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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

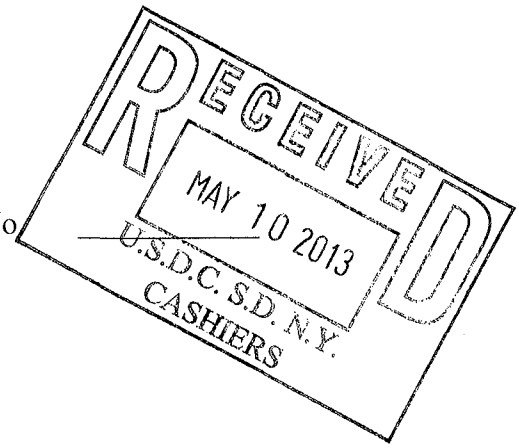
Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

C.A. No.



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.

THE PARTIES: PLAINTIFFS

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, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner of United States Patent No. 8,337,888 identified in paragraph 10 below. Purdue Pharma is also the holder of New Drug Application ("NDA") No. 022272 for the controlled-release oxycodone pain-relief medication OxyContin®, and is involved in the sales of OxyContin® in the United States.

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, NJ 07512. P.F. Labs is an owner of United States Patent No. 8,337,888 identified in paragraph 10 below, and is involved in the manufacture 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, NC 27893. Purdue Pharmaceuticals is an owner of United States Patent No. 8,337,888 identified in paragraph 10 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

THE PARTIES: DEFENDANT

5. 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 principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

6. Upon information and belief, Impax is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration No. 025847). The Registration has an active status.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This Court has personal jurisdiction over Impax because, *inter alia*, Impax has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial

District. Upon information and belief, Impax does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Impax engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States, this State, and this Judicial District specifically. Impax did not contest personal jurisdiction in this Judicial District in patent litigations concerning United States Patent Nos. 6,488,963, 7,674,799, 7,674,800, 7,683,072, 7,776,314, 8,114,383, and 8,309,060, which suits were based on the same Abbreviated New Drug Application ("ANDA") described in paragraph 11 below that Impax submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Impax Laboratories, Inc.*, No. 11-civ-2400 (SHS) (S.D.N.Y. Apr. 7, 2011) and *Purdue Pharma L.P. et al. v. Impax Laboratories, Inc.*, No. 13-civ-0763 (SHS) (S.D.N.Y. Feb. 1, 2013). Further, this Court has personal jurisdiction over Impax because, upon information and belief, Impax has an active registration status as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. In addition, upon information and belief, Impax is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202483, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

THE PATENT IN SUIT

10. Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in United States Patent No. 8,337,888 entitled

"PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT" ("the '888 patent"), including the right to sue and to recover for past infringement thereof. The '888 patent is listed in the FDA's Orange Book as covering the drug OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, which is the subject of approved NDA No. 022272. A copy of the '888 patent is attached hereto as Exhibit A, which was duly and legally issued on December 25, 2012, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

DEFENDANT'S ANDA

11. Upon information and belief, Impax submitted ANDA No. 202483 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, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets ("Impax's proposed generic copies of OxyContin®"), 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No. 022272, before the expiration of the '888 patent.

12. Upon information and belief, Impax's ANDA No. 202483 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '888 patent, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable, or not infringed" by the commercial manufacture, use or sale of Impax's proposed generic copies of OxyContin®.

13. In a letter dated March 28, 2013 addressed to Plaintiffs and received by Plaintiff Purdue Pharma on March 29, 2013, Impax provided "Notice" with respect to its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, and the '888 patent under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and

justiciable controversy.

CLAIM FOR RELIEF

14. Impax's submission of its ANDA was an act of infringement of the '888 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A), with respect to Impax's proposed generic copies of OxyContin®.

15. Upon information and belief, Impax's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, are covered by one or more claims of the '888 patent.

16. Upon information and belief, Impax's commercial manufacture, use, sale, and/or offer for sale of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '888 patent.

17. Upon information and belief, Impax has been aware of the existence of the '888 patent, and has no reasonable basis for believing that its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, will not infringe the '888 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

18. 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 '888 patent, and that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, described in ANDA No. 202483 would infringe, induce infringement of, and/or contribute to the infringement of the '888

patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202483 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 '888 patent plus any additional periods of exclusivity;

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, partners, 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 '888 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.

Dated: May 10, 2013

ROPES & GRAY LLP

Sona De
Pablo D. Hendler
1211 Avenue of the Americas
New York, NY 10036
(212) 596-9000
sona.de@ropesgray.com
pablo.hendler@ropesgray.com

Robert J. Goldman
1900 University Avenue, 6th Floor

East Palo Alto, CA 94303
(650) 617-4000
robert.goldman@ropesgray.com

Attorneys for Plaintiffs
Purdue Pharma L.P.,
The P.F. Laboratories, Inc., and
Purdue Pharmaceuticals, L.P.