IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AMNEAL PHARMACEUTICALS LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue" or "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. 9,060,976 (the "'976 patent") and 9,034,376 (the "'376 patent").

2. Plaintiffs seek judgment that Defendant has infringed the '976 patent, which is listed in the United States Food and Drug Administration ("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 '976 patent under 35 U.S.C. § 271(e)(2)(A) by filing Abbreviated New Drug Application ("ANDA") No. 203235 ("Defendant's ANDA") submitted upon information and belief in the name of Amneal Pharmaceuticals LLC to the FDA. Defendant's

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 ANDA Products").

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 on Defendant's ANDA Products.

THE PARTIES

4. 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 the '976 and '376 patents, identified in paragraphs 18-19 below. Purdue Pharma is also the holder of NDA No. 022272 for the extended-release oxycodone pain-relief medication OxyContin® and is involved in the sale of OxyContin® in the United States.

5. 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 the '976 and '376 patents, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin®.

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 '976 and '376 patents, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin®.

7. 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

8. 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.

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

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

PERSONAL JURISDICTION

11. This Court has personal jurisdiction over the Defendant by virtue of, *inter alia*, the fact that Amneal Pharmaceuticals LLC 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.

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

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

14. 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.

15. On information and belief, if ANDA No. 203235 is approved, the Defendant's 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.

16. 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.*, *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.

17. 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 commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

18. Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '976 patent, entitled "PHARMACEUTICAL

FORMULATION CONTAINING GELLING AGENT," including the right to sue and to recover for past infringement thereof. The '976 patent is listed in FDA's Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '976 patent, attached hereto as Exhibit A, was duly and legally issued on June 23, 2015, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

19. Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '376 patent, titled "PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT," including the right to sue and to recover for past infringement thereof. A copy of the '376 patent, attached hereto as Exhibit B, was duly and legally issued on May 19, 2015, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

DEFENDANT'S ANDA

20. On information and belief, on or before September 27, 2011, Defendant filed Defendant's ANDA 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 Defendant's ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

21. On information and belief, Defendant's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '976 patent, listed in the FDA's Orange Book as covering the OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of" the drug products described in Defendant's ANDA.

22. In a letter dated August 3, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about August 4, 2015, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's ANDA and Defendant's ANDA Products and the '976 patent, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

23. Defendant's submission of Defendant's ANDA No. 203235 was an act of infringement of the '976 and '376 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

24. Plaintiffs are commencing this action within the 45 day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '976 PATENT

25. Plaintiffs incorporate by reference and reallege paragraphs 1 through 24 above as though fully restated herein.

26. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 203235 to the FDA seeking approval of Defendant's ANDA Products was an act of infringement of the '976 patent by Defendant.

27. Defendant's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '976 patent.

28. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(a)-(c).

29. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '976 patent.

30. Upon information and belief, Defendant has been aware of the existence of the '976 patent, and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '976 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

31. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '976 patent. Plaintiffs do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '376 PATENT

32. Plaintiffs incorporate by reference and reallege paragraphs 1 through 31 above as though fully restated herein.

33. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 203235 to the FDA seeking approval of Defendant's ANDA Products was an act of infringement of the '376 patent by Defendant.

34. Defendant's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '376 patent.

35. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '376 patent under 35 U.S.C. § 271(a)-(c).

36. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '376 patent.

37. Upon information and belief, Defendant has been aware of the existence of the '376 patent, and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '376 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

38. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '376 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendant has infringed one or more claims of each of the '976 and '376 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendant's ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '976 and '376 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203235 and Defendant's ANDA Products, 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 last date of expiration of the '976 and '376 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Defendant, 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 is the subject of ANDA No. 203235, including Defendant's ANDA Products or any other drug product that infringes the '976 and '376 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, 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.

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