IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P. and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
ALVOGEN PINE BROOK, INC.,	)	
Defendant.	)	

COMPLAINT

Purdue Pharma L.P. ("Purdue Pharma") and Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") (collectively, "Purdue" or the "Plaintiffs"), for their Complaint against Defendant Alvogen Pine Brook, Inc. ("Alvogen" 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 Patents Nos. 9,084,816 (the "'816 patent"); 9,095,614 (the "'614 patent"); and 9,095,615 (the "'615 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208269 ("Defendant's ANDA") submitted upon information and belief in the name of Alvogen Pine Brook, Inc. to the United States Food and Drug Administration ("FDA"). Defendant's ANDA seeks approval to market a generic version of Purdue's Hysingla® ER (hydrocodone bitartrate) ("Hysingla®"), which is the subject of approved New Drug Application ("NDA") No. 206627, in 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg and 120 mg dosage strengths ("Defendant's ANDA Products").

2. On August 5, 2015, Purdue, along with The P.F. Laboratories, Inc. ("P.F. Labs") and Grünenthal GmbH ("Grünenthal"), filed a related complaint against Defendant, C.A. No. 15-687-GMS, for patent infringement of United States Patents Nos. 6,733,783 (the "'783 patent"); 8,361,499 (the "'499 patent"); 8,551,520 (the "'520 patent"); 8,647,667 (the "'667 patent"); 9,023,401 (the "'401 patent"); 8,529,948 (the "'948 patent"); 8,808,740 (the "'740 patent"); and 8,309,060 (the "'060 patent").

3. On September 8, 2015, Purdue Pharma filed another related complaint against Defendant, C.A. No. 15-784-GMS, for patent infringement of United States Patents Nos. 9,056,052 (the "'052 patent") and 9,060,940 (the "'940 patent").

4. Purdue filed C.A. Nos. 15-687-GMS and 15-784-GMS in connection with Defendant's ANDA. The patents-in-suit in those cases are listed in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluation* (the "Orange Book") as, *inter alia*, covering the use of Hysingla®, and Defendant's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the patents are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of" products described in Defendant's ANDA. *See* 35 U.S.C. § 271(e)(2).

THE PARTIES

5. 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 '816 patent, '614 patent, and '615 patent identified in paragraphs 14-16 below. Purdue Pharma is also the holder of approved NDA No. 206627 for Hysingla®, indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for

whom alternative treatment options are inadequate. Purdue Pharma sells Hysingla® in the United States.

6. 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, North Carolina 27893. Purdue Pharmaceuticals is an owner of the '816 patent, '614 patent, and '615 patent identified in paragraph 14-16 below.

7. Plaintiffs Purdue Pharma and Purdue Pharmaceuticals are associated companies.

8. On information and belief, Defendant is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 10B Bloomfield Ave., Pine Brook, New Jersey 07058.

SUBJECT MATTER JURISDICTION AND VENUE

9. 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.

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

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

PERSONAL JURISDICTION

12. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its incorporation in Delaware and its systematic and continuous marketing, manufacturing, and distributing of, *inter alia*, generic pharmaceutical products in Delaware. In addition, Defendant has previously submitted to the jurisdiction of this judicial district and has asserted

counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, *Novartis Pharm. Corp. v. Alvogen Pine Brook, Inc.*, C.A. No. 13-052-RGA (D. Del. Jan. 31, 2013) (D.I. 14); *Reckitt Benckiser Pharm., Inc. v. Alvogen Pine Brook, Inc.*, C.A. No. 13-2003-RGA (D. Del. Feb. 4, 2014) (D.I. 30); *Purdue Pharma L.P. et. al. v. Alvogen Pine Brook, Inc.*, C.A. No. 15-687-GMS (D. Del. Aug. 5, 2015) (D.I. 7).

13. Further, this Court 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, which 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

14. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '816 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '816 patent is listed in the Orange Book as covering Hysingla®, which is the subject of approved NDA No. 206627. A copy of the '816 patent, attached hereto as Exhibit A, was duly and legally issued on July 21, 2015, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

15. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '614 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '614 patent is listed in the Orange Book as covering Hysingla®, which is the subject of approved NDA No. 206627. A copy of the '614 patent, attached hereto as Exhibit B, was duly and legally issued on August 4,

2015, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

16. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '615 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '615 patent is listed in the Orange Book as covering Hysingla®, which is the subject of approved NDA No. 206627. A copy of the '615 patent, attached hereto as Exhibit C, was duly and legally issued on August 4, 2015, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

DEFENDANT'S ANDA

17. On information and belief, on or before June 19, 2015, Alvogen 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 Hysingla®, which is the subject of approved NDA No. 206627.

18. 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 '816 patent, '614 patent, and '615 patent listed in the FDA's Orange Book as, *inter alia*, covering the use of Hysingla®, which is the subject of approved NDA No. 206627, are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of" the drug products described in Defendant's ANDA.

19. In a letter dated September 1, 2015 addressed to Plaintiffs and received by Purdue on or about September 2, 2015, Defendant provided what purports to be "Notification

Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act" with respect to Defendant's ANDA and Defendant's ANDA Products, and the '816 patent, '614 patent, and '615 patent ("Notice Letter").

20. Defendant's submission of Defendant's ANDA No. 208269 was an act of infringement of the '816 patent, '614 patent, and '615 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

21. Purdue is 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 U.S. PATENT NO. 9,084,816)

22. Purdue incorporates by reference and realleges paragraphs 1 through 21 above as though fully restated herein.

23. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 208269 to the FDA seeking approval of Defendant's ANDA Products was an act of infringement of the '816 patent by Defendant.

24. Defendant's ANDA Products are covered by one or more claims of the '816 patent.

25. 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 induce the infringement of one or more claims of the '816 patent under 35 U.S.C. § 271(a)-(c).

26. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '816 patent.

27. On information and belief, Defendant knows that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '816 patent.

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

29. If Defendant's ANDA Products are approved by the FDA, Defendant will intentionally encourage acts of direct infringement of the '816 patent by others, with knowledge that their acts are encouraging infringement.

30. Upon information and belief, Defendant has been aware of the existence of the '816 patent, and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '816 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, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '816 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,095,614)

32. Purdue incorporates by reference and realleges 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. 208269 to the FDA seeking approval of Defendant's ANDA Products was an act of infringement of the '614 patent by Defendant.

34. Defendant's ANDA Products, or the use thereof, are covered by one or more claims of the '614 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 induce the infringement of one or more claims of the '614 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 '614 patent.

37. On information and belief, Defendant knows that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '614 patent.

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

39. The administration of Defendant's ANDA Products by any healthcare providers, including, but not limited to, doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '614 patent.

40. Defendant's proposed label for Defendant's ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendant's ANDA Products in a manner that will directly infringe one or more claims of the '614 patent.

41. If Defendant's 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 '614 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 '614 patent.

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

43. If Defendant's 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 ANDA Products in a manner that directly infringes one or more claims of the '614 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 '614 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

44. Upon information and belief, Defendant has been aware of the existence of the '614 patent, and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '614 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

45. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '614 patent. Purdue does not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,095,615)

46. Purdue incorporates by reference and realleges paragraphs 1 through 45 above as though fully restated herein.

47. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 208269 to the FDA seeking approval of Defendant's ANDA Products was an act of infringement of the '615 patent by Defendant.

48. Defendant's ANDA Products are covered by one or more claims of the '615 patent.

49. 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 induce the infringement of one or more claims of the '615 patent under 35 U.S.C. § 271(a)-(c).

50. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '615 patent.

51. On information and belief, Defendant knows that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '615 patent.

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

53. If approved by the FDA, Defendant will intentionally encourage acts of direct infringement of the '615 patent by others, with knowledge that their acts are encouraging infringement.

54. Upon information and belief, Defendant has been aware of the existence of the '615 patent, and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '615 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

55. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '615 patent. Purdue does 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 '816 patent, '614 patent, and '615 patent, 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 '816 patent, '614 patent, and '615 patent;

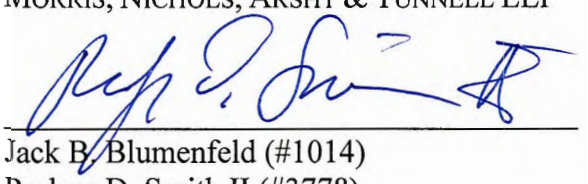
B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 208269 and Defendant's ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the '816 patent, '614 patent, and '615 patent, 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. 208269, including Defendant's ANDA Products or any other drug product that infringes the '816 patent, '614 patent, and '615 patent;

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



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