IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., and ORTHO-MCNEIL-JANSSEN-PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Purdue Pharma Products L.P., Napp Pharmaceuticals Group Ltd., and Ortho-McNeil-Janssen-Pharmaceuticals, Inc., 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. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PARTIES

4. Plaintiff Purdue Pharma Products L.P. ("Purdue") 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 is an owner by assignment of the patent in suit identified in paragraph 9 below.

5. Plaintiff Napp Pharmaceutical Group Ltd. ("Napp") is a private limited company organized and existing under the laws of the United Kingdom, having a place of business at Cambridge Science Park, Milton Road, Cambridge, CB4 0GW. Napp is an owner by assignment of the patent in suit identified in paragraph 9 below.

6. Plaintiff Ortho-McNeil-Janssen-Pharmaceuticals, Inc. ("OMJPI") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Route 202 South, Raritan, New Jersey 08869. OMJPI is a licensee of the patent in suit identified in paragraph 9 below, and OMJPI, through its divisions, markets and distributes Ultram® ER in the United States.

7. Upon information and belief, defendant Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 30831 Huntwood Avenue, Hayward, California 94544.

THE PATENT IN SUIT

8. Purdue and Napp 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 Ultram® ER:

United States Patent No. 6,254,887, entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on July 3, 2001 naming Ronald Brown Miller, Stuart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo

Hahn, and Derek Allan Prater as the inventors.

IMPAX'S ANDA

9. Upon information and belief, Impax submitted Abbreviated New Drug Application No. 90-552 ("ANDA") 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 Tramadol Hydrochloride Extended-Release Tablets, 200 mg and 300 mg ("Impax's 200 mg and 300 mg Tablets"), a generic version of Ultram® ER, which is marketed and distributed in the United States by OMJPI, before the expiration of the '887 patent.

10. Upon information and belief, Impax's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 patent, listed in the FDA's Orange Book as a patent covering the drug Ultram® ER, is invalid and/or will not be infringed by the commercial manufacture, use or sale of Impax's 200 mg and 300 mg Tablets.

11. In a letter dated September 22, 2008 addressed to Napp, Purdue, OMJPI and others, Impax provided "notice" with respect to its 200 mg and 300 mg Tablets and the '887 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Impax's 200 mg and 300 mg Tablet notice").

12. Impax's 200 mg and 300 mg Tablet notice does not provide any valid basis for concluding that the '887 patent is invalid, and provides no statement that its 200 mg and 300 mg Tablets do not infringe the '887 patent.

13. Impax's submission of its ANDA was an act of infringement of the '887 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

14. Upon information and belief, the composition of Impax's 200 mg and 300 mg Tablets is covered by one or more claims of the '887 patent.

15. Upon information and belief, Impax's commercial manufacture, use, sale, and/or offer for sale of its 200 mg and 300 mg Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '887 patent.

16. Upon information and belief, Impax has been aware of the existence of the '887 patent, and has no reasonable basis for believing that its 200 mg and 300 mg Tablets will not infringe the '887 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

17. The acts of infringement by Impax 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 Impax has infringed the '887 patent, and that the commercial sale, offer for sale, and/or manufacture of Impax's 200 mg and 300 mg Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Impax's ANDA No. 90-552, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '887 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., Impax, 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 them, and their 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 '887 patent;

D. Declaring this an exceptional case and awarding plaintiffs their attorneys' 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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