

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JANSSEN PHARMACEUTICALS,)	
INC.)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
VINTAGE PHARMACEUTICALS,)	
LLC.)	
)	
Defendant.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Janssen Pharmaceuticals, Inc., by its attorneys, for its complaint against Vintage Pharmaceuticals, LLC (“Vintage Pharmaceuticals” or “Defendant”) alleges as follows:

Nature of the Action

1. This is a civil action against Vintage Pharmaceuticals for infringement of U.S. Patent No. 6,214,815 (“the ’815 Patent”) (attached as Exhibit A). This action is being filed under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and it arises out of Vintage Pharmaceuticals’ filing of Abbreviated New Drug Application (“ANDA”) No. 207608 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 owned by Janssen.

The Parties

2. 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.

3. Upon information and belief, Defendant Vintage Pharmaceuticals is a corporation organized under the laws of Delaware, with a principal place of business at 130 Vintage Drive, Huntsville, Alabama 35811. Upon information and belief, Vintage Pharmaceuticals also does business under the name Qualitest Pharmaceuticals.

4. Upon information and belief, Defendant manufactures generic drugs for sale and use throughout the United States, including in this judicial district, alone and/or through subsidiaries and agents.

Jurisdiction and Venue

5. 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.

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

7. This Court has personal jurisdiction over Vintage Pharmaceuticals based on, *inter alia*, the fact that, on information and belief, Vintage Pharmaceuticals is incorporated in Delaware, giving rise to general personal jurisdiction in this district.

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

Count 1: Patent Infringement

9. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 8 above.

10. The '815 Patent, entitled "TRIPHASIC ORAL CONTRACEPTIVE," was 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.

11. 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.

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

13. Upon information and belief, Vintage Pharmaceuticals submitted ANDA No. 207608 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. Defendant's 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).

14. As part of its ANDA filing, Vintage Pharmaceuticals 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 Vintage Pharmaceuticals' generic version of ORTHO TRI-CYCLEN® LO.

15. By letter dated April 16, 2015, Vintage Pharmaceuticals 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 Vintage Pharmaceuticals seeks approval to engage in the commercial manufacture, use, and sale of a product that is bioequivalent to ORTHO TRI-CYCLEN® LO prior to the expiration of the '815 Patent.

16. Vintage Pharmaceuticals has infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 207608 with a Paragraph IV certification and seeking FDA approval of ANDA No. 207608 prior to the expiration of the '815 Patent.

Moreover, if Vintage Pharmaceuticals 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).

17. This is an exceptional case, entitling Plaintiff to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

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

Requested Relief

WHEREFORE, Plaintiff respectfully seeks the following relief:

- A. A judgment that Defendant 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. 207608 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 Defendant 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. 207608;
- D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 207608 would constitute infringement of the

'815 Patent, or inducing or contributing to such conduct, by Defendant 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. An award of costs and expenses in this action; and

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

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Tiffany Geyer Lydon (#3950)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
tlydon@ashby-geddes.com
amayo@ashby-geddes.com

Of Counsel:

George F. Pappas
Jeffrey B. Elikan
Benjamin C. Block
Eric R. Sonnenschein
COVINGTON & BURLING LLP
One CityCenter,
850 Tenth Street, NW
Washington, D.C. 20001
(202) 662-6000

Attorneys for Plaintiff

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