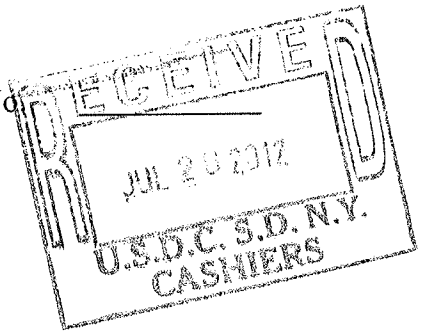
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, v. ACTAVIS ELIZABETH LLC, Defendant.	12 CV 5615 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, 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 Actavis Elizabeth LLC ("Actavis") is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, NJ 07207.

5. Upon information and belief, Actavis 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. 025892). The Registration has an active status and is valid through February 28, 2015.

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 Actavis because, *inter alia*, Actavis has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Actavis 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, Actavis 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. Actavis 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") No. 202434 described in paragraph 10 below that Actavis submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Actavis Elizabeth LLC*, No. 11-civ-2038 (SHS) (S.D.N.Y. Mar. 23, 2011). Further, this Court has personal jurisdiction over Actavis because Actavis 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, Actavis is actively preparing to make the proposed generic copies of OxyContin® that are the subject of its ANDA No. 202434, 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 PATENT IN SUIT

9. 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. On February 14, 2012, Purdue Pharma submitted the paperwork to list the '383 patent in the FDA's Orange Book as covering 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg dosage strengths of the drug OxyContin®, which is the subject of approved NDA No. 022272. On June 26, 2012, Purdue Pharma submitted the paperwork to list the '383 patent in the FDA's Orange Book as covering 60 mg and 80 mg dosage strengths of the drug OxyContin®. 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

10. Upon information and belief, Actavis submitted ANDA No. 202434 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 '383 patent.

11. Upon information and belief, Actavis's ANDA No. 202434 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 "invalid, unenforceable or will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of [the proposed generic copies of OxyContin®]."

12. In a letter dated June 6, 2012 addressed to Plaintiffs and received by Purdue Pharma on June 6, 2012, Actavis 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 patent under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and justiciable controversy.

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

13. Actavis'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 Actavis's

proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

14. Upon information and belief, Actavis'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.

15. Upon information and belief, Actavis'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.

16. Upon information and belief, Actavis 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.

17. The acts of infringement by Actavis 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 ACTAVIS'S PROPOSED GENERIC COPIES OF OXYCONTIN® 60 MG AND 80 MG

18. Upon information and belief, once the FDA grants tentative approval of Actavis's ANDA, Actavis 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, without authority from Plaintiffs, its proposed generic copies of OxyContin®, 60 mg and 80 mg, whose compositions are covered by one or more claims of the '383 patent.

19. Upon information and belief, Actavis has been aware of the existence of

the '383 patent but, once the FDA grants tentative approval of Actavis's ANDA, Actavis 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.

20. Once the FDA grants tentative approval of Actavis's ANDA, these substantial activities engaged in by Actavis directed toward infringement, contributory infringement, and active inducement of infringement as set forth above demonstrate the existence of an actual and justiciable controversy (*see* paragraph 12 above), and, if allowed to continue and progress, will inevitably constitute infringement, contributory infringement, and active inducement of 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 the First Claim for Relief:

A. Adjudging that Actavis 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. 202434 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. 202434, 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., Actavis, 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 the Second Claim for Relief:

F. Declaring that the manufacture, use, and substantial preparations for offering for sale of Actavis's proposed generic copies of OxyContin®, 60 mg and 80 mg, if allowed to continue and progress, will constitute infringement, contributory infringement and active inducement of infringement of the '383 patent;

G. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 283 and Rule 65, Fed. R. Civ. P., Actavis, 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;

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

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

Dated: July 20, 2012

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Dated: July 20, 2012

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