IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., and GRÜNENTHAL GMBH,	)	
Plaintiffs,	)	C.A. No. 18-404 (RGA)
v.	)	
INTELLIPHARMACEUTICS INTERNATIONAL INC., INTELLIPHARMACEUTICS CORPORATION, and INTELLIPHARMACEUTICS LTD.,	)	
Defendants.	)	

AMENDED AND SUPPLEMENTAL COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively, "Purdue") and Grünenthal GmbH ("Grünenthal") (Purdue and Grünenthal, collectively, Plaintiffs), for their Amended and Supplemental Complaint against Intellipharmaceutics International Inc., Intellipharmaceutics Corporation, and Intellipharmaceutics Ltd. (collectively, "Intellipharmaceutics" or "Defendants"), aver as follows.[1]

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 Patent Nos. 9,775,808 (the "'808 patent"); 9,763,886 (the "'886 patent"); 9,763,933 (the "Mannion '933

[1] Pursuant to the August 17, 2018 Scheduling Order (D.I. 46 ¶ 2), Plaintiffs are filing this Amended and Supplemental Complaint to assert a newly issued Purdue patent from U.S. Patent Application No. 15/015,763, and as a result, The P.F. Laboratories, Inc. is being added as a plaintiff to the action.

patent"); 9,675,610 (the "'610 patent"); and 10,076,497 (the "'497 patent") (collectively, "the patents-in-suit"). This action relates to New Drug Application ("NDA") No. 209653 ("Defendants' NDA") submitted upon information and belief in the name of Intellipharmaceutics to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the '808, '886, Mannion '933, '610, and '497 patents. The '808, Mannion '933, and '610 patents are 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 '808, '886, Mannion '933, '610, and '497 patents under 35 U.S.C. § 271(e)(2)(A) by filing NDA No. 209653, submitted upon information and belief in the name of Intellipharmaceutics to the FDA. Defendants' NDA seeks approval to market extended-release oxycodone-hydrochloride tablets in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg dosage strengths ("Defendants' NDA Products") and designates Purdue's OxyContin®, which is the subject of approved NDA No. 022272, as the Reference Listed Drug.

THE PARTIES

3. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the '808, '886, Mannion '933, and '497 patents, identified in paragraphs 38-40 and 42 below, and Purdue Pharma is an exclusive licensee of the '610 patent, identified in paragraph 41 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.

4. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the '808, '886, Mannion '933, and '497 patents, identified in paragraphs 38-40 and 42 below.

5. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901. P.F. Labs is an owner of the '497 patent, identified in paragraph 42 below.

6. Plaintiff Grünenthal GmbH ("Grünenthal") is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of the '610 patent, identified in paragraph 41 below.

7. On information and belief, Intellipharmaceutics International Inc. ("IPC International") is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International is in the business of making and selling pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, IPC International owns, directly or through its wholly owned subsidiary Intellipharmaceutics Ltd. ("IPC Ltd."), 100% of the common shares of Intellipharmaceutics Corporation ("IPC Corp.").

8. On information and belief, IPC Ltd. is a Delaware corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC Ltd. is a wholly owned subsidiary of IPC International and is

controlled and/or dominated by IPC International. On information and belief, IPC Ltd., with the assistance and/or direction of IPC International and/or IPC Corp., develops, manufactures, markets, offers to sell, and sells drug products for sale and use in the state of Delaware and throughout the United States.

9. On information and belief, IPC Corp. is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International owns, directly or through its wholly owned subsidiary IPC Ltd., 100% of the common shares of IPC Corp. On information and belief, IPC Corp. is the operating affiliate of IPC Ltd. On information and belief, IPC Corp., with the assistance and/or direction of IPC International and/or IPC Ltd., develops, manufactures, markets, offers to sell, and sells drug products for sale and use in the State of Delaware and throughout the United States.

10. On information and belief, IPC Corp. is controlled and/or dominated by IPC International. On information and belief, IPC International operates through its wholly owned subsidiary and agent, IPC Ltd.

11. On information and belief, IPC Ltd., IPC Corp., and IPC International have common officers and directors and have represented to the public that they are a unitary entity.

12. On information and belief, the acts of IPC Corp. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Ltd. and/or IPC International.

13. On information and belief, the acts of IPC Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Corp. and/or IPC International.

14. On information and belief, the acts of IPC International complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Corp. and/or IPC Ltd.

SUBJECT MATTER JURISDICTION AND VENUE

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

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

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

18. Defendants have agreed not to contest venue in the District of Delaware in this action and will not move to change the venue of this action.

19. On information and belief, IPC International, IPC Corp., and IPC Ltd. have previously been sued in this district and have not challenged venue. *See, e.g., Purdue Pharma L.P. et al. v. Intellipharmaceutics Corp. at al.* (D. Del. C.A. No. 17-392-RGA).

PERSONAL JURISDICTION

20. Defendants have agreed not to contest personal jurisdiction for purposes of this action, and will not move to dismiss this action on grounds that the District of Delaware lacks personal jurisdiction over Defendants for purposes of the action.

21. On information and belief, IPC International, IPC Corp. and IPC Ltd. are in the business of formulating, manufacturing and commercializing pharmaceutical products.

22. On information and belief, IPC International, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops drug products for sale and use throughout the United States, including within this judicial district.

23. On information and belief, IPC Corp., with the assistance and/or at the direction of IPC Ltd. and/or IPC International, develops drug products for sale and use throughout the United States, including within this judicial district.

24. On information and belief, IPC Ltd., with the assistance and/or at the direction of IPC Corp. and/or IPC International, develops drug products for sale and use throughout the United States, including within this judicial district.

25. On information and belief, IPC International, IPC Corp. and IPC Ltd. operate as an integrated, unitary business.

26. On information and belief, IPC Ltd., through IPC Corp., develops both branded and generic controlled-release pharmaceutical products, and licenses these developed products for commercialization.

27. On information and belief, IPC International, IPC Corp. and IPC Ltd. acted in concert to develop Defendants' NDA Products and to prepare and file Defendants' NDA, an application pursuant to § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) ("§ 505(b)(2)") that references Purdue's OxyContin® NDA No. 022272 and seeks approval from the FDA to sell Defendants' NDA Products throughout the United States and in this judicial district.

28. On information and belief, IPC International and/or IPC Ltd., through their authorized agent and subsidiary, IPC Corp., submitted NDA No. 209653 to the FDA. On information and belief, IPC International and IPC Ltd. have attributed the acts of IPC Corp. to themselves. On information and belief, IPC International, IPC Ltd. and IPC Corp. thus acted as a single entity in connection with preparing and submission of NDA No. 209653. On further information and belief, IPC Corp. acted as an agent of IPC International and/or IPC Ltd.

29. On information and belief, and as previously noted, IPC Ltd. is a corporation organized and existing under the laws of Delaware. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over IPC Ltd.

30. On information and belief, by virtue of, *inter alia,* IPC Ltd.'s relationship with IPC International in connection with the preparation and/or filing of NDA No. 209653, and their systematic and continuous activities in Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has personal jurisdiction over IPC International.

31. On information and belief, by virtue of, *inter alia*, IPC Ltd.'s relationship with IPC Corp. in connection with the preparation and/or filing of NDA No. 209653, and their systematic and continuous activities in Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has personal jurisdiction over IPC Corp.

32. On information and belief, separate and apart from its relationship with IPC Ltd., IPC International has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State of Delaware, at least by incorporating and/or maintaining the incorporation of its subsidiary and/or agent IPC Ltd. under Delaware law, and identifying the

Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, as the registered agent of IPC Ltd.

33. On information and belief, IPC Corp. and IPC Ltd. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Elan Corp. v. IntelliPharmaCeutics Corp.* (D. Del. C.A. No. 07-603-SLR); *Purdue Pharma L.P. at al. v. Intellipharmaceutics Corp. et al.* (D. Del. C.A. No. 17-392-RGA).

34. On information and belief, by virtue of, *inter alia,* Intellipharmaceutics' continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, and the actions on behalf of IPC International and IPC Corp. in connection with NDA No. 209653 undertaken by their agent IPC Ltd., a Delaware corporation, this Court has personal jurisdiction over IPC International, IPC Corp. and IPC Ltd. These activities satisfy due process and confer personal jurisdiction over IPC International, IPC Corp. and IPC Ltd. consistent with the Delaware long arm statute.

35. On information and belief, if NDA No. 209653 is approved, Defendants' NDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

36. This Court further has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff

P.F. Labs, which is a corporation organized and existing under the laws of the State of New Jersey.

37. Alternatively, assuming that the above facts do not establish personal jurisdiction over IPC International and/or IPC Corp., this Court may exercise jurisdiction over each pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) IPC International and IPC Corp. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) IPC International and IPC Corp. have sufficient contacts with the United States as a whole, including but not limited to preparing and submitting NDA No. 209653 to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over IPC International and IPC Corp. satisfies due process.

THE PATENTS-IN-SUIT

THE '808 PATENT

38. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners 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 A, 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.

THE '886 PATENT

39. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners 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 B, 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.

THE MANNION '933 PATENT

40. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners 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 C, 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.

THE '610 PATENT

41. Grünenthal is the lawful owner of all right, title, and interest in the '610 patent, titled "ABUSE-PROOFED DOSAGE FORM," including the right to sue and to recover for past infringement thereof. Purdue Pharma is an exclusive licensee of the '610 patent from Grünenthal, with the right to enforce the '610 patent. The '610 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '610 patent, attached hereto as Exhibit D, was duly and legally issued on June 13, 2017, naming Johannes Bartholomäus and Heinrich Kugelmann as the inventors.

THE '497 PATENT

42. Purdue Pharma, Purdue Pharmaceuticals, and P.F. Labs are the lawful owners of all right, title, and interest in the '497 patent, titled "PHARMACEUTICAL

FORMULATION CONTAINING GELLING AGENT," including the right to sue and to recover for past infringement thereof. A copy of the '497 patent is attached hereto as Exhibit E, which was duly and legally issued on September 18, 2018, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

DEFENDANTS' NDA

43. On information and belief, on or about November 22, 2016, and after November 16, 2016, Defendants filed Defendants' NDA No. 209653, which they have periodically supplemented and/or amended, under § 505(b)(2), seeking approval to engage in the commercial manufacture, use, or sale of Defendants' NDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

44. In a letter dated March 5, 2018, addressed to Plaintiffs and received by Purdue Pharma on or about March 6, 2018, Defendants provided a "Notice of Paragraph IV Certification" with respect to Defendants' NDA and Defendants' NDA Products and, *inter alia*, the '808, Mannion '933, and '610 patents, under § 505(b)(2) ("March 2018 Notice Letter").

45. Plaintiffs commenced this action with the filing of their original complaint on April 7, 2018, asserting, *inter alia*, the '808, Mannion '933, and '610 patents (D.I. 2) within the 45-day period after receiving the March 2018 Notice Letter as described in 21 U.S.C. § 355(c)(3)(C)(iii).

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

46. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 45 above as though fully restated herein.

47. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '808 patent by Defendants.

48. Defendants' NDA Products, or the use thereof, are covered by one or more claims of the '808 patent, including but not limited to independent claim 1, which recites, *inter alia*, a pharmaceutical composition comprising: at least one active agent comprising oxycodone or a pharmaceutically acceptable salt thereof; and at least one high molecular weight polyethylene oxide (PEO), having an approximate molecular weight of from 1 million to 15 million; 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 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.

49. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' NDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c).

50. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '808 patent.

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

52. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '808 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,886)

53. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 52 above as though fully restated herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '886 patent by Defendants.

55. The manufacture of Defendants' NDA Products, or the sale, offer for sale, or use thereof, are covered by one or more claims of the '886 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of producing a plurality of solid oral extended release pharmaceutical dosage forms comprising the steps of: mixing at least one active agent, at least one high molecular weight polyethylene oxide (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 the softening temperature of the high molecular weight PEO for a curing time of at least about

5 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; optionally providing the cured matrix compositions with at least one film coating, after curing and cooling; wherein (a) the molecular weight of each PEO is based on rheological measurements; (b) the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form; (c) the total weight of each dosage form is calculated by excluding the combined weight of said film coatings; and (d) each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent.

56. If approved by the FDA, Defendants will infringe the ’886 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a) or (g) and/or by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b).

57. Defendants, through at least their labeling and manufacturing process, will intentionally induce infringement of the ’886 patent by at least patients who will take Defendants’ NDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendants’ NDA Products.

58. Defendants’ NDA Products constitute a material part of the inventions covered by the claims of the ’886 patent.

59. Upon information and belief, Defendants have been aware of the existence of the ’886 patent and have no reasonable basis for believing that Defendants’ NDA Products will not infringe the ’886 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

60. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '886 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,933)

61. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 60 above as though fully restated herein.

62. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the Mannion '933 patent by Defendants.

63. Defendants' NDA Products, or the use thereof, are covered by one or more claims of the Mannion '933 patent, including but not limited to independent claim 1, which recites, *inter alia*, a pharmaceutical composition comprising: at least one active agent; at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million; optionally at least one 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 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.

64. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' NDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Mannion '933 patent under 35 U.S.C. § 271(a)-(c).

65. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the Mannion '933 patent.

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

67. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the Mannion '933 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,675,610)

68. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 67 above as though fully restated herein.

69. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '610 patent by Defendants.

70. Defendants' NDA Products, or the use or manufacture thereof, are covered by one or more claims of the '610 patent, including but not limited to independent claim 1, which recites, *inter alia*, a solid dosage form for oral administration with reduced potential for

parenteral abuse, said dosage form comprising: (a) one or more active ingredients having potential for abuse selected from the group consisting of (among others) oxycodone and a pharmaceutically acceptable salt thereof; and (b) one or more viscosity-increasing agents in a quantity such that an aqueous extract of a total content of the dosage form when comminuted and combined with 10 ml of water at 25° C forms a gel that can be drawn up into and injected back out of a hypodermic needle having a diameter of 0.9 mm, into a further quantity of water, wherein threads of the gel injected from said needle remain visible to the naked eye in said further quantity of water at 37° C.

71. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' NDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '610 patent under 35 U.S.C. § 271(a)-(c).

72. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '610 patent.

73. Upon information and belief, Defendants been aware of the existence of the '610 patent and have no reasonable basis for believing that Defendants' NDA Products will not infringe the '610 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

74. Unless Defendants are enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendants' infringement of the '610 patent. Grünenthal and Purdue Pharma do not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,076,497)

75. Purdue incorporates by reference and realleges paragraphs 1 through 74 above as though fully restated herein.

76. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '497 patent by Defendants.

77. The manufacture of Defendants' NDA Products, or the sale, offer for sale, or use thereof, are covered by one or more claims of the '497 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of preparing an abuse deterrent controlled release dosage form comprising, *inter alia*, preparing a mixture comprising oxycodone or a pharmaceutically acceptable salt thereof, a copolymer, and a gelling agent; forming the mixture into a matrix; and coating the matrix, wherein the abuse deterrent dosage form forms a gel when subjected to certain tampering and the dosage form has a ratio of gelling agent to oxycodone active ingredient from about 8:1 to about 1:8.

78. If approved by the FDA, Defendants will infringe the '497 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a) or (g) and/or by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b).

79. Defendants, through at least their labeling and manufacturing process, will intentionally induce infringement of the '497 patent by at least patients who will take Defendants' NDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendants' NDA Products.

80. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '497 patent.

81. Upon information and belief, at least as of August 10, 2018, when Purdue's counsel provided notification to Defendants' counsel, Defendants have been aware that the claims in the '497 patent were allowed by the U.S. Patent and Trademark Office and would issue in a patent. Defendants have no reasonable basis for believing that Defendants' NDA Products will not infringe the '497 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

82. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '497 patent. Purdue does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the '808, '886, Mannion '933, '610, and '497 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendants' NDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '808, '886, Mannion '933, '610, and '497 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 209653 and Defendants' NDA Products, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the last date of expiration of the '808, '886, Mannion '933, '610, and '497 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., 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 NDA No. 209653, including Defendants' NDA Products or any other drug product that infringes the '808, '886, Mannion '933, '610, and '497 patents;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

John J. Normile
Pablo D. Hendler
Kelsey I. Nix
Gasper J. LaRosa
Kenneth S. Canfield
Christopher J. Harnett
Sarah A. Geers
Lisamarie LoGuidice
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939

Jason G. Winchester
JONES DAY
77 West Wacker Drive
Chicago, IL 60601
(312) 269-4373

Attorneys for Plaintiffs Purdue Pharma L.P. and Purdue Pharmaceuticals L.P.,

Jennifer H. Roscetti
Matthew J. Luneack
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

Anthony C. Tridico
FINNEGAN EUROPE LLP
16 Old Bailey
London EC4M 7EG United Kingdom
011 44 20 3178 7883

Attorneys for Plaintiff Grünenthal GmbH

September 24, 2018

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 24, 2018, upon the following in the manner indicated:

Neal C. Belgam, Esquire — *VIA ELECTRONIC MAIL*
Eve H. Ormerod, Esquire
SMITH, KATZENSTEIN & JENKINS LLP
1000 West Street, Suite 1501
Wilmington, DE 19801
Attorneys for Defendants

Shashank Upadhye, Esquire — *VIA ELECTRONIC MAIL*
Joseph E. Cwik, Esquire
Yixin H. Tang, Esquire
Brent Batzer, Esquire
Adam D. Sussman, Esquire
Samuel J. Ruggio, Esquire
Erin R. Conway, Esquire
AMIN TALATI UPADHYE LLP
100 S. Wacker Drive, Suite 2000
Chicago, IL 60606
Attorneys for Defendants

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)