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.	)	
ACTAVIS LABORATORIES FL, 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 Actavis Laboratories FL, Inc. ("Actavis" 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. 9,056,052 (the "'052 patent"); 9,060,940 (the "'940 patent"); 9,084,816 (the "'816 patent"); and 9,095,614 (the "'614 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208389 ("Actavis's ANDA") submitted, upon information and belief, in the name of Actavis Laboratories FL, Inc. to the United States Food and Drug Administration ("FDA"). Actavis'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 ("Actavis's ANDA Products").

2. On August 5, 2015, Purdue, along with The P.F. Laboratories, Inc. and Grünenthal GmbH, filed a related complaint against Defendant, C.A. No. 15-686-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. Purdue filed C.A. No. 15-686-GMS in connection with Actavis's ANDA. The patents-in-suit in that case are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluation* (the "Orange Book") as, *inter alia*, covering the use of Hysingla®, and Actavis's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that those patents are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of" products described in Actavis's ANDA. *See* 35 U.S.C. § 271(e)(2).

THE PARTIES

4. 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 '052 patent, '940 patent, '816 patent, and '614 patent identified in paragraphs 17-20 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.

5. 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 and the '614 patent, identified in paragraphs 19-20 below.

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

7. On information and belief, Defendant is a corporation organized and existing under the laws of the State of Florida, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

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 subject matter jurisdiction 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*, its systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of its ANDA, as set forth below.

12. 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.

13. On information and belief, if Actavis's ANDA is approved, the Actavis'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.

14. In addition, Defendant has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Cephalon, Inc. v. Actavis Laboratories FL, Inc., Actavis, Inc., Actavis Pharma, Inc., and Watson Laboratories, Inc.*, C.A. No. 14-776-SLR-SRF, D.I. 16 (D. Del. July 25, 2014) (consenting to jurisdiction); *Forest Laboratories, Inc. et al. v. Apotex Corp. and Watson Laboratories, Inc.-Florida*, C.A. No. 14-200-LPS, D.I. 22 and D.I. 48 (D. Del. Apr. 22, 2014) (consenting to jurisdiction and stating that Watson Laboratories, Inc. Florida changed its name to Actavis Laboratories FL, Inc. on April 21, 2014); and *Purdue Pharma L.P. et al. v. Actavis Laboratories FL, Inc.*, C.A. No. 15-686-GMS, D.I. 7 (D. Del. August 5, 2015) (consenting to jurisdiction).

15. 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 that has led to foreseeable harm and injury to Plaintiffs, which are limited partnerships organized and existing under the laws of the State of Delaware.

16. Defendant has agreed not to challenge personal jurisdiction for purposes of this action.

THE PATENTS-IN-SUIT

17. Purdue Pharma is the lawful owner of all right, title, and interest in the '052 patent, titled "CONTROLLED RELEASE HYDROCODONE FORMULATIONS," including the right to sue and to recover for past infringement thereof. The '052 patent is listed in the Orange Book as covering Hysingla®, which is the subject of approved NDA No. 206627. A copy of the '052 patent, attached hereto as Exhibit A, was duly and legally issued on June 16, 2015, naming Benjamin Oshlack, Hua-Pin Huang, John K. Masselink, and Alfred Tonelli as the inventors.

18. Purdue Pharma is the lawful owner of all right, title, and interest in the '940 patent, titled "CONTROLLED RELEASE HYDROCODONE," including the right to sue and to recover for past infringement thereof. The '940 patent is listed in the Orange Book as covering Hysingla®, which is the subject of approved NDA No. 206627. A copy of the '940 patent, attached hereto as Exhibit B, was duly and legally issued on June 23, 2015, naming Benjamin Oshlack, Hua-Pin Huang, John K. Masselink, and Alfred Tonelli as the inventors.

19. 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 C, 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.

20. 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 D, 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.

ACTAVIS'S ANDA

21. On information and belief, on or before June 23, 2015, Actavis filed its 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 Actavis's ANDA Products, generic products based on the Reference Listed Drug Hysingla®, which is the subject of approved NDA No. 206627.

22. On information and belief, Actavis's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '052 patent, '940 patent, '816 patent, and '614 patent listed in the 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 Actavis's ANDA.

23. In a letter dated September 21, 2015 addressed to Plaintiffs and received by Purdue on or about September 22, 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 Actavis's ANDA and Actavis's ANDA Products, and the '052 patent, '940 patent, '816 patent, and '614 patent (the "Notice Letter").

24. Actavis's submission of Actavis's ANDA was an act of infringement of the '052 patent, '940 patent, '816 patent, and '614 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

25. 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. 9,056,052)

26. Purdue incorporates by reference and realleges paragraphs 1 through 25 above as though fully restated herein.

27. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 208389 to the FDA seeking approval of Actavis's ANDA Products was an act of infringement of the '052 patent by Defendant.

28. Actavis's ANDA Products are covered by one or more claims of the '052 patent.

29. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '052 patent under 35 U.S.C. § 271(a)-(c).

30. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '052 patent.

31. On information and belief, Defendant knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '052 patent.

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

33. If Actavis's ANDA Products are approved by the FDA, Defendant will intentionally encourage acts of direct infringement of the '052 patent by others, with knowledge that their acts are encouraging infringement.

34. Upon information and belief, Defendant has been aware of the existence of the '052 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '052 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

35. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Actavis's infringement of the '052 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,060,940)

36. Purdue incorporates by reference and realleges paragraphs 1 through 35 above as though fully restated herein.

37. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 208389 to the FDA seeking approval of Actavis's ANDA Products was an act of infringement of the '940 patent by Defendant.

38. Actavis's ANDA Products, or the use thereof, are covered by one or more claims of the '940 patent.

39. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '940 patent under 35 U.S.C. § 271(a)-(c).

40. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '940 patent.

41. On information and belief, Defendant knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '940 patent.

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

43. The administration of Actavis'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 '940 patent.

44. Actavis's proposed label for Actavis's ANDA Products will explicitly instruct Healthcare Providers and patients to use Actavis's ANDA Products in a manner that will directly infringe one or more claims of the '940 patent.

45. If Actavis'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 '940 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 '940 patent.

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

47. If Actavis'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 Actavis's proposed label, to use Actavis's ANDA Products in a

manner that directly infringes one or more claims of the '940 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 '940 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 '940 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '940 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 will be substantially and irreparably harmed by Actavis's infringement of the '940 patent. Purdue does not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,084,816)

50. Purdue incorporates by reference and realleges paragraphs 1 through 49 above as though fully restated herein.

51. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 208389 to the FDA seeking approval of Actavis's ANDA Products was an act of infringement of the '816 patent by Defendant.

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

53. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis'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).

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

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

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

57. If Actavis'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.

58. Upon information and belief, Defendant has been aware of the existence of the '816 patent, and has no reasonable basis for believing that Actavis'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.

59. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Actavis's infringement of the '816 patent. Purdue does not have an adequate remedy at law.

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

60. Purdue incorporates by reference and realleges paragraphs 1 through 59 above as though fully restated herein.

61. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 208389 to the FDA seeking approval of Actavis's ANDA Products was an act of infringement of the '614 patent by Defendant.

62. Actavis's ANDA Products, or the use thereof, are covered by one or more claims of the '614 patent.

63. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis'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).

64. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '614 patent.

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

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

67. The administration of Actavis'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.

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

69. If Actavis'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.

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

71. If Actavis'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 Actavis's proposed label, to use Actavis'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.

72. Upon information and belief, Defendant has been aware of the existence of the '614 patent, and has no reasonable basis for believing that Actavis'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.

73. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Actavis's infringement of the '614 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 '052 patent, '940 patent, '816 patent, and '614 patent, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Actavis's ANDA Products would infringe, induce

infringement of, and/or contribute to the infringement of one or more claims of each of the '052 patent, '940 patent, '816 patent, and '614 patent;

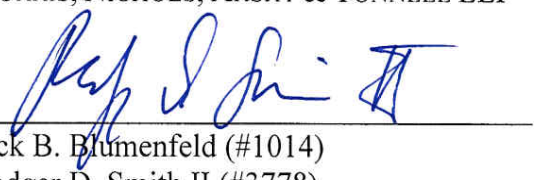
B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Actavis's ANDA and Actavis's ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the '052 patent, '940 patent, '816 patent, and '614 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 Actavis's ANDA, including Actavis's ANDA Products or any other drug product that infringes the '052 patent, '940 patent, '816 patent, and '614 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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November 3, 2015