UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. MALLINCKRODT INC., Defendant.	Civil Action No. 06-CV-13095

FIRST AMENDED COMPLAINT

Plaintiffs, Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue"), for their Complaint herein, aver as follows:

Nature of the Action

1. This is an action for a judgment of patent infringement 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 and 2202.

The Parties

2. Plaintiff, Purdue Pharma L.P. ("Purdue Pharma"), is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, Stamford, Connecticut 06901. Purdue Pharma is an owner by assignment of the patents-in-suit identified in paragraph 9 below, and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®, which is listed in the United States Food and Drug Administration's ("FDA")

Approved Drug Products With Therapeutic Equivalence Evaluations, a copy of which is attached hereto as Exhibit A.

3. Plaintiff, The P.F. Laboratories, Inc. ("P.F. Labs"), is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey 07512. P.F. Labs is an owner by assignment of the patents-in-suit identified in paragraph 9 below and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

4. Plaintiff, Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals"), is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893. Purdue Pharmaceuticals is an owner by assignment of the patents-in-suit identified in paragraph 9 below and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. Upon information and belief, defendant, Mallinckrodt Inc. ("Mallinckrodt"), is a corporation organized and existing under the laws of the State of New York, having places of business at 111 Eighth Avenue, New York, New York 10011, and 675 McDonnell Boulevard, PO Box 5840, St. Louis, Missouri 63134. Upon information and belief, Mallinckrodt is currently transacting business in this judicial district by making and shipping, or using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products in this judicial district. Mallinckrodt derives substantial revenue from interstate or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and this judicial district. Mallinckrodt has committed, and

unless enjoined will continue to commit, tortious acts without the State of New York that Mallinckrodt expects or should reasonably expect to have consequences in the State of New York.

Jurisdiction and Venue

6. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Jurisdiction over Mallinckrodt is proper in this Court by virtue of, *inter alia*, defendant's incorporation, place of business, and transaction of business in New York.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

The Patents-in-Suit

9. Plaintiffs, Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in and to the following United States patents, including all right to sue and to recover for past infringement thereof, which patents contain one or more claims covering the composition and method of use of controlled-release oxycodone pain-relief medication:

(a) United States Patent No. 5,549,912, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("'912 Patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on August 27, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors;

(b) United States Patent No. 5,508,042, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("'042 Patent"), a copy of which is attached

hereto as Exhibit C, which was duly and legally issued on April 16, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors; and

(c) United States Patent No. 5,656,295, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("'295 Patent"), a copy of which is attached hereto as Exhibit D, which was duly and legally issued on August 12, 1997, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors.

10. On January 5, 2004, the United States District Court for the Southern District of New York ("District Court") issued an Opinion and Order in *Purdue Pharma L.P. v. Endo Pharms., Inc.*, Civil Action Nos. 00-CV-8029 (SHS), 01-CV-2109 (SHS), and 01-CV-8177 (SHS) (S.D.N.Y.) ("the Endo action"), holding the '912, '042, and '295 Patents (1) infringed by Endo Pharmaceuticals, Inc. ("Endo") and Endo Pharmaceuticals Holdings Inc. ("Endo Holdings") and (2) unenforceable due to inequitable conduct ("Endo Unenforceability Order"). Furthermore, the District Court enjoined Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company (collectively, "Purdue Plaintiffs") from further enforcement of the '912, '042, and '295 Patents ("Endo Injunction").

11. On January 12, 2004, the Purdue Plaintiffs filed a Notice of Appeal to the Court of Appeals for the Federal Circuit ("Federal Circuit") seeking, *inter alia*, relief from the Endo Injunction.

12. On January 13, 2004, the Purdue Plaintiffs moved the District Court to suspend the Endo Injunction. On February 17, 2004, the District Court denied that motion.

13. On June 28, 2004, the District Court issued a Memorandum Order in *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, Civil Action Nos. 01-CV-8507 (SHS), 01-CV-11212 (SHS), and 03-CV-2312 (SHS) (S.D.N.Y.) ("the Teva action"), granting a motion by

Teva Pharmaceuticals USA, Inc. ("Teva") for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Teva Collateral Estoppel Order").

14. On January 5, 2005, the District Court issued an Order in *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH,* Civil Action No. 99-CV-3658 (SHS) (S.D.N.Y.) ("the Roxane action"), granting a motion by Boehringer Ingelheim GmbH, Roxane Laboratories, Inc., and Boehringer Ingelheim Corp. ("Roxane") for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Roxane Collateral Estoppel Order").

15. On January 5, 2005, the District Court issued an Order in *Purdue Pharma L.P. v. Impax Labs., Inc.,* Civil Action No. 02-CV-2803 (SHS) (S.D.N.Y.) ("the Impax action"), granting a motion by Impax Laboratories, Inc. ("Impax") for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Impax Collateral Estoppel Order").

16. On June 7, 2005, the Federal Circuit issued an Opinion affirming the Endo Unenforceability Order.

17. On February 1, 2006, the Federal Circuit withdrew its June 7, 2005 Opinion and issued a new Opinion (1) affirming the portion of the District Court's January 5, 2004 Opinion and Order adjudging the '912, '042, and '295 Patents infringed by Endo and Endo Holdings; (2) vacating the Endo Unenforceability Order; and (3) remanding for further proceedings.

18. On March 29, 2006, the District Court entered the mandate from the Federal Circuit's February 1, 2006 Opinion.

19. On October 3, 2006, the Purdue Plaintiffs and Impax filed a Proposed Stipulated Order with the District Court seeking vacatur of the Impax Collateral Estoppel Order.

20. On October 6, 2006, the Court entered a Consent Judgment in the Endo action finding the Purdue patents infringed.

21. On October 12, 2006, the Court entered a Consent Judgment in the Teva action finding the Purdue patents valid, enforceable, and infringed, and vacating the Teva Collateral Estoppel Order in all respects.

22. On October 17, 2006, the Purdue Plaintiffs and Roxane filed a Proposed Stipulated Order with the District Court seeking vacatur of the Roxane Collateral Estoppel Order.

23. On November 24, 2006, the Court entered the Proposed Stipulated Orders from the Impax and Roxane actions vacating the Impax and Roxane Collateral Estoppel Orders.

Count I
Patent Infringement Related to Mallinckrodt's Oxycodone Hydrochloride Extended-Release Tablets

24. Plaintiffs incorporate by reference the averments of Paragraphs 1-23 as if set forth herein.

25. To obtain approval to engage in the commercial manufacture, use, or sale of oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, generic versions of Purdue's OxyContin®, before the expiration date of the '912, '042, and '295 Patents, Mallinckrodt submitted to the FDA an Abbreviated New Drug Application ("ANDA"), No. 77-822, pursuant to 21 U.S.C. § 355(j).

26. Upon information and belief, Mallinckrodt filed with ANDA No. 77-822 a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification")

alleging that the '912, '042, and '295 Patents are invalid, unenforceable, or will not be infringed by Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

27. On or about October 4, 2005, Purdue received a letter from Mallinckrodt purporting to be a Notice of Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter") informing Purdue of Mallinckrodt's submission of ANDA No. 77-822 and explaining that the sole basis for its Paragraph IV Certification with respect to the '912, '042, and '295 Patents is the alleged collateral estoppel effect of the Endo Unenforceability Order and the Federal Circuit's June 7, 2005 Opinion affirming the Endo Unenforceability Order.

28. But for the Endo Unenforceability Order and Endo Injunction, the District Court's February 17, 2004 denial of the Purdue Plaintiffs' motion seeking relief therefrom, and the Teva, Roxane, and Impax Collateral Estoppel Orders, Purdue would have been free to bring an action for infringement of the '912, '042, and '295 Patents against Mallinckrodt within 45 days from receipt of the Notice Letter, which would have triggered, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a 30-month stay of FDA approval of Mallinckrodt's ANDA No. 77-822.

29. Upon information and belief, the composition and methods for controlling pain used in Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, as set forth in ANDA 77-822, are claimed in one or more claims of the '912, '042, and '295 Patents.

30. Upon information and belief, Mallinckrodt's ANDA No. 77-822 contains information to show that its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg: (a) are bioequivalent to Purdue's OxyContin®; (b) have the same active ingredient as Purdue's OxyContin®; (c) have the same route of administration, dosage form, and

strengths as Purdue's OxyContin®; and (d) have the same, or substantially the same, proposed labeling as Purdue's OxyContin®.

31. Pursuant to 35 U.S.C. § 271(e)(2)(A), Mallinckrodt's submission to the FDA of ANDA No. 77-822 to obtain approval to engage in the commercial manufacture, use, or sale of Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, was an act of infringement of the '912, '042, and '295 Patents.

32. Pursuant to 35 U.S.C. § 271(a), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute direct infringement of the '912, '042, and '295 Patents.

33. Pursuant to 35 U.S.C. § 271(b), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute induced infringement of the '912, '042, and '295 Patents.

34. Pursuant to 35 U.S.C. § 271(c), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute contributory infringement of the '912, '042, and '295 Patents.

35. Upon information and belief, Mallinckrodt has been aware of the existence of the '912, '042, and '295 Patents but nevertheless has been and is now infringing those patents by seeking approval to engage in the commercial manufacture, use, or sale of oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg. This infringement by Mallinckrodt has been and continues to be willful and deliberate and in total disregard for Purdue's lawful rights under the '912, '042, and '295 Patents, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

36. Upon information and belief, Mallinckrodt has been aware of the Federal Circuit's February 1, 2006 Opinion vacating the Endo Unenforceability Order but nevertheless has maintained its Paragraph IV Certification based solely on the alleged collateral estoppel effect of the Endo Unenforceability Order. This conduct by Mallinckrodt renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

37. The acts of infringement by Mallinckrodt set forth above with respect to Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will cause Purdue irreparable harm for which they have no adequate remedy at law, including irreparable harm within the State of New York and this judicial district, and will continue unless preliminarily and permanently enjoined by this Court.

Count II
Patent Infringement Related to Third-Party Oxycodone Hydrochloride Extended-Release Tablets

38. Plaintiffs incorporate by reference the averments of Paragraphs 1-37 as if set forth herein.

39. Upon information and belief, to obtain approval to engage in the commercial manufacture, use or sale of oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, generic versions of Purdue's OxyContin® ("Third-Party Products"), before the expiration date of the '912, '042, and '295 Patents, several third-parties, including, but not limited to, Endo, have submitted to the FDA ANDAs, and amendments thereto, pursuant to 21 U.S.C. § 355(j) ("Third-Party ANDAs").

40. Since at least April 2004, one or more third-parties have been manufacturing, using, and selling one or more of their Third-Party Products.

41. Upon information and belief, Mallinckrodt has been a supplier of the active pharmaceutical ingredient oxycodone for use in one or more Third-Party Products, including, but not limited to, one or more of Endo's Third-Party Products.

42. Pursuant to 35 U.S.C. § 271(b), Mallinckrodt's supply of the active pharmaceutical ingredient oxycodone for use in one or more Third-Party Products, including, but not limited to, one or more of Endo's Third-Party Products, constitutes induced infringement of the '912, '042, and '295 Patents.

43. Pursuant to 35 U.S.C. § 271(c), Mallinckrodt's supply of the active pharmaceutical ingredient oxycodone for use in one or more Third-Party Products, including, but not limited to, one or more of Endo's Third-Party Products, constitutes contributory infringement of the '912, '042, and '295 Patents.

44. Upon information and belief, Mallinckrodt has been aware of the existence of the '912, '042, and '295 Patents but nevertheless has been and is now infringing those patents by supplying the active pharmaceutical ingredient oxycodone for use in one or more Third-Party Products, including, but not limited to, one or more of Endo's Third-Party Products. This infringement by Mallinckrodt has been and continues to be willful and deliberate and in total disregard for Purdue's lawful rights under the '912, '042, and '295 Patents, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that the '912, '042, and '295 Patents are valid and enforceable;

B. Adjudging that Mallinckrodt has infringed the '912, '042, and '295 Patents and that such infringement has been willful and deliberate;

C. Ordering Mallinckrodt to amend its Paragraph IV Certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. Ordering, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than 30 months from the date of receipt by Purdue of the Notice Letter;

E. Ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than the last date of expiration of the '912, '042, or '295 Patents;

F. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Rule 65, Fed. R. Civ. P., Mallinckrodt, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from the commercial manufacture, use, offer to sell, or sale within, or importation into, the United States, of any drug product or active pharmaceutical ingredient that infringes the '912, '042, and '295 Patents;

G. Awarding Plaintiffs damages, together with prejudgment interest and costs, to the full extent provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

H. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. For such other and further relief as the Court may deem proper and just under the circumstances.

Respectfully submitted,

Date: January 19, 2007

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CERTIFICATE OF SERVICE

James E. Baker, certifies and declares under penalty of perjury pursuant to 28 U.S.C § 1746 that on January 19, 2007, he caused the annexed FIRST AMENDED COMPLAINT, to be served ~~by electronic transmission in accordance with the Court's Procedures for Electronic Case Filing and~~ by delivering a true copy, enclosed in a properly addressed wrapper into the custody of the overnight delivery service: Federal Express, prior to the latest time designated by them for overnight delivery on the following counsel:

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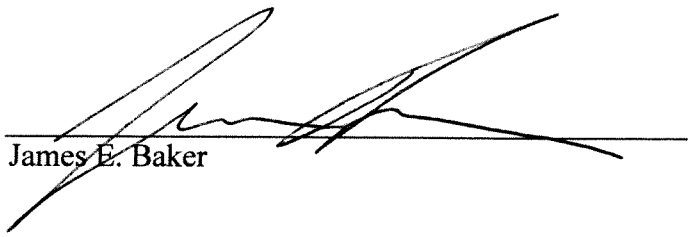
I declare under penalty of perjury that the foregoing is true and correct.



James E. Baker