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.

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

17. On information and belief, Amneal 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. 17-1421; *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 17-210; *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-1152; *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; and *Forest Laboratories, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 14-508.

18. On information and belief, if ANDA No. 203235 as amended is approved, Amneal'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. This Court further has personal jurisdiction over Amneal by virtue of the fact that Amneal 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 Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

THE '416 PATENT

20. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '416 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '416 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. Attached as Exhibit A is a copy of the '416 patent, which was duly and legally issued on September 26, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '808 PATENT

21. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '808 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '808 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. Attached as Exhibit B is a copy of the '808 patent, which was duly and legally issued on October 3, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

AMNEAL'S AMENDED ANDA

22. On information and belief, on or before September 27, 2011, Amneal filed Amneal's ANDA No. 203235 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 Amneal's ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

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

24. On information and belief, on or before October 30, 2015, Amneal filed Amneal's Amended 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 Amneal's Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

25. In a letter dated November 21, 2017, addressed to Plaintiffs and received by Purdue Pharma on or about November 22, 2017, Kashiv Pharma ("Kashiv") purports to have provided a "Notice of Paragraph IV Certification" with respect to Amneal's Amended ANDA and Amneal's Amended ANDA Products, and the '416 and '808 patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter"). Kashiv also purports to be the owner of Amneal's Amended ANDA. In the Notice Letter, Kashiv alleges that "it submitted" ANDA No. 203235 to the FDA. However, according to "Amneal Pharmaceuticals, LLC Detailed Factual and Legal Bases of Non-Infringement and/or Invalidity" ("Amneal's Allegations"), attached to the Notice Letter, "Amneal Pharmaceuticals, LLC ('Amneal') filed [Amneal's Amended ANDA]" and "Amneal was the owner of ANDA No. 203235 as originally filed on September 27, 2011.

26. Further, Amneal alleges to have "acted as agent [of Kashiv] by filing certain ANDA papers with the FDA on behalf of Kashiv." However, on information and belief,

at least through about September 2017, Amneal filed all ANDA papers in its own name on its own behalf.

27. Amneal also alleges to have "transferred ownership of the ANDA" to Kashiv. Amneal further alleges to be "the exclusive licensee" of Amneal's Amended ANDA Products. However, on information and belief, Amneal did not transfer ownership of Amneal's Amended ANDA to Kashiv. On information and belief, Amneal is the current owner of Amneal's Amended ANDA.

28. However, even if Kashiv is the current owner of Amneal's Amended ANDA, on information and belief, Amneal is still liable for infringement of the patents in suit due to its continued active involvement in Amneal's Amended ANDA and because it intends to directly benefit if Amneal's Amended ANDA is approved. On information and belief, Amneal and Kashiv are related corporate entities that are both members of the same corporate family, the "AE Companies." *See* http://aecompaniesllc.com/ (identifying Amneal and Kashiv as member organizations). On further information and belief, Amneal contributed employees to the various teams responsible for preparing Amneal's Amended ANDA, and Amneal's employees prepared and executed documents related to Amneal's Amended ANDA. Moreover, on information and belief, Amneal is still actively involved in Amneal's Amended ANDA, at least because Amneal, as the exclusive licensee of Amneal's Amended ANDA Products, will be involved in, and directly benefit from, the marketing and distribution of those products in the United States if Amneal's Amended ANDA is approved. *See, e.g.*, *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009) ("'Active involvement' includes 'marketing and distributing the approved generic drugs in the United States.'") (denying motion to dismiss for lack of § 271(e)(2) liability).

29. Plaintiffs commenced this action within the 45-day period after receiving the Notice Letter dated November 21, 2017, as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,770,416)

30. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 29 above as though fully restated herein.

31. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 203235, as amended, to the FDA seeking approval of Amneal's Amended ANDA Products was an act of infringement of the '416 patent by Amneal.

32. Amneal's Amended ANDA Products, or use thereof, are covered by one or more claims of the '416 patent, including but not limited to independent claim 1, which recites, *inter alia*, a pharmaceutical composition comprising: at least active agent comprising an opioid or a pharmaceutically acceptable salt, and at least one high molecular weight polyethylene oxide (PEO), having an approximate molecular weight of from 1 million to 8 million; wherein (a) the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for a curing time of about 15 minutes to about 8 hours at a curing temperature of about 60 C to about 90 C, (iii) cooled, and (iv) hardened; (b) the high molecular weight PEO is at least partially melted upon curing and comprises at least about 50% (by weight) of the dosage form; (c) the active agent comprises at least about 1.3% (by weight) of the dosage form; (d) the molecular weight of each PEO is based on rheological measurements; (e) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings; and (f) the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.5%, and the dosage form provides a hardness of at least about 439 N.

33. If approved by the FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of Amneal's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '416 patent under 35 U.S.C. § 271(a)-(c).

34. Amneal's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '416 patent.

35. Upon information and belief, Amneal has been aware of the existence of the '416 patent and has no reasonable basis for believing that the manufacture, use, sale, or offer for sale of Amneal's Amended ANDA Products will not infringe the '416 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

36. Unless Amneal is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Amneal's infringement of the '416 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,775,808)

37. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 29 above as though fully restated herein.

38. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 203235 as amended to the FDA seeking approval of Amneal's Amended ANDA Products was an act of infringement of the '808 patent by Amneal.

39. Amneal's Amended ANDA Products, or the use thereof, are covered by one or more claims of the '808 patent, including but not limited to independent claim 1, which recites, *inter alia,* a pharmaceutical composition comprising: at least one active agent comprising

oxycodone or a pharmaceutically acceptable salt thereof; and at least one high molecular weight polyethylene oxide (PEO), having an approximate molecular weight of from 1 million to 15 million; at least one of an additive and a film coating; wherein (a) the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO, (iii) cooled, and (iv) hardened; (b) the high molecular weight PEO comprises at least about 30% (by weight) of the dosage form; (c) the molecular weight of each PEO is based on rheological measurements; and (d) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings.

40. If approved by the FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of Amneal's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c).

41. Amneal's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '808 patent.

42. Upon information and belief, Amneal has been aware of the existence of the '808 patent and has no reasonable basis for believing that Amneal's Amended ANDA Products will not infringe the '808 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

43. Unless Amneal is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Amneal's infringement of the

'808 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Amneal has infringed one or more claims of each of the '416 and '808 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Amneal's Amended ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '416 and '808 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203235 as amended and Amneal's Amended 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 '416 and '808 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 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 is the subject of ANDA No. 203235 as amended, including Amneal's Amended ANDA Products or any other drug product that infringes the '416 and '808 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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