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ATTORNEYS FOR *Plaintiffs Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co.*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
WATSON PHARMACEUTICALS, INC. WATSON LABORATORIES, INC., and WATSON PHARMA, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendants Watson Laboratories, Inc. ("Watson Labs"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") and Watson Pharma, Inc. ("Watson Pharma") (collectively, "Watson") (collectively "Watson"), 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. Watson Pharmaceuticals is a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California, and its commercial headquarters at 360 Mount Kemble Avenue, Morristown, New Jersey.

4. Watson Labs is a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California.

5. Watson Pharma is a Delaware corporation, having its principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey.

6. Watson Labs and Watson Pharma are wholly-owned subsidiaries of Watson Pharmaceuticals.

NATURE OF ACTION

7. This is an action for infringement of United States Patent Nos. 5,662,933 ("the '933 patent") and 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

8. 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).

9. Watson is in the business of making and selling generic drug products. Watson organizes its operations not by corporation, but by division, such that the Generic Division of Watson is responsible for developing and submitting Abbreviated New Drug Applications ("ANDAs") in reliance upon contributions from Watson Pharmaceuticals, Watson Laboratories and Watson Pharma. Each Watson entity acts as the agent of the other. Watson Pharmaceuticals makes generic drug products for sale and use throughout the United States, including in this judicial district.

10. Watson Pharmaceuticals is registered to do business in New Jersey, and maintains a registered agent for service of process in New Jersey. It conducts business in New Jersey on its own behalf and/or through its agents, Watson Pharma and Watson Labs

11. Watson Labs and Watson Pharma transact business in New Jersey, including contracting with and/or purchasing goods and services with companies located in New Jersey, selling products in New Jersey, and engaging in commercial activity in New Jersey.

12. Watson has listed its their generic drug products in the New Jersey formulary issued by the State of New Jersey Department of Health and Senior Services Drug Utilization Review Council.

FACTUAL BACKGROUND

13. On September 2, 1997, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '933 patent, entitled "Controlled Release Formulation (Albuterol)" to Edward Mendell Co., Inc., as assignee. A true and correct copy of the '933 patent is attached as Exhibit A.

14. 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 B.

15. Edward Mendell Co., Inc. was renamed Penwest Pharmaceuticals Co. on October 20, 1997.

16. Penwest is the assignee and owner of the '933 and '456 patents, and Endo is an exclusive licensee of that patent in the relevant field of use pursuant to a strategic alliance agreement with Penwest.

17. 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.

18. On October 19, 2007, Endo submitted information regarding the '933 and '456 patents 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 '933 and '456 patents in the Orange Book with respect to OPANA® ER tablets, pursuant to 21 C.F.R. § 314.53(e).

19. Prior to January 19, 2010, Watson 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.

20. On or about January 19, 2010, Watson sent Penwest and Endo a notice letter stating that it had submitted ANDA No. 200792 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 '933 and '456 patents.

21. In that notice letter, Watson advised Penwest and Endo that Watson's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that it was Watson'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 '933 or '456 patents.

22. In its statement of factual and legal bases for that opinion, Watson did not assert that the '933 or '456 patents were invalid.

INFRINGEMENT OF THE '933 PATENT

23. Plaintiff incorporates each of the preceding paragraphs 1 through 22 as if fully set forth herein.

24. Watson's submission of an ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '933 patent under 35 U.S.C. § 271(e)(2)(A).

25. The commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets by Watson would infringe the '933 patent.

26. Upon information and belief, Watson was aware of the existence of the '933 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 '933 patent constitutes infringement of that patent. This is an exceptional case.

INFRINGEMENT OF THE '456 PATENT

27. Plaintiffs incorporate each of the preceding paragraphs 1 to 26 as if fully set forth herein.

28. Watson'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).

29. The commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets by Watson would infringe the '456 patent.

30. Upon information and belief, Watson 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 Watson has infringed the '933 and '456 patents;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Watson's ANDA No. 200792 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 '933 and '456 patents, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Watson Pharmaceuticals, Watson Labs, Watson Pharma, and each of their respective officers, agents, servants and employees, and those persons in active concert or

participation with any of them, from infringement of the '933 or '456 patents for the full terms 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.

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