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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., RHODES TECHNOLOGIES and GRÜNENTHAL GMBH,

Plaintiffs,

v.

ABHAI, LLC and KVK-TECH, INC.,

Defendants.

C.A. No. 3:16-CV-58-J-32JRK

COMPLAINT

INJUNCTIVE RELIEF SOUGHT

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 Defendants Abhai, LLC ("Abhai") and KVK-TECH, Inc. ("KVK") (collectively, "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. 7,674,799 ("the '799 patent"); 7,674,800 ("the '800 patent"); 7,683,072 ("the '072 patent"); 8,114,383 ("the '383 patent"); 8,309,060 ("the '060 patent"); 8,337,888 ("the '888 patent"); 8,808,741 ("the '741 patent"); 8,894,987 ("the '987 patent"); 8,894,988 ("the '988 patent"); 9,060,976 ("the '976 patent"); and 9,073,933 ("the '933 patent") (collectively, "the patents-in-

suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 207493 ("Defendants' ANDA") submitted upon information and belief in the name of Defendants to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and '933 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 ANDA No. 207493, submitted upon information and belief in the name of Defendants to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved New Drug Application ("NDA") No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' ANDA Products"). As set forth in paragraphs 28-65, certain claims of the '799, '800, '072, '383, '060, and '888 patents have been found infringed but invalid in previous lawsuits. Appeals from those judgments of invalidity are pending.

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 '799, '800, '072, '888, '741, '987, '988, '976, and '933 patents, identified in paragraphs 28-37 and 58-70 below, and Purdue Pharma is an exclusive licensee of the '060 and '383 patents, identified in paragraphs 38-57 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 '799, '800, '072, '888, '741, '987, '988, '976, and '933 patents, identified in paragraphs 28-37 and 58-70 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 '799, '800, '072, '888, '976, and '933 patents, identified in paragraphs 28-37, 58-65, and 69-70 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 '799, '800, '072, and '933 patents, identified in paragraphs 28-37 and 70 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 and '383 patents, identified in paragraphs 38-57 below.

8. On information and belief, Defendant Abhai is a limited liability company organized and existing under the laws of the State of Florida, having a principal place

of business at 194 Inlet Drive, St. Augustine, FL 32080.

9. On information and belief, Defendant KVK is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 110 Terry Drive, Suite 200, Newtown, PA 18940.

10. On information and belief, Defendant Abhai develops, manufactures, and/or markets pharmaceutical products throughout the United States, including in this judicial district, through its own actions and through the actions of its agents, including KVK.

11. On information and belief, Defendant KVK develops, manufactures, and/or markets pharmaceutical products throughout the United States, including in this judicial district, through its own actions and through the actions of its agents, including Abhai.

12. On information and belief, Defendants Abhai and KVK collaborate in the development, manufacture, marketing, and sale of pharmaceutical products throughout the United States, including in this judicial district. On further information and belief, Abhai is the registrant of approved ANDA No. 207488 for extended release methylphenidate hydrochloride. On further information and belief, KVK is involved in manufacturing, marketing, and/or sale of the generic drug products described in approved ANDA No. 207488.

13. On further information and belief, Defendants Abhai and KVK are working in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the Defendants' ANDA Products described in ANDA No. 207493, as well as the generic drug products described in approved ANDA No. 207488. On further information and belief, Abhai submitted Defendants' ANDA to the FDA on behalf of, and as the agent of KVK. On further information and belief, KVK provided what purports to be a "Notice of Paragraph IV Certifications" for Defendants' ANDA to Plaintiffs on

behalf of, and as the agent of Abhai.

14. On information and belief, Defendants Abhai and KVK closely coordinate their commercial activities and simultaneously share senior corporate officers. On further information and belief, Abhai is managed and controlled by Anthony Tabasso, Abhai's only Authorized Member. On further information and belief, KVK is also managed and controlled by Anthony Tabasso, KVK's President and Chief Executive Officer ("CEO"). On further information and belief, Anthony Tabasso has been the President and CEO of KVK since August 2013. On further information and belief, Anthony Tabasso has been the only Authorized Member of Abhai since Abhai's organization as a limited liability company in April 2014. On further information and belief, Anthony Tabasso has simultaneously managed and controlled Abhai and KVK since April 2014.

15. On information and belief, Defendants Abhai and KVK were jointly involved in the preparation and submission of the Defendants' ANDA. On further information and belief, KVK's employee Frank Nekoranik performed work necessary to the preparation and submission of Defendants' ANDA, including but not limited to providing what purports to be a "Notice of Paragraph IV Certification" for ANDA No. 207493 to Plaintiffs.

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

SUBJECT MATTER JURISDICTION AND VENUE

17. 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.

18. This Court has subject matter jurisdiction pursuant to 28 U.S.C.

§§ 1331 and 1338(a).

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

PERSONAL JURISDICTION

20. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* their systematic and continuous contacts with Florida and contacts with Florida in connection with the submission of Defendants' ANDA, as set forth below.

21. On information and belief, Defendant Abhai is a Florida limited liability company, and Abhai's principal place of business is located at 194 Inlet Drive, St. Augustine, FL 32080.

22. On information and belief, Defendant KVK has admitted to personal jurisdiction in this Court, and has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in a prior Middle District of Florida action, *Braintree Laboratories, Inc. v. Gator Pharmaceuticals, Inc. et al.*, Docket No. 3:13-cv-00389 (M.D. Fla. Apr. 15, 2013).

23. On information and belief, Defendant KVK is licensed in the State of Florida as a "Non-Resident Prescription Drug Manufacturer," License Number 26707, expiring January 31, 2017.

24. On information and belief, Defendant KVK has a pending Product Registration with the State of Florida.

25. On information and belief, Defendant KVK is listed as an approved drug labeler with Florida Medicaid, Labeler Code 10702.

26. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of Florida and throughout the

United States.

27. On information and belief, if ANDA No. 207493 is approved, the Defendant's ANDA Products would, among other things, be marketed and distributed in Florida, and/or prescribed by physicians practicing and dispensed by pharmacies located within Florida, all of which would have a substantial effect on Florida.

THE PATENTS-IN-SUIT

THE '799, '800, AND '072 PATENTS

28. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '799 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '799 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '799 patent is attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

29. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '800 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '800 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

30. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '072 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN

25 PPM 14-HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '072 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '072 patent is attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

31. The '799, '800, and '072 patents have been the subject of previous District Court litigation in which certain claims were found infringed but invalid for obviousness, a judgment that is currently being appealed.

32. On March 23, 2011 and June 28, 2012, Purdue and Rhodes filed suit against Teva Pharmaceuticals USA, Inc. ("Teva") in the Southern District of New York, Civil Action Nos. 11-cv-2037-SHS and 12-cv-5083-SHS, alleging infringement of, *inter alia*, the '799, '800, and '072 patents ("the *Teva* case"). In response, Teva denied infringement and asserted that the claims of the '799, '800, and '072 patents were invalid. A twelve-day bench trial relating, *inter alia*, to these patents was held in September and October 2013.

33. On January 14, 2014, the Southern District of New York (Stein, J.) issued Findings of Fact and Conclusions of Law in the *Teva* case ("the Teva decision"). The accused products were found to infringe the asserted claims of the '799, '800, and '072 patents and the claims were found to satisfy the disclosure and claiming requirements of 35 U.S.C. § 112. However, the asserted claims of the '799, '800, and '072 patents were also found invalid for obviousness. On January 22, 2014, the Court entered Judgment holding, *inter alia*, that: (a) Claims 3 and 19 of the '799 patent are invalid; (b) Claims 30-34 and 76-79 of the '800 patent are invalid; and (c) Claims 1, 4, and 5 of the '072 patent are invalid.

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 Teva 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. Purdue and Rhodes did not have a full and fair opportunity to litigate the validity of the '799, '800, and '072 patents before Judge Stein. *See id*. Therefore, to give collateral estoppel effect to Judge Stein's holding of invalidity of claims 3 and 19 of the '799 patent, claims 30-34 and 76-79 of the '800 patent, and claims 1, 4, and 5 of the '072 patent would be contrary to "justice and equity" as stated by the Supreme Court in *Blonder-Tongue*.

36. On February 12, 2014, Plaintiffs Purdue and Rhodes filed notices of appeal of the Southern District of New York's judgment of invalidity in the *Teva* case, including the judgment with respect to the claims of the '799, '800, and '072 patents, to the Court of Appeals for the Federal Circuit ("the Federal Circuit"). The District Court's judgment was amended on April 16, 2014 and July 14, 2014, and notices of appeal were filed by Purdue and Rhodes on May 20, 2014 and July 23, 2014, respectively.

37. The appeal was fully briefed and oral argument was held on November 3, 2015.

THE '383 AND '060 PATENTS

38. Grünenthal is the lawful owner of all right, title, and interest in the '383 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 '383 patent

from Grünenthal, with the right to enforce the ’383 patent. The ’383 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the ’383 patent, attached hereto as Exhibit D, was duly and legally issued on February 14, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors.

39. 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 E, was duly and legally issued on November 13, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors.

40. The ’383 patent has been the subject of previous District Court litigation in which certain claims were found infringed but invalid for anticipation and obviousness, a judgment that is currently being appealed.

41. On June 28, 2012, Purdue Pharma and Grünenthal filed suit against Teva alleging infringement of, *inter alia*, the ’383 patent (“the *Teva ’383* case”). In response, Teva denied infringement and argued that the asserted claims of the ’383 patent were invalid. A twelve-day bench trial relating, *inter alia*, to the ’383 patent was held in September and October 2013.

42. On January 14, 2014, the Southern District of New York (Stein, J.) issued Findings of Fact and Conclusions of Law in the *Teva ’383* case (“the Teva ’383

Decision"). The accused products were found to infringe the asserted claims of the '383 patent. However, the asserted claims of the '383 patent were found invalid for anticipation and obviousness. On January 22, 2014, the Court entered Judgment holding, *inter alia*, that: Claims 1, 2, 5, 7, and 8 of the '383 patent are invalid.

43. 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 Teva '383 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").

44. Grünenthal and Purdue Pharma did not have a full and fair opportunity to litigate the validity of the '383 patent before Judge Stein. *See id.* Therefore, to give collateral estoppel effect to Judge Stein's holding of invalidity of claims 1, 2, 5, 7, and 8 of the '383 patent would be contrary to "justice and equity" as stated by the Supreme Court in *Blonder-Tongue*.

45. On February 12, 2014, Purdue Pharma and Grünenthal filed notices appealing the Southern District of New York's Judgment of invalidity in the *Teva '383* case, including the Judgment with respect to the claims of the '383 patent, to the Federal Circuit. The District Court's Judgment was amended on April 16, 2014 and July 14, 2014, and Purdue Pharma and Grünenthal each filed amended notices of appeal on May 20, 2014 and July 23, 2014 to account for each set of amendments to the Judgment.

46. The appeal was fully briefed and oral argument was held on

November 3, 2015.

47. 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 ’383 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”).

48. Defendants filed a Motion for Partial Summary Judgment of Collateral Estoppel in the *Endo* cases requesting the Court to “hold invalid claims 1, 2, 5, 7, and 9 of the ’383 patent” based on Judge Stein’s invalidity holding in the *Teva* ’383 case. C.A. No. 13-cv-436, D.I. 71 at 15. Prior to filing their opposition, Grünenthal and Endo informed Defendants that they were no longer asserting claims 1, 2, 5, and 7 of the ’383 patent, mooting Defendants’ Motion with respect to those claims. E. Sommers’ letter to Defendants dated March 3, 2015. Accordingly, Grünenthal and Endo addressed only claim 9 of the ’383 patent (as well as the asserted claims of the ’060 patent) in their Opposition to Defendants’ Motion. C.A. No. 13-cv-436, D.I. 78 at 2-3, 7-11. Acknowledging the mootness of their Motion with respect to claims 1, 2, 5, and 7, the Defendants’ Reply in support of their original Motion “request[ed] that the Court [] grant their motion and hold invalid [only] claim 9 of the ’383 patent.” C.A. No. 13-cv-436, D.I. 103 at 10. Nevertheless, Judge Griesa ruled that claims 1, 2, 5, and 7 were invalid on the basis of collateral estoppel (“Judge Griesa’s Collateral Estoppel Decision”). C.A. No. 13-cv-436, D.I. 117 at 4-5.

49. The Court erred in concluding that collateral estoppel applied to

claims 1, 2, 5, and 7 for at least two reasons: (1) Defendants' motion was mooted with respect to claims 1, 2, 5, and 7 of the '383 patent and (2) the Teva '383 Decision does not qualify for a collateral estoppel defense under the patent validity/collateral estoppel law as articulated by the Supreme Court in *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").

50. Grünenthal did not have a full and fair opportunity to litigate the validity of the '383 patent. *See id.* Therefore, to give collateral estoppel effect to the Teva '383 Decision holding claims 1, 2, 5, and 7 of the '383 patent invalid would be contrary to "justice and equity" as stated by the Supreme Court in *Blonder-Tongue*.

51. Grünenthal filed notices of appeal to the Federal Circuit on September 11, 2015 that include an appeal of Judge Griesa's Collateral Estoppel Decision.

52. The '060 patent has been the subject of previous District Court litigation in which certain claims were found infringed but invalid for obviousness, a judgment that is currently being appealed.

53. In the *Endo* cases, Grünenthal also alleged infringement of the '060 patent by Actavis Inc., Actavis South Atlantic LLC, and other defendants by submission of ANDAs seeking approval to market generic versions of branded product, Opana® ER CRF.

54. 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 29-32 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.

55. 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”).

56. 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*.

57. Grünenthal filed notices of appeal from the Endo Decision to the Federal Circuit on September 11, 2015.

THE ’888 PATENT

58. Purdue is the lawful owner of all right, title, and interest in the ’888 patent, titled “PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT,” including the right to sue and to recover for past infringement thereof. The ’888 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the ’888 patent is attached hereto as Exhibit F, which was duly and legally issued on December 25, 2012, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder

as the inventors.

59. The ’888 patent has been the subject of previous District Court litigation in which certain claims were found infringed but invalid for obviousness and indefiniteness, a judgment that is currently being appealed.

60. On May 17, 2013, Purdue filed suit against Amneal in the Southern District of New York, Civil Action No. 11-cv-08153-SHS alleging infringement of the ’888 patent (“the *Amneal I* case”). In response, Amneal denied infringement and asserted that the claims of the ’888 patent were invalid. In September and October of 2013, the Court held a bench trial in the consolidated actions of *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc*., Nos. 11-cv-2037 and 12-cv-5083; *Purdue Pharma L.P. et al. v. IMPAX Labs., Inc*., No. 11-cv-2400; and *Purdue Pharma L.P. et al. v. Sandoz Inc*., Nos. 11-cv-4694 and 12-cv-5082 (“the 2013 trial”). Because the evidence presented at the 2013 trial related to the claims and defenses at issue in the *Amneal I* case, the parties agreed to adopt the entire record as part of the factual record in the *Amneal I* action.

61. On April 8, 2015, the Southern District of New York (Stein, J.) issued Findings of Fact and Conclusions of Law in the *Amneal I* case (“Amneal I Decision”). Amneal’s proposed products were found to infringe the asserted claims of the ’888 patent. However, the asserted claims of the ’888 patent were also found invalid for obviousness and, as to one asserted claim, indefiniteness. On April 9, 2015, the Court entered Judgment holding, *inter alia*, that: (a) Claims 5, 7, 23, and 24 of the ’888 patent are invalid; and (b) Amneal’s counterclaim for declaratory judgment for non-infringement of claims 5, 7, 23, and 24 is denied.

62. 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 Amneal I 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").

63. Purdue did not have a full and fair opportunity to litigate the validity of the '888 patent before Judge Stein. *See id.* Therefore, to give collateral estoppel effect to Judge Stein's holding of invalidity of claims 5, 7, 23, and 24 of the '888 patent would be contrary to "justice and equity" as stated by the Supreme Court in *Blonder-Tongue*.

64. On May 8, 2015, Purdue filed a notice of appeal of the Southern District of New York's judgment of invalidity in the *Amneal I* case to the Federal Circuit.

65. On December 23, 2015, Purdue filed its Reply brief to the Federal Circuit.

THE '741 PATENT

66. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '741 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '741 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '741 patent is attached hereto as Exhibit G, which was duly and legally issued on August 19, 2014, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '987 PATENT

67. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of

all right, title, and interest in the '987 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '987 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '987 patent is attached hereto as Exhibit H, which was duly and legally issued on November 25, 2014, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '988 PATENT

68. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '988 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '988 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '988 patent is attached hereto as Exhibit I, which was duly and legally issued on November 25, 2014, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '976 PATENT

69. 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 J, was duly and legally issued on June 23, 2015, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

THE '933 PATENT

70. 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 K, 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.

DEFENDANTS' ANDA

71. On information and belief, on or before December 7, 2015, Defendants filed Defendants' ANDA in the name of Defendants with the FDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

72. On information and belief, Defendants subsequently submitted in their ANDA a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and '933 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale or importation of" the drug products described in Defendants' ANDA.

73. In a letter dated December 7, 2015, addressed to Plaintiffs and

received by Purdue Pharma on or about December 8, 2015, Defendant KVK, acting as Defendant Abhai's U.S. Agent, provided on behalf of both Defendants what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

74. In the Notice Letter, Defendants offered confidential access to portions of Defendants' ANDA on terms and conditions set forth in Exhibit B of the Notice Letter ("Defendants' Offer"). Plaintiffs accepted Defendants' Offer, and received only extensively redacted ANDA materials, effectively barring Plaintiffs from access to Defendants' respective roles in the preparation and submission of Defendants' ANDA. On information and belief, Plaintiffs have reason to believe that the redactions may relate to the role of KVK in the submission of Defendants' ANDA and the manufacturing, marketing, and sale of Defendants' ANDA products.

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

76. Plaintiffs commenced this action within the 45 day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 7,674,799)

77. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 76 above as though fully restated herein.

78. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of

infringement of the ’799 patent by Defendants.

79. Defendants’ ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’799 patent, including but not limited to independent claims 1-3, which recite, *inter alia*, an oral dosage form comprising from about 5 mg to about 320 mg of oxycodone hydrochloride having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone, and various claims that depend therefrom.

80. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of Defendants’ ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’799 patent under 35 U.S.C. § 271(a)-(c).

81. Defendants’ ANDA Products constitute a material part of the inventions covered by the claims of the ’799 patent.

82. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants’ infringement of the ’799 patent. Purdue and Rhodes do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 7,674,800)

83. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 82 above as though fully restated herein.

84. Pursuant to 35 U.S.C. § 271(e)(2), Defendants’ submission of ANDA No. 207493 to the FDA seeking approval of Defendants’ ANDA Products was an act of infringement of the ’800 patent by Defendants.

85. On information and belief, Defendants’ ANDA Products, or the use

or manufacture thereof, are covered by one or more claims of the ’800 patent, including but not limited to independent claims 1 and 57, which recite, *inter alia*, a process for preparing an oxycodone salt substantially free of 14-hydroxycodeinone, and various claims dependent therefrom, and independent claim 38, which recites, *inter alia*, an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone prepared by the claimed process, and various claims dependent therefrom.

86. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of Defendants’ ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’800 patent under 35 U.S.C. § 271(a)-(c).

87. Defendants’ ANDA Products constitute a material part of the inventions covered by the claims of the ’800 patent.

88. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants’ infringement of the ’800 patent. Purdue and Rhodes do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 7,683,072)

89. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 88 above as though fully restated herein.

90. Pursuant to 35 U.S.C. § 271(e)(2), Defendants’ submission of ANDA No. 207493 to the FDA seeking approval of Defendants’ ANDA Products was an act of infringement of the ’072 patent by Defendants.

91. Defendants’ ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’072 patent, including but not limited to independent claim

1, which recites oxycodone hydrochloride having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone, and various claims dependent therefrom.

92. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '072 patent under 35 U.S.C. § 271(a)-(c).

93. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '072 patent.

94. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '072 patent. Purdue and Rhodes do not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,114,383)

95. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 95 above as though fully restated herein.

96. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '383 patent by Defendants.

97. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '383 patent, including but not limited to independent claim 1, which recites, *inter alia*, a dosage form comprising an active ingredient with abuse potential, at least 60% by weight of polyalkylene oxide having a molecular weight of 1-15 million, wherein the dosage form has a breaking strength of at least 500 N; dependent claim 5, which recites, *inter*

alia, a process for the production of a dosage form according to claim 1 comprising mixing and pressing the components to yield the dosage forms with exposure to heat; and various claims dependent therefrom.

98. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '383 patent under 35 U.S.C. § 271(a)-(c).

99. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '383 patent.

100. Unless Defendants are enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendants' infringement of the '383 patent. Grünenthal and Purdue Pharma do not have an adequate remedy at law.

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

101. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 100 above as though fully restated herein.

102. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '060 patent by Defendants.

103. Defendants' 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, and various

claims dependent therefrom; dependent claim 25, which recites, *inter alia*, a process for production of the dosage form of claim 1 comprising mixing and pressing the components to yield the dosage form with exposure to heat, and various claims dependent therefrom; and dependent claim 28, which recites a method of treating a therapeutic condition in a patient comprising administering a dosage form according to claim 1, and various claims dependent therefrom.

104. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '060 patent under 35 U.S.C. § 271(a)-(c).

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

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

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

108. The administration of Defendants' 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.

109. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a manner that will directly infringe one or more claims of the '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.

110. If Defendants' ANDA 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.

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

112. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '060 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '060 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

113. 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.

SIXTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,337,888)

114. Purdue incorporates by reference and realleges paragraphs 1 through 113 above as though fully restated herein.

115. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '888 patent by Defendants.

116. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '888 patent, including but not limited to independent claim 1, which recites, *inter alia*, a controlled release oral dosage form providing a therapeutic effect for at least about 12 hours, comprising from about 2.5 mg to about 320 mg oxycodone and a gelling agent comprising polyethylene oxide to impart a viscosity of at least about 10 cP when subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid, and various claims dependent therefrom.

117. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '888 patent under 35 U.S.C. § 271(a)-(c).

118. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '888 patent.

119. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '888 patent. Purdue does not have an adequate remedy at law.

SEVENTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,808,741)

120. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference

and reallege paragraphs 1 through 119 above as though fully restated herein.

121. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '741 patent by Defendants.

122. Defendants' ANDA Products, or the use thereof, are covered by one or more claims of the '741 patent, including but not limited to independent claims 1, 6, and 17, which recite *inter alia*, a method of treating pain comprising administering to a patient a convection cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 4,000,000 and oxycodone, and various claims dependent therefrom.

123. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '741 patent under 35 U.S.C. § 271(a)-(c).

124. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '741 patent.

125. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '741 patent.

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

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

claims of the ’741 patent.

128. Defendants’ proposed label for Defendants’ ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants’ ANDA Products in a manner that will directly infringe one or more claims of the ’741 patent, including but not limited to independent claims 1, 6, and 17, which recite *inter alia*, a method of treating pain comprising administering to a patient a convection cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 4,000,000 and oxycodone, and various claims dependent therefrom. 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.

129. If Defendants’ ANDA 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 ’741 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 ’741 patent.

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

131. If Defendants’ ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants’ proposed label, to use Defendants’ ANDA Products in a manner that directly infringes one or more claims of the ’741 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the ’741 patent, and Defendants will

affirmatively and specifically intend to cause direct infringement.

132. Upon information and belief, Defendants have been aware of the existence of the ’741 patent, and have no reasonable basis for believing that Defendants’ ANDA Products will not infringe the ’741 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

133. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants’ infringement of the ’741 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

EIGHTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,894,987)

134. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 133 above as though fully restated herein.

135. Pursuant to 35 U.S.C. § 271(e)(2), Defendants’ submission of ANDA No. 207493 to the FDA seeking approval of Defendants’ ANDA Products was an act of infringement of the ’987 patent by Defendants.

136. Defendants’ ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’987 patent, including but not limited to independent claims 1, 38, and 60, which recite, *inter alia*, a process for preparing a dosage form combining oxycodone hydrochloride with PEO having a molecular weight of approximately 4,000,000, wherein the flattened cured shaped tablet has a particular in-vitro dissolution release profile, and various claims dependent therefrom.

137. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of Defendants’ ANDA Products will infringe, contribute

to the infringement of, and/or induce the infringement of one or more claims of the ’987 patent under 35 U.S.C. § 271(a)-(c).

138. Defendants’ ANDA Products constitute a material part of the inventions covered by the claims of the ’987 patent.

139. Upon information and belief, Defendants have been aware of the existence of the ’987 patent, and have no reasonable basis for believing that Defendants’ ANDA Products will not infringe the ’987 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

140. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants’ infringement of the ’987 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

NINTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,894,988)

141. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 140 above as though fully restated herein.

142. Pursuant to 35 U.S.C. § 271(e)(2), Defendants’ submission of ANDA No. 207493 to the FDA seeking approval of Defendants’ ANDA Products was an act of infringement of the ’988 patent by Defendants.

143. Defendants’ ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’988 patent, including but not limited to independent claims 1 and 6, which recite *inter alia*, a cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 4,000,000 and oxycodone, and various claims dependent therefrom.

144. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '988 patent under 35 U.S.C. § 271(a)-(c).

145. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '988 patent.

146. Upon information and belief, Defendants have been aware of the existence of the '988 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '988 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

147. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '988 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

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

148. Purdue incorporates by reference and realleges paragraphs 1 through 147 above as though fully restated herein.

149. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '976 patent by Defendants.

150. Defendants' 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 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.

151. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(a)-(c).

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

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

154. 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.

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

155. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 154 above as though fully restated herein.

156. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '933 patent by Defendants.

157. Defendants' 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

claims 1 and 16, which recite, *inter alia*, an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

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

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

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

161. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and '933 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendants' ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and '933 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any

approval of ANDA No. 207493 and Defendants' ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976 and '933 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 ANDA No. 207493, including Defendants' ANDA Products or any other drug product that infringes the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and '933 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.

Date: January 20, 2016

TRIAL COUNSEL:

Paul C. Huck, Jr.
Florida Bar #968358
JONES DAY
600 Brickelly Avenue
Miami, FL 33131
(305) 714-9727
paulhuck@jonesday.com

Attorneys for Plaintiffs

OF COUNSEL:

John J. Normile
Gasper J. LaRosa
Kenneth S. Canfield
Lisamarie LoGiudice
Sarah A. Geers
JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3777

Jason G. Winchester
JONES DAY
77 W. Wacker Drive
Chicago, IL 60601

Attorneys for Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., and Rhodes Technologies

Basil J. Lewris
Jennifer H. Roscetti
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiff Grünenthal GmbH