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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| PURDUE PHARMA L.P., and PURDUE PHARMACEUTICALS L.P.<br><br>Plaintiffs,<br>v.<br><br>ELITE LABORATORIES, INC. and ELITE PHARMACEUTICALS, INC.,<br><br>Defendants. | ) | C.A. No. 1:23-cv-22221-KMW-AMD |

**FIRST AMENDED COMPLAINT**

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P. (collectively, "Purdue" or "Plaintiffs") for their First Amended Complaint against Defendants Elite Laboratories, Inc. and Elite Pharmaceuticals, Inc. (collectively, "Elite" or "Defendants"), aver as follows:

## LOCAL RULE 10.1(a) COMPLIANCE

1. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") has its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431; Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") has its principal place of business at 4701 International Boulevard W., Wilson, NC 27893; Defendants both have their principal place of business at 165 Ludlow Ave, Northvale, New Jersey 07647.

## NATURE OF THE ACTION

2. 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. 9,763,933 ("the Mannion '933 patent"); 9,770,416 ("the '416 patent"); 9,492,389 ("the '389 patent"); 9,492,391 ("the '391 patent"); 9,492,392 ("the '392 patent"); 9,492,393 ("the '393 patent"); 9,775,808 ("the '808 patent"); 9,775,811 ("the '811 patent"); 9,763,886 ("the '886 patent"); and 11,964,056 ("the '056 patent") (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 217939 submitted, upon information and belief, in the name of Defendants to the United States Food and Drug Administration ("FDA").

3. Plaintiffs seek judgment that Defendants have infringed the patents-in-suit, which are—with the exception of the '811 patent and the '886 patent

—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. Defendants have infringed the patents-in-suit at least under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 217939 ("Defendants' ANDA"), submitted, upon information and belief, in the name of Defendants to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved New Drug Application ("NDA") No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' ANDA Products"). The '811 patent and the '886 patent are directed to the processes for manufacture of OxyContin®.

## THE PARTIES

4. Purdue Pharma is a limited partnership organized and existing under the laws of the State of Delaware. Purdue Pharma is an owner of the patents-in-suit identified in paragraphs 26-35 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.

5. Purdue Pharmaceuticals is a limited partnership organized and existing under the laws of the State of Delaware. Purdue Pharmaceuticals is an owner of the patents-in-suit, identified in paragraphs 26-35 below.

6. On information and belief, Defendant Elite Laboratories, Inc. ("Elite Labs") is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 165 Ludlow Ave, Northvale, New Jersey 07647.

7. On information and belief, Defendant Elite Pharmaceuticals, Inc., USA ("Elite Pharma") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 165 Ludlow Ave, Northvale, New Jersey 07647.

8. On information and belief, Elite Labs is registered to do business in New Jersey as a Foreign For-Profit Corporation.

9. On information and belief, Elite Pharma is registered to do business in New Jersey as a Foreign For-Profit Corporation.

10. On information and belief, Defendant Elite Labs is a wholly-owned subsidiary of Elite Pharma.

11. On information and belief, Defendants develop, manufacture, distribute and/or market pharmaceutical products throughout the United States,

including in this judicial district, through their own actions and through the actions of their agents.

12. On information and belief, Defendants are working in concert with respect to the development, regulatory approval, marketing, sale and/or distribution of pharmaceutical products, including the Defendants' ANDA Products described in Defendants' ANDA.

13. On information and belief, Defendants closely coordinate their commercial activities and simultaneously share senior corporate officers.

14. On information and belief, Defendants were jointly involved in the preparation and submission of Defendants' ANDA.

15. On information and belief, if Defendants' ANDA is approved, Defendants will be jointly involved in the manufacturing, marketing, distributing and/or sale of Defendants' ANDA Products.

## SUBJECT MATTER JURISDICTION AND VENUE

16. 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.

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

18. Defendants have stipulated that "[f]or purposes of only the

Action, Defendants will not contest venue in the District of New Jersey," and "Defendants therefore will not move to dismiss the Action on the grounds that the District of New Jersey is an improper venue for the Action." (Dkt. No. 11 at 3 ¶ 2.)

19. Notwithstanding Defendants' stipulation, venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) because Defendants have a regular and established place of business in this judicial district and because Defendants have committed acts of infringement in this judicial district.

## PERSONAL JURISDICTION

20. Defendants have stipulated that "[f]or purposes of only the Action, Defendants will not contest jurisdiction over their persons," and "Defendants therefore will not move to dismiss the Action on grounds that the United States District Court for the District of New Jersey lacks jurisdiction over Defendants in the Action." (Dkt. No. 11 at 3 ¶ 1.)

21. Notwithstanding Defendants' stipulation to personal jurisdiction, on information and belief, this Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* having their principal place of business located at 165 Ludlow Ave, Northvale, New Jersey.

22. Moreover, on information and belief, this Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* their systematic and

continuous contacts with New Jersey and contacts with New Jersey in connection with the submission of Defendants' ANDA, as set forth below.

23. On information and belief, work related to Defendants' ANDA submission occurred at Defendants' principal place of business located at 165 Ludlow Ave, Northvale, New Jersey.

24. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of New Jersey and throughout the United States.

25. On information and belief, if Defendants' ANDA is approved, the Defendants' ANDA Products would, among other things, be marketed and distributed in New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey.

## THE PATENTS-IN-SUIT

26. Purdue is the lawful owner of all right, title and interest in the Mannion '933 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The Mannion '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the Mannion '933 patent is attached hereto as Exhibit A, which was duly and legally issued on September 19,

2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

27. Purdue is the lawful owner of all right, title and interest in the '416 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '416 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '416 patent is attached hereto as Exhibit B, which was duly and legally issued on September 26, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

28. Purdue is the lawful owner of all right, title and interest in the '389 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '389 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '389 patent is attached hereto as Exhibit C, 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.

29. Purdue is the lawful owner of all right, title and interest in the '391 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '391 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No.

022272. A copy of the '391 patent is attached hereto as Exhibit D, 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.

30. Purdue is the lawful owner 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 E, 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.

31. Purdue is the lawful owner 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 F, 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.

32. Purdue is the lawful owner of all right, title and interest in the '808 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '808 patent is listed in the

Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '808 patent is attached hereto as Exhibit G, which was duly and legally issued on October 3, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

33. Purdue is the lawful owner of all right, title and interest in the '056 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '056 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '056 patent is attached hereto as Exhibit H, which was duly and legally issued on April 23, 2024, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

34. Purdue is the lawful owner of all right, title and interest in the '811 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '811 patent is attached hereto as Exhibit I, which was duly and legally issued on October 3, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

35. Purdue is the lawful owner of all right, title and interest in the '886 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '886 patent is

attached hereto as Exhibit J, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

**DEFENDANTS' ANDA**

36. On information and belief, on or before September 28, 2023, Defendants filed Defendants' ANDA in the name of Defendants 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, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

37. On information and belief, Defendants subsequently submitted in their ANDA a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the patents-in-suit, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed" by the commercial manufacture, use, offer for sale, sale or importation of the drug products described in Defendants' ANDA.

38. In a letter dated September 28, 2023, addressed to and received by Purdue Pharma on or about September 29, 2023, Defendants provided what

purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the Orange Book patents, except the '056 patent, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

39. In a letter dated March 28, 2025, addressed to and received by Purdue Pharma on or about March 31, 2025, Defendants provided what purports to be a supplemental "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the Orange Book patents, including the '056 patent, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Supplemental Notice Letter").

40. Defendants' submission of Defendants' ANDA was an act of infringement of the Orange Book patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

41. 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. 9,763,933)

42. Purdue incorporates by reference and realleges paragraphs 1 through 41 above as though fully restated herein.

43. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the Mannion '933 patent by Defendants.

44. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the Mannion '933 patent, either literally or under the doctrine of equivalents, including claims 9-10 depending from independent claim 1, and claims 13, 25-26, and 29-30 depending from independent 11. Independent claims 1 and 11 recite, *inter alia*, a pharmaceutical composition comprising an extended-release matrix, wherein said composition comprises at least one active agent and at least one high molecular weight polyethylene oxide ("PEO") having an approximate molecular weight of 1 million to 15 million.

45. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 9-10, 13, 25, 26, and 29-30 of the Mannion '933 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 Mannion '933 patent.

46. Defendants' ANDA Products constitute a material part of the

inventions covered by claims 9-10, 13, 25, 26, and 29-30 of the Mannion '933 patent.

47. Upon information and belief, Defendants have been aware of the existence of the Mannion '933 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the Mannion '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

48. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the Mannion '933 patent. Purdue has no adequate remedy at law.

## SECOND CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,770,416)

49. Purdue incorporates by reference and realleges paragraphs 1 through 48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '416 patent by Defendants.

51. On information and belief, Defendants' ANDA Products, or use thereof, are covered by one or more claims of the '416 patent, either literally or under the doctrine of equivalents, including but not limited to independent claims 1 and 12, which recite, *inter alia*, a pharmaceutical composition comprising: at least one active agent comprising an opioid or a pharmaceutically acceptable salt, and at least

one high molecular weight PEO, having an approximate molecular weight of from 1 million to 8 million; wherein (a) the active agent and high molecular weight PEO are combined in a solid oral extended-release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for a curing time of about 15 minutes to about 8 hours at a curing temperature of about 60° C to about 90° C, (iii) cooled, and (iv) hardened; (b) the high molecular weight PEO is at least partially melted upon curing and comprises at least about 50% (by weight) of the dosage form; (c) the active agent comprises at least about 1.3% (by weight) of the dosage form; (d) the molecular weight of each PEO is based on rheological measurements; (e) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings; and (f) the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.5%, and the dosage form provides a hardness of at least about 439 N, and claims 2-5, 9-11, 13-16, and 19-29 dependent therefrom.

52. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 1-5, 9-16, and 19-29 of the '416 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 '416 patent.

53. Defendants' ANDA Products constitute a material part of the inventions covered by claims 1-5, 9-16, and 19-29 of the '416 patent.

54. Upon information and belief, Defendants have been aware of the existence of the '416 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '416 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

55. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '416 patent. Purdue has no adequate remedy at law.

## THIRD CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,389)

56. Purdue incorporates by reference and realleges paragraphs 1 through 55 above as though fully restated herein.

57. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '389 patent by Defendants.

58. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '389 patent, either literally or under the doctrine of equivalents, including claims 18-20 and 28-30 depending from

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 PEO having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof; wherein said high molecular weight PEO is at least 54% by weight of the total weight of the uncoated tablet.

59. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 18-20, and 28-30 of the '389 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 '389 patent.

60. Defendants' ANDA Products constitute a material part of the inventions covered by claims 18-20, and 28-30 of the '389 patent.

61. Upon information and belief, Defendants have been aware of the existence of the '389 patent and have no reasonable basis for believing that

Defendants' ANDA Products will not infringe the '389 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

62. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '389 patent. Purdue has no adequate remedy at law.

## FOURTH CLAIM FOR RELIEF
### (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,391)

63. Purdue incorporates by reference and realleges paragraphs 1 through 62 above as though fully restated herein.

64. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '391 patent by Defendants.

65. Defendants' ANDA Products, or the use thereof, are covered by one or more claims of the '391 patent, either literally or under the doctrine of equivalents, including claims 18-20 and 28-30 depending from 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 PEO 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.

66. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 18-20, and 28-30 of the '391 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 '391 patent.

67. Defendants' ANDA Products constitute a material part of the inventions covered by claims 18-20, and 28-30 of the '391 patent.

68. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of claims 18-20, and 28-30 of the '391 patent.

69. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Defendants' ANDA Products.

70. The administration of Defendants' ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '391 patent, either literally or under the doctrine of

equivalents.

71. 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 '391 patent, either literally or under the doctrine of equivalents, including claims 18-20 and 28-30 depending from 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 PEO 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. 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.

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 claims 18-20, and 28-30 of the '391 patent, either literally or under the doctrine of equivalents. 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 '391 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 claims 18-20, and 28-30 of the '391 patent, either literally or under the doctrine of equivalents. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe claims 18-20, and 28-30 of the '391 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

75. Upon information and belief, Defendants have been aware of the existence of the '391 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '391 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

76. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '391 patent. Purdue has no adequate remedy at law.

## FIFTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,392)

77. Purdue incorporates by reference and realleges paragraphs 1 through 76 above as though fully restated herein.

78. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '392 patent by Defendants.

79. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '392 patent, either literally or under the doctrine of equivalents, including claims 17-19 and 27-29 depending from 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 PEO having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof.

80. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 17-19, and 27-29 of the '392 patent under 35 U.S.C. § 271(a)-(c), either literally or

under the doctrine of equivalents. 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 '392 patent.

81. Defendants' ANDA Products constitute a material part of the inventions covered by claims 17-19, and 27-29 of the '392 patent.

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

83. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '392 patent. Purdue has no adequate remedy at law.

## SIXTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,393)

84. Purdue incorporates by reference and realleges paragraphs 1 through 83 above as though fully restated herein.

85. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '393 patent by Defendants.

86. Defendants' ANDA Products, or the use thereof, are covered by

one or more claims of the '393 patent, either literally or under the doctrine of equivalents, including claims 17-19 and 27-29 depending from 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 PEO 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.

87. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 17-19, and 27-29 of the '393 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 '393 patent.

88. Defendants' ANDA Products constitute a material part of the inventions covered by claims 17-19, and 27-29 of the '393 patent.

89. On information and belief, Defendants know that Defendants'

ANDA Products are especially made or especially adapted for use in the infringement of claims 17-19, and 27-29 of the '393 patent.

90. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Defendants' ANDA Products.

91. The administration of Defendants' ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe claims 17-19, and 27-29 of the '393 patent, either literally or under the doctrine of equivalents.

92. 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 '391 patent, either literally or under the doctrine of equivalents, including claims 17-19 and 27-29 depending from 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 PEO 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. 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.

93. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe claims 17-19, and 27-29 of the '393 patent, either literally or under the doctrine of equivalents. 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 '393 patent.

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

95. 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 claims 17-19, and 27-29 of the '393 patent, either literally or under the doctrine of equivalents. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe claims 17-19, and 27-29 of the '393 patent, and Defendants will affirmatively and specifically intend to cause

direct infringement.

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

97. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '393 patent. Purdue has no adequate remedy at law.

## SEVENTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,775,808)

98. Purdue incorporates by reference and realleges paragraphs 1 through 97 above as though fully restated herein.

99. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '808 patent by Defendants.

100. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '808 patent, either literally or under the doctrine of equivalents, including claims 8 and 10 depending from independent claim 1, and claims 16-17, 20, 22-23, and 25-30 depending from independent claim 11. Independent claims 1 and 11 recite, *inter alia*, a pharmaceutical composition

comprising at least one active agent comprising oxycodone or a pharmaceutically acceptable salt thereof; at least one high molecular weight PEO, having an approximate molecular weight of from 1 million to 15 million; and at least one of an additive and a film coating wherein (a) the active agent and high molecular weight PEO are combined in a solid oral extended-release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO, (iii) cooled, and (iv) hardened; (b) the high molecular weight PEO is at least partially melted upon curing and comprises at least about 30% (by weight) of the dosage form; (c) the molecular weight of each PEO is based on rheological measurements; and (d) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings.

101. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 8, 10, 16-17, 20, 22-23, and 25-30 of the '808 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. 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 '808 patent.

102. Defendants' ANDA Products constitute a material part of the inventions covered by claims 8, 10, 16-17, 20, 22-23, and 25-30 of the '808 patent.

103. Upon information and belief, Defendants have been aware of the existence of the '808 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '808 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

104. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '808 patent. Purdue has no adequate remedy at law.

## EIGHTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 11, 964, 056)

105. Purdue incorporates by reference and realleges paragraphs 1 through 104 above as though fully restated herein.

106. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '056 patent by Defendants.

107. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '056 patent, either literally or under the doctrine of equivalents, including independent claims 1, 19, and 20, which recite, *inter alia*, a solid oral extended-release dosage form, comprising an extended release

matrix comprising an oxycodone hydrochloride in certain dosage strengths, magnesium stearate, butylated hydroxytoluene and polyethylene oxide (PEO) having an approximate molecular weight of 1 million Da to 15 million Da based on rheological measurements, wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form, a film coat overcoated on the extended release matrix; wherein the dosage form provides a certain dissolution rate, Cmax, or no more than certain deviations between dissolution rates in simulated gastric fluid without enzymes ("SGF") at 37° C comprising 40% ethanol and SGF at 37° C without ethanol, and wherein the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.0% as determined by Archimedes Principle using a liquid of known density ($\rho_o$), and claims 2-15 dependent therefrom.

108. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 1-15, and 19-20 of the '056 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. Since at least June 27, 2024, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '056 patent.

109. Defendants' ANDA Products constitute a material part of the

inventions covered by claims 1-15, and 19-20 of the '056 patent.

110. Upon information and belief, Defendants have been aware of the existence of the '056 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '056 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

111. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '056 patent. Purdue has no adequate remedy at law.

## NINTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,775,811)

112. Purdue incorporates by reference and realleges paragraphs 1 through 111 above as though fully restated herein.

113. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '811 patent by Defendants.

114. On information and belief, the process for making Defendants' ANDA Products is covered by one or more claims of the '811 patent, either literally or under the doctrine of equivalents, including claims 28-30 depending from independent claim 11, which recites, *inter alia*, a method of producing a plurality of extended release pharmaceutical dosages and tablets

comprising the steps of: mixing an active agent comprising oxycodone or a pharmaceutically acceptable salt thereof, and at least one high molecular weight PEO, having an approximate molecular weight of from 1 million to 8 million to provide a PEO composition; compressing the PEO composition to provide a plurality of shaped matrix compositions; curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least about 60° C for a curing time of at least about 10 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; combining any of the matrix compositions with at least one additive, before or after curing; wherein the molecular weight of each PEO is based on rheological measurements; the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form or at least about 50% (by weight) of each tablet; the active agent for dosage forms comprises at least about 2.4% (by weight) of each dosage form or at least about 5% (by weight); the total weight is calculated by excluding the combined weight of film coatings; and each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent.

115. On information and belief, Defendants' ANDA Products, or the use or manufacture thereof, are covered by claims 28-30 of the '811 patent, either literally or under the doctrine of equivalents.

116. If approved by the FDA, Defendants' commercial manufacture,

use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claims 28-30 of the '811 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents.

117. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe claims 28-30 of the '811 patent under 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

118. Defendants' ANDA Products constitute a material part of the inventions covered by claims 28-30 of the '811 patent.

119. On information and belief, Defendants have been aware of the existence of the '811 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '811 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

120. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '811 patent. Purdue has no adequate remedy at law.

## TENTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,773,886)

121. Purdue incorporates by reference and realleges paragraphs 1

through 120 above as though fully restated herein.

122. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of Defendants' ANDA to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '886 patent by Defendants.

123. On information and belief, the method for making Defendants' ANDA Products is covered by one or more claims of the '886 patent, either literally or under the doctrine of equivalents, including claim 30 depending from independent claim 11, which recites, *inter alia*, a method of producing a plurality of solid oral extended release pharmaceutical dosages and tablets comprising the steps of: mixing an active agent comprising mixing at least one active agent (in the tablet form, the agent comprises an opioid of pharmaceutically acceptable salt thereof) and at least one high molecular weight PEO, having an approximate molecular weight of from 1 million to 15 million to provide a PEO composition; compressing the PEO composition to provide a plurality of shaped matrix compositions; curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least PEO's softening temperature for a curing time of at least about 5 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; wherein the molecular weight of each PEO is based on rheological measurements; the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form generally or at least about 50% (by weight) of each tablet; the total

weight is calculated by excluding the combined weight of film coatings; and each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent.

124. Defendants' ANDA Products, or the use or manufacture thereof, are covered by claim 30 of the '886 patent, either literally or under the doctrine of equivalents.

125. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claim 30 of the '886 patent under 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents.

126. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe claim 30 of the '886 patent under 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

127. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '886 patent.

128. On information and belief, Defendants have been aware of the existence of the '886 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '886 patent, thus rendering the

case "exceptional," as that term is used in 35 U.S.C. § 285.

129. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '886 patent. Purdue has no adequate remedy at law.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Find that Defendants have infringed one or more claims of each of the patents-in-suit, and that the commercial sale, offer for sale, use, importation, 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 patents-in-suit, either literally or under the doctrine of equivalents;

B. Find, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA and Defendants' 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 patents-in-suit, 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 Fed. R. Civ. P. 65, 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 Defendants' ANDA, including Defendants' ANDA Products or any other drug product that infringes the patents-in-suit;

D. Declare this an exceptional case and award Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Award Plaintiffs such other and further relief as this Court may deem just and proper.

s/ Wayne W. Fang_____
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