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

ENDO PHARMACEUTICALS INC.,

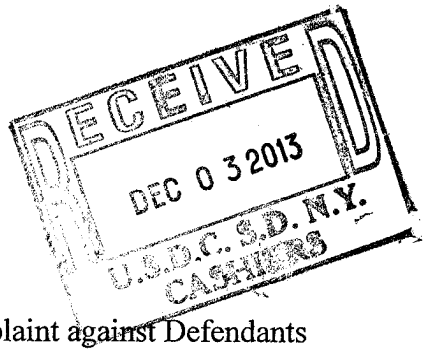
Plaintiff,

v.

RANBAXY LABORATORIES LTD., RANBAXY INC., and RANBAXY PHARMACEUTICALS INC.,

Defendants.

C.A. No. 13 CV 8597



COMPLAINT

Plaintiff Endo Pharmaceuticals Inc. ("Endo") for its Complaint against Defendants Ranbaxy Laboratories Limited ("RLL"), Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. ("RPI") (collectively, "Defendants" or "Ranbaxy"), 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, an innovative opioid painkiller designed to be crush-resistant (alternatively referred to herein as "OPANA® ER CRF").

2. Defendant RLL is an Indian corporation, organized and existing under the country of India, and having its headquarters and principal place of business at Plot No. 90, Sector 32, Gurgaon-122001, Haryana, India.

3. Upon information and belief, RLL is an international pharmaceutical company engaged in the development, manufacture, distribution, sale and marketing of pharmaceuticals

for sale and use in over 150 countries around the world and throughout the United States, including in this judicial district.

4. Defendant Ranbaxy Inc. is a wholly-owned subsidiary of RLL organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

5. Upon information and belief, Ranbaxy Inc. is the North American commercial arm of RLL, which is engaged in the development, manufacture, distribution, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

6. Defendant RPI is a wholly-owned subsidiary of RLL organized and existing under the laws of the State of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257.

7. Upon information and belief, RPI is a generic pharmaceutical company engaged in the development, manufacture, distribution, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

8. Upon information and belief, RLL controls and directs the operations of Ranbaxy Inc. and RPI, and together all three companies have acted as each other's alter ego, agent, and partner in the development and preparation of Abbreviated New Drug Application ("ANDA") No. 204527 ("Ranbaxy's ANDA") for generic "Oxymorphone Hydrochloride Extended-Release Tablets" ("Ranbaxy Generic Oxymorphone ER Tablets").

NATURE OF ACTION

9. This is an action 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

10. 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).

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

12. 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.

13. Defendants maintain continuous and systematic contacts with the State of New York and this District. Defendants market and sell pharmaceutical products throughout 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.

14. Upon information and belief, Defendants currently sell significant quantities of over fifty (50) different generic drug products in the Southern District of New York. Those products include, for example, generic versions of Lipitor®, Ativan® CIV, and Imitrex® CD. Defendants publish a list of generic products manufactured and sold by Ranbaxy in the United States at http://www.ranbaxy.com/us/products/generic-products/.

15. Ranbaxy Inc. and RPI are registered as Foreign Business Corporations by the New York State Department of State, Division of Corporations. Ranbaxy Inc. and RPI list as their registered agent Corporation Service Company, 80 State Street, Albany, NY 12207-2543.

16. RPI 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 No. 025942). The registration has an active status and is valid through February 28, 2015.

17. Upon information and belief, Defendants intend to distribute and sell generic OPANA® ER in this judicial district should Ranbaxy's ANDA be approved by FDA.

18. Furthermore, the Defendants recently admitted that this Court had jurisdiction over each of them in another case by the Plaintiff involving the same patents-in-suit, *Endo Pharmaceuticals Inc. v. Ranbaxy Laboratories Ltd., et al.* 13-cv-4343 (TPG) (S.D.N.Y.).

19. 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

20. On December 12, 2011, FDA approved Endo's New Drug Application ("NDA") 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.

21. 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

22. 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.

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

24. 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.

25. 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.

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

27. Information regarding the Endo '122 Patent was submitted to FDA for listing in the Orange Book. Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the '122 Patent in the Orange Book with reference to NDA 201655.

28. 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.

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

30. Information regarding the Endo '216 Patent was submitted to FDA for listing in the Orange Book. Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the '216 Patent in the Orange Book with reference to NDA 201655.

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

DEFENDANTS' INFRINGING PRODUCT

32. Sometime before October 30, 2013, Defendants filed ANDA No. 204527 ("Ranbaxy's 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 manufacturing, use and sale of the Ranbaxy Generic Oxymorphone ER Tablets ("ANDA Products") as a generic version of OPANA® ER CRF. In a letter dated October 30, 2013 ("Notice Letter"), Ranbaxy notified Endo that Ranbaxy had made an allegation under § 505(j)(2)(A)(vii)(IV) as part of filing ANDA No. 204527 with FDA.

33. Upon information and belief, Defendants plan to market and sell Ranbaxy's Generic Oxymorphone ER Tablets as a generic substitute for and in competition with OPANA® ER CRF.

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

35. Defendants' manufacture and sale of Ranbaxy's 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

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

37. Ranbaxy's submission of ANDA No. 204527 to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '482 Patent under 35 U.S.C. § 271(e)(2)(A).

38. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '482 Patent. If granted approval, Ranbaxy intends to launch its ANDA Products before expiration of the '482 Patent.

39. Defendants' commercial manufacture, offer for sale, or sale of the Ranbaxy Generic Oxymorphone ER Tablets in the strengths set forth in Ranbaxy's October 30, 2013 Notice Letter will infringe the '482 Patent under 35 U.S.C. § 271(a)-(c).

40. Any launch by Ranbaxy of its ANDA Products before expiration of the '482 Patent would cause Endo to suffer immediate and irreparable harm.

41. Ranbaxy was aware of the existence of the '482 Patent, as demonstrated by its reference to that patent in its Notice Letter, and was aware that the filing of its Paragraph IV Certification with respect to the '482 Patent would constitute infringement of the patent. Defendants' infringement is willful.

COUNT II: INFRINGEMENT OF THE '122 PATENT

42. Endo incorporates each of paragraphs 1-41 above as if set forth fully herein.

43. Ranbaxy's submission of ANDA No. 204527 to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '122 Patent under 35 U.S.C. § 271(e)(2)(A).

44. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '122 Patent. If granted approval, Ranbaxy intends to launch its ANDA Products before expiration of the '122 Patent.

45. Defendants' commercial manufacture, offer for sale, or sale of the Ranbaxy Generic Oxymorphone ER Tablets in the strengths set forth in Ranbaxy's October 30, 2013 Notice Letter will infringe the '122 Patent under 35 U.S.C. § 271(a)-(c).

46. Any launch by Ranbaxy of its ANDA Products before expiration of the '122 Patent would cause Endo to suffer immediate and irreparable harm.

47. Ranbaxy was aware of the existence of the '122 Patent, as demonstrated by its reference to that patent in its Notice Letter, and was aware that the filing of its Paragraph IV Certification with respect to the '122 Patent would constitute infringement of the patent. Defendants' infringement is willful.

COUNT III: INFRINGEMENT OF THE '216 PATENT

48. Endo incorporates each of paragraphs 1-47 above as if set forth fully herein.

49. Ranbaxy's submission of ANDA No. 204527 to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '216 Patent under 35 U.S.C. § 271(e)(2)(A).

50. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '216 Patent. If granted approval, Ranbaxy intends to launch its ANDA Products before expiration of the '216 Patent.

51. Defendants' commercial manufacture, offer for sale, or sale of the Ranbaxy Generic Oxymorphone ER Tablets in the strengths set forth in Ranbaxy's October 30, 2013 Notice Letter will infringe the '216 Patent under 35 U.S.C. § 271(a)-(c).

52. Any launch by Ranbaxy of its ANDA Products before expiration of the '216 Patent would cause Endo to suffer immediate and irreparable harm.

53. Ranbaxy was aware of the existence of the '216 Patent, as demonstrated by its reference to that patent in its Notice Letter, and was aware that the filing of its Paragraph IV Certification with respect to the '216 Patent would constitute infringement of the patent. Defendants' infringement is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Endo respectfully requests the following relief:

A. A judgment that Defendants have infringed and are infringing the '482 Patent and a declaration that Defendants' commercial manufacture, distribution, use and sale of the Ranbaxy Generic Oxymorphone ER Tablets would infringe the '482 Patent;

B. A judgment that Defendants have infringed and are infringing the '122 Patent and a declaration that Defendants' commercial manufacture, distribution, use and sale of the Ranbaxy Generic Oxymorphone ER Tablets would infringe the '122 Patent;

C. A judgment that Defendants have infringed and are infringing the '216 Patent and a declaration that Defendants' commercial manufacture, distribution, use and sale of the Ranbaxy Generic Oxymorphone ER Tablets would infringe the '216 Patent;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Ranbaxy's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the '482,'122, and '216 Patents, including any extensions;

E. 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;

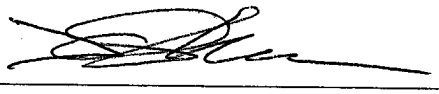
F. An order that damages or other monetary relief be awarded to Endo if Ranbaxy engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Ranbaxy's ANDA Products, or in inducing such conduct by others, before the expiration of the '482,'122, and '216 Patents, and any additional period of exclusivity to which Endo is or becomes entitled, and that any such damages or monetary relief be trebled and awarded to Endo with prejudgment interest;

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

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

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

Dated: December 3, 2013

By: 

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