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

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P.,
RHODES TECHNOLOGIES,
and GRÜNENTHAL GMBH,

Plaintiffs,

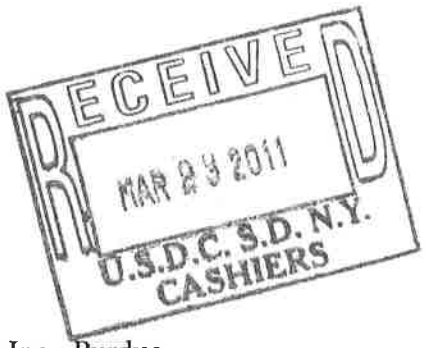
v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

11 CIV 2037

C.A. No. _____



COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, 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 owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 14-16 below, and an exclusive licensee of United States Patent No. 7,776,314 identified in paragraph 17 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 Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 14-16 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 Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 14-16 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 14-16 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

6. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are associated companies.

7. 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 No. 7,776,314 identified in paragraph 17 below.

THE PARTIES: DEFENDANT

8. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

9. Upon information and belief, Teva 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 Nos. 025905, 028138 and 029801). The Registrations have an active status and are valid through February 29, 2012, September 30, 2012 and August 31, 2012, respectively.

10. Upon information and belief, Teva is registered as a Foreign Business Corporation by the New York State Department of State, Division of Corporations and lists Corporate Creations Network Inc., 15 North Mill Street, Nyack, NY 10960 as its registered agent.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Teva because, *inter alia*, Teva has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Teva 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, Teva engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Teva has previously consented to personal jurisdiction in this Judicial District in patent litigation concerning an earlier ANDA that Teva submitted to the FDA that was also directed to generic oxycodone hydrochloride extended release tablets. *See Purdue Pharma L.P. et al. v. Teva Pharms. USA, Inc.*, No. 01-civ-8507 (SHS) (S.D.N.Y. Sept. 14, 2001). Moreover, in connection with its present ANDA No. 202455 and Paragraph IV Notice Letter that forms the basis of this action described in paragraphs 18-20 below, Teva provided an Offer of Confidential Access to that ANDA ("Offer"). Teva's Offer states that Teva agrees to "irrevocably submit to and accept, generally and unconditionally, the exclusive personal jurisdiction of the courts of the State of New York, and of the U.S. District Court for the Southern District of New York, [and] waives its right to assert any objection or defense based on venue or forum non conveniens" with respect to the Offer. Further, this Court has personal jurisdiction over Teva because Teva is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions and as a Foreign Business Corporation by the New York State Department of State, Division of Corporations. In addition, upon information and belief, Teva is actively preparing to make the proposed generic copies of OxyContin® that are the subject of Abbreviated New Drug Application ("ANDA") No. 202455, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

THE PATENTS IN SUIT

14. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,799 entitled

"OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '799 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '799 patent is attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

15. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,800 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '800 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

16. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,683,072 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '072 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '072 patent is attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

17. Plaintiff Grünenthal is the lawful owner of all right, title and interest in

United States Patent No. 7,776,314 entitled "ABUSE-PROOFED DOSAGE SYSTEM" ("the '314 patent"), including the right to sue and to recover for past infringement thereof. Plaintiff Purdue Pharma is the exclusive licensee of the '314 patent from Grünenthal, with the right to enforce the '314 patent. The '314 patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '314 patent is attached hereto as Exhibit D, which was duly and legally issued on August 17, 2010, naming Johannes Bartholomäus and Heinrich Kugelmann as the inventors.

DEFENDANT'S ANDA

18. Upon information and belief, Teva submitted ANDA No. 202455 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 ("proposed generic copies of OxyContin®") based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No. 022272, before the expiration of the '799, '800, '072, and '314 patents.

19. Upon information and belief, ANDA No. 202455 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '799, '800, '072, and '314 patents, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, are "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

20. In a letter dated February 9, 2011 addressed to Plaintiffs and received by Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes on February 10, 2011, Teva provided "notice" with respect to its proposed generic copies of OxyContin® and the '799, '800, '072, and '314 patents under 21 U.S.C. § 355(j)(2)(B) ("Notice Letter"). Teva's Notice Letter included an Offer of Confidential Access in which Teva submitted to and accepted

exclusive personal jurisdiction of the courts of the State of New York and of the U.S. District Court for the Southern District of New York with respect to that Offer.

21. Teva's submission of its ANDA was an act of infringement of the '799, '800, '072, and '314 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, Teva's proposed generic copies of OxyContin® are covered by one or more claims of the '799, '800, '072, and '314 patents.

23. Upon information and belief, Teva's commercial manufacture, use, sale, and/or offer for sale of the proposed generic copies of OxyContin® would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '799, '800, '072, and '314 patents.

24. Upon information and belief, Teva has been aware of the existence of the '799, '800, '072, and '314 patents, and has no reasonable basis for believing that the proposed generic copies of OxyContin® will not infringe the '799, '800, '072, and '314 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

25. The acts of infringement by Teva 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 Teva has infringed the '799, '800, '072, and '314 patents, and that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin® described in ANDA No. 202455 would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, '072, and '314 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202455, 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 dates of expiration of the '799, '800, '072, and '314 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., Teva, 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 '799, '800, '072, and '314 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: March 23, 2011

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Dated: March 23, 2011

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