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,
BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,
and GRÜNENTHAL GMBH,

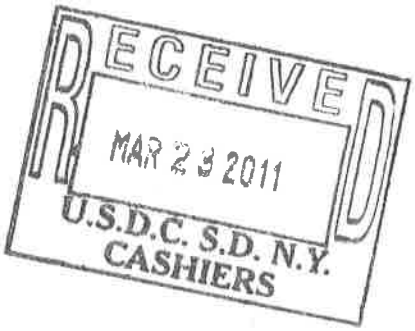
Plaintiffs,

v.

WATSON LABORATORIES, INC. – FLORIDA,
and ANDRX LABS, LLC,

Defendants.

C.A. No. 11 CIV 2036



COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of The University of Texas System, 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

18-20 below, an exclusive sublicensee of United States Patent No. 6,488,963 identified in paragraph 17 below, and an exclusive licensee of United States Patent No. 7,776,314 identified in paragraph 21 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 18-20 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 18-20 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 18-20 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 Board of Regents of The University of Texas System ("University of Texas") is an agency organized and existing under the laws of the State of Texas, having an address at 201 West 7th Street, Austin, TX 78701. University of Texas is the owner of United States Patent No. 6,488,963 identified in paragraph 17 below.

8. 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 21 below.

THE PARTIES: DEFENDANTS

9. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida ("Watson") is a corporation organized and existing under the laws of the State of Florida, having a registered address of 4955 Orange Drive, Davie, FL 33314.

10. Upon information and belief, Watson 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. 028681 and 028729). The Registrations have an active status and are valid through October 31, 2013 and December 31, 2013, respectively. Registration No. 028729 identifies Watson's address as 4955 Orange Drive, Davie, FL 33314.

11. Upon information and belief, Defendant Andrx Labs, LLC ("Andrx") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at the same address as Watson, 4955 Orange Drive, Davie, FL 33314.

12. Upon information and belief, Watson and Andrx are in the same corporate

family, and are subsidiaries of the same parent company, Andrx Corp., and the same grandparent company, Watson Pharmaceuticals, Inc. Upon information and belief, Watson and Andrx share certain employees, directors, and/or officers. The same individual, Ms. Janet Vaughn, signed Watson's Paragraph IV Notice Letter as Watson's Director of Regulatory Affairs and signed Andrx's Paragraph IV Notice Letter as Andrx's Director of Regulatory affairs, which Notice Letters are described in paragraph 26 below. The same attorney, G. Michael Bryner, Esq., is identified as Watson's in-house counsel in Watson's Paragraph IV Notice Letter and as Andrx's in-house counsel in Andrx's Paragraph IV Notice Letter. Upon information and belief, Watson controls both Watson's and Andrx's filings and submissions with the FDA.

JURISDICTION AND VENUE

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

14. This Court has personal jurisdiction over Watson because, *inter alia*, Watson has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Watson 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, Watson 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. Watson, formerly known as Andrx Pharmaceuticals, Inc., was subject to personal jurisdiction in this Judicial District in patent litigation concerning an earlier ANDA that Watson submitted to the FDA directed to generic omeprazole (Prilosec®). *See Astra Aktiebolag v. Andrx Pharms., Inc.*, No. 1:99-cv-08926-BSJ (S.D.N.Y.); *Astra Aktiebolag v. Andrx Pharms., Inc.*, No. 1:99-cv-09887-BSJ (S.D.N.Y.). Further, this Court has personal

jurisdiction over Watson because Watson is registered 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, Watson is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202352, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

15. This Court also has personal jurisdiction over Andrx because, *inter alia*, Andrx has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Andrx, either directly or indirectly through Watson as alleged above, 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, Andrx, either directly or indirectly through Watson as alleged above, 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. In addition, upon information and belief, Andrx, either directly or indirectly through Watson and/or in active concert with Watson as alleged above, is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202372, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

THE PATENTS IN SUIT

17. Plaintiff University of Texas is the lawful owner of all right, title and interest in United States Patent No. 6,488,963 entitled "HOT-MELT EXTRUDABLE PHARMACEUTICAL FORMULATION" ("the '963 patent"), including the right to sue and to

recover for past infringement thereof. Plaintiff University of Texas granted an exclusive license under the '963 patent to Abbott Laboratories, who in turn, granted an exclusive sublicense under that patent to Plaintiff Purdue Pharma. The '963 patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '963 patent is attached hereto as Exhibit A, which was duly and legally issued on December 3, 2002, naming James W. McGinity and Feng Zhang as the inventors.

18. 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 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.

19. 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 C, 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.

20. 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 D, 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.

21. 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 E, which was duly and legally issued on August 17, 2010, naming Johannes Bartholomäus and Heinrich Kugelmann as the inventors.

DEFENDANTS' ANDAS

22. Upon information and belief, Watson submitted Abbreviated New Drug Application No. 202352 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 '963, '799, '800, '072, and '314 patents.

23. Upon information and belief, Watson's ANDA No. 202352 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '963, '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 "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of [the proposed generic copies of OxyContin®]."

24. Upon information and belief, Andrx submitted Abbreviated New Drug Application No. 202372 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 '963, '799, '800, '072, and '314 patents.

25. Upon information and belief, Andrx's ANDA No. 202372 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '963, '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 "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

26. In letters dated February 7, 2011 addressed to Plaintiffs and received by Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes on February 8, 2011, Watson and Andrx each provided "Notice" with respect to their respective proposed generic copies of OxyContin® and the '963, '799, '800, '072, and '314 patents under 21 U.S.C. §

355(j)(2)(B).

27. Watson's and Andrx's submission of their ANDAs was an act of infringement of the '963, '799, '800, '072, and '314 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, Watson's and Andrx's proposed generic copies of OxyContin® are covered by one or more claims of the '963, '799, '800, '072, and '314 patents.

29. Upon information and belief, Watson's and Andrx'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 '963, '799, '800, '072, and '314 patents.

30. Upon information and belief, Watson and Andrx have been aware of the existence of the '963, '799, '800, '072, and '314 patents, and have no reasonable basis for believing that the proposed generic copies of OxyContin® will not infringe the '963, '799, '800, '072, and '314 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

31. The acts of infringement by Watson and Andrx 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 Watson and Andrx have infringed the '963, '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. 202352 and ANDA No. 202372 would infringe, induce infringement of, and/or contribute to the infringement of the '963,

'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. 202352 and ANDA No. 202372, 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 '963, '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., Watson and Andrx, their 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 '963, '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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