IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P. and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACCORD HEALTHCARE INC. and ACCORD HEALTHCARE INC. USA,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, "Purdue" or "Plaintiffs"), for their Complaint against Defendants Accord Healthcare Inc. and Accord Healthcare Inc. USA (collectively, "Accord" or "Defendants"), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 11,304,908 ("the '908 patent") and 11,304,909 ("the '909 patent") (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213564 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 patents-in-suit, which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication. Defendants 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. 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").

3. On October 8, 2020, Plaintiffs filed a related Complaint against Defendants, C.A. No. 20-1362-RGA, 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). The previous action was also filed in connection with Defendants' 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 Defendants' ANDA.

THE PARTIES

4. 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 patents-in-suit, identified in paragraphs 26-27 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.

5. 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 patents-in-suit, identified in paragraphs 26-27 below.

6. 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 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

7. On information and belief, Defendant Accord Healthcare Inc., USA ("Accord USA") is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

8. On information and belief, Defendants Accord Healthcare and Accord USA are both wholly-owned subsidiaries of Intas Pharmaceuticals Limited.

9. On information and belief, Defendants Accord Healthcare and Accord USA develop, manufacture, distribute and/or market pharmaceutical products throughout the United States, including in this judicial district, through their own actions and through the actions of their agents, including Accord USA acting as an agent for Accord Healthcare.

10. On further information and belief, Defendants Accord Healthcare and Accord USA 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. 213564.

11. On information and belief, Defendants Accord Healthcare and Accord USA closely coordinate their commercial activities and simultaneously share senior corporate officers.

12. On information and belief, Defendant Accord USA will distribute Defendants' ANDA Products when approved.

13. On information and belief, Defendants Accord Healthcare and Accord USA were jointly involved in the preparation and submission of Defendants' ANDA.

14. On further information and belief, if Defendants' ANDA is approved, Defendants Accord Healthcare and Accord USA will be jointly involved in the manufacturing, marketing, distributing and/or sale of Defendants' ANDA Products.

SUBJECT MATTER JURISDICTION AND VENUE

15. 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.

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

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Defendants have also agreed not to challenge venue for the purposes of this action.

PERSONAL JURISDICTION

18. Defendants have agreed not to challenge personal jurisdiction for the purposes of this action.

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

20. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of Delaware and throughout the United States.

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

22. This Court further has personal jurisdiction over Defendants by virtue of the fact that they directed their "Notice of Paragraph IV Certification" to Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

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

24. This Court further has personal jurisdiction over Defendant Accord Healthcare because Defendant Accord Healthcare has been a defendant and counter-claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, *Otsuka Pharmaceutical Co. et al. v. Accord Healthcare Inc.*, C.A. No. 19-1987-LPS (D. Del.), D.I. 9 (Accord Healthcare's 2/24/20 Answer, Affirmative Defenses And Counterclaims, Paragraphs 8, 9, and 13 ("Accord does not contest that subject matter jurisdiction is proper in this judicial district pursuant to 35 U.S. §§ 1331 and 1338(a) for purposes of this civil action only"; "Accord will not contest personal jurisdiction or venue in this Court for purposes of this civil action only"; and "Accord will not contest personal jurisdiction in this Court for purposes of this civil action only.")); *Novartis Pharmaceuticals Corp. v. Accord*

Healthcare, Inc. et al., C.A. No. 18-1043-LPS (D. Del.), D.I. 46 (Accord Healthcare's 8/18/18 Answer To Complaint And Additional Defenses, Paragraphs 12, 13, 216 and 217 ("For purposes of this action only, Accord consents to jurisdiction and venue in the Court"; "For purposes of this action only, Accord does not contest [subject matter] jurisdiction or venue in this Court"; and "For the purpose of this action only, Accord does not contest personal jurisdiction over Accord")); *Biogen International GmbH et al. v. Accord Healthcare Inc.*, C.A. No. 17-872-LPS (D. Del.), D.I.8 (Accord Healthcare's 10/16/17 Answer, Affirmative Defenses, And Counterclaims, Paragraphs 7, 1 [sic], and 3 [sic] (Accord "admits that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 35 U.S. §§ 1331 and 1338(a)"; "does not contest venue or personal jurisdiction in this proceeding"; and "does not contest personal jurisdiction in this proceeding")); and *Purdue Pharma L.P et al. v. Accord Healthcare Inc. et al.*, C.A. No. 20-cv-01362-RGA (D. Del.), D.I. 14 (Accord Healthcare's 3/12/2021 Answer, Affirmative Defenses, and Counterclaims, at Answer to Paragraphs 19-25 ("Accord does not contest personal jurisdiction in this proceeding.")).

25. This Court further has personal jurisdiction over Defendant Accord USA because Defendant Accord USA has been a defendant and counter claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, in *Pfizer Inc. et al v. Accord Healthcare Inc. USA*, C.A. No. 13-1155-GMS (D. Del.), Accord USA did not object to personal jurisdiction and venue in Delaware. *See* D.I. 9 (Accord USA's 8/21/13 Answer And Counterclaims, Paragraphs 6 and 7 ("Accord does not contest personal jurisdiction by this Court over Accord for purposes of this action only"; "Accord does not contest venue in this judicial district for purposes of this action only")).

THE PATENTS-IN-SUIT

26. Purdue is the lawful owner of all right, title and interest in the '908 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '908 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '908 patent is attached hereto as Exhibit A, which was duly and legally issued on April 19, 2022, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

27. Purdue is the lawful owner of all right, title and interest in the '909 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '909 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '909 patent is attached hereto as Exhibit B, which was duly and legally issued on April 19, 2022, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

DEFENDANTS' ANDA

28. On information and belief, on or before August 25, 2020, 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.

29. 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 the patents-in-suit, each of which is 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.

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

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

32. 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. 11,304,908)

33. Purdue incorporates by reference and reallege paragraphs 1 through 32 above as though fully restated herein.

34. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '908 patent by Defendants.

35. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '908 patent, including but not limited to independent claims 1 and 21, which recite, *inter alia*, a solid oral extended release pharmaceutical dosage form, comprising a shaped, convection heated, and cooled extended release matrix, wherein said matrix comprises at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of at least 800,000, and at least one opioid analgesic, and wherein

the shaped matrix is convection heated to a certain temperature for a certain time period and thereafter cooled, and a plurality of convection heated particles of PEO adhere to or fuse with each other within the matrix, and various claims dependent therefrom.

36. 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 '908 patent under 35 U.S.C. § 271(a)-(c). 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 '908 patent.

37. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '908 patent.

38. Upon information and belief, Defendants have been aware of the existence of the '908 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '908 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

39. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '908 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,304,909)

40. Purdue incorporates by reference and reallege paragraphs 1 through 32 above as though fully restated herein.

41. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '909 patent by Defendants.

42. Defendants' ANDA Products, or the use thereof, are covered by one or more claims of the '909 patent, including but not limited to independent claims 1 and 21, which recite, *inter alia*, a method of treating pain comprising administering to a patient in need thereof a solid oral extended release pharmaceutical dosage form, comprising a shaped, convection heated, and cooled extended release matrix, wherein said matrix comprises at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of at least 800,000, and at least one opioid analgesic, and wherein the shaped matrix is convection heated to a certain temperature for a certain time period and thereafter cooled, and a plurality of convection heated particles of PEO adhere to or fuse with each other within the matrix, and various claims dependent therefrom.

43. 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 '909 patent under 35 U.S.C. § 271(a)-(c). 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 '909 patent.

44. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '909 patent.

45. Upon 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 '909 patent.

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

47. 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 '909 patent.

48. 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 '909 patent, including but not limited to independent claims 1 and 21, which recite, *inter alia*, a method of treating pain comprising administering to a patient in need thereof a solid oral extended release pharmaceutical dosage form, comprising a shaped, convection heated, and cooled extended release matrix, wherein said matrix comprises at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of at least 800,000, and at least one opioid analgesic, and wherein the shaped matrix is convection heated to a certain temperature for a certain time period and thereafter cooled, and a plurality of convection heated particles of PEO adhere to or fuse with each other within the matrix, and various claims dependent therefrom.

49. 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 '909 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 ’909 patent.

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

51. 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 ’909 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 ’909 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

52. Upon information and belief, Defendants have been aware of the existence of the ’909 patent and have no reasonable basis for believing that Defendants’ ANDA Products will not infringe the ’909 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

53. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants’ infringement of the ’909 patent. Purdue does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the ’908 and ’909 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 '908 and '909 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 213564 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 '908 and '909 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. 213564, including Defendants' ANDA Products or any other drug product that infringes the '908 and '909 patents;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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July 8, 2022