc., by its attorneys, for its complaint against Glenmark Generics Ltd. and Glenmark Generics Inc., USA (“Glenmark Generics USA”) (collectively, “Glenmark” or “Defendants”) alleges as follows:

The Parties

1. Plaintiff is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

2. Upon information and belief, Defendant Glenmark Generics USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

3. Upon information and belief, Glenmark Generics USA manufactures, markets, distributes, and sells numerous generic pharmaceutical products throughout the United States, including in this judicial district, alone and/or through its agents and subsidiaries.

4. Upon information and belief, Defendant Glenmark Generics Ltd. is a company organized and existing under the laws of India having its principal place of business at Glenmark House, HDO Corporate Building, Wing A, B.D. Sawant Marg, Chakala, Andheri (E), Mumbai 400099, India. Upon information and belief, Defendant Glenmark Generics Ltd. is a subsidiary of Glenmark Pharmaceuticals Ltd.

5. Upon information and belief, Glenmark Generics Ltd. is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district, alone and/or through its agents and operating subsidiaries, including Glenmark Generics USA.

6. Upon information and belief, Glenmark Generics USA is a wholly-owned subsidiary of Glenmark Generics Ltd.

Jurisdiction and Venue

7. 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.

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

9. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff, a corporation having its principal place of business in New Jersey.

10. Glenmark Generics USA is also subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its presence in New Jersey and its widespread and continuous contacts with New Jersey.

11. Glenmark Generics Ltd. is also subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its presence in New Jersey through its wholly-owned subsidiary and agent, Glenmark Generics USA, and its widespread and continuous contacts with New Jersey, including through its wholly-owned subsidiary and agent, Glenmark Generics USA, and its sales of products in New Jersey and derivation of substantial revenues therefrom.

12. Glenmark Generics Ltd. and Glenmark Generics USA have previously submitted to the jurisdiction of the U.S. District Court for the District of New Jersey.

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

Count 1: Patent Infringement

14. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 13 above.

15. 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. Plaintiff is the owner of the ’815 Patent. A copy of the ’815 Patent is attached hereto as Exhibit A.

16. Plaintiff 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.

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

18. Upon information and belief, Glenmark Generics Ltd., itself or through its agent Glenmark Generics USA, submitted Abbreviated New Drug Application (“ANDA”) No. 204057 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.

19. Upon information and belief, Glenmark Generics USA aided and assisted in submission of ANDA No. 204057 and intends 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.

20. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '815 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. As part of the ANDA filing, Glenmark Generics Ltd., itself or through its agent Glenmark Generics USA, has purportedly provided written certification to the FDA that the claims of the '815 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of ORTHO TRI-CYCLEN® LO.

22. By letter dated July 5, 2012, Defendants gave written notice of Glenmark Generics Ltd.'s certification of invalidity and/or non-infringement of the '815 Patent, alleging that the '815 Patent is invalid, and informing Plaintiff that Glenmark Generics Ltd. 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.

23. Glenmark Generics Ltd. has infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204057 with a Paragraph IV

certification and seeking FDA approval of ANDA No. 204057 prior to the expiration of the '815 Patent. Moreover, if Glenmark Generics Ltd. commercially uses, offers for sale, or sells its generic version of ORTHO TRI-CYCLEN® LO, or induces or contributes to such conduct, it would further infringe the '815 Patent under § 271(a), (b), and/or (c).

24. Glenmark Generics USA is jointly and severally liable for any infringement of the '815 Patent. Upon information and belief, Glenmark Generics USA participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 204057 and the Paragraph IV certification to the FDA. Additionally, upon information and belief, Glenmark Generics USA will market and/or distribute the generic version of ORTHO TRI-CYCLEN® LO if ANDA No. 204057 is approved by the FDA.

25. Glenmark Generics USA's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 204057 and its Paragraph IV certification to the FDA constitutes infringement of the '815 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark Generics USA commercially uses, offers for sale, or sells the generic version of ORTHO TRI-CYCLEN® LO, or induces or contributes to such conduct, it would further infringe the '815 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

27. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '815 Patent. Plaintiff does not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiff seeks the following relief:

A. A judgment that Defendants 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. 204057 is not earlier than the expiration date of the '815 Patent, or any later expiration of exclusivity for the '815 Patent to which Plaintiff is or becomes entitled;

C. A permanent injunction restraining and enjoining Defendants 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. 204057;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 204057 would constitute infringement of the '815 Patent, or inducing or contributing to such conduct, by Defendants 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.

August 9, 2012

MCCARTER & ENGLISH, LLP

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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 consolidated matters *Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al. v. Watson Laboratories, Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Sandoz Inc.*, and *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Lupin Ltd., et al.*, Docket No. 08-5103 (SRC) (CLW); in the matter *Janssen Pharmaceuticals, Inc., et al. v. Mylan Inc., et al.*, Docket No. 10-6018 (SRC) (CLW); in the matter *Janssen Pharmaceuticals, Inc. v. Sun Pharma Global FZE, et al.*, Docket No. 11-06089 (SRC) (CLW); in the matter *Janssen Pharmaceuticals, Inc. v. Haupt Pharma, Inc. et al.*, Docket No. 12-03034 (SRC) (CLW); and in the matter *Ortho-McNeil Pharmaceutical, Inc., et al. v. Barr Laboratories, Inc.*, No. 03-4678 (SRC).

/s/ John E. Flaherty
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