IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 15-192 (SLR) (SRF)
	)	
ACTAVIS LABORATORIES UT, INC.,	)	
	)	
Defendant.	)	

AMENDED COMPLAINT

Plaintiff Purdue Pharma L.P. ("Purdue" or "Plaintiff"), for its Amended Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant"), 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 ("ANDA") No. 205748 ("Defendant's ANDA") submitted upon information and belief in the name of Watson Laboratories, Inc., which subsequently changed its name to Actavis Laboratories UT, Inc., to the U.S. Food and Drug Administration ("FDA"). Defendant's ANDA seeks approval to market a generic version of Purdue's Butrans® (buprenorphine) Transdermal System ("Butrans®") in the 5 mcg/hr, 10 mcg/hr, 15 mcg/hr, and 20 mcg/hr dosage strengths ("Defendant's ANDA Products").

2. This action is further related to C.A. Nos. 14-1227 (SLR) (SRF) and 14-1410 (SLR) (SRF), which involve the same parties-in-interest and the same patents-in-suit,

wherein Plaintiff initially brought an action for patent infringement against, *inter alia*, Defendant based on Watson Laboratories, Inc.'s ("Watson") submission of ANDA No. 204937 to the FDA, seeking approval to market generic versions of Purdue's Butrans® in the 5 mcg/hr, 10 mcg/hr, and 20 mcg/hr dosage strengths. By stipulation, Defendant was subsequently dismissed from C.A. No. 14-1227 (SLR) (SRF) and was defined as a "Watson Entity" for the purposes of jurisdiction, venue, and discovery. (C.A. No. 14-1227 (SLR) (SRF), D.I. 7.) C.A. No. 14-1410 (SLR) (SRF) was subsequently filed based on Watson's ANDA Amendment seeking approval to market a generic version of Butrans® in the 15 mcg/hr strength. Also filed in the latter case was a stipulation, also defining Defendant as a "Watson Entity" for the purposes of jurisdiction, venue, and certain discovery. (C.A. No. 14-1410 (SLR) (SRF), D.I. 6.)

THE PARTIES

3. Plaintiff 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 Butrans®, 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. Purdue also sells Butrans® in the United States.

4. 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 577 South Chipeta Way, Salt Lake City, Utah 84108-1222.

5. On information and belief, Actavis is in the business of developing, manufacturing, and/or offering for sale generic pharmaceutical products.

SUBJECT MATTER JURISDICTION AND VENUE

5. This Action arises under the patent laws of the United States, including 35 U.S.C. § 271.

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

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

PERSONAL JURISDICTION

8. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its incorporation in Delaware and its systematic and continuous contacts with Delaware.

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

THE PATENTS-IN-SUIT

10. 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.

11. On April 27, 2016, Purdue filed a Request for Certificate of Correction for the '408 patent. Purdue proposed that the following language be added to the specification of the '408 patent: "The subject matter of the claimed invention was made by or on behalf of the below listed parties to a joint research agreement. The joint research agreement was in effect on or before the date of the claimed invention was made and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. The parties to the joint research agreement are 1) Purdue Pharma L.P., U.S.A., and 2) LTS Lohmann Therapie Systeme GmbH & Co. KG, Germany."

12. On July 1, 2016, the PTO approved the Certificate of Correction for the '408 patent. A copy of the communication approving the Certificate of Correction is attached hereto as Exhibit B.

13. 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. The '489 patent duly and legally issued on August 10, 2010, naming Robert F. Reder, Robert F. Kaiko, and Paul D. Goldenheim as the inventors.

14. On April 27, 2016, Purdue filed a Request for Certificate of Correction for the '489 patent. Purdue proposed that the following language be added to the specification of the '489 patent: "The subject matter of the claimed invention was made by or on behalf of the below listed parties to a joint research agreement. The joint research agreement was in effect on or

before the date of the claimed invention was made and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. The parties to the joint research agreement are 1) Purdue Pharma L.P., U.S.A., and 2) LTS Lohmann Therapie Systeme GmbH & Co. KG, Germany."

15. On June 14, 2016, the PTO issued the requested Certificate of Correction for the '489 patent. A copy of the '489 patent bearing the issued Certificate of Correction is attached hereto as Exhibit C.

16. 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. The '571 patent duly and legally issued on August 24, 2010, naming Robert F. Reder, Robert F. Kaiko, and Paul D. Goldenheim as the inventors.

17. On April 27, 2016, Purdue filed a Request for Certificate of Correction for the '571 patent. Purdue proposed that the following language be added to the specification of the '571 patent: "The subject matter of the claimed invention was made by or on behalf of the below listed parties to a joint research agreement. The joint research agreement was in effect on or before the date of the claimed invention was made and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. The parties to the joint research agreement are 1) Purdue Pharma L.P., U.S.A., and 2) LTS Lohmann Therapie Systeme GmbH & Co. KG, Germany."

18. On June 28, 2016, the PTO issued the requested Certificate of Correction for the ’571 patent. A copy of the ’571 patent bearing the issued Certificate of Correction is attached hereto as Exhibit D.

DEFENDANT’S ANDA

19. On information and belief, on or before January 28, 2015, Actavis filed ANDA No. 205748 with the FDA (“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 a generic version of Purdue’s Butrans® (buprenorphine) Transdermal System, 5 mcg/hr, 10 mcg/hr, 15 mcg/hr, and 20 mcg/hr (“Defendant’s ANDA Products”), based on the Reference Listed Drug Butrans®, which is the subject of approved NDA No. 021306.

20. Defendant’s 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 Defendant’s ANDA.

21. In a letter dated January 28, 2015 addressed to Purdue and received by Purdue on or about January 29, 2015, Defendant provided “notice” with respect to Defendant’s ANDA and the products described therein, and the ’408, ’489, and ’571 patents under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (“Notice Letter”).

22. Defendant’s submission of Defendant’s 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

23. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

24. Defendant's submission of Defendant's 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 Defendant's ANDA Products.

25. Defendant's ANDA Products are covered by one or more claims of the '408 patent.

26. If approved by the FDA, Defendant's commercial manufacture, use, 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 '408 patent under 35 U.S.C. § 271(a)-(c).

27. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '408 patent.

28. 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 '408 patent.

29. There are no substantial noninfringing uses of Defendant's ANDA Products.

30. 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, for the treatment of pain, will directly infringe one or more claims of the '408 patent.

31. 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 '408 patent.

32. Defendant's proposed label for Defendant's 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.

33. 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 '408 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 '408 patent.

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

35. 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 '408 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 '408 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

36. On information and belief, Defendant has been aware of the existence of the ’408 patent since at least January 28, 2015, and has no reasonable basis for believing that the use of Defendant’s ANDA Products according to its proposed labeling will not infringe the ’408 patent. The substantive weakness of Defendant’s 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.

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

SECOND CLAIM FOR RELIEF:
INFRINGEMENT OF THE ’489 PATENT

38. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-37.

39. Defendant’s submission of Defendant’s 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 Defendant’s ANDA Products.

40. Defendant’s ANDA Products are covered by one or more claims of the ’489 patent.

41. If approved by the FDA, Defendant’s commercial manufacture, use, 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 ’489 patent under 35 U.S.C. § 271(a)-(c).

42. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '489 patent.

43. 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 '489 patent.

44. There are no substantial noninfringing uses of Defendant's ANDA Products.

45. The administration of ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '489 patent.

46. 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 '489 patent.

47. Defendant's proposed label for Defendant's 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.

48. 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 '489 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 '489 patent.

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

50. 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 '489 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 '489 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

51. On information and belief, Defendant has been aware of the existence of the '489 patent since at least January 28, 2015, and has no reasonable basis for believing that the use of Defendant's ANDA Products according to its proposed labeling will not infringe the '489 patent. The substantive weakness of Defendant's 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.

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

THIRD CLAIM FOR RELIEF:
INFRINGEMENT OF THE '571 PATENT

53. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-52.

54. Defendant's submission of Defendant's 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 Defendant's ANDA Products.

55. Defendant's ANDA Products are covered by one or more claims of the '571 patent.

56. If approved by the FDA, Defendant's commercial manufacture, use, 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 '571 patent under 35 U.S.C. § 271(a)-(c).

57. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '571 patent.

58. 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 '571 patent.

59. There are no substantial noninfringing uses of Defendant's ANDA Products.

60. The administration of Defendant's ANDA products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '571 patent.

61. 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 '571 patent.

62. Defendant's proposed label for Defendant's 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.

63. 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 '571 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 '571 patent.

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

65. 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 '571 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 '571 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

66. On information and belief, Defendant has been aware of the existence of the '571 patent since at least January 28, 2015, and has no reasonable basis for believing that the use of Defendant's ANDA Products according to its proposed labeling will not infringe the '571 patent. The substantive weakness of Defendant's 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment:

A. Adjudging that Defendant has 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 Defendant's 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. 205748, 5, 10, 15, 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., 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. 205748, 5, 10, 15, and 20 mcg/hr, 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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