

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

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
SANDOZ, INC.	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Wyeth, by its attorneys, for its complaint against Sandoz, Inc. (“Sandoz”), alleges as follows:

**The Parties**

1. Plaintiff Wyeth is a corporation organized and existing under the laws of Delaware and has its headquarters at 5 Giralda Farms, Madison, New Jersey 07940.
2. Upon information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of Colorado, has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and does business in the State of Delaware.
3. Upon information and belief, Sandoz is in the business of manufacturing, distributing and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

**Jurisdiction and Venue**

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,500,814 (“the ‘814 patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Sandoz based on Sandoz's continuous and systematic business contacts with the State of Delaware. Additionally, in a telephone conversation on May 23, 2008, counsel for Sandoz agreed that Sandoz would not contest jurisdiction in this judicial district for this action.

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

#### Count 1: Patent Infringement

7. Wyeth realleges paragraphs 1 through 6 above as if fully set forth herein.

8. On December 31, 2002, the United States Patent and Trademark Office duly and legally issued the '814 patent, entitled "Hormonal Contraceptive." A true and correct copy of the '814 patent is attached hereto as Exhibit A.

9. Wyeth is the assignee of the '814 patent, which discloses and claims, *inter alia*, methods for hormonal contraception.

10. Wyeth currently markets a prescription oral contraceptive product under the trademark LYBREL® pursuant to approved New Drug Application ("NDA") 21-864. LYBREL® is covered by the claims of the '814 patent. As the patent owner, Wyeth is authorized to enforce the '814 patent.

11. Upon information and belief, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 90-262 ("Sandoz ANDA") to the Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of LYBREL® before the expiration of the '814 patent.

12. On or about April 18, 2008, Plaintiff received a letter dated April 16, 2008 stating that Sandoz had filed the Sandoz ANDA seeking approval to manufacture, use and sell a generic version of LYBREL® before the expiration of the '814 patent. The letter purports to notify Wyeth that the Sandoz ANDA contains a certification pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that Sandoz's manufacture, use or sale of the Sandoz ANDA product will not infringe any claims of the '814 patent, that the '814 patent is invalid, and/or that the '814 patent is unenforceable.

13. Defendant is liable for infringement of the '814 patent under 35 U.S.C. §271(e)(2)(A) by virtue of its filing the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to expiration of the '814 patent.

14. Wyeth is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Sandoz ANDA be a date that is not a date earlier than the expiration of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth is or becomes entitled.

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

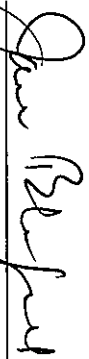
16. Wyeth will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the '814 patent. Wyeth does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Wyeth seeks the following relief:

- A. A judgment that Sandoz has infringed the '814 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 the Sandoz ANDA, No. 90-262, be not earlier than the expiration date of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth 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. 90-262;
- D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 90-262 would constitute infringement of the '814 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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