UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	C. A. No. _____
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

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

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

3. This Court has personal jurisdiction over defendant Apotex Corp. because Apotex Corp. is incorporated under the laws of the State of Delaware. This Court has personal jurisdiction over defendant Apotex Inc. because, on information and belief, Apotex Inc. is doing business throughout the United States, including within this judicial district.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b), (c), and (d), and 1400(b).

THE PARTIES

5. 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, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an assignee of the patent in suit identified in paragraph 10 below, and markets and sells in the United States the controlled-release oxycodone hydrochloride pain relief medication OxyContin® Tablets ("OxyContin®").

6. 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 assignee of the patent in suit identified in paragraph 10 below and manufactures OxyContin® in the United States.

7. 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 assignee of the patent in suit identified in paragraph 10 below and manufactures OxyContin® in the United States.

8. Upon information and belief, defendant Apotex Inc. is a Canadian corporation, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

9. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

THE PATENT IN SUIT

10. Plaintiffs are the lawful owners of all right, title, and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering OxyContin® and contains one or more claims covering OxyContin®'s method of use:

United States Patent No. 5,508,042, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("the'042 patent"), a copy of which is attached hereto as Exhibit A, 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.

APOTEX'S ANDA

11. Upon information and belief, defendants (collectively, "Apotex") submitted Abbreviated New Drug Application ("ANDA") No. 78-840 to the FDA, 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 Oxycodone Hydrochloride CR Tablets 10, 20, 40, and 80 mg ("Apotex's Tablets"), a generic version of Purdue's OxyContin®, before the expiration of the '042 patent.

12. Upon information and belief, Apotex's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '042 patent, listed in the FDA's Orange Book as covering the reference listed drug OxyContin®, is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's Tablets.

13. In a letter dated August 1, 2007 addressed to plaintiff Purdue Pharma and "Euro-Celtigue, S.A.," Apotex sent "notice" with respect to its 10, 20, 40, and 80 mg Tablets and the '042 patent under 21 U.S.C. §355(j)(2)(B)(ii) ("Apotex's notice"). Purdue Pharma received Apotex's notice on or about August 2, 2007.

14. Apotex's notice does not provide any valid basis for concluding that the '042 patent is invalid, unenforceable, and/or not infringed.

15. Upon information and belief, the method of use of Apotex's Tablets is covered by one or more claims of the '042 patent.

16. Upon information and belief, Apotex's submission of its ANDA was an act of infringement of the '042 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

17. Upon information and belief, Apotex's commercial manufacture, use, sale, and/or offer for sale of its Tablets would infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '042 patent.

18. Upon information and belief, Apotex has been aware of the existence of the '042 patent, and has no reasonable basis for believing that Apotex's Tablets will not infringe the '042 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

19. The acts of infringement by Apotex set forth above will cause plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, plaintiffs pray for judgment:

A. Adjudging that Apotex has infringed the '042 patent, and that the commercial sale, offer for sale, and/or manufacture of Apotex's Tablets would infringe, induce infringement of, and contribute to the infringement of the '042 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex's ANDA No. 78-804, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date that is not earlier than the date of expiration of the '042 patent;

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

D. Declaring this an exceptional case and awarding plaintiffs their attorney's fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding plaintiffs such other and further relief as this Court may deem just and proper.

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