IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SANDOZ, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendant Sandoz, Inc. ("Sandoz"), allege as follows:

PARTIES

1. Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain, including OPANA®ER.

2. Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite II, Danbury, Connecticut 06810-5120. Penwest is a drug development company focused primarily on the identification, development and commercialization of products for diseases of the nervous system using its expertise in drug development and drug delivery technology, including the extended-release technology used in OPANA®ER.

3. Upon information and belief, Sandoz is a Colorado corporation, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. Upon information and belief, Sandoz is manufacturing generic drug products for sale and use throughout the United States, including in this judicial district.

NATURE OF ACTION

5. This is an action for infringement of United States Patent No. 5,958,456 ("the '456 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

FACTUAL BACKGROUND

7. On September 28, 1999, the PTO duly and legally issued the '456 patent, entitled "Controlled Release Formulation (Albuterol)" to Edward Mendell Co, Inc., as assignee. A true and correct copy of the '456 patent is attached as Exhibit A.

8. Penwest is the assignee and owner of the '456 patent, and Endo is an exclusive licensee of that patent in the relevant field of use pursuant to a strategic alliance agreement with Penwest.

9. On June 22, 2006, the United States Food and Drug Administration (the "FDA") approved Endo's new drug application No. 21-610 for OPANA®ER tablets, which contain oxymorphone hydrochloride, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

10. On October 19, 2007, Endo submitted information regarding the '456 patent to the FDA for listing in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations* (referred to as the "Orange Book"), with respect to OPANA®ER tablets. The FDA thereafter listed the '456 patent in the Orange Book with respect to OPANA®ER tablets, pursuant to 21 C.F.R. § 314.53(e).

11. Upon information and belief, prior to July 9, 2008, Sandoz submitted to the FDA paperwork purporting to constitute an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths, as generic versions of OPANA®ER tablets.

12. On July 9, 2008, Sandoz sent Penwest and Endo a notice stating that it had submitted ANDA No. 90-565 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths prior to the expiration of the '456 patent (the "First Sandoz Notice").

13. The First Sandoz Notice advised Penwest and Endo that Sandoz's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that it was Sandoz's opinion that the proposed manufacture, importation, use, sale, or offer for sale of the generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '456 patent.

14. In its statement of factual and legal bases for that opinion, the Sandoz Notice did not assert that the '456 patent is invalid.

15. On August 22, 2008, Penwest and Endo filed Civil Action No. 08-534 against Sandoz in this District Court. This suit is captioned *Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. v. Sandoz Inc.*, C.A. 08-534 and is an action for infringement of the '456 patent.

16. Upon information and belief, some time prior to November 17, 2008, Sandoz amended its ANDA to seek approval to engage in the commercial manufacture, use, and sale of oxymorphone hydrochloride extended-release oral tablets in 7.5 mg, 15 mg and 30 mg strengths, as generic versions of OPANA®ER tablets.

17. On November 17, 2008, Sandoz sent Penwest and Endo a notice stating that it had submitted ANDA No. 90-565 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release oral tablets in the additional 7.5 mg, 15 mg and 30 mg strengths prior to the expiration of the '456 patent (the "Second Sandoz Notice").

18. The Second Sandoz Notice advised Penwest and Endo that Sandoz's Second ANDA included a paragraph IV certification that it was Sandoz's opinion that the proposed manufacture, importation, use, sale, or offer for sale of the generic oxymorphone hydrochloride extended-release tablets described in its Second ANDA would not infringe any claim of the '456 patent.

19. The Second Sandoz Notice did not recite any basis for alleging that any claim of the '456 patent is invalid or unenforceable.

INFRINGEMENT OF THE '456 PATENT

20. Plaintiffs incorporate each of the preceding paragraphs 1 to 19 as if fully set forth herein.

21. Sandoz's submission of its ANDA to the FDA, and amendments thereto, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '456 patent under 35 U.S.C. § 271(e)(2)(A).

22. Sandoz's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would infringe the '456 patent.

23. Upon information and belief, Sandoz was aware of the existence of the '456 patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '456 patent constitutes infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Sandoz has infringed the '456 patent;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Sandoz's ANDA No. 90-565 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '456 patent, including any extensions;

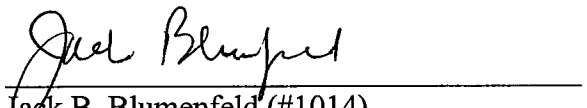
C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sandoz, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '456 patent for the full term thereof, including any extensions; and

D. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Mary B. Graham (#2256)
Julia Heaney (#3052)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mgraham@mnat.com
jheaney@mnat.com

Attorneys for Plaintiffs Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co.

Of Counsel:

Martin J. Black
Ann M. Caviani Pease
Robert D. Rhoad
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000

December 30, 2008