13 CV 3372

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

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC., and
PURDUE PHARMACEUTICALS L.P.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

C.A. No. _____

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. 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 11 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 11 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 11 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

THE PARTIES: DEFENDANT

5. Upon information and belief, Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, NJ 08807. Upon information and belief, Amneal maintains an administrative office at 85 Adams Avenue, Hauppauge, NY 11788; an oral solids manufacturing facility at 75 Adams Avenue, Hauppauge, NY 11788; an oral solids and softgels manufacturing facility at 50 Horseblock Road, Brookhaven, NY 11719; and an oral solids research and development facility at 50 Horseblock Road, Brookhaven, NY 11719.

6. Upon information and belief, Amneal 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. 028841). The Registration has an active status and is valid through January 31, 2014.

7. Upon information and belief, Amneal is registered as a Foreign Limited Liability Company by the New York State Department of State, Division of Corporations with a listed address to receive process of 85 Adams Avenue, Hauppauge, New York 11788.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Amneal because, *inter alia*, Amneal has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Amneal 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, Amneal engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Amneal 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") described in paragraph 12 below that Amneal submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals, LLC*, No. 11-civ-8153 (SHS) (S.D.N.Y. Nov. 10, 2011). Further, this Court has personal jurisdiction over Amneal because, upon information and belief, Amneal is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. This Court also has personal jurisdiction over Amneal because, upon information and belief, Amneal is registered as a Foreign Limited Liability Company by the New York State Department of State, Division of Corporations. In addition,

upon information and belief, Amneal is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 203235 described in paragraph 12 below, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

THE PATENT IN SUIT

11. 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 titled "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.

DEFENDANT'S ANDA

12. Upon information and belief, Amneal submitted ANDA No. 203235 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, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, ("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 '888 patent.

13. Upon information and belief, Amneal's ANDA No. 203235 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 "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents" by the commercial manufacture, use, sale, offer for sale, or importation of its proposed generic copies of OxyContin®.

14. In a letter dated April 4, 2013 addressed to Plaintiff Purdue Pharma and received by Plaintiff Purdue Pharma on April 5, 2013, Amneal 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.

CLAIM FOR RELIEF

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

16. Upon information and belief, Amneal'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.

17. Upon information and belief, Amneal's commercial manufacture, use, sale, and/or offer for sale of its 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.

18. Upon information and belief, Amneal 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.

19. The acts of infringement by Amneal 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:

20. Adjudging that Amneal has infringed the '888 patent, and that the commercial sale, offer for sale, use, and/or manufacture of its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, described in ANDA No. 203235 would infringe, induce infringement of, and/or contribute to the infringement of the '888 patent;

21. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203235, 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;

22. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Amneal, 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;

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

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

Dated: May 17, 2013

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