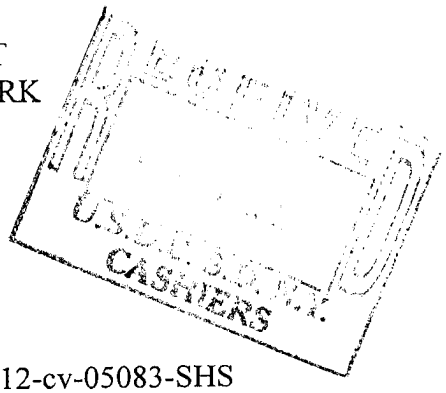
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK



PURDUE PHARMA L.P.
and GRÜNENTHAL GMBH,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No. 1.12-cv-05083-SHS

AMENDED COMPLAINT

Plaintiffs Purdue Pharma L.P. and Grünenthal GmbH hereby timely amend their Complaint as a matter of course pursuant to Fed. R. Civ. P. 15(a)(1). Plaintiffs 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, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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 No. 8,114,383 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 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. 8,114,383 identified in paragraph 10 below.

THE PARTIES: DEFENDANT

4. 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.

5. 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, 2012, August 31, 2012, and February 28, 2015, respectively.

6. 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

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 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, and 7,776,314, which suit was based on the same Abbreviated New Drug Application ("ANDA") No. 202455 described in paragraph 11 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-civ-2037 (SHS) (S.D.N.Y. Mar. 23, 2011). Moreover, in connection with its present ANDA No. 202455 and Paragraph IV Notice Letter that forms the basis of this action described in paragraphs 11-13 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 ANDA No. 202455, 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. Grünenthal 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. 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 certain dosage strengths of the drug OxyContin®, 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.

DEFENDANT'S ANDA

11. 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, and 40 mg, based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No. 022272, before the expiration of the '383 patent.

12. 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 '383 patent, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

13. In a letter dated May 14, 2012 addressed to Plaintiffs and received by Purdue Pharma on May 15, 2012, Teva provided "Notice" with respect to its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg and the '383 patent under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and justiciable controversy. 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.

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2) WITH RESPECT TO TEVA'S PROPOSED GENERIC COPIES OF OXYCONTIN® 10 MG, 15 MG, 20 MG, 30 MG, AND 40 MG

14. Teva's submission of its ANDA was an act of infringement of the '383 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, and 40 mg.

15. Upon information and belief, Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg, are covered by one or more claims of the '383 patent.

16. 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, and 40 mg, would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '383 patent.

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

18. 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.

SECOND CLAIM FOR RELIEF:
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT WITH RESPECT TO TEVA'S PROPOSED GENERIC COPIES OF OXYCONTIN® 60 MG AND 80 MG

19. Upon information and belief, if and when the FDA grants tentative approval of Teva's ANDA, Teva will undertake substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '383 patent by making, using, and undertaking substantial preparations for offering to sell Teva's proposed generic copies of OxyContin®, 60 mg and 80 mg, and such acts will constitute infringement, contributory infringement and active inducement of infringement of one or more claims of the '383 patent.

20. Upon information and belief, Teva has been aware of the existence of the '383 patent but, if and when the FDA grants tentative approval of Teva's ANDA, Teva will nevertheless engage in substantial activities directed toward infringing, contributorily infringing, and actively inducing infringement of the '383 patent. These activities will be in total disregard for Plaintiffs' lawful rights under the '383 patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

21. If and when the FDA grants tentative approval of Teva's ANDA and Teva undertakes substantial activities directed toward infringement, contributory infringement, and

active inducement of infringement as set forth above, such acts will demonstrate the existence of an actual and justiciable controversy (*see* Paragraph 12 above) and will inevitably constitute infringement, contributory infringement, and active inducement of the infringement of the '383 patent, will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless preliminarily and permanently enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

On Plaintiffs' First Claim for Relief, as Set Forth in the Complaint:

A. Adjudging that Teva has infringed the '383 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, and 40 mg, described in ANDA No. 202455 would infringe, induce infringement of, and/or contribute to the infringement of the '383 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, and 40 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 '383 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 '383 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.

On Plaintiffs' Second Claim for Relief, as Set Forth in the Complaint:

F. Declaring that if and when the FDA grants tentative approval of Teva's ANDA and Teva undertakes substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '383 patent by making, using, and undertaking substantial preparations for offering to sell Teva's proposed generic copies of OxyContin®, 60 mg and 80 mg, such acts will constitute infringement, contributory infringement, and active inducement of infringement of one or more claims of the '383 patent;

G. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 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 if and when the FDA grants tentative approval of Teva's ANDA, committing such acts and substantial activities directed toward infringement, contributory infringement, and active inducement of infringement of the '383 patent by making, using, and undertaking substantial preparations for offering to sell within the United States, or import into the United States, any drug product that infringes one or more claims of the '383 patent;

H. Declaring this case an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. § 285; and

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I. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: August 16, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on August 16, 2012, I caused the foregoing AMENDED COMPLAINT to be served via e-mail on counsel for Teva Pharmaceuticals USA, Inc. as follows:

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