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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.,
PURDUE PHARMACEUTICALS L.P.,
and GRÜNENTHAL GMBH,

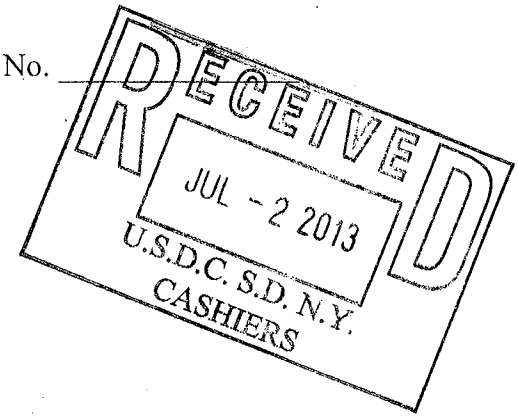
Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No. _____



COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals 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 owner of United States Patent No. 8,337,888 identified in paragraph 12 below and an exclusive licensee of United States Patent No. 8,309,060 identified in paragraph 13 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 12 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 12 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. 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. 8,309,060 identified in paragraph 13 below.

THE PARTIES: DEFENDANT

6. 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.

7. 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. 028138, 029801, and 025905). The Registrations have an

active status and are valid through September 30, 2015, August 31, 2015, and February 28, 2015, respectively.

8. 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

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

10. 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, this State, and this Judicial District specifically. Teva did not contest personal jurisdiction in this Judicial District in patent litigation concerning United States Patent Nos. 7,674,799, 7,674,800, 7,683,072, 7,776,314, and 8,114,383 which suits were based on the same Abbreviated New Drug Application ("ANDA") No. 202455 described in paragraph 14 below that Teva submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 11-cv-2037 (SHS) (S.D.N.Y. Mar. 23, 2011); *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 12-cv-5083 (SHS) (S.D.N.Y. June 26, 2012). 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 ANDA No. 202455, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

THE PATENTS IN SUIT

12. 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.

13. 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

14. 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®"), 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 and '060 patents.

15. Upon information and belief, Teva's ANDA No. 202455 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 [the proposed generic copies of OxyContin®]."

16. In a letter dated May 21, 2013 addressed to Plaintiffs and received by Purdue Pharma on May 22, 2013, Teva 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.

17. Upon information and belief, Teva's ANDA No. 202455 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '060 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 [the proposed generic copies of OxyContin®]."

18. In a letter dated May 21, 2013 addressed to Plaintiffs and received by Purdue Pharma on May 22, 2013, Teva 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 '060 patent under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and justiciable controversy.

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '888 PATENT

19. Teva'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 Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg.

20. Upon information and belief, Teva'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.

21. Upon information and belief, Teva'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.

22. Upon information and belief, Teva 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.

23. The acts of infringement by Teva set forth above will cause Plaintiffs

Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

SECOND CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '060 PATENT

24. Teva's submission of its ANDA was an act of infringement of the '060 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A), with respect to Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg.

25. Upon information and belief, Teva'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 '060 patent.

26. Upon information and belief, Teva'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 '060 patent.

27. Upon information and belief, Teva has been aware of the existence of the '060 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 '060 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

28. The acts of infringement by Teva set forth above will cause Plaintiffs Purdue Pharma and Grünenthal irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

On the First Claim for Relief:

A. Adjudging that Teva 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. 202455 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. 202455, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, 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., 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 '888 patent;

D. Declaring this an exceptional case and awarding Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals such other and further relief as this Court may deem just and proper.

On the Second Claim for Relief:

F. Adjudging that Teva has infringed the '060 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. 202455 would infringe, induce infringement of, and/or contribute to the infringement of the '060 patent;

G. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202455, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, 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 '060 patent plus any additional periods of exclusivity;

H. 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 '060 patent;

I. Declaring this an exceptional case and awarding Plaintiffs Purdue Pharma and Grünenthal their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

J. Awarding Plaintiffs Purdue Pharma and Grünenthal such other and further relief as this Court may deem just and proper.

Dated: July 2, 2013

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Dated: July 2, 2013

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