IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

PURDUE PHARMA L.P. and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	
v.	)	Case No. 5:24-cv-284-FL
ACCORD HEALTHCARE INC,	)	
Defendant.	)	

ACCORD HEALTHCARE, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PURDUE'S FIRST AMENDED COMPLAINT

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. 11,826,472 ("the '472 patent"), 11,904,055 ("the '055 patent"), 11,938,225 ("the '225 patent"), 11,964,056 ("the '056 patent") and 12,246,094 ("the '094 patent") (collectively, "the patents-in-suit"), attached as Exhibits A-E.

ANSWER: Accord Healthcare, Inc. ("Accord") admits that Plaintiffs purport to bring this action for alleged infringement of the '472, '055, '225,'056, and '094 patents under the patent laws of the United States, Title 35, United States Code. Accord denies any remaining allegations in this paragraph.

2. This action relates to Abbreviated New Drug Application ("ANDA") No. 213564 submitted upon information and belief in the name of Defendant to the United States Food and Drug Administration ("FDA").

ANSWER: Accord admits that it submitted ANDA No. 213564 in the name of Accord Healthcare, Inc. Accord denies any remaining allegations in this paragraph.

3. Plaintiffs seek judgment that Defendant has infringed the patents-in-suit. Defendant have infringed the patents-in-suit at least under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 213564, submitted upon information and belief in the name of Defendants to the FDA.

ANSWER: Accord admits that it filed ANDA No. 213564 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to market oxycodone hydrochloride tablets. Accord denies any remaining allegations in this paragraph.

4. Purdue's OxyContin® is the subject of approved New Drug Application ("NDA") No. 022272.

ANSWER: Accord admits that Purdue's OxyContin® is the subject of approved NDA No. 022272. Accord denies any remaining allegations in this paragraph.

5. Defendant's ANDA seeks approval to market a generic version of OxyContin® in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendant's ANDA Products") prior to expiration of the patents-in-suit.

ANSWER: Admitted.

6. On October 8, 2020, Plaintiffs filed a related Complaint against Defendants, C.A. No. 20-01362-RGA (D. Del.) ("*Purdue v. Accord I*"), for infringement of United States Patent Nos. 9,763,933 ("the Mannion '933 patent"); 9,775,808 ("the '808 patent"); 9,763,886 ("the '886 patent"); 9,073,933 ("the '933 patent"); 9,522,919 ("the '919 patent"); and 10,407,434 ("the '434 patent).

ANSWER: Accord admits that Plaintiffs filed a Complaint in C.A. No. 20-1362-RGA, on October 8, 2020 asserting the identified patents. Accord denies any remaining allegations in this paragraph.

7. *Purdue v. Accord I* was filed in connection with Defendant's ANDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the Mannion '933, '808, '933, '919 and '434 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 products described in Defendant's ANDA. The '886 patent is not an Orange Book-listed patent.

ANSWER: Accord admits that Accord Healthcare, Inc. filed ANDA No. 213564 with a Paragraph IV certification with respect to the Mannion '933, '808, '933, '919 and '434 patents. Accord admits that the Mannion '933, '808, '933, '919 and '434 patents are listed in the Orange Book as associated with NDA No. 022272. Accord admits that the '886 patent is not listed in the Orange Book. Accord denies any remaining allegations in this paragraph.

8. On April 11, 2023, Judge Richard G. Andrews found claim 3 of the Mannion '933 patent, claim 3 of the '808 patent, claim 6 of the '886 patent, claims 3 and 11 of the '933 patent, and claim 21 of the '919 patent invalid for obviousness under 35U.S.C. § 103.

ANSWER: Admitted.

9. Purdue appealed Judge Andrews' decision in *Purdue v. Accord I* to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"). *See Purdue Pharma L.P. v. Accord Healthcare, Inc.*, No. 23-1953 (Fed. Cir.). On December 30, 2024, the Federal Circuit affirmed Judge Andrews' decision. Purdue's deadline to file a petition for writ of *certiorari* is currently April 30, 2025.

ANSWER: Admitted.

10. On July 8, 2022, Plaintiffs filed a related Complaint against Defendants, C.A. No. 22-00913-WCB (D. Del.) ("*Purdue v. Accord II*"), for infringement of United States Patent Nos. 11,304,908 ("the '908 patent") and 11,304,909 ("the '909 patent").

ANSWER: Accord admits that Plaintiffs filed a Complaint in C.A. No. 22-00913-WCB on July 8, 2022. Accord denies any remaining allegations in this paragraph.

11. *Purdue v. Accord II* was filed in connection with Defendant's ANDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '908 and '909 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 products described in Defendant's ANDA.

ANSWER: Accord admits that Accord Healthcare, Inc. filed ANDA No. 213564 with a Paragraph IV certification with respect to the '908 and '909 patents. Accord admits that the '908 and '909 patents are listed in the Orange Book as associated with NDA No. 022272. Accord denies any remaining allegations in this paragraph.

12. *Purdue v. Accord II* was originally assigned to Judge Andrews. On December 31, 2023, Judge Andrews took senior status and the case was reassigned to Judge William C. Bryson of the United States Court of Appeals for the Federal Circuit, who was sitting by designation. Judge Bryson held a two-day bench trial in February 2024. On September 9, 2024, Judge Bryson found claims 1, 10, 18, 23, 28, and 29 of the '908 patent invalid for obviousness under 35 U.S.C. § 103.

ANSWER: Admitted.

13. Purdue appealed Judge Bryson's decision in *Purdue v. Accord II* to the Federal Circuit. *See Purdue Pharma L.P. v. Accord Healthcare, Inc.*, No. 25-1060 (Fed. Cir.). Briefing is ongoing, and Purdue's reply brief is currently due May 14, 2025.

ANSWER: Accord admits Purdue appealed Judge Bryson's decision in *Accord II* regarding claim 18 only. Accord denies that Purdue appealed Judge Bryson's decision with regard to claims 1, 10, 23, 28 or 29.

THE PARTIES

14. 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. 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.

ANSWER: Accord admits that Purdue Pharma is the holder of approved NDA No. 022272. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

15. 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 International Boulevard W., Wilson, North Carolina 27893.

ANSWER: Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

16. Plaintiffs own the patents-in-suit, identified in paragraphs 31-34 below and attached hereto as Exhibits A-D.

ANSWER: Accord admits that Purdue Pharmaceuticals is an assignee of record for the patents-in-suit. Accord admits that Exhibits A-D purport to be copies of the patents-in-suit. Accord denies any remaining allegations in this paragraph.

17. On information and belief, Defendant Accord Healthcare Inc. ("Accord Healthcare") is a company organized and existing under the laws of the State of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617.

ANSWER: Admitted.

18. On information and belief, Defendant is a wholly owned subsidiary of Intas Pharmaceuticals Limited.

ANSWER: Admitted.

19. On information and belief, Defendant develops, manufactures, distributes 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.

ANSWER: Accord admits that it markets and distributes generic pharmaceutical products in the United States. Accord denies any remaining allegations in this paragraph.

SUBJECT MATTER JURISDICTION AND VENUE

20. 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.

ANSWER: Accord admits that Plaintiffs purport that 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. Accord denies any remaining allegations in this paragraph.

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

ANSWER: Paragraph 27 states a legal conclusion to which no answer is required. To the extent an answer is required, Accord admits that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. §§ 1331 and 1338(a). Accord denies any remaining allegations in this paragraph.

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

ANSWER: Paragraph 28 states a legal conclusion to which no answer is required. To the extent an answer is required, Accord does not contest venue in this proceeding. Accord denies any remaining allegations in this paragraph.

23. Venue is proper as to Defendant because it is incorporated in the State of North Carolina.

ANSWER: Accord admits that Accord Healthcare, Inc. is incorporated in the State of North Carolina. Accord denies any remaining allegations in this paragraph.

24. Venue is proper as to Defendant, because, on information and belief, Defendant has filed amendments to Defendant's ANDA from their place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617. Thus, Defendant has committed an act of infringement in, and also have a primary place of business in, the Eastern District of North Carolina.

ANSWER: Accord admits that Accord Healthcare, Inc. is incorporated in the State of North Carolina. Accord denies any remaining allegations in this paragraph.

PERSONAL JURISDICTION

25. Personal jurisdiction is proper as to Defendant because it is incorporated in the State of North Carolina.

ANSWER: Accord admits that Accord Healthcare, Inc. is incorporated in the State of North Carolina. Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

26. This Court also has personal jurisdiction over Defendant by virtue of, *inter alia,* its systematic and continuous contacts with North Carolina and contacts with North Carolina in connection with the submission of Defendant's ANDA, as set forth below.

ANSWER: Accord admits that Accord Healthcare, Inc. is incorporated in the State of North Carolina. Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

27. On information and belief, Defendant is in the business of preparing generic pharmaceuticals that they distribute in the State of North Carolina and throughout the United States.

ANSWER: Accord admits that it markets and distributes generic pharmaceutical products in the United States. Accord denies any remaining allegations in this paragraph.

28. On information and belief, if ANDA No. 213564 is approved, then Defendant's ANDA Products would, among other things, be marketed and distributed in North Carolina, and/or prescribed by physicians practicing and dispensed by pharmacies located within North Carolina, all of which would have a substantial effect on the State of North Carolina.

ANSWER: Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

29. This Court further has personal jurisdiction over Defendant because it has purposely availed itself of the benefits of North Carolina's laws such that it should reasonably anticipate being hauled into court here.

ANSWER: Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

30. It is not fundamentally unfair or unreasonable for Defendants to litigate this action in this District.

ANSWER: Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

31. Purdue is the lawful owner of all right, title and interest in the '472 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '472 patent is attached hereto as Exhibit A, which was duly and legally issued on November 28, 2023, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

ANSWER: Accord admits that the '472 patent is entitled "TAMPER RESISTANT DOSAGE FORMS." Accord admits that Exhibit A purports to be a copy of the '472 patent. Accord admits that the '472 patent lists William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

32. Purdue is the lawful owner of all right, title and interest in the '055 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '055 patent is attached hereto as Exhibit B, which was duly and legally issued on February 20, 2024, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

ANSWER: Accord admits that the ’055 patent is entitled “TAMPER RESISTANT DOSAGE FORMS.” Accord admits that Exhibit B purports to be a copy of the ’055 patent. Accord admits that the ’055 patent lists William H. McKenna, Richard O. Mannion, Edward P. O’Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

33. Purdue is the lawful owner of all right, title and interest in the ’225 patent, titled “TAMPER RESISTANT DOSAGE FORMS,” including the right to sue and to recover for past infringement thereof. A copy of the ’225 patent is attached hereto as Exhibit C, which was duly and legally issued on March 26, 2024, naming William H. McKenna, Richard O. Mannion, Edward P. O’Donnell, and Haiyong H. Huang as the inventors.

ANSWER: Accord admits that the ’225 patent is entitled “TAMPER RESISTANT DOSAGE FORMS.” Accord admits that Exhibit C purports to be a copy of the ’225 patent. Accord admits that the ’225 patent lists William H. McKenna, Richard O. Mannion, Edward P. O’Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

34. Purdue is the lawful owner of all right, title and interest in the ’056 patent, titled “TAMPER RESISTANT DOSAGE FORMS,” including the right to sue and to recover for past infringement thereof. A copy of the ’056 patent is attached hereto as Exhibit D, which was duly and legally issued on April 23, 2024, naming William H. McKenna, Richard O. Mannion, Edward P. O’Donnell, and Haiyong H. Huang as the inventors.

ANSWER: Accord admits that the ’056 patent is entitled “TAMPER RESISTANT DOSAGE FORMS.” Accord admits that Exhibit D purports to be a copy of the ’056 patent. Accord admits that the ’056 patent lists William H. McKenna, Richard O. Mannion, Edward P. O’Donnell, and

Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

35. Purdue is the lawful owner of all right, title and interest in the '094 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '094 patent is attached hereto as Exhibit E, which was duly and legally issued on April 23, 2024, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

ANSWER: Accord admits that the '094 patent is entitled "TAMPER RESISTANT DOSAGE FORMS." Accord admits that Exhibit E purports to be a copy of the '094 patent. Accord admits that the '094 patent lists William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

DEFENDANT'S ANDA

36. On information and belief, on or before August 25, 2020, Defendant filed Defendant's ANDA in the name of Defendant 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 Defendant's ANDA Products generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

ANSWER: Accord admits that it filed ANDA No. 213564 on or before August 25, 2020, in the name of Accord Healthcare, Inc., seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is OxyContin®, which is the subject of approved NDA No. 022272. Accord denies any remaining allegations in this paragraph.

37. In a letter dated August 25, 2020, addressed to Plaintiffs and received by Purdue Pharma on or about August 26, 2020, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's ANDA and Defendant's ANDA Products, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

ANSWER: Accord admits that Accord Healthcare, Inc. sent a letter dated August 25, 2020 to Plaintiffs providing a Notice of Paragraph IV Certification with respect to Accord's ANDA and the Mannion '933, '808, '933, '919 and '434 patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Accord denies any remaining allegations in this paragraph.

38. In a second letter dated May 26, 2022, addressed to Plaintiffs and received by Purdue Pharma on or about May 27, 2022, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's ANDA and Defendant's ANDA Products, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

ANSWER: Accord admits that Accord Healthcare, Inc. sent a letter dated May 26, 2022 to Plaintiffs providing a Notice of Paragraph IV Certification with respect to Accord's ANDA and the '908 and '909 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Accord denies any remaining allegations in this paragraph.

39. In a third letter dated August 28, 2024, addressed to Plaintiffs and received by Purdue Pharma on or about August 29, 2024, Defendant provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendant's ANDA and Defendant's ANDA Products, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

ANSWER: Accord admits that Accord Healthcare, Inc. sent a letter dated August 28, 2024 to Plaintiffs providing a Notice of Paragraph IV Certification with respect to Accord's ANDA and

the ’056 patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Accord denies any remaining allegations in this paragraph.

40. In a fourth letter dated March 25, 2025, addressed to Plaintiffs and received by Purdue Pharma on or about March 26, 2025, Defendant provided what purports to be a “Notice of Paragraph IV Certification” with respect to Defendant’s ANDA and Defendant’s ANDA Products, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

ANSWER: Accord admits that Accord Healthcare, Inc. sent a letter dated March 25, 2025 to Plaintiffs providing a Notice of Paragraph IV Certification with respect to Accord’s ANDA and the ’094 patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Accord denies any remaining allegations in this paragraph.

41. Defendant’s submission of Defendant’s ANDA is an act of infringement of the patents-in-suit under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

42. Defendant’s amendments to Defendant’s ANDA are also acts that infringe the patents-in-suit.

ANSWER: Denied.

43. Following USPTO issuance of the patents-in-suit, Plaintiffs commenced this action without unreasonable delay.

ANSWER: Denied.

FIRST CLAIM FOR RELIEF

(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,826,472)

44. Purdue incorporates by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

ANSWER: Accord incorporates its answers to each of the prior paragraphs.

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 213564 to the FDA seeking approval of Defendant's ANDA Products, including any amendments thereto was an act of infringement of the '472 patent by Defendants.

ANSWER: Denied.

46. On information and belief, Defendant's ANDA Products, or the use or manufacture thereof, are covered by independent claim 1 of the '472 patent and certain claims dependent therefrom. Independent claim 1 recites:

> A solid oral extended release dosage form, comprising:
> an extended release matrix comprising an active agent and polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 8 million Da based on rheological measurements, wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form,
>
> wherein the dosage form provides a dissolution rate, which when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C., is between 12.5 and 55% (by wt) active agent released after 1 hour, between 25 and 65% (by wt) active agent released after 2 hours, between 45 and 85% (by wt) active agent released after 4 hours and between 55 and 95% (by wt) active agent released after 6 hours,
>
> wherein the dosage form provides an in-vitro dissolution rate, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) comprising 40% ethanol at 37° C., characterized by the percent amount of active released at 0.5 hours, that deviates no more than about 20% points 0.5 hours from the corresponding in-vitro dissolution rate measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C. without ethanol,
>
> wherein the dosage form is cured at a curing temperature ranging from about 68° C. to about 85° C.,
>
> wherein the curing time is from about 30 minutes to about 4 hours,

wherein the dosage form is a tablet, wherein the dosage form when subjected to a maximum force of about 196 N or about 439 N in a tablet hardness test, does not break,

wherein the tablet when subjected to an indentation test resists a work of at least about 0.06 J without cracking,

wherein the active agent is an opioid analgesic,

wherein the opioid analgesic is oxycodone hydrochloride,

wherein the dosage form provides a mean tmax of oxycodone at about 2 to about 6 hours,

wherein the dosage form comprises from about 10 mg to about 160 mg oxycodone hydrochloride and wherein the dosage form provides a mean maximum plasma concentration (Cmax) of oxycodone from about 6 ng/mL to about 240 ng/mL,

wherein the oxycodone hydrochloride has a 14-hydroxycodeinone level of less than about 25 ppm,

wherein the extended release matrix further comprises a PEO having an approximate molecular weight of 100, 000 Da to 900,000 Da based on rheological measurements.

ANSWER: Denied.

47. If approved by the FDA, Defendant's commercial manufacture, use, sale, and/or offer for sale of Defendant's ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of the '472 patent under 35 U.S.C. § 271(a)-(c). Since at least the issue date of the '472 patent, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '472 patent.

ANSWER: Denied.

48. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '472 patent.

ANSWER: Denied.

49. Upon information and belief, Defendant knows that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '472 patent.

ANSWER: Denied.

50. Upon information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Defendant's ANDA Products.

ANSWER: Denied.

51. Defendant has been aware of the existence of the '472 patent and have no reasonable basis for believing that Defendant's ANDA Products will not infringe the '472 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

ANSWER: Denied.

52. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '472 patent. Purdue has no adequate remedy at law.

ANSWER: Denied.

SECOND CLAIM FOR RELIEF

(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,904,055)

53. Purdue incorporates by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

ANSWER: Accord incorporates its answers to each of the prior paragraphs.

54. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 213564 to the FDA seeking approval of Defendant's ANDA Products, including any amendments thereto,

was an act of infringement of the ’055 patent by Defendants.

ANSWER: Denied.

55. On information and belief, the process for making Defendant’s ANDA Products, is covered by the independent claim of the ’055 patent and certain dependent claims therefrom. Independent claim 1 recites:

> A process of preparing a solid oral extended release pharmaceutical dosage form, comprising:
>
> combining: (1) polyethylene oxide, and (2) oxycodone hydrochloride, to form a composition;
>
> shaping the composition to form an extended release matrix formulation; and
>
> curing said extended release matrix formulation at a temperature ranging from about 68° C. to about 85° C. for about 30 minutes to about 4 hours, to form the dosage form,
>
> wherein the extended release matrix comprises:
>
> from about 10 mg to about 160 mg oxycodone hydro- chloride; a polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 8 million Da based on rheological measurements; and
>
> a PEO having an approximate molecular weight of 100,000 Da to 900,000 Da based on rheological measurements,
>
> wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form,
>
> wherein the dosage form provides a dissolution rate, which when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C., is between 12.5 and 55% (by wt) active agent released after 1 hour, between 25 and 65% (by wt) active agent released after 2 hours, between 45 and 85% (by wt) active agent released after 4 hours and between 55 and 95% (by wt) active agent released after 6 hours,
>
> wherein the dosage form provides an in-vitro dissolution rate,

> when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF)comprising 40% ethanol at 37° C., characterized by the percent amount of active released at 0.5 hours, that deviates no more than about 20% points 0.5 hours from the corresponding in-vitro dissolution rate measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C. without ethanol,
>
> wherein the dosage form is a tablet,
>
> wherein the dosage form when subjected to a maximum force of about 196 N or about 439 N in a tablet hardness test, does not break,
>
> wherein the tablet when subjected to an indentation test resists a work of at least about 0.06J without cracking,
>
> wherein the dosage form provides a mean tmax of oxycodone at about 2 to about 6 hours,
>
> wherein the administration of the dosage form provides a mean maximum plasma concentration (Cmax) of oxycodone from about 6 ng/mL to about 240 ng/mL, and
>
> wherein the oxycodone hydrochloride has a 14-hydroxy-codeinone level of less than about 25 ppm.

ANSWER: Denied.

56. If approved by the FDA, Defendant's importation, offer for sale, sale, and/or use of Defendant's ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of the '055 patent under 35 U.S.C. § 271(a)-(c), and/or (g). Since at least the issue date of the '055 patent, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '055 patent.

ANSWER: Denied.

57. Defendant, through at least its labeling and manufacturing process, will intentionally induce infringement of the ’055 patent by at least patients who will take Defendant’s NDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendant’s NDA Products.

ANSWER: Denied.

58. Defendant’s ANDA Products constitute a material part of the inventions covered by the claims of the ’055 patent.

ANSWER: Denied.

59. Upon information and belief, Defendant knows that Defendant’s ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the ’472 patent.

ANSWER: Denied.

60. Upon information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Defendant’s ANDA Products.

ANSWER: Denied.

61. Upon information and belief, Defendant has been aware of the existence of the ’055 patent and has no reasonable basis for believing that Defendant’s ANDA Products will not infringe the ’055 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

ANSWER: Denied.

62. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant’s infringement of the ’055 patent. Purdue has no adequate remedy at law.

ANSWER: Denied.

THIRD CLAIM FOR RELIEF

(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,938,225)

63. Purdue incorporates by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

ANSWER: Accord incorporates its answers to each of the prior paragraphs.

64. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 213564 to the FDA seeking approval of Defendant's ANDA Products, including any amendments thereto, was an act of infringement of the '225 patent by Defendants.

ANSWER: Denied.

65. On information and belief, Defendant's ANDA Products, or the use thereof, are covered by the independent claim of the '225 patent and certain dependent claims therefrom. Independent claim 1 recites:

> A method of treating pain comprising orally administering to a patient in need thereof a solid oral extended release dosage form comprising:
>
> an extended release matrix comprising from about 10 mg to about 160 mg oxycodone hydrochloride;
>
> a polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 8 million Da based on rheological measurements; and
>
> a PEO having an approximate molecular weight of 100,000 Da to 900,000 Da based on rheological measurements,
>
> wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form,
>
> wherein the dosage form provides a dissolution rate, which when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C, is between 12.5 and 55% (by wt) active agent released after 1 hour, between 25 and 65% (by wt) active agent released after 2 hours,

between 45 and 85% (by wt) active agent released after 4 hours and between 55 and 95% (by wt) active agent released after 6 hours,

wherein the dosage form provides an in-vitro dissolution rate, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) comprising 40% ethanol at 37° C, characterized by the percent amount of active released at 0.5 hours, that deviates no more than about 20% points 0.5 hours from the corresponding in-vitro dissolution rate measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C without ethanol,

wherein the dosage form is cured at a curing temperature ranging from about 68° C to about 85° C,

wherein the curing time is from about 30 minutes to about 4 hours, wherein the dosage form is a tablet,

wherein the dosage form when subjected to a maximum force of about 196 N or about 439 N in a tablet hardness test, does not break,

wherein the tablet when subjected to an indentation test resists a work of at least about 0.06 J without cracking,

wherein the dosage form provides a mean t*max* of oxycodone at about 2 to about 6 hours,

wherein the administration of the dosage form provides a mean maximum plasma concentration (C*max*) of oxycodone from about 6 ng/mL to about 240 ng/mL, and

wherein the oxycodone hydrochloride has a 14-hydroxycodeinone level of less than about 25 ppm.

ANSWER: Denied.

66. The administration 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 '255 patent.

ANSWER: Denied.

67. Defendant's proposed label for Defendant's ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendant's ANDA Products in a manner that will directly infringe one or more claims of the '225 patent.

ANSWER: Denied.

68. Defendants, through at least their labeling and manufacturing process, will intentionally induce infringement of the '225 patent by at least patients who will take Defendant's NDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendant's NDA Products.

ANSWER: Denied.

69. If approved by the FDA, Defendant's importation, offer for sale, sale, and/or use of Defendant's ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of the '225 patent under 35 U.S.C. § 271(a)-(c), and/or (g).

ANSWER: Denied.

70. Since at least the issue date of the '225 patent, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '225 patent.

ANSWER: Denied.

71. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '225 patent.

ANSWER: Denied.

72. Upon information and belief, Defendants know that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '225 patent.

ANSWER: Denied.

73. Upon information and belief, Defendant has had and continue to have knowledge that there is no substantial non-infringing use for Defendant's ANDA Products.

ANSWER: Denied.

74. The administration of Defendant's ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '225 patent, including but not limited to independent claim 1 recited above.

ANSWER: Denied.

75. Defendant's proposed label for Defendant's ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendant's ANDA Products in a manner that will directly infringe one or more claims of the '225 patent.

ANSWER: Denied.

76. If Defendant's 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 '225 patent. Since at least the date of the Notice Letter, Defendant has acted with knowledge, or at least with willful blindness, that the induced acts would constitute infringement of the '225 patent.

ANSWER: Denied.

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

ANSWER: Denied.

78. If Defendant's 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 Defendant's proposed label, to use Defendant's ANDA Products in a manner that directly infringes one or more claims of the '225 patent. hus, Defendants will aid, abet, urge, or encourage others, including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '225 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

ANSWER: Denied.

79. Upon information and belief, Defendant has been aware of the existence of the '225 patent and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '225 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

ANSWER: Denied.

80. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant's infringement of the '225 patent. Purdue has no adequate remedy at law.

ANSWER: Denied.

FOURTH CLAIM FOR RELIEF

(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,964,056)

81. Purdue incorporates by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

ANSWER: Accord incorporates its answers to each of the prior paragraphs.

82. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 213564 to the FDA seeking approval of Defendant's ANDA Products, including amendments thereto, was an act of infringement of the '056 patent by Defendants.

ANSWER: Denied.

83. On information and belief, Defendant's ANDA Products, or the use or manufacture thereof, are covered by independent claim 1 of the '056 patent and certain dependent claims therefrom. Independent claim 1 recites:

> A solid oral extended release dosage form, comprising:
>
> an extended release matrix comprising an active agent, magnesium stearate, butylated hydroxytoluene and polyethylene oxide (PEO) having an approximate molecular weight of 1 million Dato 15 million Da based on rheological measurements,
>
> wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form, a film coat overcoated on the extended release matrix,
>
> wherein the dosage form provides a dissolution rate, which when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C, is between 12.5 and 55% (by wt) active agent released after 1 hour, between 25 and 65% (by wt) active agent released after 2 hours, between 45 and 85% (by wt) active agent released after 4 hours and between 55 and 95% (by wt) active agent released after 6 hours, and
>
> wherein the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.0% as determined by Archimedes Principle using a liquid of known density (po).

ANSWER: Denied.

84. On information and belief, Defendant's ANDA Products, or the use or manufacture thereof, are covered by independent claim 19 of the '056 patent. Independent Claim 19 recites:

> A solid oral extended release dosage form comprising: (i) an extended release matrix comprising from about 10 mg to about 160 mg oxycodone hydrochloride, magnesium stearate, butylated hydroxytoluene and polyethylene oxide (PEO) having an approximate molecular weight of 1 million Dato 15 million Da based on rheological measurements,
>
> wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form and (ii) a film coat overcoated on the extended release matrix; wherein the dosage form provides a

> mean maximum plasma concentration (C*max*) of oxycodone from about 6 ng/mL to about 240 ng/mL and
>
> wherein the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.0% as determined by Archimedes Principle using a liquid of known density (po).

ANSWER: Denied.

85. On information and belief, Defendant's ANDA Products, or the use or manufacture thereof, are covered by independent claim 20 of the '056 patent. Independent Claim 20 recites:

> A solid oral extended release dosage form comprising: (i) an extended release matrix comprising oxycodone hydrochloride, magnesium stearate, butylated hydroxytoluene and polyethylene oxide (PEO) having an approximate molecular weight of 1 million Dato 15 million Da based on rheological measurements and (ii) a film coat overcoated on the extended release matrix;
>
> wherein the dosage form provides an in-vitro dissolution rate, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) comprising 40% ethanol at 37° C, characterized by the percent amount of oxycodone hydrochloride released at 0.5 hours, that deviates no more than about 20% points 0.5 hours from the corresponding in-vitro dissolution rate measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C without ethanol and
>
> wherein the dosage form is expanded upon curing, as measured by a decrease in density of at least about 1.0% as determined by Archimedes Principle using a liquid of known density (po).

ANSWER: Denied.

86. If approved by the FDA, Defendant's commercial manufacture, use, importation, sale, and/or offer for sale of Defendant's ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of the '056 patent under 35 U.S.C. § 271(a)-(c). Since at least the issue date of the '056 patent, Defendant has acted with knowledge,

or at least with willful blindness of the fact, that the induced acts would constitute infringement of the ’056 patent.

ANSWER: Denied.

87. Upon information and belief, Defendant knows that Defendant’s ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the ’056 patent.

ANSWER: Denied.

88. Upon information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Defendant’s ANDA Products.

ANSWER: Denied.

89. Defendant’s ANDA Products constitute a material part of the inventions covered by the claims of the ’056 patent.

ANSWER: Denied.

90. Upon information and belief, Defendant has been aware of the existence of the ’056 patent and has no reasonable basis for believing that Defendant’s ANDA Products will not infringe the ’056 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

ANSWER: Denied.

91. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendant’s infringement of the ’056 patent. Purdue has no adequate remedy at law.

ANSWER: Denied.

FIFTH CLAIM FOR RELIEF

(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,246,094)

92. Purdue incorporates by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

ANSWER: Accord incorporates its answers to each of the prior paragraphs.

93. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 213564 to the FDA seeking approval of Defendant's ANDA Products, including any amendments thereto was an act of infringement of the '094 patent by Defendant.

ANSWER: Denied.

94. On information and belief, Defendant's ANDA Products, or the use or manufacture thereof, are covered by independent claims 17-19 of the '094 patent.

Independent claims 17-19 recite:

> 17. A solid oral extended release dosage form comprising: an extended release matrix comprising from about 10 mg to about 160 mg oxycodone hydrochloride, magnesium stearate and polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 15 million Da based on rheological measurements, wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form; wherein the dosage form provides a mean maximum plasma concentration (Cmax) of oxycodone from about 6 ng/ml to about 240 ng/ml and wherein the density of the extended release matrix is equal to or less than about 1.20 g/cm3 as determined by Archimedes Principle using a liquid of known density (ρ0); wherein the extended release matrix is shaped to form a tablet and convection heated in a coating pan for a time period of at least about 5 minutes at a temperature of at least about 60° C. and thereafter cooled.
> 18. A solid oral extended release dosage form comprising: an extended release matrix comprising oxycodone hydrochloride, magnesium stearate and polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 15 million Da based on rheological measurements; wherein the dosage form provides an in-vitro dissolution rate, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) comprising 40% ethanol at 37° C., characterized by the percent amount of oxycodone hydrochloride released at 0.5 hours, that deviates no more than about 20% points 0.5 hours from the corresponding in-vitro dissolution rate measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C. without

ethanol and wherein the density of the extended release matrix is equal to or less than about 1.20 g/cm3 as determined by Archimedes Principle using a liquid of known density (ρ0); wherein the extended release matrix is shaped to form a tablet and convection heated in a coating pan for a time period of at least about 5 minutes at a temperature of at least about 60° C. and thereafter cooled.

19. A solid oral extended release dosage form, comprising: a shaped extended release matrix comprising oxycodone hydrochloride, magnesium stearate and polyethylene oxide (PEO) having an approximate molecular weight of 2 million Da to 15 million Da based on rheological measurements, wherein the PEO comprises at least about 30% (by weight) of the total weight of the dosage form, wherein the extended release matrix is shaped to form a tablet and convection heated in a coating pan for a time period of at least about 5 minutes at a temperature of at least about 60° C. and thereafter cooled, wherein the dosage form provides a dissolution rate, which when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C., is between 12.5 and 55% (by wt) oxycodone hydrochloride released after 1 hour, between 25 and 65% (by wt) oxycodone hydrochloride released after 2 hours, between 45 and 85% (by wt) oxycodone hydrochloride released after 4 hours and between 55 and 95% (by wt) oxycodone hydrochloride released after 6 hours, and wherein the density of the extended release matrix is equal to or less than about 1.20 g/cm3 as determined by Archimedes Principle using a liquid of known density (ρ0).

ANSWER: Denied.

95. If approved by the FDA, Defendant's commercial manufacture, use, sale, and/or offer for sale of Defendant's ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of the '094 patent under 35 U.S.C. § 271(a)-(c). Since at least the issue date of the '094 patent, Defendant has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '094 patent.

ANSWER: Denied.

96. Defendant's ANDA Products constitute a material part of the inventions covered by the claims of the '094 patent.

ANSWER: Denied

97. Upon information and belief, Defendant knows that Defendant's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '094 patent.

ANSWER: Denied

98. Upon information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Defendant's ANDA Products.

ANSWER: Denied

99. Defendant has been aware of the existence of the '094 patent and has no reasonable basis for believing that Defendant's ANDA Products will not infringe the '094 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

ANSWER: Denied

100. Unless Defendant is enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '094 patent. Purdue has no adequate remedy at law.

ANSWER: Denied

RESPONSE TO PRAYER FOR RELIEF

Accord denies that Plaintiffs are entitled to any relief described in the section of the Complaint entitled "Prayer for Relief," and deny that Plaintiffs are entitled to any relief whatsoever. Accord further denies any allegation in the Complaint not specifically admitted above.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The claims of the '472 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq.

SECOND AFFIRMATIVE DEFENSE

The claims of the '055 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq.

THIRD AFFIRMATIVE DEFENSE

The claims of the '225 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq.

FOURTH AFFIRMATIVE DEFENSE

The claims of the '056 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated May 28, 2024.

FIFTH AFFIRMATIVE DEFENSE

The claims of the '094 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated March 25, 2025.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

SEVENTH AFFIRMATIVE DEFENSE

(Res Judicata and/or Collateral Estoppel)

Plaintiffs' claims, and issues relating to those claims, are barred as a result of adjudications on the merits of other judicial proceedings including *Accord I* and *Accord II*.

EIGHT AFFIRMATIVE DEFENSE

Plaintiffs' patent infringement claims are barred in whole or in part under the doctrine of prosecution laches.

As described below, on information and belief, Plaintiffs engaged in an unreasonable and undue delay in the prosecution of the Asserted Patents, which has prejudiced Accord. Thus, as a matter of equity, the Asserted Patents cannot be enforced against Accord.

RESERVATION OF DEFENSES

Accord reserves the right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

Pursuant to Fed. R. Civ. P. 13, for its counterclaims against Plaintiffs Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, "Purdue" or "Plaintiffs"), Defendant Accord Healthcare, Inc. ("Accord") states as follows:

1. This Counterclaim for declaratory relief arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
2. The Court has subject matter jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338.
3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).
4. Upon information and belief, 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.

5. Upon information and belief, 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.

6. The present civil action is Plaintiffs' third action against Accord for infringement of patent claims of patents that claim priority through a series of continuations to the ultimate parent application, U.S. application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No. 8,894,987.

7. Plaintiff is holder of New Drug Application ("NDA") No. 022272 that was approved on April 5, 2010.

8. NDA 022272 is directed to Plaintiffs' OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication.

9. On October 4, 2017, Plaintiff submitted U.S. Patent No. 9,775,808 (the '808 patent) for inclusion in the Orange Book listing for NDA No. 022272.

10. On September 19, 2017, Plaintiff submitted U.S. Patent No. 9,763,933 ("the '933 patent") for inclusion in the Orange Book listing for NDA No. 022272.

11. On August 25, 2020, Accord filed Abbreviated New Drug Application ("ANDA") No. 213564 with the FDA seeking approval to market a generic version of Purdue's OxyContin.

12. Based on the filing of ANDA No. 213564, on October 8, 2020, Plaintiffs sued Accord in the District Court of Delaware for infringement of, *inter alia*, patent claims from the

’933 patent and the ’808 patent under 35 U.S.C. § 271(e)(2)(A), hereinafter, the “*Purdue v. Accord I*” case.

13. After a three-day bench trial held from September 19 to September 21, 2022, on April 11, 2023, Judge Andrews issued a trial opinion finding all asserted claims in the *Purdue v. Accord I* case invalid as obvious.

14. Judge Andrews entered final judgement in the *Purdue v. Accord I* case on April 26, 2023.

15. On September 21, 2020, Plaintiffs filed U.S. Patent Applications 17/027,222 (“the 222 app.”) and 17/027,307 (“the 307 app”). These applications, through a series of continuations, claim priority to U.S. application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No. 8,894,987.

16. On April 19, 2022, the 222 app. issued as U.S. Patent No. 11,304,908 (“the ’908 patent”) and the 307 app. issued as U.S. Patent No. 11,304,909 (“the ’909 patent”).

17. On April 21, 2022, Plaintiff submitted the ’908 patent and the ’909 patent for inclusion in the Orange Book listing for NDA No. 022272.

18. Based on the filing of ANDA No. 213564, on July 8, 2022, Plaintiffs sued Accord, for the second time, in the District Court of Delaware for infringement of the ’908 patent and the ’909 patent under 35 U.S.C. § 271(e)(2)(A), hereinafter, the “*Purdue v. Accord II*” case.

19. Circuit Judge William C. Bryson, sitting by designation, held a two-day bench trial on February 12 and 13, 2024 in the *Purdue v. Accord II* case.

20. After the issuance of the patents asserted in the *Purdue v. Accord I* case and before the filing of the patent applications that resulted in the ’055 patent, the ’472 patent, the

’225 patent and the ’056 patent, Plaintiffs filed, prosecuted and abandoned five intervening continuation applications.

21. Plaintiffs filed U.S. Patent Application No. 15/597,885 on May 17, 2017.

22. U.S. Patent Application No. 15/597,885 went abandoned on February 22, 2018.

23. Plaintiffs filed U.S. Patent Application No. 15/885,074 on January 31, 2018.

24. U.S. Patent Application No. 15/885,074 went abandoned on April 25, 2019.

25. Plaintiffs filed U.S. Patent Application No. 16/386,963 on April 17, 2019.

26. U.S. Patent Application No. 16/386,963 went abandoned on December 31, 2019.

27. Plaintiffs filed U.S. Patent Application No. 16/697,855 on November 27, 2019.

28. U.S. Patent Application No. 16/697,855 went abandoned on August 18, 2020.

29. Plaintiffs filed U.S. Patent Application No. 16/931,803 on July 17, 2020.

30. U.S. Patent Application No. 16/931,803 went abandoned on July 2, 2022.

31. On August 22, 2022, Plaintiffs filed U.S. Patent Application 17/892,553 (“the 553 application”). The 553 application, through a series of continuations, claims priority to U.S. Application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No. 8,894,987. On February 20, 2024, the 553 application issued as U.S. Patent No. 11,904,055 (“the ’055 patent”).

32. U.S. Patent Application 17/892,553 is a child of U.S. Patent Application No. 16/931,803.

33. On May 5, 2023, Plaintiffs filed U.S. Patent Application 18/143,927 (“the 927 application”). The 927 application, through a series of continuations, claims priority to U.S. application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No.

8,894,987. On November 28, 2023, the 927 application issued as U.S. Patent No. 11,826,472 ("the '472 patent").

34. Plaintiffs requested the United States Patent Office prioritize examination of the 927 application as a track 1 application. The USPTO granted the request and prioritized examination of the 927 application.

35. U.S. Patent Application 18/143,927 is a child of U.S. Patent Application 17/892,553.

36. On June 5, 2023, Plaintiffs filed U.S. Patent Application 18/205,786 ("the 786 application"). The 786 application, through a series of continuations, claims priority to U.S. application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No. 8,894,987. On March 26, 2024, the 786 application issued as U.S. Patent No. 11,938,225 ("the '225 patent").

37. Plaintiffs requested the United States Patent Office prioritize examination of the 786 application as a track 1 application. The USPTO granted the request and prioritized examination of the 786 application.

38. U.S. Patent Application 18/205,786 is a child of U.S. Patent Application 18/143,927.

39. On September 27, 2023, Plaintiffs filed U.S. Patent Application 18/475,755 ("the 755 application"). The 755 application, through a series of continuations, claims priority to U.S. application No. 11/844,872, filed on Aug. 24, 2007, now U.S. Patent No. 8,894,987. On April 23, 2024, the 755 application issued as U.S. Patent No. 11,964,056 ("the '056 patent").

40. Plaintiffs requested the United States Patent Office prioritize examination of the 755 application as a track 1 application. The USPTO granted the request and prioritized examination of the 755 application.

41. U.S. Patent Application 18/475,755 is a child of U.S. Patent Application 18/205,786.

42. U.S. Patent Application No. 18/603,884 was filed on March 13, 2024. On March 11, 2025, the 884 application issued as U.S. Patent No. 12,246,094 ("the '094 patent").

43. Based on the filing of ANDA No. 213564, on May 21, 2024, Plaintiffs filed this suit against Accord for infringement of the '055 patent, the '472 patent, the '225 patent and the '056 patent under 35 U.S.C. § 271(e)(2)(A), hereinafter, the "*Purdue v. Accord III*" case.

44. The patent applications that resulted in the '055 patent, the '472 patent, the '225 patent and the '056 patent were filed during the pendency of the *Purdue v. Accord II* case.

45. The '055 patent, the '472 patent, the '225 patent, '056 patent and '094 patent will expire on August 24, 2027.

46. Plaintiffs have admitted that, starting in 2020 and continuing through to 2024 with the filing of the present civil action, they have filed three separate civil actions asserting a total of 12 patents against Accord. See Exhibit A.

47. The federal court management statistics published on the United States Courts website indicates that for the 12-month period ending in December 2023, the median time (months) from filing to trial of a civil case filed in the Eastern District of North Carolina district court was thirty-one months. *See* https://www.uscourts.gov/file/78409/download (last visited July 24, 2024).

48. Plaintiffs' delay in filing the patent applications that resulted in the '055 patent, the '472 patent, the '225 patent, '056 patent and the '094 patent was unreasonable and unjustified.

49. Defendant has been embroiled in multiplied litigation related to Plaintiffs' NDA longer than it otherwise would be because Plaintiffs delayed the filing of the patent applications with claims that resulted in the '055 patent, the '472 patent, the '225 patent, '056 patent, and the '094 patent, thereby multiplying the expenses to Accord.

50. Plaintiffs delayed the filing the patent applications that resulted in the '055 patent, the '472 patent, the '225 patent, the '056 patent, and the '094 patent to undermine the goals of the Hatch-Waxman Act.

51. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

52. Accord suffered prejudice attributable to Plaintiffs' delay in filing the patent applications that resulted in the '055 patent, the '472 patent, the '225 patent, the '056 patent, and the '094 patent.

COUNT I

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '055 PATENT DUE TO PROSECUTION LACHES

53. Accord restates, realleges, and incorporates by reference the allegations made in the Affirmative Defenses above and in Paragraphs 1-52 of this Counterclaim.

54. Plaintiffs' delay in filing the patent application that resulted in the '055 patent was unreasonable and unjustified.

55. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

56. Accord suffered prejudice attributable to Plaintiffs' delay in filing the patent applications that resulted in the '055 patent.

57. Prosecution laches renders the ’055 patent unenforceable.

COUNT II

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE ’472 PATENT DUE TO PROSECUTION LACHES

58. Accord restates, realleges, and incorporates by reference the allegations made in the Affirmative Defenses above and in Paragraphs 1-57 of this Counterclaim.

59. Plaintiffs’ delay in filing the patent application that resulted in the ’472 patent was unreasonable and unjustified.

60. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

61. Accord suffered prejudice attributable to Plaintiffs’ delay in filing the patent applications that resulted in the ’472 patent.

62. Prosecution laches renders the ’472 patent unenforceable.

COUNT III

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE ’225 PATENT DUE TO PROSECUTION LACHES

63. Accord restates, realleges, and incorporates by reference the allegations made in the Affirmative Defenses above and in Paragraphs 1-62 of this Counterclaim.

64. Plaintiffs’ delay in filing the patent application that resulted in the ’225 patent was unreasonable and unjustified.

65. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

66. Accord suffered prejudice attributable to Plaintiffs' delay in filing the patent applications that resulted in the '225 patent.

67. Prosecution laches renders the '225 patent unenforceable.

COUNT IV

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '056 PATENT DUE TO PROSECUTION LACHES

68. Defendant restates, realleges and incorporates by reference the allegations made in the Affirmative Defenses above and in Paragraphs 1-67 of this Counterclaim.

69. Plaintiffs' delay in filing the patent application that resulted in the '056 patent was unreasonable and unjustified.

70. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

71. Accord suffered prejudice attributable to Plaintiffs' delay in filing the patent applications that resulted in the '056 patent.

72. Prosecution laches renders the '056 patent unenforceable.

COUNT V

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '094 PATENT DUE TO PROSECUTION LACHES

73. Defendant restates, realleges and incorporates by reference the allegations made in the Affirmative Defenses above and in Paragraphs 1-72 of this Counterclaim.

74. Plaintiffs' delay in filing the patent application that resulted in the '094 patent was unreasonable and unjustified.

75. Prior to and after the filing of its ANDA, Accord invested in and continues to invest in developing a generic version of Oxycontin®.

76. Accord suffered prejudice attributable to Plaintiffs' delay in filing the patent applications that resulted in the '094 patent.

77. Prosecution laches renders the '094 patent unenforceable.

WHEREFORE, Defendant Accord Healthcare, Inc. respectfully prays the Court that:

1. Plaintiffs have and recover nothing of Defendant Accord;
2. Plaintiffs' prayer for relief be denied in its entirety;
3. Plaintiffs' Complaint be dismissed with prejudice;
4. The Court enter judgment declaring that the '055 patent is unenforceable;
5. The Court enter judgment declaring that the '472 patent is unenforceable;
6. The Court enter judgment declaring that the '225 patent is unenforceable;
7. The Court enter judgment declaring that the '056 patent is unenforceable;
8. The Court enter judgment declaring that the '094 patent is unenforceable;
9. The Court enter judgment declaring that the Plaintiffs shall file no further civil actions against Accord in connection with Accord's Abbreviated New Drug Application No. 213564;
10. The Court declare this case exceptional pursuant to 35 U.S.C. § 285 and award Accord its reasonable attorney's fees;
11. The costs of this action be taxed against Plaintiffs; and
12. Accord have such other and further relief as the Court shall deem just and proper.

Dated: May 16, 2025

/s/ William G. Pagán

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Local Civil Rule 83.1(d)
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CERTIFICATE OF SERVICE

I hereby certify that on this date I electronically filed the foregoing ACCORD HEALTHCARE, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PURDUE'S FIRST AMENDED COMPLAINT with the Clerk of Court using the CM/ECF system that will give notice of such filings to all attorneys currently of record in the above-captioned case.

This the 16th day of May, 2025.

By: /s/ William G. Pagán
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