

07 CV 4810  
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

4810

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PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC., and  
PURDUE PHARMACEUTICALS L.P.,

Plaintiffs,

v.

KV PHARMACEUTICAL COMPANY,

Defendant.  
\_\_\_\_\_

Civil Action No. \_\_\_\_\_

JUN 06 2007

**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 because counsel for  
defendant KV Pharmaceutical Company ("KV") stated that "KV will consent to jurisdiction in  
the Southern District of New York for any action Purdue might be considering bringing against

KV's ANDA for 15 mg controlled-release oxycodone," which is the action averred in this Complaint.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) 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 patents in suit identified in paragraph 9 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 patents in suit identified in paragraph 9 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 patents in suit identified in paragraph 9 below and manufactures OxyContin® in the United States.

8. Upon information and belief, defendant KV is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2503 South Hanley Road, St. Louis, Missouri 63144.

## THE PATENTS IN SUIT

9. Plaintiffs 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 are listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering OxyContin® and contain one or more claims covering OxyContin®'s composition and method of use:

A. 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;

B. United States Patent No. 5,656,295, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("the '295 patent"), a copy of which is attached hereto as Exhibit B, 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;

C. United States Patent No. 5,549,912, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("the '912 patent"), a copy of which is attached hereto as Exhibit C, 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.

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## KV'S ANDA

10. Upon information and belief, KV submitted Abbreviated New Drug Application ("ANDA") No. 78-506 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 Extended-Release Tablets 15 mg ("KV's Tablets"), a

generic version of Purdue's OxyContin®, before the expiration of the '042, '295, and '912 patents.

11. Upon information and belief, KV's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '042, '295, and '912 patents, listed in the FDA's Orange Book as patents covering the reference listed drug OxyContin®, are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of KV's Tablets.

12. In a letter dated May 2, 2007 addressed to the plaintiffs, KV sent "notice" with respect to its 15 mg Tablets and the '042, '295, and '912 patents under 21 U.S.C. §355(j)(2)(B)(ii) ("KV's 15 mg notice"). The plaintiffs received KV's 15 mg notice on or about May 3, 2007.

13. KV's notice does not provide any valid basis for concluding that the '042, '295, and '912 patents are invalid, unenforceable, and/or not infringed.

14. Upon information and belief, the composition and method of use of KV's Tablets are covered by one or more claims of the '042, '295, and '912 patents.

15. Upon information and belief, KV's submission of its ANDA was an act of infringement of the '042, '295, and '912 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

16. Upon information and belief, KV'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, '295, and '912 patents.

17. Upon information and belief, KV has been aware of the existence of the '042, '295, and '912 patents, and has no reasonable basis for believing that KV's Tablets will not

infringe the '042, '295, and '912 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

18. The acts of infringement by KV 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 KV has infringed the '042, '295, and '912 patents, and that the commercial sale, offer for sale, and/or manufacture of KV's Tablets would infringe, induce infringement of, and contribute to the infringement of the '042, '295, and '912 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of KV's ANDA No. 78-506, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date which is not earlier than the last date of expiration of the '042, '295, and '912 patents;

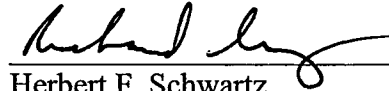
C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., KV, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation 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, '295, and '912 patents;

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.

June 6, 2007

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