IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs, Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, "Purdue" or "Plaintiffs"), for their Complaint against Defendant Amneal Pharmaceuticals, LLC ("Amneal"), 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. 9,770,416 (the "'416 patent") and 9,775,808 (the "'808 patent") (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 203235 as amended ("Amneal's Amended ANDA") submitted, upon information and belief, by Amneal to the United States Food and Drug Administration ("FDA"). Plaintiffs seek judgment that Amneal has infringed the '416 and '808 patents. The '416 and '808 patents 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. Amneal has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing Amneal's Amended ANDA. Amneal'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 ("Amneal's Amended ANDA Products").

2. On September 17, 2015, Purdue filed a related complaint against Amneal, C.A. No. 15-831-RGA, for patent infringement of U.S. Patent Nos. 9,060,976 (the "'976 patent") and 9,034,376 (the "'376 patent"). The previous action was filed in connection with Amneal's ANDA No. 203235, 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 "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal."

3. On December 15, 2015, Purdue filed a related complaint against Amneal, C.A. No. 15-1152-RGA, for patent infringement of U.S. 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 "Kupper '933 patent"). The previous action was filed in connection with Amneal's Amended ANDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and Kupper '933 patents, listed in the Orange Book as covering OxyContin®, are "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal."

4. On March 1, 2017, Purdue filed a related complaint against Amneal, C.A. No. 17-210-RGA, for patent infringement of United States Patent Nos. 9,492,392 (the "'392 patent"); 9,492,393 (the "'393 patent"); and 9,522,919 (the "'919 patent"). The previous action was filed in connection with Amneal's Amended ANDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '392, '393, and '919 patents, listed in the Orange Book as covering OxyContin®, are "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal."

5. On October 10, 2017, Purdue filed a related complaint against Amneal, C.A. No. 17-1421-RGA, for patent infringement of United States Patent Nos. 9,763,886 (the "'886 patent"), 9,763,933 (the "Mannion '933 patent")[1], and 9,675,610 (the "'610 patent"). The previous action was filed in connection with Amneal's Amended ANDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '610 patent, listed in the Orange Book as covering OxyContin®,[2] is "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal."

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[1] The Mannion '933 patent is different from U.S. Patent No. 9,073,933, which is one of the patents-in-suit in related action C.A. No. 15-1152-RGA, and which has been referred to as the "'933 patent." To avoid confusion, Plaintiffs refer to U.S. Patent No. 9,073,933 as the Kupper '933 patent.

[2] The Mannion '933 patent is also listed in the Orange Book as covering OxyContin®, but no "Paragraph IV" certification had been received as of the filing of the lawsuit.

6. Purdue has also filed, concurrently with the filing of the present Complaint, a related complaint against Kashiv Pharma, LLC ("Kashiv") for patent infringement of the Mannion '933, '416, and '808 patents ("the Concurrent Kashiv Action"). The Concurrent Kashiv Action is identical to the present Complaint, except that in the Concurrent Kashiv Action, (a) Kashiv is the sole-named Defendant, and (b) there are allegations of infringement with respect to the Mannion '933 patent, which was previously asserted against Amneal in the related C.A. No. 17-1421. On information and belief, Amneal (not Kashiv) is the owner of Amneal's Amended ANDA. Plaintiffs filed the Concurrent Kashiv Action out of an abundance of caution should Kashiv demonstrate that it, in fact, is the owner of Amneal's Amended ANDA.

THE PARTIES

7. 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 '416 and '808 patents. 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.

8. 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 '416 and '808 patents.

9. On information and belief, Amneal 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

10. 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.

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

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Amneal resides in this judicial district and because Amneal has committed acts of infringement in this judicial district.

PERSONAL JURISDICTION

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

14. 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 Street, Wilmington, Delaware 19801.

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

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