IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON LABORATORIES, INC., ACTAVIS LABORATORIES UT, INC. (formerly WATSON LABORATORIES, INC. (Delaware)), and ACTAVIS PLC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Purdue Pharma L.P. ("Purdue" or "Plaintiff"), for its Complaint against Defendants Watson Laboratories, Inc., Actavis Laboratories UT, Inc. (formerly, Watson Laboratories, Inc. (Delaware)) and Actavis plc, avers 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 Reissue Patent Nos. RE41,408 (the "'408 patent"), RE41,489 (the "'489 patent"), and RE41,571 (the "'571 patent"). This action relates to Abbreviated New Drug Application No. 204937 submitted in the name of Watson Laboratories, Inc. ("Defendants' ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Purdue's Butrans® (buprenorphine) Transdermal System (5 mcg/hr, 10 mcg/hr, and 20 mcg/hr; "Defendants' ANDA Products").

THE PARTIES

2. Plaintiff Purdue Pharma L.P. ("Purdue") 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 is the owner of the '408, '489 and '571 patents. Purdue is also the holder of approved NDA No. 021306 for the Butrans® (buprenorphine) Transdermal System, for the management of pain. Purdue also sells Butrans® in the United States.

3. On information and belief, Defendant Watson Laboratories, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, California 92880 and at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On further information and belief, Watson is a subsidiary of Actavis plc ("Actavis").

4. On information and belief, on September 17, 2014, a Certificate of Amendment was filed with the Delaware Secretary of State, by which Watson Laboratories, Inc., a corporation organized and existing under the laws of the State of Delaware, changed its name to Actavis Laboratories UT, Inc. ("Actavis Labs"), a named defendant in this action. On further information and belief, Actavis Labs is a corporation organized and existing under the laws of the State of Delaware (DE File #2293487), having places of business at 575, 577, and 579 Chipeta Way, Salt Lake City, Utah. On further information and belief, Actavis Labs maintains a registered agent in Delaware, The Corporation Trust Company. On further information and belief, Actavis Labs is a subsidiary of Actavis.

5. On information and belief, Watson and Actavis Labs are in the business of developing, manufacturing and/or offering for sale generic pharmaceutical products and are wholly owned subsidiaries of Actavis. On further information and belief, Watson, Actavis Labs,

and Actavis are, at the very least, agents of each other and/or operate in concert as integrated parts of Actavis's generic pharmaceutical division. On further information and belief, Watson and Actavis Labs are the alter egos of Actavis where a unity of interest and ownership exists between Watson, Actavis Labs, and Actavis, such that separate personalities of the three corporate entities in reality do not exist and thus, will be collectively referred to herein as "Defendants."

6. On information and belief, Defendant Actavis, formerly known as Actavis, Inc., is a corporation organized and existing under the laws of the Country of Ireland, having a principal place of business at 1 Grand Canal Square Dublin 2, Docklands Dublin, 07054 Ireland. On further information and belief, Actavis conducts its principal United States operations at the same address as Watson, *i.e.*, at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

SUBJECT MATTER JURISDICTION AND VENUE

7. 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.

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

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

PERSONAL JURISDICTION

10. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of ANDA No. 204937 ("Defendants' ANDA"), as

set forth below, and for other reasons that will be developed and presented to the Court if personal jurisdiction is challenged.

11. As reported in Actavis's 2013 Annual Report on behalf of itself and its subsidiaries, including Watson, Actavis operates as "a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand name ('brand' or 'branded'), biosimilar and over-the-counter ('OTC') pharmaceutical products." As described in the 2013 Annual Report, one of Actavis's business segments is "Actavis Pharma," whose "business is focused on maintaining a leading position within []the U.S. generics market," among others, and whose "strategy in the U.S. is to develop generic pharmaceuticals that are difficult to formulate or manufacture or will complement or broaden our existing product lines." As also reported in the 2013 Annual Report, the Actavis Pharma Product Portfolio for the U.S. comprises "approximately 250 generic pharmaceutical product families."

12. According to Actavis's 2013 Annual Report, Actavis and its subsidiaries "predominantly market [their] generic products to various drug wholesalers, mail order, government and national retail drug and food store chains utilizing a small team of sales and marketing professionals," and sell their "generic prescription products primarily under the 'Watson Laboratories,' 'Watson Pharma' and 'Actavis Pharma' labels." On information and belief, Actavis, directly, or through related companies, intends to sell products made pursuant to Defendants' ANDA ("Defendants' ANDA Products") through these distribution and retail channels in Delaware.

13. On information and belief, Actavis and Watson share common officers and directors.

14. On information and belief, Watson and Actavis Labs are within the control of Actavis for the purposes of responding to discovery in this action.

15. On information and belief, Actavis has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Watson.

16. On information and belief, Actavis, directly or through related companies, has engaged in substantial and continuous contacts with Delaware that satisfy due process and confer personal jurisdiction over Actavis in Delaware on the basis of general jurisdiction.

17. On information and belief, Actavis directs the activities of the other Actavis entities, including Watson and Actavis Labs and, directly or through related companies, are responsible for sales of Actavis products to customers in Delaware, from which Actavis derives substantial revenue.

18. On information and belief, Watson, directly or through related companies, has engaged in substantial and continuous contacts with Delaware that satisfy due process and confer personal jurisdiction over Watson in Delaware on the basis of general jurisdiction.

19. On information and belief, Watson and Actavis Labs develop and manufacture pharmaceutical products for the United States market for Actavis, and have developed and manufactured such products that are available at pharmacies or elsewhere in the United States, including Delaware. On information and belief, Watson and Actavis Labs derive substantial revenue from the sale of products to customers in Delaware.

20. On information and belief, various products for which Watson is the named applicant on approved ANDAs are available in retail pharmacies in Delaware.

21. As further evidence of personal jurisdiction over Actavis, formerly Actavis, Inc., Actavis has been sued for patent infringement in this district and has not contested personal jurisdiction (*see, e.g.*, C.A. No. 13-496).

22. As further evidence of personal jurisdiction over Watson, in *Cephalon Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009), this Court found general personal jurisdiction over Watson due to its extensive contacts with Delaware. Additionally, Watson has been sued for patent infringement in this district and has not contested personal jurisdiction (*see, e.g.*, C.A. Nos. 12-258, 12-1124, and 12-1726). Further, Watson has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court (*see, e.g.*, C.A. Nos. 12-258, 12-1124, and 12-1726).

23. On information and belief, Actavis Labs is registered to do business in Delaware, has designated a registered agent, The Corporation Trust Company, in Delaware, and maintains a status that is active and in good standing (DE File #2293487).

24. On information and belief, and consistent with their practice with respect to other generic products, Watson, Actavis Labs, and Actavis acted in concert to prepare and submit ANDA No. 204937. For example, by letter dated August 11, 2014, Watson directed Plaintiff to send any written notice regarding confidential access to Defendants' ANDA to Brian Anderson, Esq., via an Actavis email address, brian.andcrson@actavis.com and Actavis's U.S. Headquarters address, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

THE PATENTS-IN-SUIT

25. Purdue is the lawful owner of all right, title and interest in the '408 patent entitled "METHOD OF PROVIDING SUSTAINED ANALGESIA WITH BUPRENORPHINE," including the right to sue and to recover for past infringement thereof.

The ’408 patent is listed in the FDA’s *Approved Drug Products With Therapeutic Equivalence Evaluation* (“Orange Book”) as covering Butrans®, which is the subject of approved NDA No. 021306. A copy of the ’408 patent, attached hereto as Exhibit A, was duly and legally issued on June 29, 2010, naming Robert F. Reder, Robert F. Kaiko, and Paul D. Goldenheim as the inventors.

26. Purdue is the lawful owner of all right, title and interest in the ’489 patent entitled “METHOD OF PROVIDING SUSTAINED ANALGESIA WITH BUPRENORPHINE,” including the right to sue and to recover for past infringement thereof. The ’489 patent is listed in the Orange Book as covering Butrans®, which is the subject of approved NDA No. 021306. A copy of the ’489 patent, attached hereto as Exhibit B, was duly and legally issued on August 10, 2010, naming Robert F. Reder, Robert F. Kaiko, and Paul D. Goldenheim as the inventors.

27. Purdue is the lawful owner of all right, title and interest in the ’571 patent entitled “METHOD OF PROVIDING SUSTAINED ANALGESIA WITH BUPRENORPHINE,” including the right to sue and to recover for past infringement thereof. The ’571 patent is listed in the Orange Book as covering Butrans®, which is the subject of approved NDA No. 021306. A copy of the ’571 patent, attached hereto as Exhibit C, was duly and legally issued on August 24, 2010, naming Robert F. Reder, Robert F. Kaiko, and Paul D. Goldenheim as the inventors.

DEFENDANTS’ ANDA

28. On information and belief, on or before June 6, 2013, Defendants filed Defendants’ ANDA in the name of Watson Laboratories, Inc. with the FDA, 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 Defendants' ANDA Products, based on the Reference Listed Drug Butrans®, which is the subject of approved NDA No. 021306.

29. Defendants' ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '408, '489, and '571 patents, listed in the FDA's Orange Book, *inter alia*, as covering the use of the Butrans®, which is the subject of approved NDA No. 021306, are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Defendants' ANDA."

30. In a letter dated August 11, 2014 addressed to Purdue and received by Purdue on or about August 15, 2014, Defendants provided "notice" with respect to Defendants' ANDA Products and the '408, '489, and '571 patents under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

31. Defendants' submission of Defendants' ANDA was an act of infringement of the '408, '489, and '571 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

FIRST CLAIM FOR RELIEF:
INFRINGEMENT OF THE '408 PATENT

32. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-30.

33. Defendants' submission of Defendants' ANDA containing a Paragraph IV certification with respect to the '408 patent was an act of infringement of the '408 patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A), with respect to Defendants' ANDA Products.

34. Defendants' ANDA Products are covered by one or more claims of the '408 patent.

35. If approved by the FDA, Defendants' commercial manufacture, use, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '408 patent under 35 U.S.C. § 271(a)-(c).

36. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '408 patent.

37. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '408 patent.

38. There are no substantial noninfringing uses of Defendants' ANDA Products.

39. The administration of Defendants' ANDA Products by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, for the treatment of pain, will directly infringe one or more claims of the '408 patent.

40. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a manner that will directly infringe one or more claims of the '408 patent.

41. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct a Healthcare Provider or a patient to individually perform all steps of one or more claims of the '408 patent.

42. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '408 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '408 patent.

43. Defendants intend to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

44. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '408 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '408 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

45. On information and belief, Defendants have been aware of the existence of the '408 patent since at least May 30, 2013, and have no reasonable basis for believing that the use of Defendants' ANDA Products according to Defendants' proposed labeling will not infringe the '408 patent. The substantive weakness of Defendants' position set out in the Notice Letter causes this case to stand out from other cases, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

46. The acts of infringement by Defendants set forth above will cause Purdue irreparable harm for which it has no adequate remedy at law, and such harm will continue unless Defendants are enjoined by this Court.

SECOND CLAIM FOR RELIEF:
INFRINGEMENT OF THE '489 PATENT

47. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-45.

48. Defendants' submission of Defendants' ANDA containing a Paragraph IV certification with respect to the '489 patent was an act of infringement of the '489 patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A), with respect to Defendants' ANDA Products.

49. Defendants' ANDA Products are covered by one or more claims of the '489 patent.

50. If approved by the FDA, Defendants' commercial manufacture, use, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '489 patent under 35 U.S.C. § 271(a)-(c).

51. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '489 patent.

52. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '489 patent.

53. There are no substantial noninfringing uses of Defendants' ANDA Products.

54. The administration of Defendants' ANDA Products by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare

Providers"), and patients, for the treatment of pain, will directly infringe one or more claims of the '489 patent.

55. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a manner that will directly infringe one or more claims of the '489 patent.

56. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct a Healthcare Provider or a patient to individually perform all steps of one or more claims of the '489 patent.

57. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '489 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '489 patent.

58. Defendants intend to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

59. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '489 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '489 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

60. On information and belief, Defendants have been aware of the existence of the ’489 patent since at least May 30, 2013, and have no reasonable basis for believing that the use of Defendants’ ANDA Products according to Defendants’ proposed labeling will not infringe the ’489 patent. The substantive weakness of Defendants’ position set out in the Notice Letter causes this case to stand out from other cases, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

61. The acts of infringement by Defendants set forth above will cause Purdue irreparable harm for which it has no adequate remedy at law, and such harm will continue unless Defendants are enjoined by this Court.

THIRD CLAIM FOR RELIEF:
INFRINGEMENT OF THE ’571 PATENT

62. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-60.

63. Defendants’ submission of Defendants’ ANDA containing a Paragraph IV certification with respect to the ’571 patent was an act of infringement of the ’571 patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A), with respect to Defendants’ ANDA Products.

64. Defendants’ ANDA Products are covered by one or more claims of the ’571 patent.

65. If approved by the FDA, Defendants’ commercial manufacture, use, sale, and/or offer for sale of Defendants’ ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the ’571 patent under 35 U.S.C. § 271(a)-(c).

66. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '571 patent.

67. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '571 patent.

68. There are no substantial noninfringing uses of Defendants' ANDA Products.

69. The administration of Defendants' ANDA Products by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, for the treatment of pain, will directly infringe one or more claims of the '571 patent.

70. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a manner that will directly infringe one or more claims of the '571 patent.

71. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct a Healthcare Provider or a patient to individually perform all steps of one or more claims of the '571 patent.

72. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '571 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '571 patent.

73. Defendants intend to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

74. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '571 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '571 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

75. On information and belief, Defendants have been aware of the existence of the '571 patent since at least May 30, 2013, and have no reasonable basis for believing that the use of Defendants' ANDA Products according to Defendants' proposed labeling will not infringe the '571 patent. The substantive weakness of Defendants' position set out in the Notice Letter causes this case to stand out from other cases, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

76. The acts of infringement by Defendants set forth above will cause Purdue irreparable harm for which it has no adequate remedy at law, and such harm will continue unless Defendants are enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment:

A. Adjudging that Defendants have infringed one or more claims of each of the '408, '489, and '571 patents, and that the commercial sale, offer for sale, use, import and/or

manufacture of Defendants' ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '408, '489, and '571 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204937, 5 mcg/hr, 10 mcg/hr, and 20 mcg/hr, 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 '408, '489, and '571 patents, plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendants, their 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. 204937 or any other drug product that infringes the '408, '489, and '571 patents;

D. Declaring this an exceptional case and awarding Plaintiff its attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiff 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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