IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ROXANE LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Mallinckrodt LLC ("Mallinckrodt"), for their Complaint against Defendant Roxane Laboratories, Inc. ("Roxane"), 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. Plaintiff Mallinckrodt is a Delaware company, having its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri 63042. Mallinckrodt manufactures and distributes products used in diagnostic procedures and in the treatment of pain and related conditions.

3. Upon information and belief, Roxane Laboratories, Inc. 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.

NATURE OF ACTION

5. 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

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 the Defendant by virtue of the fact that, *inter alia*, it has committed — or aided, abetted, planned, contributed to, or participated in the commission of — tortious conduct in the State of Delaware that has led to foreseeable harm and injury to Endo and Mallinckrodt.

9. Upon information and belief, Roxane has 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) ("ANDA No. 20-0822" or "Roxane's ANDA"), seeking approval to engage in the commercial manufacturing, use, and sale of generic oxymorphone hydrochloride extended release tablets ("Roxane's Generic Oxymorphone ER Tablets") as a generic version of the discontinued, non-crush-resistant formulation of OPANA® ER.

10. Upon information and belief, Roxane intends to distribute and sell generic OPANA® ER in a non-tamper resistant form in this judicial district should ANDA No. 20-0822 be approved by FDA.

11. Moreover, Roxane maintains continuous and systematic contacts with the State of Delaware and this District.

12. Upon information and belief, Roxane currently sells significant quantities of generic drug products in this District. Those products include, for example, generic versions of Flonase®, Seroquel®, and Cozaar®. A list of generic products manufactured and sold by Roxane in the United States are at https://www.rli-touchpoint.com/tpPortal/appmanager/touchpoint/rli?_nfpb=true&_pageLabel=rli_productcatalog_book.

13. Furthermore, Roxane Pharmaceuticals has been sued as a patent infringer in this Court, and has declined to contest that this Court has personal jurisdiction over it. *See, e.g.*, *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, No. 14-cv-922-LPS; *Teijin Ltd. v. Roxane Labs., Inc.*, No. 14-cv-189-SLR.

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

FACTUAL BACKGROUND

Endo's OPANA® ER CRF NDA

15. 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.

16. 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.

17. Opana ER CRF is bioequivalent to the original Opana ER.

18. 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.

19. 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 '737 PATENT

20. On August 19, 2014, the PTO duly and legally issued U.S. Patent No. 8,808,737 ("the '737 Patent"), entitled "Method of Treating Pain Utilizing Controlled Release Oxymorphone Pharmaceutical Compositions and Instruction on Dosing for Renal Impairment" to Endo Pharmaceuticals Inc. as assignee. Harry Ahdieh is named as the inventor. A true and correct copy of the '737 Patent is attached as Exhibit A.

21. Endo is the sole owner and assignee of the '737 Patent.

22. Opana ER CRF is covered by one or more claims of the '737 Patent.

23. Endo has submitted patent information regarding the '737 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '737 Patent in the Orange Book for Opana ER CRF.

THE '779 PATENT

24. On October 28, 2014, the PTO duly and legally issued U.S. Patent No. 8,871,779 ("the '779 Patent"), entitled "Process for Preparing Morphinan-6-One Products with Low Levels of α,β-Unsaturated Ketone Compounds" to Mallinckrodt as assignee. Henry J. Buehler, William E. Dummitt, Anthony Mannino, Dennis C. Aubuchon, and Hong Gu are named as inventors. A true and correct copy of the '779 Patent is attached as Exhibit B.

25. Mallinckrodt is the assignee and owner of the '779 Patent.

26. Endo has an exclusive license to the '779 Patent from Mallinckrodt in the appropriate field of use, including the exclusive right to enforce the '779 Patent in that field.

27. Opana ER CRF is covered by one or more claims of the '779 Patent.

28. Endo has submitted patent information regarding the '779 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '779 Patent in the Orange Book for Opana ER CRF.

ROXANE'S ANDA FILING

29. Before December 28, 2009, Roxane filed Abbreviated New Drug Application (ANDA No. 20-0822), 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 ("Roxane's Generic Oxymorphone ER Tablets") as a generic version of the discontinued, non-crush-resistant formulation of OPANA® ER.

30. In response, Endo filed suit against Roxane in the District of New Jersey alleging infringement of U.S. Patent No. 5,958,456 ("the '456 Patent") by Roxane's Generic Oxymorphone ER Tablets. *See Endo Pharmaceuticals Inc., et al. v. Roxane Laboratories, Inc*., United States District Court, District of New Jersey, Nos. 10-cv-00534-KSH-PS and 10-cv-1964-KSH-PS. Endo and Roxane settled their infringement dispute in March, 2011. The cases were dismissed by Order dated May 11, 2011.

31. Although the parties' settlement agreement granted Roxane a license under the '456 Patent to make and sell its Generic Oxymorphone ER Tablets, nothing in the agreement grants Roxane any license or other right to practice the inventions claimed in the '737 or '779 Patents.

32. Upon information and belief, Defendant plans to market and sell Roxane's Generic Oxymorphone ER Tablets described in ANDA No. 20-0822 in competition with Opana® ER CRF.

33. Defendant's marketing and sale of Roxane's Generic Oxymorphone ER Tablets will cause wholesale drug distributors, prescribing physicians and pharmacies to purchase, prescribe, and dispense it in competition with Opana® ER CRF.

34. Defendant's manufacture and sale of Roxane'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.

35. Pursuant to its ANDA, Roxane is seeking FDA approval to make, use, and sell its Generic Oxymorphone ER Tablets prior to expiration of the '737 and '779 Patents.

ENDO'S COUNT I: INFRINGEMENT OF THE '737 PATENT

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

37. The submission of Roxane's ANDA No. 20-0822 to FDA constitutes infringement of the '737 Patent under 35 U.S.C. § 271(e)(2)(A).

38. Roxane is seeking FDA approval to engage in the commercial manufacture, use, or sale of Roxane's Generic Oxymorphone ER Tablets before expiration of the '737 Patent. On information and belief, if granted approval, Roxane intends to launch its Generic Oxymorphone ER Tablets before expiration of the '737 Patent.

39. Any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane's Generic Oxymorphone ER Tablets before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the

'737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

40. Any such launch by Roxane of its Generic Oxymorphone ER Tablets before expiration of the '737 Patent would cause Endo to suffer immediate and irreparable harm.

ENDO'S COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '737 PATENT

41. Endo incorporates each of paragraphs 1-40 above as if set forth fully herein.

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

43. There is an actual case or controversy such that the Court may entertain Endo'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.

44. Defendant has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Roxane's Generic Oxymorphone ER Tablets before expiration of the '737 Patent.

45. Defendant's actions, including, but not limited to filing ANDA 20-0822 and enging in the 10-cv-00534-KSH-PS and 10-cv-1964-KSH-PS patent litigations, indicate its intention to manufacture, offer to sell, and sell the products that are the subject of that ANDA before expiration of the '737 Patent, and further indicate a refusal to change the course of its action in the face of acts by Endo.

46. Any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane's Generic Oxymorphone ER Tablets before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the

'737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

47. Endo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane's Generic Oxymorphone ER Tablets by Defendant before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT III:
INFRINGEMENT OF THE '779 PATENT

48. Endo and Mallinckrodt incorporate each of paragraphs 1-35 above as if set forth fully herein.

49. The submission of Roxane's ANDA No. 20-0822 to FDA constitutes infringement of the '779 Patent under 35 U.S.C. § 271(e)(2)(A).

50. Roxane is seeking FDA approval to engage in the commercial manufacture, use, or sale of its Generic Oxymorphone ER Tablets before expiration of the '779 Patent. On information and belief, if granted approval, Roxane intends to launch Roxane's Generic Oxymorphone ER Tablets before expiration of the '779 Patent.

51. Any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane's Generic Oxymorphone ER Tablets before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

52. Any launch by Roxane of its Generic Oxymorphone ER Tablets before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

53. Upon information and belief, Defendants are aware of the existence of the ’779 Patent, and are aware that the commercial manufacture, sale, and offer for sale of Roxane’s Generic Oxymorphone ER Tablets constitutes infringement of the ’779 Patent.

ENDO AND MALLINCKRODT’S COUNT IV:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’779 PATENT

54. Endo and Mallinckrodt incorporate each of paragraphs 1-35 and 48-53 above as if set forth fully herein.

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

56. There is an actual case or controversy such that the Court may entertain Plaintiffs’ 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.

57. Defendant has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Roxane’s Generic Oxymorphone ER Tablets before expiration of the ’779 Patent.

58. Defendant’s actions, including, but not limited to filing ANDA 20-0822 and engaging in the 10-cv-00534-KSH-PS and 10-cv-1964-KSH-PS patent litigations, indicate its intention to manufacture, offer to sell, sell and/or import the products that are the subject of that ANDA before expiration of the ’779 Patent, and further indicate a refusal to change the course of its action in the face of acts by Plaintiff.

59. Any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane’s Generic Oxymorphone ER Tablets before expiration of the ’779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’779 Patent under 35 U.S.C. § 271(a)-(c).

60. Any launch by Roxane of its Generic Oxymorphone ER Tablets before expiration of the ’779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

61. Plaintiffs are entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Roxane’s Generic Oxymorphone ER Tablets by Defendant before expiration of the ’779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’779 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo and Mallinckrodt respectfully request the following relief:

A. A judgment that Roxane has infringed the ’737 Patent, and a declaration that Roxane’s commercial manufacture, distribution, use, and sale of its Generic Oxymorphone ER Tablets would infringe the ’737 Patent;

B. A declaration that the ’737 Patent is valid and enforceable;

C. A judgment that Roxane has infringed the ’779 Patent, and a declaration that Roxane’s commercial manufacture, distribution, use, and sale of its Generic Oxymorphone ER Tablets would infringe the ’779 Patent;

D. A declaration that the ’779 Patent is valid and enforceable;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Roxane’s ANDA No. 20-0822 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 ’737 and ’779 Patents, including any extensions;

F. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, 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 '737 and '779 Patents for the full terms thereof, including any extensions;

G. An order that damages or other monetary relief be awarded to Plaintiffs if Roxane engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Roxane's Generic Oxymorphone ER Tablets, or in inducing such conduct by others, prior to the expiration of the '737 and '779 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 Plaintiffs with prejudgment interest;

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.

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