IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
INTELLIPHARMACEUTICS INTERNATIONAL INC., INTELLIPHARMACEUTICS CORPORATION, and INTELLIPHARMACEUTICS LTD.,	)	
Defendants.	)	

COMPLAINT

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

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,060,976 (the ''976 patent"); 9,073,933 (the ''933 patent"); 9,522,919 (the ''919 patent"); 9,492,389 (the ''389 patent"); 9,492,391 (the ''391 patent"); and 8,309,060 (the ''060 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 '976, '933, '919, '389, '391, and '060 patents (collectively, "the Orange Book patents"), which 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 Orange Book 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 a generic version of Purdue's OxyContin®, which is the subject of approved NDA No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' NDA Products"). As set forth in paragraphs 43-48, certain claims of the '060 patent have been found infringed but invalid in a previous lawsuit. An appeal from that judgment of invalidity is pending. To conserve the resources of the Court and the parties, Plaintiffs will seek a partial stay of this action against Intellipharmaceutics with respect to the '060 patent held invalid until final adjudication of the pending appeal.

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 '976, '933, '919, '389, and '391 patents, identified in paragraphs 38-42 below, and Purdue Pharma is an exclusive licensee of the '060 patent, identified in paragraph 43-48 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 '976, '933, '919, '389, and '391 patents, identified in paragraphs 38-42 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, Stamford, CT 06901. P.F. Labs is an owner of the '976, '933, and '919, patents, identified in paragraphs 38-40 below.

6. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '933 and '919 patents, identified in paragraphs 39-40 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

7. 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 '060 patent, identified in paragraphs 43-48 below.

8. 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 generic 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."), 100.00% of the common shares of Intellipharmaceutics Corporation ("IPC Corp.").

9. 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 generic drug products for sale and use in the state of Delaware and throughout the United States.

10. 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., 100.0% 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 generic drug products for sale and use in the State of Delaware and throughout the United States.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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

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

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

PERSONAL JURISDICTION

20. Defendants have agreed not to contest personal jurisdiction for purposes of the action, and will not move to dismiss the action on grounds that the United States District Court for 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 generic 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 generic 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 generic 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 new 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 Rexista®, a generic version of Purdue's OxyContin®, and to seek approval from the FDA to sell Rexista® 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).

34. On information and belief, by virtue of, *inter alia,* IPC's 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 Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

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 '976 PATENT

38. Purdue is the lawful owner of all right, title, and interest in the '976 patent, titled "PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT," including the right to sue and to recover for past infringement thereof. The '976 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '976 patent, attached hereto as Exhibit A, was duly and legally issued on June 23, 2015, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

THE '933 PATENT

39. Purdue and Rhodes are the lawful owners of all right, title and interest in the '933 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '933 patent is attached hereto as Exhibit B,

which was duly and legally issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

THE '919 PATENT

40. Purdue and Rhodes are the lawful owners of all right, title and interest in the '919 patent, titled "OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '919 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '919 patent is attached hereto as Exhibit C, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

THE '389 PATENT

41. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners 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 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.

THE '391 PATENT

42. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners 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 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.

THE '060 PATENT

43. Grünenthal is the lawful owner of all right, title, and interest in the '060 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 '060 patent from Grünenthal, with the right to enforce the '060 patent. The '060 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '060 patent, attached hereto as Exhibit F, was duly and legally issued on November 13, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors.

44. Plaintiff Grünenthal filed patent infringement actions in the United States District Court for the Southern District of New York against Actavis Inc., Actavis South Atlantic LLC, and other defendants alleging infringement of, *inter alia*, the '060 patent by submission of ANDAs seeking approval to market generic versions of a different branded product, Opana® ER oxymorphone hydrochloride crush resistant formulation ("Opana® ER CRF"). Those actions are *Endo Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals, LLC et al.*, C.A. No. 12-cv-8115, -8060, -8317, 13-civ-435, -436 (S.D.N.Y.) (TPG) ("the *Endo* cases").

45. The *Endo* cases, with respect to the '060 patent, were tried between March 23, 2015 and April 24, 2015, before the Honorable Thomas P. Griesa. On August 14, 2015, Judge Griesa issued Findings of Fact and Conclusions of Law, and on August 24, 2015, Judge Griesa entered judgment ("the Endo Decision"). The Endo Decision concluded, *inter alia*, that defendants in those actions infringed claims 1, 4, 9, 24-25, 27, and 29-34 of the '060 patent.

With respect to the validity of the '060 patent, although the Endo Decision rejected defendants' invalidity defenses based on 35 U.S.C. §§ 102 and 112, the Endo Decision concluded that the above-identified claims of the '060 patent were invalid based on obviousness a judgment that is currently being appealed.

46. It is well established that "a judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379-80 (Fed. Cir. 1999) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 332-34 (1971)). The Endo Decision does not qualify for a collateral estoppel defense under *Blonder-Tongue*. 402 U.S. at 332-34 (stating that there is no full and fair opportunity to litigate where, for example, "the court[] wholly failed to grasp the technical subject matter and issues in suit").

47. Grünenthal did not have a full and fair opportunity to litigate the validity of the '060 patent. *See id*. Therefore, to give collateral estoppel effect to the Endo Decision would be contrary to "justice and equity" as stated by the Supreme Court in *Blonder-Tongue*.

48. The appeal was fully briefed on March 27, 2017, and oral argument has not yet been set.

DEFENDANTS' NDA

49. On information and belief, on or before February 23, 2017, Defendants filed Defendants' NDA No. 209653 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(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.

50. On information and belief, Defendants submitted in the NDA a "Paragraph IV" certification under 21 U.S.C. § 355(b)(3)(D) alleging that the '976, '933, '919, '389, '391, and '060 patents, listed in the FDA's Orange Book as covering the OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" the drug products described in Defendants' NDA.

51. In a letter dated February 23, 2017, addressed to Plaintiffs and received by Purdue Pharma on or about February 24, 2017, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' NDA and Defendants' NDA Products, and the Orange Book patents, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

52. Plaintiffs commenced this action within the 45-day period after receiving the 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. 9,060,976)

53. Purdue incorporates 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 '976 patent by Defendants.

55. Defendants' NDA Products, or the use or manufacture thereof, are covered by claim 1 of the '976 patent, which recites, inter alia, an extended release abuse deterrent dosage form comprising PEO having a molecular weight of from about 300,000 daltons to about

5,000,000 daltons and oxycodone or a pharmaceutically acceptable salt thereof, wherein the core matrix is heated to melt at least a portion of the PEO, and PEG applied onto the core.

56. 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 '976 patent under 35 U.S.C. § 271(a)-(c).

57. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '976 patent.

58. Upon information and belief, Defendants have been aware of the existence of the '976 patent, and has no reasonable basis for believing that Defendants' NDA Products will not infringe the '976 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

59. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '976 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,073,933)

60. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 52 above as though fully restated herein.

61. 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 '933 patent by Defendants.

62. Defendants' NDA Products, or the use or manufacture thereof, are covered by one or more claims of the '933 patent, including but not limited to independent claim 1,

which recites, inter alia, an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

63. 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 '933 patent under 35 U.S.C. § 271(a)-(c).

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

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

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

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,522,919)

67. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 52 above as though fully restated herein.

68. 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 '919 patent by Defendants.

69. Defendants' NDA Products, or the use or manufacture thereof, are covered by one or more claims of the '919 patent, including but not limited to independent claim 1,

which recites, *inter alia*, an oxycodone hydrochloride composition wherein the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone hydrochloride is 0.04% or less as measured by HPLC, and various claims dependent therefrom.

70. 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 '919 patent under 35 U.S.C. § 271(a)-(c).

71. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '919 patent.

72. Upon information and belief, Defendants have been aware of the existence of the '919 patent, and has no reasonable basis for believing that Defendants' NDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

73. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '919 patent. Purdue and Rhodes do not have an adequate remedy at law.

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

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

75. 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 '389 patent by Defendants.

76. Defendants' NDA Products, or the use thereof, are covered by one or more claims of the '389 patent, including but not limited to 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 polyethylene oxide having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

77. 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 '389 patent under 35 U.S.C. § 271(a)-(c).

78. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '389 patent.

79. Upon information and belief, Defendants have been aware of the existence of the '389 patent, and has no reasonable basis for believing that Defendants' NDA Products will not infringe the '389 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

80. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '389 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

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

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

82. 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 '391 patent by Defendants.

83. Defendants' NDA Products, or the use thereof, are covered by one or more claims of the '391 patent, including but not limited to 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 polyethylene oxide having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

84. 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 '391 patent under 35 U.S.C. § 271(a)-(c).

85. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '391 patent.

86. Upon information and belief, Defendants have been aware of the existence of the '391 patent, and has no reasonable basis for believing that Defendants' NDA Products will

not infringe the '391 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

87. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '391 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

SIXTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,309,060)

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

89. 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 '060 patent by Defendants.

90. Defendants' NDA Products, or the use or manufacture thereof, are covered by one or more claims of the '060 patent, including but not limited to independent claim 1, which recites, inter alia, an abuse-proofed, thermoformed dosage form comprising an active ingredient with abuse potential, and at least one polymer having a molecular weight of at least 0.5 million, wherein the dosage form has a breaking strength of at least 500 N, and various claims dependent therefrom, and various claims dependent therefrom.

91. 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 '060 patent under 35 U.S.C. § 271(a)-(c).

92. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '060 patent.

93. On information and belief, Defendants know that Defendants' NDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '060 patent.

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

95. The administration of Defendants' NDA Products by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '060 patent.

96. Defendants' proposed label for Defendants' NDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' NDA Products in a manner that will directly infringe one or more claims of the '060 patent, including but not limited to claim 28, which recites a method of treating a therapeutic condition in a patient comprising administering a dosage form according to claim 1 and dependent claim 29, which recites that the therapeutic condition is pain. 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.

97. If Defendants' NDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '060 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '060 patent.

98. Unless Defendants are enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendants' infringement of the '060 patent. Grünenthal and Purdue Pharma do 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 '976, '933, '919, '389, '391, and '060 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 '976, '933, '919, '389, '391, and '060 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 '976, '933, '919, '389, '391, and '060 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 '976, '933, '919, '389, '391, and '060 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.

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