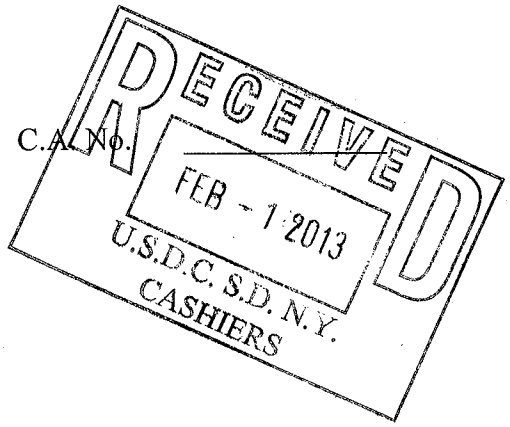
13 CV 763

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

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	C.A. No.



COMPLAINT

Plaintiffs Purdue Pharma L.P. and Grünenthal GmbH 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 exclusive licensee of United States Patent Nos. 8,114,383 and 8,309,060 identified in paragraphs 9-10 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 Grünenthal GmbH ("Grünenthal") is a corporation organized and

existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of United States Patent Nos. 8,114,383 and 8,309,060 identified in paragraphs 9-10 below.

THE PARTIES: DEFENDANT

4. 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.

5. 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

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

7. 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 litigation concerning United States Patent Nos. 6,488,963, 7,674,799, 7,674,800, 7,683,072, and 7,776,314, which suit was 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). Further, this Court has personal jurisdiction over Impax because, upon information and belief, Impax has an active registration status in the 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.

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

THE PATENTS IN SUIT

9. Plaintiff Grünenthal GmbH is the lawful owner of all right, title and interest in United States Patent No. 8,114,383 entitled "ABUSE-PROOFED DOSAGE FORM" ("the '383 patent"), including the right to sue and to recover for past infringement thereof. Plaintiff Purdue Pharma is an exclusive licensee of the '383 patent from Grünenthal, with the right to enforce the '383 patent. The '383 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 '383 patent is attached hereto as Exhibit A, which was duly and legally issued on February 14, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors.

10. Plaintiff Grünenthal GmbH is the lawful owner of all right, title and interest in United States Patent No. 8,309,060 entitled "ABUSE-PROOFED DOSAGE FORM"

("the '060 patent"), including the right to sue and to recover for past infringement thereof. Plaintiff Purdue Pharma is an exclusive licensee of the '060 patent from Grünenthal, with the right to enforce the '060 patent. The '060 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 '060 patent is attached hereto as Exhibit B, which was duly and legally issued on November 13, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić 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 '383 and '060 patents.

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 '383 and '060 patents, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable or not infringed" by the commercial manufacture, use or sale of Impax's proposed generic copies of OxyContin®.

13. 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, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, based on the RLD OxyContin®, which is the subject of approved NDA No. 022272, before the expiration of the '383 and '060 patents.

14. In a letter dated December 20, 2012 addressed to Plaintiffs and received by Plaintiff Purdue Pharma on December 24, 2012, 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 '383 and '060 patents under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and justiciable controversy.

CLAIM FOR RELIEF

15. Impax's submission of its ANDA was an act of infringement of the '383 and '060 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A) with respect to Impax's proposed generic copies of OxyContin®.

16. 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 '383 and '060 patents.

17. 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 '383 and '060 patents.

18. Upon information and belief, Impax has been aware of the existence of the '383 and '060 patents, and have no reasonable basis for believing that their proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, will not infringe the '383 and '060 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

19. 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 '383 and '060 patents, 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 '383 and '060 patents;

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 '383 and '060 patents 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 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 '383 and '060 patents;

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: February 1, 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 Plaintiff
Purdue Pharma L.P.

Dated: February 1, 2013

WILK AUSLANDER LLP

Stephen D. Hoffman (SH 6089)
1515 Broadway, 43rd Floor
New York, NY 10036
(212) 981-2300
shoffman@wilkauslander.com

Attorneys for Plaintiff
Grünenthal GmbH

Of Counsel for Grünenthal GmbH:

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Basil J. Lewris
Joann M. Neth
Jennifer H. Roscetti
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000
bill.lewris@finnegan.com
joann.neth@finnegan.com
jennifer.roscetti@finnegan.com

Anthony C. Tridico
Avenue Louise 326, Box 37
Brussels, Belgium B-1050
011 32 2 646 03 53
anthony.tridico@finnegan.com