

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

JANSSEN PHARMACEUTICALS, )  
INC. )

Plaintiff, )

v. )

Civil Action No. \_\_\_\_\_

SUN PHARMA GLOBAL FZE and )  
SUN PHARMACEUTICAL )  
INDUSTRIES, Inc. )

Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Janssen Pharmaceuticals, Inc., by its attorneys, for its complaint against Sun Pharma Global FZE (“Sun Global”) and Sun Pharmaceuticals Industries, Inc. (“Sun Pharma”) (collectively “Defendants” or “Sun”) 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 Sun Global is a corporation organized under the laws of the United Arab Emirates with its

principal place of business at Office #43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), P.O. Box #122304, Sharjah, United Arab Emirates.

3. Upon information and belief, Defendant Sun Pharma is a Michigan corporation with its principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512.

4. Upon information and belief, both Sun Global and Sun Pharma are wholly-owned subsidiaries of Sun Pharmaceutical Industries, Ltd.

5. Upon information and belief, Defendants manufacture numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone and/or through subsidiaries and agents.

6. Upon information and belief, Sun Global, itself or through its subsidiary, agent and/or alter ego Sun Pharma, holds various Abbreviated New Drug Applications on file with the U.S. Food and Drug Administration (“FDA”), pursuant to which it manufactures, sells, and distributes generic copies of pharmaceutical products.

## **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 each of Sun Global and Sun Pharma 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. Sun Pharma 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. Sun Global is also subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its presence in New Jersey through its subsidiary, agent and/or alter-ego Sun Pharma, and its widespread and continuous contacts with New Jersey through its subsidiaries, agents, and/or alter-egos.

12. Sun Global and Sun Pharma each have, on multiple occasions, 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, Sun Global, itself or through its subsidiary, agent and/or alter-ego Sun Pharma, submitted

Abbreviated New Drug Application (“ANDA”) No. 20-3317 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. 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).

19. As part of its ANDA filing, Sun Global, itself or through its subsidiary, agent and/or alter-ego Sun Pharma, 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 Sun’s generic version of ORTHO TRI-CYCLEN® LO.

20. By letter dated September 6, 2011, Sun gave written notice of its certification of invalidity and/or noninfringement of the ’815 Patent, alleging that the ’815 Patent is anticipated, obvious, and invalid, and informing Plaintiff that Sun 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.

21. Sun Global has infringed the ’815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 20-3317 with a Paragraph IV certification and seeking FDA approval of ANDA No. 20-3317 prior to

the expiration of the '815 Patent. Moreover, if Sun Global 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).

22. Sun Pharma is jointly and severally liable for any infringement of the '815 Patent. Upon information and belief, Sun Pharma participated in, contributed to, aided, abetted and/or induced the submission of ANDA 20-3317 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Sun Pharma will market and/or distribute Sun's generic version of ORTHO TRI-CYCLEN® LO if ANDA 20-3317 is approved by the FDA.

23. Sun Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 20-3317 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 Sun Pharma commercially uses, offers for sale, or sells Sun's 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).

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

25. 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. 20-3317 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. 20-3317;
- D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 20-3317 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.

MCCARTER & ENGLISH, LLP

By: /s/ John E. Flaherty

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October 17, 2011

**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) (MAS), in the matter *Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al. v. Mylan Inc., et al.,* Docket No. 10-6018 (SRC) (MAS) and of the patent at issue in *Ortho-McNeil Pharmaceutical, Inc., et al. v. Barr Laboratories, Inc.,* No. 03-4678 (SRC).

/s/ John E. Flaherty  
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