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,	)	
	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
ASCENT PHARMACEUTICALS, INC.,	)	
Defendant.	)	

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 Ascent Pharmaceuticals, Inc. ("Ascent" or "Defendant"), 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"); 9,147,533 (the "'533 patent"); 9,861,582 (the "'582 patent"); 8,309,060 (the "'060 patent"); and 9,675,610 (the "'610 patent") (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 211178 ("Defendant's ANDA") submitted upon information and belief in the name of Ascent to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendant has infringed the '976, '933, '919, '060, and '610 patents (collectively, "the Orange Book patents-in-suit"), which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), extended-release pain medication. Defendant has infringed the Orange Book patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 211178 (as supplemented and/or amended), submitted upon information and belief in the name of Ascent to the FDA. Defendant's ANDA (as supplemented and/or amended) 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, 60 mg and 80 mg dosage strengths ("Defendant's ANDA Products").

3. Defendant's ANDA originally sought approval only for the 40 mg dosage strength of Defendant's ANDA Products, and there is a lawsuit pending relating to that dosage strength (C.A. No. 18-83-RGA (D. Del.)). The instant lawsuit relates to the remaining dosage strengths, i.e., the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products.

4. As set forth in paragraphs 30-36, certain claims of the '060 patent have been found infringed but invalid in a previous lawsuit. A motion to vacate that judgment of invalidity is pending.

5. Plaintiffs also seek judgment that Defendant has infringed the '533 patent and '582 patent, which are not listed in the FDA's Orange Book, under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 211178 on Defendant's ANDA Products.

THE PARTIES

6. 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, '533, and '582 patents, identified in paragraphs 25-29 below, and Purdue Pharma is an exclusive licensee of the '060 and '610 patents, identified in paragraphs 30-37 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.

7. 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, and '582 patents, identified in paragraphs 25-27 and 29 below.

8. 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 06901-3431. P.F. Labs is an owner of the '976, '933, '919, and '582 patents, identified in paragraphs 25-27 and 29 below.

9. Plaintiff 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 26-27 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

10. Plaintiff 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 and '610 patents, identified in paragraphs 30-37 below.

11. On information and belief, Ascent is a New York corporation having a principal place of business at 550 South Research Place, Central Islip, New York. On information and belief, Ascent is in the business of manufacturing and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, Ascent is a subsidiary of Hetero Drugs Limited ("Hetero").

JURISDICTION AND VENUE

12. 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.

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

14. In the related 18-83 action, Ascent stipulated and agreed that it would not contest personal jurisdiction or venue. (18-83, D.I. 9.)

15. Ascent has agreed that it will not contest personal jurisdiction or venue in this case.

16. On information and belief, Ascent is in the business of formulating, manufacturing and commercializing pharmaceutical products.

17. On information and belief, Ascent, 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.

18. On information and belief, Ascent, with the assistance and/or at the direction of Hetero, develops generic drug products for sale and use throughout the United States, including within this judicial district.

19. On information and belief, Camber Pharmaceuticals, Inc. ("Camber") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue Piscataway, New Jersey. Camber has admitted "personal jurisdiction and venue are proper in the District of Delaware that Camber is incorporated in Delaware . . . ." *AstraZeneca AB et al. v. Camber Pharmaceuticals Inc.*, 15-cv-00927 (D. Del, D.I. 30). Camber is a subsidiary of Hetero. *See id.*

20. On information and belief, Ascent, Camber, and Hetero are intimately connected and operate as an integrated, unitary business. On information and belief, Hetero is the parent company of both Ascent and Camber. On information and belief, Ascent manufactures products for commercialization by Camber.

21. On information and belief, by virtue of, *inter alia*, Ascent's systematic and continuous activity in Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, and Ascent's relationship with Camber, which is incorporated in Delaware, this Court has personal jurisdiction over Ascent.

22. On information and belief, if ANDA No. 211178 is approved, Defendant's ANDA 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.

23. This Court further has personal jurisdiction over Defendant by virtue of the fact that Defendant has 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.

24. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because on information and belief, Camber is incorporated in this judicial district, and Ascent and Camber operate as an integrated business and are intimately connected, with Ascent manufacturing products for Camber. By virtue of this integrated and intimate corporate family relationship, venue is proper in this Court.

THE PATENTS-IN-SUIT

THE '976 PATENT

25. 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

26. 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

27. 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 ’533 PATENT

28. Purdue Pharma is the lawful owner of all right, title and interest in the ’533 patent, titled “TAMPER RESISTANT PHARMACEUTICAL FORMULATIONS,” including the right to sue and to recover for past infringement thereof. A copy of the ’533 patent is attached hereto as Exhibit D, which was duly and legally issued on October 6, 2015, naming Debora Guido and Haiyong Hugh Huang as the inventors.

THE ’582 PATENT

29. Purdue is the lawful owner of all right, title and interest in the ’582 patent, titled “PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT,” including the right to sue and to recover for past infringement thereof. A copy of the ’582 patent is attached hereto as Exhibit E, which was duly and legally issued on January 9, 2018, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

THE ’060 PATENT

30. 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.

31. 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”).

32. 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.

33. Grünenthal appealed that invalidity determination to the Federal Circuit. Before the appeals could be resolved, however, the Endo defendants withdrew their ANDAs from the FDA and the Federal Circuit consequently dismissed the appeals without prejudice. In view of the Federal Circuit's dismissal of the appeals, Grünenthal has now moved the Federal Circuit to vacate the district court's judgment.

34. 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").

35. 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*.

36. Grünenthal filed its motion to vacate the district court's judgment on May 25, 2018. Briefing is not yet complete, and oral argument (if any) has not yet been set.

THE '610 PATENT

37. 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 G, was duly and legally issued on June 13, 2017, naming Johannes Bartholomäus and Heinrich Kugelmann as the inventors.

DEFENDANT’S ANDA

38. On information and belief, on or before November 27, 2017, Defendant filed Defendant’s ANDA No. 211178 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, or sale of Defendant’s ANDA Products, a generic product based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

39. On information and belief, Defendant submitted in the ANDA a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the ’976, ’933, ’919, ’060, and ’610 patents, listed in the FDA’s 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 or sale of” the drug product described in Defendant’s ANDA.

40. In a letter addressed to Plaintiffs dated November 27, 2017, Defendant provided what purports to be a Notice of Paragraph IV Certification (“November 2017 Notice Letter”) with respect to Defendant’s ANDA and the 40 mg dosage strength of Defendant’s ANDA Products, and, *inter alia*, the Orange Book patents-in-suit, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

41. In response to the November 2017 Notice Letter, on January 11, 2018, Plaintiffs filed C.A. No. 18-83-RGA accusing Defendant of infringing the patents-in-suit based on the 40 mg dosage strength of Defendant's ANDA Products. That action is on-going.

42. In a letter addressed to Plaintiffs dated April 24, 2018, and received by Purdue and Rhodes on or about May 1, 2018, and Grünenthal on or about May 2, 2018, Defendant provided what purports to be a Supplemental Notice of Paragraph IV Certification ("2018 Notice Letter") with respect to Defendant's ANDA and the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products, and, *inter alia*, the Orange Book patents-in-suit, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

43. Plaintiffs commenced this action accusing Defendant of infringing the patents-in-suit based on the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products within the 45-day period after receiving the 2018 Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

44. The 30-month stay of FDA approval of Defendant's ANDA with respect to the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) commenced upon receipt of the 2018 Notice Letter by Plaintiffs.

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,060,976)

45. Purdue incorporates by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

46. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg

dosage strengths of Defendant's ANDA Products was an act of infringement of the '976 patent by Defendant.

47. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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 a core matrix 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 matrix.

48. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of claim 1 of the '976 patent under 35 U.S.C. § 271(a)-(c).

49. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the invention covered by the claim of the '976 patent.

50. Upon information and belief, Defendant has been aware of the existence of the '976 patent at least as early as the November 27, 2017 date of Defendant's original Paragraph IV certification, and has no reasonable basis for believing that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '976 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

51. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's 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)

52. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 51 above as though fully restated herein.

53. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products was an act of infringement of the '933 patent by Defendant.

54. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

55. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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) and/or (g).

56. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '933 patent.

57. Upon information and belief, Defendant has been aware of the existence of the '933 patent at least as early as the November 27, 2017 date of Defendant's original Paragraph IV certification, and has no reasonable basis for believing that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

58. Unless Defendant is enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendant's 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)

59. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 58 above as though fully restated herein.

60. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products was an act of infringement of the '919 patent by Defendant.

61. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

62. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg

dosage strengths of Defendant's ANDA 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).

63. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '919 patent.

64. Upon information and belief, Defendant has been aware of the existence of the '919 patent at least as early as the November 27, 2017 date of Defendant's original Paragraph IV certification, and has no reasonable basis for believing that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

65. Unless Defendant is enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendant's 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. 9,149,533)

66. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 65 above as though fully restated herein.

67. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products was an act of infringement of the '533 patent by Defendant.

68. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '533 patent, including but not limited to independent claim 1, which recites, *inter alia*, a solid oral dosage form comprising a heat-labile gelling agent, a thermal stabilizer, a drug susceptible to abuse, and a pH modifying agent.

69. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more of the claims of the '533 patent under 35 U.S.C. § 271(a)-(c).

70. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '533 patent.

71. Upon information and belief, Defendant has been aware of the existence of the '533 patent at least as early as the January 11, 2018 filing date of C.A. No. 18-83-RGA, and has no reasonable basis for believing that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '533 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

72. Unless Defendant is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Defendant's infringement of the '533 patent. Purdue Pharma does not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,861,582)

73. Purdue incorporates by reference and realleges paragraphs 1 through 72 above as though fully restated herein.

74. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products was an act of infringement of the '582 patent by Defendant.

75. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '582 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of preparing an abuse-deterrent controlled-release oral dosage form comprising preparing a matrix comprising oxycodone or a pharmaceutically acceptable salt thereof and a gelling agent comprising polyethylene oxide having a weight-average molecular weight of about 50,000 to about 750,000, and applying to the matrix a coating comprising polyvinyl alcohol; the dosage form forming a gel when subjected to tampering comprising dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid; the dosage form having a ratio of polyethylene oxide to oxycodone or pharmaceutically acceptable salt thereof from about 1:1 to about 30:1; and the dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient; and wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent.

76. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will infringe, contribute to the infringement of,

and/or induce the infringement of one or more of the claims of the '582 patent under 35 U.S.C. § 271(a)-(c) and/or (g).

77. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '582 patent.

78. Upon information and belief, Defendant has been aware of the existence of the '582 patent at least as early as the January 11, 2018 filing date of C.A. No. 18-83-RGA, and has no reasonable basis for believing that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '582 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

79. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '582 patent. Purdue does not have an adequate remedy at law.

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

80. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 79 above as though fully restated herein.

81. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products is an act of infringement of the '060 patent by Defendant.

82. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

83. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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) and/or (g).

84. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '060 patent.

85. On information and belief, Defendant knows that the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products is especially made or especially adapted for use in the infringement of one or more claims of the '060 patent.

86. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products.

87. The administration of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

88. Defendant's proposed label for the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will explicitly instruct Healthcare

Providers and patients to use the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

89. If the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products is approved by the FDA, Defendant will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '060 patent. Since at least the date of the 2018 Notice Letter, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '060 patent.

90. Unless Defendant is enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendant's infringement of the '060 patent. Grünenthal and Purdue Pharma do not have an adequate remedy at law.

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

91. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 90 above as though fully restated herein.

92. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 211178 to the FDA seeking approval of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products was an act of infringement of the '610 patent by Defendant.

93. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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.

94. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA 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).

95. The 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products constitutes a material part of the inventions covered by the claims of the '610 patent.

96. Upon information and belief, Defendant has been aware of the existence of the '610 patent at least as early as the November 27, 2017 date of Defendant's original Paragraph IV certification, and has no reasonable basis for believing that the 10 mg, 15 mg,

20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products will not infringe the '610 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

97. Unless Defendant is enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendant's infringement of the '610 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 Defendant has infringed one or more claims of each of the '976, '933, '919, '533, '582, '060, and '610 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '976, '933, '919, '533, '582, '060, and '610 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 211178 and the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's 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 '976, '933, '919, '533, '582, '060, and '610 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., Defendant, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business

entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 211178, including the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg, and 80 mg dosage strengths of Defendant's ANDA Products or any other drug product that infringes the '976, '933, '919, '533, '582, '060, and '610 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

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June 7, 2018