IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC. and PURDUE PHARMACEUTICALS L.P., | ) | |
| Plaintiffs, | ) | Civil Action No. _____ |
| v. | ) | |
| KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC, | ) | |
| 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 defendants because defendants reside in and, upon information and belief, are doing business in this Judicial District.

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 owner by assignment of the patents 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. P.F. Labs is an owner by assignment of the patents 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 owner by assignment of the patents in suit identified in paragraph 10 below and manufactures OxyContin® in the United States.

8. Upon information and belief, defendant KV Pharmaceutical Company ("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. Upon information and belief, KV is currently doing business in this Judicial District by making and shipping into this Judicial District, or using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products.

9. Upon information and belief, defendant Actavis Totowa LLC ("Actavis") is a company organized and existing under the laws of the State of Delaware, having a place of business at 4 Taft Road, Totowa, New Jersey 07512. Upon information and belief, Actavis is currently doing business in this Judicial District by making and shipping into this Judicial District, or using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products.

**THE PATENTS IN SUIT**

10. 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 contain one or more claims covering the composition and method of use of OxyContin®:

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.

**KV'S ANDA**

11. Upon information and belief, KV submitted Abbreviated New Drug Application ("ANDA") No. 78-506 to the U.S. Food and Drug Administration ("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 10 mg, 20 mg, 40 mg and 80 mg ("KV's Tablets"), a generic version of Purdue's OxyContin®, before the expiration of the '042, '295 and '912 patents.

12. 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 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of KV's Tablets.

13. In a letter dated December 6, 2006 addressed to the plaintiffs, KV sent "notice" with respect to its 10 mg, 20 mg, 40 mg and 80 mg Tablets and the '042, '295 and '912 patents as provided by 21 U.S.C. § 355(j)(2)(B)(ii) ("KV's notice"). The plaintiffs received KV's notice on or about December 11, 2006.

14. 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.

15. 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.

16. 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).

17. 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.

18. 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.

19. 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.

**ACTAVIS' ANDA**

20. Upon information and belief, Actavis submitted ANDA No. 78-507 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 10 mg, 20 mg, 40 mg and 80 mg ("Actavis' Tablets"), a generic version of Purdue's OxyContin®, before the expiration of the '042 patent.

21. Upon information and belief, Actavis' ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '042 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Actavis' Tablets.

22. In a letter dated December 4, 2006 addressed to the plaintiffs, Actavis sent "notice" with respect to the '042 patent as provided by 21 U.S.C. § 355(j)(2)(B)(ii) ("Actavis' notice"). The plaintiffs received Actavis' notice between December 6 and 11, 2006.

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

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

25. Upon information and belief, Actavis' 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).

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

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

28. The acts of infringement by Actavis 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 or '912 patent;

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

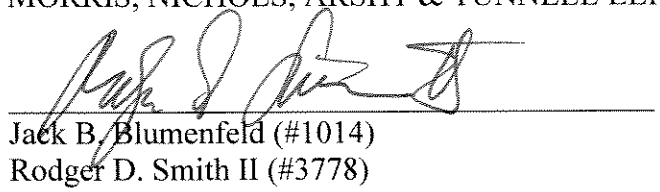
E. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Actavis' ANDA No. 78-507, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date that is not earlier than the date of expiration of the '042 patent;

F. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Actavis, 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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