

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ENDO PHARMACEUTICALS INC. and)
PENWEST PHARMACEUTICALS CO.,)

Plaintiffs,)

v.)

ROXANE LABORATORIES INC.,)

Defendant.)

C.A. No. _____

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. (“Endo”) and Penwest Pharmaceuticals Co. (“Penwest”) for their Complaint against defendant Roxane Laboratories, Inc. (“Roxane”), 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 2981 Route 22, Patterson, New York 12563. 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, Roxane is a corporation organized under the laws of Nevada, having its principal place of business at 1809 Wilson Road, Columbus, OH 43228-8601.

4. Upon information and belief, Roxane is manufacturing generic drug products for sale and use throughout the United States, including in this judicial district. Roxane is registered to do business in New Jersey, and maintains a registered agent for service of process in New Jersey.

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 December 28, 2009, Roxane 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 a 40 mg strength, as a generic version of OPANA® ER tablets.

12. On or about December 28, 2009, Roxane sent Penwest and Endo a notice stating that it had submitted ANDA No. 200822 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release oral tablets in a 40 mg strength prior to the expiration of the ‘456 patent (the “First Roxane Notice”).

13. The First Roxane Notice advised Penwest and Endo that Roxane’s ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “paragraph IV certification”) that it was Roxane’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 First Roxane Notice did not assert that the '456 patent is invalid.

15. Upon information and belief, Roxane subsequently amended its ANDA.

16. On or about March 18, 2010, Roxane sent Penwest and Endo another notice stating that it had submitted an amendment to ANDA No. 200822 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release oral tablets in 5, 7.5, 10, 15, 20, and 30 mg strengths prior to the expiration of the '456 patent (the "Second Roxane Notice").

17. The Second Roxane Notice advised Penwest and Endo that Roxane's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that it was Roxane'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.

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

COUNT I

INFRINGEMENT OF THE '456 PATENT

19. Plaintiffs incorporate each of the preceding paragraphs 1 to 18 as if fully set forth herein.

20. Roxane's submission of an ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '456 patent under 35 U.S.C. § 271 (e)(2)(A).

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

22. Upon information and belief, Roxane 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 Roxane 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 Roxane's ANDA No. 200822 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 Roxane, 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.

Dated: April 16, 2010

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