IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC.,

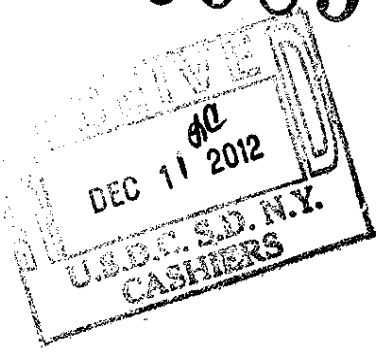
Plaintiff,

v.

ACTAVIS INC. and
ACTAVIS SOUTH ATLANTIC LLC,

Defendants.

C.A. No. 12 CV 8985



COMPLAINT

Plaintiff Endo Pharmaceuticals Inc. ("Endo") for its Complaint against Defendants Actavis Inc. and Actavis South Atlantic LLC (collectively "Defendants"), allege as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceuticals company engaged in the research, development, sale and marketing of prescription pharmaceuticals used, among other things, to treat and manage pain. Endo markets and distributes OPANA® ER, an innovative opioid painkiller designed to be crush-resistant (alternatively referred to herein as "Opana ER CRF")

2. Upon information and belief, defendant Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis Inc. is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial

district.

3. Upon information and belief, Actavis South Atlantic LLC ("ASA") is a limited liability company, organized and existing under the laws of the State of Delaware, having its principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325. ASA is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Actavis Inc. controls and directs the operations of ASA, and ASA and Actavis Inc. have acted as each other's alter ego, agent, and partner in the development, manufacturing, distribution, offer for sale, and sale in this judicial district of the infringing product at issue — generic, non crush-resistant "Oxymorphone Hydrochloride Extended-Release Tablets CII" ("Actavis Generic Oxymorphone ER Tablets").

NATURE OF ACTION

5. This is an action arising under 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) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

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

8. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, planned, contributed to, or participated in the commission of — tortious conduct which will lead to foreseeable harm and

injury to Plaintiff in the State of New York. A substantial part of the events giving rise to Plaintiff's claims occurred in this judicial district. The infringing product at issue is being sold in this judicial district.

9. Defendants maintain continuous and systematic contacts with the State of New York and this District. Defendants market and sell pharmaceutical products through the United States, including the State of New York, and regularly, systematically, and currently transact business in the Southern District of New York, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

10. Upon information and belief, Defendants currently sell significant quantities of over forty (40) different generic drug products in the Southern District of New York. Those products include, for example, generic versions of Wellbutrin XL®, Xanax®, and Cardizem® CD. A list of generic products manufactured and sold by Defendants in the United States is provided by Actavis at http://www.actavis.us/en/products/new.htm.

11. Based on the facts and causes alleged herein, and for additional reasons to be developed through discovery, this Court has personal jurisdiction over the Defendants.

FACTUAL BACKGROUND

Endo's Opana ER CRF NDA

12. On December 12, 2011, FDA approved Endo's Supplemental New Drug Application ("sNDA") 201655, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for Opana ER CRF, which is designed to be a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain.

13. Opana ER CRF is distributed and sold throughout the United States for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

THE PATENTS

14. On December 14, 2010, the PTO duly and legally issued U.S. Patent No. 7,851,482 (the '482 Patent), entitled "Method For Making Analgesics" to Johnson Matthey Public Limited Company ("Johnson Matthey") as assignee. Jen-Sen Dung, Erno M. Keskeny, and James J. Mencel are named as inventors. A true and correct copy of the '482 Patent is attached as Exhibit A.

15. Endo has acquired full title to the '482 Patent, and is now the sole owner and assignee of the '482 Patent.

16. Information regarding the Endo '482 Patent was submitted to FDA for listing in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2). Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the '482 Patent in the Orange Book with reference to NDA 201655.

17. On November 13, 2012, the PTO duly and legally issued U.S. Patent No. 8,309,122 (the '122 Patent), entitled "Oxymorphone Controlled Release Formulations" to Endo Pharmaceuticals, Inc. as assignee. Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee are named as inventors. A true and correct copy of the '122 Patent is attached as Exhibit B.

18. Endo is the sole owner and assignee of the '122 Patent.

19. Information regarding the Endo '122 Patent has been submitted to FDA for listing in the Orange Book.

20. On December 11, 2012, the PTO duly and legally issued U.S. Patent No. 8,329,216 (the '216 Patent), entitled "Oxymorphone Controlled Release Formulations" to Endo Pharmaceuticals, Inc. as assignee. Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee are named as inventors. A true and correct copy of the '216 Patent is attached as Exhibit C.

21. Endo is the sole owner and assignee of the '216 Patent.

22. Information regarding the Endo '216 Patent has been submitted to FDA for listing in the Orange Book.

23. Opana ER CRF is covered by one or more claims of each of the '482, '122 and '216 Patents.

DEFENDANTS' INFRINGING PRODUCT

24. On or about February 2008, ASA filed Abbreviated New Drug Application ("ANDA") No. 79-046 seeking approval to engage in the commercial manufacturing, use and sale of the Actavis's Generic Oxymorphone ER Tablets as a generic version of the original, non-crush-resistant formulation of Opana® ER (the "Discontinued Formulation").

25. In response, Endo filed suit against ASA for infringement of U.S. Patent No. 5,958,456 ("'456 patent"). *See Endo Pharmaceuticals Inc., et. al v. Actavis South Atlantic LLC*, United States District Court, District of New Jersey, Dkt. Nos. 2:08-cv-03482-KSH-PS and 2:08-cv-01563-KSH-PS. Endo and ASA settled their infringement dispute in February 2009.

26. Although the parties' settlement agreement granted Actavis a license under the '456 patent to make and sell its Generic Oxymorphone ER Tablets, nothing in the agreement grants Defendants any license or other rights under the '482, '122 or '216 Patents.

27. Defendants currently make and sell 7.5 mg and 15 mg strengths of the Actavis's

Generic Oxymorphone ER Tablets.

28. Defendants' manufacture and sale of the Actavis Generic Oxymorphone ER Tablets has caused Endo to suffer harm, including without limitation, irreparable injury to its business reputation and goodwill, lost sales of Opana® ER CRF, the loss of the benefit of its investment in developing the reformulated crush-resistant version of Opana® ER, and price erosion for Opana® ER CRF.

COUNT I: INFRINGEMENT OF THE '482 PATENT

29. Endo incorporates each of paragraphs 1-28 above as if set forth fully herein.

30. Defendants' commercial manufacture, sale, and offer for sale of the Actavis Generic Oxymorphone ER Tablets constitutes an infringement of the '482 Patent under 35 U.S.C. § 271(a)-(c).

31. Upon information and belief, Defendants are aware of the existence of the '482 Patent, and are aware that the commercial manufacture, sale, and offer for sale of filing of the Actavis Generic Oxymorphone ER Tablets constitutes infringement of the '482 Patent. Defendants' infringement is willful.

COUNT II: INFRINGEMENT OF THE '122 PATENT

32. Plaintiffs incorporate each of paragraphs 1-31 above as if set forth fully herein.

33. Defendants' commercial manufacture, sale, and offer for sale of the Actavis Generic Oxymorphone ER Tablets constitutes an infringement of the '122 Patent under 35 U.S.C. § 271(a)-(c).

34. Upon information and belief, Defendants are aware of the existence of the '122 Patent, and are aware that the commercial manufacture, sale, and offer for sale of filing of the Actavis Generic Oxymorphone ER Tablets constitutes infringement of the '122 Patent.

Defendants' infringement is willful.

COUNT III: INFRINGEMENT OF THE '216 PATENT

35. Endo incorporates each of paragraphs 1-34 above as if set forth fully herein.

36. Defendants' commercial manufacture, sale, and offer for sale of the Actavis Generic Oxymorphone ER Tablets constitutes an infringement of the '216 Patent under 35 U.S.C. § 271(a)-(c).

37. Upon information and belief, Defendants were aware of the pending issuance of the '216 Patent, and were aware that the commercial manufacture, sale, and offer for sale of filing of the Actavis Generic Oxymorphone ER Tablets would constitute infringement of the patent upon the '216 Patent's issuance. Defendants' infringement is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo respectfully requests the following relief:

A. A judgment that Defendants have infringed and are infringing the '482 Patent;

B. A judgment that Defendants have infringed and are infringing the '122 Patent;

C. A judgment that Defendants have infringed and are infringing the '216 Patent;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '482, '122, and '216 Patents, for the full terms thereof, including any extensions;

E. An order that damages or other monetary relief be awarded to Endo because of Defendants' engaging in the commercial manufacture, use, offer to sell, sale, distribution or importation of the Actavis Generic Oxymorphone ER Tablets, or in inducing such conduct by others, prior to the expiration of the '482, '122, and '216 Patents, and any additional period of

exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Endo with prejudgment interest;

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

G. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Endo in this action; and

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

Dated: December 11, 2012

By: _____

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