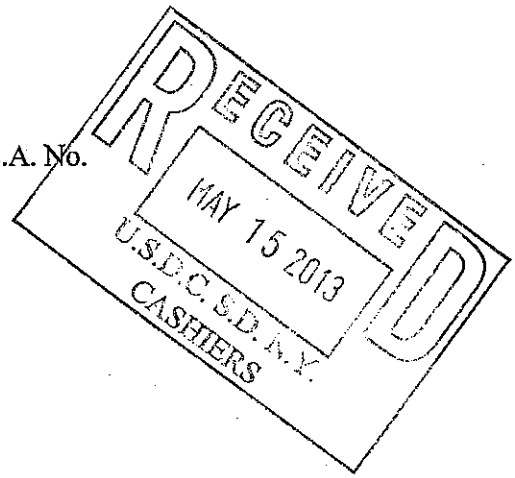
13 CV 3284

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

ENDO PHARMACEUTICALS INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC., Defendants.	C.A. No.



COMPLAINT

Plaintiff Endo Pharmaceuticals Inc. ("Endo") for its Complaint against Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively "Par" or "Defendants"), allege as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, PA 19355. 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 CRF, an innovative tamper-resistant opioid.

2. Upon information and belief, Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Upon information and belief, Par Pharmaceutical Companies, Inc. is a pharmaceutical company engaged in the research, development, manufacturing, marketing,

distribution, and sale of prescription pharmaceutical products throughout the United States, including in this judicial district.

4. Upon information and belief, Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Upon information and belief, Par Pharmaceutical, Inc. is a wholly-owned subsidiary of and serves as the generic drug division for Par Pharmaceutical Companies, Inc.

6. Upon information and belief, the acts of Par Pharmaceutical, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Par Pharmaceutical Companies, Inc.

NATURE OF ACTION

7. This is an action for arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *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) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

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

10. This Court has personal jurisdiction over both 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 in the State of New York that has led to foreseeable harm and injury to Plaintiff.

11. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. are registered with the New York State Department of State as corporations actively conducting business within New York and maintain registered agents within the state.

12. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. collaborate in the research, development, manufacture, testing, distribution and/or the sale of a number of pharmaceutical products manufactured and sold pursuant to approved abbreviated new drug applications within the United States and the State of New York generally and this judicial district specifically.

13. Upon information and belief, Defendants conduct research & development, manufacturing, supply chain activities, account services, and distribution through one or more of their facilities, located in this judicial district. Furthermore, Par Pharmaceutical Companies, Inc. states on its website (http://www.parpharm.com/index.php?option=com content&view=article&id=72&Itemid=29) that it "[e]mploys more than 600 professionals in offices in Woodcliff Lake, New Jersey (Corporate Headquarters), Spring Valley, New York (Research & Development, Manufacturing, Supply Chain, and Account Services) and Suffern, New York (Distribution)."

14. Upon information and belief, Par intends to distribute and sell generic OPANA® ER in a non-tamper resistant form in this judicial district should ANDA No. 200792 be approved by FDA.

15. Moreover, Par maintains continuous and systematic contacts with the State of New York and this District.

16. Upon information and belief, Defendants currently sell significant quantities of generic drug products in New York. Those products include, inter alia, generic versions of

Ambien® CR and Wellbutrin® XL. Examples of other generic products manufactured and sold by Par are at http://www.parpharm.com/generics/index.php?option=comproducts&view=default&articleid=46&Itemid=79.

17. Upon information and belief, Par Pharmaceutical Companies, Inc. is registered with the New York State Department of State as a corporation actively conducting business within New York.

18. Upon information and belief, Par Pharmaceutical, Inc. is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration Nos. 027015, 029055, and 101405.) The Registrations have an active status and are valid through November 30, 2013, July 31, 2014, and October 31, 2015, respectively.

19. Upon information and belief, Par plans to continue to maintain continuous and systematic contacts with the State of New York, including but not limited to, its aforementioned business of manufacturing, testing, distributing, and selling pharmaceuticals.

20. Furthermore, Par accepted that the U.S. District Court for the Southern District of New York has personal jurisdiction over it in *Endo Pharmaceuticals Inc., et al. v. Par Pharmaceutical Companies, Inc. et al.*, 12-cv-09261-TPG.

21. 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

22. On June 22, 2006, the United States Food and Drug Administration ("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.

23. 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.

24. OPANA® ER CRF is bioequivalent to the original OPANA® ER.

25. OPANA® ER CRF is a crush-resistant tablet that is intended to make the active ingredient, oxymorphone hydrochloride, more difficult to abuse. Endo discontinued sales of non-crush-resistant OPANA® ER (the "Discontinued Formulation") after FDA approved its sNDA for OPANA® ER CRF.

26. 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.

ENDO'S PATENTS

27. 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.

28. Endo subsequently acquired full title to the '482 Patent, and accordingly, Endo is now the sole owner and assignee of the '482 Patent.

29. 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.

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

31. 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.

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

33. Both OPANA® ER CRF and the original, now discontinued formulation of Opana ER are covered by one or more claims of each of the '482, '122, and '216 Patents.

34. Each of the '482, '122, and '216 Patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") with reference to OPANA® ER CRF. Endo has also listed three additional patents licensed from Grünenthal GMBH, U.S. Patents 8,114,383, 8,192,722, and 8,309,060.

DEFENDANTS' INFRINGING PRODUCT

35. Before January 19, 2010, Watson Pharmaceuticals, Inc. ("Watson") filed Abbreviated New Drug Application ("ANDA") No. 200792 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacturing, use, and sale of generic oxymorphone hydrochloride extended release tablets ("Defendants' Generic Oxymorphone ER Tablets") as a generic version of the discontinued, non-crush-resistant formulation of OPANA® ER.

36. In response, Endo filed suit against Watson in the District of New Jersey alleging infringement of U.S. Patent No. 5,662,933 ("the '933 Patent") and U.S. Patent No. 5,958,456 ("the '456 Patent") by Defendants' Generic Oxymorphone ER Tablets. *See Endo Pharmaceuticals Inc., et al. v. Watson Pharmaceuticals, Inc.*, United States District Court, District of New Jersey, Dkt. No. 10-cv-1242 KSH-PS. Endo and Watson settled their infringement dispute in October, 2010. The case was dismissed by Order dated October 21, 2010. Nothing in the agreement granted Watson any license or other right to practice the inventions claimed in the '482, '122, or '216 Patents.

37. The '482, '122, and '216 Patents had not issued at the time Watson submitted its certification under § 505(j) of the Federal Food, Drug and Cosmetic Act.

38. Upon information and belief, in 2012 Watson sold ANDA No. 200792 to Par in accordance with a Consent Agreement with the United States Federal Trade Commission, described at http://www.ftc.gov/opa/2012/10/watson.shtm.

39. Upon information and belief, some time before November 8, 2012, Par submitted to 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 crush-resistant oxymorphone hydrochloride extended-release tablets as a generic version of the product described in sNDA 201655.

40. In a letter dated November 8, 2012, received by Endo on November 12, 2012, Par purported to notify Endo that Par had submitted ANDA No. 20-4340, naming Par Pharmaceutical, Inc. as the ANDA applicant and seeking approval to manufacture, use, or sell Par's ANDA Product before the expiration of the '482, '383, and '722 Patents. On November

16, 20120 Par sent Endo a letter that was substantially similar to the November 8, 2012 letter. The Par Notice Letters claimed that Par's ANDA included a Paragraph IV Certification stating that it was Par's opinion that the claims of the '482, '383, and '722 Patents are invalid, unenforceable, or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of the Par ANDA Products.

41. In response, Endo filed suit against Par in the Southern District of New York, alleging infringement of the '482, '383, and '722 Patents based on Par's filing of ANDA No. 20-4340. *See Endo Pharmaceuticals Inc. et al. v. Par Pharmaceutical Companies, Inc., et al.*, 12-cv-09261-UA. That Complaint also included three Counts asserting infringement of the '122, '216, and '060 Patents, which each issued after Par sent its Notice Letters to Endo.

42. Upon information and belief, Defendants plan to market and sell their Generic Oxymorphone ER Tablets described in ANDA No. 200792 as a generic substitute for OPANA® ER, and in competition with OPANA® ER CRF.

43. Defendants' marketing and sale of Defendants' Generic Oxymorphone ER Tablets will cause wholesale drug distributors, prescribing physicians and pharmacies to purchase, prescribe, and dispense in competition with and as a substitute for OPANA® ER CRF.

44. Defendants' manufacture and sale of Defendants' Generic Oxymorphone ER Tablets will cause Endo to suffer immediate and irreparable 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 OPANA® ER and the reformulated crush-resistant version of OPANA® ER, and price erosion for OPANA® ER CRF.

COUNT I

(INFRINGEMENT OF THE '482 PATENT)

45. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

46. Watson's submission of an ANDA and amendments thereto to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations of which it notified Endo on or about January 19, 2010, under which Par now seeks approval to market Defendants' Generic Oxymorphone ER Tablets prior to expiration of the '482 Patent, constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

47. Defendants' commercial manufacture, offer for sale, or sale of Defendants' Generic Oxymorphone ER Tablets in the strengths set forth in its January 19, 2010 notice letter will infringe the '482 Patent under 35 U.S.C. § 271(a)-(c).

48. 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 Defendants' Generic Oxymorphone ER Tablets will constitute infringement of the Patent.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '482 PATENT)

49. Endo incorporates each of paragraphs 1-48 above as if set forth fully herein.

50. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

52. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' Generic Oxymorphone ER Tablets before the expiration of the '482 Patent.

53. Defendants' actions, including, but not limited to, purchasing Watson's ANDA No. 200792, filing Par's ANDA No. 20-4340, and engaging in the 12-cv-9261-TPG patent litigation indicate their intention to manufacture, offer to sell, sell and/or import the products that

are the subject of that ANDA before the expiration of the '482 Patent, and further indicate a refusal to change the course of its action in the face of acts by Plaintiff.

54. Any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets before the expiration of the '482 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '482 Patent.

55. Plaintiff is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets by Defendants before the expiration of the '482 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '482 Patent.

COUNT III

(INFRINGEMENT OF THE '122 PATENT)

56. Endo incorporates each of paragraphs 1-55 above as if set forth fully herein.

57. Watson's submission of an ANDA and amendments thereto to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations of which it notified Endo on or about January 19, 2010, under which Par now seeks approval to market Defendants' Generic Oxymorphone ER Tablets prior to expiration of the '122 Patent, constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

58. Defendants' commercial manufacture, offer for sale, or sale of Defendants' Generic Oxymorphone ER Tablets in the strengths set forth in its January 19, 2010 notice letter will infringe the '122 Patent under 35 U.S.C. § 271(a)-(c).

59. 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 Defendants' Generic Oxymorphone ER Tablets will constitute infringement of the Patent.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '122 PATENT)

60. Endo incorporates each of paragraphs 1-59 above as if set forth fully herein.

61. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

63. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' Generic Oxymorphone ER Tablets before the expiration of the '122 Patent.

64. Defendants' actions, including, but not limited to, purchasing Watson's ANDA No. 200792, filing Par's ANDA No. 20-4340, and engaging in the 12-cv-9261-TPG patent litigation indicate their intention to manufacture, offer to sell, sell and/or import the products that are the subject of that ANDA before the expiration of the '122 Patent, and further indicate a refusal to change the course of its action in the face of acts by Plaintiff.

65. Any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets before the expiration of the '122 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '122 Patent.

66. Plaintiff is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets by Defendants before the expiration of the '122 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '122 Patent.

COUNT V

(INFRINGEMENT OF THE '216 PATENT)

67. Endo incorporates each of paragraphs 1-66 above as if set forth fully herein.

68. Watson's submission of an ANDA and amendments thereto to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations of which it notified Endo on or about January 19, 2010, under which Par now seeks approval to market Defendants' Generic Oxymorphone ER Tablets prior to expiration of the '216 Patent, constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

69. Defendants' commercial manufacture, offer for sale, or sale of Defendants' Generic Oxymorphone ER Tablets in the strengths set forth in its January 19, 2010 notice letter will infringe the '216 Patent under 35 U.S.C. § 271(a)-(c).

70. Upon information and belief, Defendants are aware of the '216 Patent, and are aware that the commercial manufacture, sale, and offer for sale of filing of Defendants' Generic Oxymorphone ER Tablets will constitute infringement of the Patent.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '216 PATENT)

71. Endo incorporates each of paragraphs 1-70 above as if set forth fully herein.

72. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

74. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' Generic Oxymorphone ER Tablets before the expiration of the '216 Patent.

75. Defendants' actions, including, but not limited to, purchasing Watson's ANDA No. 200792, filing Par's ANDA No. 20-4340, and engaging in the 12-cv-9261-TPG patent litigation indicate their intention to manufacture, offer to sell, sell and/or import the products that are the subject of that ANDA before the expiration of the '216 Patent, and further indicate a refusal to change the course of its action in the face of acts by Plaintiff.

76. Any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets before the expiration of the '216 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '216 Patent.

77. Plaintiff is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Oxymorphone ER Tablets by Defendants before the expiration of the '216 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '216 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Endo respectfully requests the following relief:

A. A judgment that Defendants infringe the '482 Patent;

B. A declaration that Defendants' commercial manufacture, distribution, use and sale of Defendants' Generic Oxymorphone ER Tablets would infringe the '482 Patent;

C. A judgment that Defendants infringe the '122 Patent;

D. A declaration that Defendants' commercial manufacture, distribution, use and sale of Defendants' Generic Oxymorphone ER Tablets would infringe the '122 Patent;

E. A judgment that Defendants infringe the '216 Patent;

F. A declaration that Defendants' commercial manufacture, distribution, use and sale of Defendants' Generic Oxymorphone ER Tablets would infringe the '216 Patent;

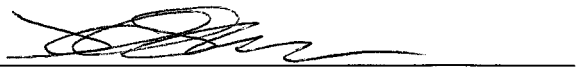
G. Preliminary and permanent injunctive relief restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '482, '122, and '216 Patents, for the full terms thereof, including any extensions;

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

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

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

Dated: May 15, 2013

By: 

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