

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE
PHARMACEUTICALS L.P., THE P.F.
LABORATORIES, INC., RHODES
TECHNOLOGIES and GRÜNENTHAL
GMBH,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

C.A. No. _____

COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. (collectively, “Purdue”), Rhodes Technologies (“Rhodes”) and Grünenthal GmbH (“Grünenthal”) (collectively, “Plaintiffs”), for their Complaint against Defendant Amneal Pharmaceuticals, LLC (“Amneal” or “Defendant”), 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, for infringement of United States Patent Nos. 7,674,799 (the “’799 patent”); 7,674,800 (the “’800 patent”); 7,683,072 (the “’072 patent”); 8,114,383 (the “’383 patent”); 8,309,060 (the “’060 patent”); 8,337,888 (the “’888 patent”); 8,808,741 (the “’741 patent”); 8,894,987 (the “’987 patent”); 8,894,988 (the “’988 patent”); 9,060,976 (the “’976 patent”); 9,034,376 (the “’376 patent”); and 9,073,933 (the “’933 patent”) (collectively, “the patents-in-suit”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 203235 as amended (“Defendant’s Amended ANDA”) submitted upon

information and belief in the name of Amneal to the United States Food and Drug Administration (“FDA”).

2. Plaintiffs seek judgment that Defendant has infringed the ’799, ’800, ’072, ’383, ’060, ’888, ’741, ’987, ’988, ’976 and ’933 patents (collectively, “the Orange Book patents”), which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* (“Orange Book”) as covering Purdue’s OxyContin® (oxycodone hydrochloride) (“OxyContin®”), an extended-release pain medication. Defendant has infringed the Orange Book patents under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 203235 as amended, submitted upon information and belief in the name of Amneal to the FDA. Defendant’s Amended ANDA seeks approval to market a generic version of Purdue’s OxyContin®, which is the subject of approved NDA No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths (“Defendant’s Amended ANDA Products”). As set forth in paragraphs 21-58, certain claims of the ’799, ’800, ’072, ’383, ’060 and ’888 patents have been found infringed but invalid in previous lawsuits. Appeals from those judgments of invalidity are pending. To conserve the resources of the Court and the parties, Plaintiffs will seek a partial stay of this action against Amneal with respect to the patents held invalid until final adjudication of the pending appeals.

3. Plaintiffs also seek judgment that Defendant has infringed the ’376 patent, which is not listed in the FDA’s Orange Book, under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 203235 as amended on Defendant’s Amended ANDA Products.

4. On September 17, 2015, Purdue filed a related complaint against Defendant, C.A. No. 15-831-SLR, for patent infringement of the ’976 and ’376 patents. The previous action was filed in connection with Defendant’s ANDA, which contained a “Paragraph

IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’976 patent, listed in the Orange Book as covering OxyContin®, is “invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of” the drug products described in Defendant’s ANDA.

THE PARTIES

5. 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, Connecticut 06901-3431. Purdue Pharma is an owner of the ’799, ’800, ’072, ’888, ’741, ’987, ’988, ’976, ’376 and ’933 patents, identified in paragraphs 21-30, and 51-64 below, and Purdue Pharma is an exclusive licensee of the ’060 and ’383 patents, identified in paragraphs 31-50 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

6. 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 the ’799, ’800, ’072, ’888, ’976, ’376 and ’933 patents, identified in paragraphs 21-30, 51-58, and 62-64 below.

7. 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 One Stamford Forum, Stamford, CT 06901. P.F. Labs is an owner of the ’799, ’800, ’072, ’888, ’976, ’376 and ’933 patents, identified in paragraphs 21-30, 51-58, and 62-64 below.

8. 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 the '799, '800, '072 and '933 patents, identified in paragraphs 21-30 and 64 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

9. 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 the '060 and '383 patents, identified in paragraphs 31-50 below.

10. On information and belief, Defendant is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd floor, Bridgewater, NJ 08807.

SUBJECT MATTER JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

PERSONAL JURISDICTION

14. This Court has personal jurisdiction over the Defendant by virtue of, *inter alia*, the fact that Amneal is a Delaware limited liability company, Defendant's systematic and continuous contacts with Delaware, and Defendant's contacts with Delaware in connection with the submission of its ANDA, as set forth below.

15. On information and belief, Amneal is registered to conduct business within the State of Delaware and maintains as a registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St, Wilmington, Delaware 19801.

16. On information and belief, Amneal holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses from the Delaware Board of Pharmacy.

17. On information and belief, Defendant is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States.

18. On information and belief, if ANDA No. 203235 as amended is approved, the Defendant’s Amended ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

19. On information and belief, Defendant has admitted to, consented to or has not contested, the jurisdiction of this Court, and/or has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of Delaware actions, *e.g.*, *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-831; *Forest Laboratories, LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 15-756; *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-697; *Forest Laboratories, LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 15-430; *Merck Sharpe & Dohme Corp. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-250; *Forest Laboratories, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 14-508.

20. This Court further has personal jurisdiction over Defendant by virtue of the fact that Defendant has committed, or aided, abetted, contributed to, and/or participated in the

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