IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs, Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. (collectively, "Purdue") and Rhodes Technologies ("Rhodes") (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. 9,492,392 (the ''392 patent"); 9,492,393 (the ''393 patent"); and 9,522,919 (the ''919 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 '392, '393 and '919 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").

3. On December 15, 2015, Purdue filed a related complaint against Defendant, 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"); 8,337,888 (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"). The previous action was filed in connection with Defendant'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, '888, '741, '987, '988, '976, '376 and '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 September 17, 2015, Purdue filed a related complaint against Defendant, 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 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 ""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."

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, CT 06901. Purdue Pharma is an owner of the '392, '393 and '919 patents, identified in paragraphs 20-22 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 '392, '393 and '919 patents, identified in paragraphs 20-22 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 '919 patent, identified in paragraphs 20-22 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 '919 patent, identified in paragraph 22 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

9. 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

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(b), 1391(c), and 1400(b).

PERSONAL JURISDICTION

13. 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.

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, Defendant 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, if ANDA No. 203235 as amended is approved, 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.

18. 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. 15-1152; *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.

19. 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, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

THE '392 PATENT

20. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '392 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '392 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '392 patent is attached hereto as Exhibit A, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '393 PATENT

21. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '393 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '393 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '393 patent is attached hereto as Exhibit B, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '919 PATENT

22. Purdue and Rhodes are the lawful owners of all right, title and interest in the '919 patent, titled "OXYCODONE COMPOSITIONS," including the right to sue and to

recover for past infringement thereof. The '919 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '919 patent is attached hereto as Exhibit C, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANT'S AMENDED ANDA

23. On information and belief, on or before September 27, 2011, Defendant filed Defendant'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 Defendant's ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Defendant subsequently submitted in its ANDA a "Paragraph IV" certification under 21 U.S.C. § 355U)(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.

24. 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 Amended ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

25. On information and belief, on or before October 30, 2015, Defendant filed Defendant'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 Defendant's Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Defendant's Amended ANDA contained a "Paragraph IV" certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging that the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976 and '933 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, 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 products described in Defendant's Amended ANDA.

26. In a letter dated October 30, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about November 2, 2015, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's Amended ANDA and Defendant's Amended ANDA Products, and the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976 and '933 patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

27. On information and belief, on or before January 16, 2017, Defendant filed Defendant's Amended 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 Defendant's Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Defendant's Amended ANDA contained a "Paragraph IV" certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging, *inter alia,* that the '392, '393 and '919 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, 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 products described in Defendant's Amended ANDA.

28. In a letter dated January 16, 2017, addressed to Plaintiffs and received by Purdue Pharma on or about January 17, 2017, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's Amended ANDA and Defendant's Amended ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

29. Plaintiffs commenced 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 U.S. PATENT NO. 9,492,392)

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), Defendant's submission of ANDA No. 203235 as amended to the FDA seeking approval of Defendant's Amended ANDA Products was an act of infringement of the '392 patent by Defendant.

32. Defendant's Amended ANDA Products, or the use thereof, are covered by one or more claims of the '392 patent, including but not limited to independent claim 1, which recites *inter alia*, a cured shaped pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression, by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having an approximate molecular weight

selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

33. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '392 patent under 35 U.S.C. § 271(a)-(c).

34. Defendant's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '392 patent.

35. Upon information and belief, Defendant has been aware of the existence of the '392 patent, and has no reasonable basis for believing that Defendant's Amended ANDA Products will not infringe the '392 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

36. Unless Defendant is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendant's infringement of the '392 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. 9,492,393)

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), Defendant's submission of ANDA No. 203235 as amended to the FDA seeking approval of Defendant's Amended ANDA Products was an act of infringement of the '393 patent by Defendant.

39. Defendant's Amended ANDA Products, or the use thereof, are covered by one or more claims of the '393 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '393 patent under 35 U.S.C. § 271(a)-(c).

40. Defendant's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '393 patent.

41. On information and belief, Defendant knows that Defendant's Amended ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '393 patent.

42. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Defendant's Amended ANDA Products.

43. The administration of Defendant's Amended ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '393 patent.

44. Defendant's proposed label for Defendant's Amended ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendant's Amended ANDA Products in a manner that will directly infringe one or more claims of the '393 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom. OxyContin® is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

45. If Defendant's Amended ANDA Products are approved by the FDA, Defendant will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '393 patent. Since at least the date of the Notice Letter, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '393 patent.

46. Defendant intends to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

47. If Defendant's Amended ANDA Products are approved by the FDA, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Defendant's Amended ANDA Products in a manner that directly infringes one or more claims of the '393 patent. Thus, Defendant will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '393 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

48. Upon information and belief, Defendant has been aware of the existence of the '393 patent, and has no reasonable basis for believing that Defendant's Amended ANDA Products will not infringe the '393 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

49. Unless Defendant is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendant's infringement of the '393 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,522,919)

50. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 29 above as though fully restated herein.

51. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 203235 as amended to the FDA seeking approval of Defendant's Amended ANDA Products was an act of infringement of the '919 patent by Defendant.

52. Defendant's Amended ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '919 patent, including but not limited to independent

claims 1, 4, 12 and 18, which recite, *inter alia*, an oxycodone hydrochloride composition wherein the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone hydrochloride is 0.04% or less as measured by HPLC, and various claims dependent therefrom.

53. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(a)-(c).

54. Defendant's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '919 patent.

55. Upon information and belief, Defendant has been aware of the existence of the '919 patent, and has no reasonable basis for believing that Defendant's Amended ANDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

56. Unless Defendant is enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendant's infringement of the '919 patent. Purdue and Rhodes 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 '392, '393 and '919 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendant's Amended ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '392, '393 and '919 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 Defendant'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 '392, '393 and '919 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., 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 as amended, including Defendant's Amended ANDA Products or any other drug product that infringes the '392, '393 and '919 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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