IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACCORD HEALTHCARE INC., ACCORD HEALTHCARE LIMITED and INTAS PHARMACEUTICALS LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Accord Healthcare Inc. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

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

6. On information and belief, Defendant Accord Healthcare Ltd. ("Accord Ltd.") is a corporation organized and existing under the laws of India, having a place of business at Corporate House, Nr. Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380 054, India.

7. On information and belief, Defendant Intas Pharmaceuticals Limited ("Intas") is a corporation organized and existing under the laws of India, with a place of business at Corporate House, Nr. Sola Bridge, S.G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India.

8. On information and belief, Accord Inc. is a wholly-owned subsidiary of Intas, and is controlled and dominated by Intas.

9. On information and belief, Accord Ltd. is a wholly-owned subsidiary of Intas, and is controlled and dominated by Intas.

10. On information and belief, Intas is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Accord Inc., acting in concert with Intas and/or Accord Ltd., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Accord Inc., acting in concert with Intas and/or Accord Ltd., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

11. On information and belief, Accord Inc., Accord Ltd., and/or Intas acted in concert to prepare and submit ANDA No. 213340 for Accord Inc.'s 2.5 mg rivaroxaban tablets ("Accord's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Accord Ltd. and/or Intas.

12. On information and belief, Accord Inc., Accord Ltd. and/or Intas are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Accord's ANDA Product at issue.

13. On information and belief, following any FDA approval of ANDA No. 213340, Accord Inc., Accord Ltd. and/or Intas will act in concert to market, distribute, offer for sale, and sell Accord's ANDA Product throughout the United States and within Delaware. These three entities are hereafter collectively referred to as "Accord."

14. On information and belief, following any FDA approval of ANDA No. 213340, Accord knows and intends that Accord's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

15. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Accord Inc., Accord Ltd., and Intas because, among other things, on information and belief: (1) Accord Inc., acting in concert with Accord Ltd. and/or Intas, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's ANDA Product in the United States, including in Delaware; and (2) Accord Inc., Accord Ltd. and/or Intas will market, distribute, offer for sale, and/or sell Accord's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 213340, and will derive substantial revenue from the use or consumption of Accord's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 213340 is approved, the generic Accord product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies

located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

18. Alternatively, if Accord Ltd.'s connections with Delaware, including its connections with Accord Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Accord Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Accord Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

19. Alternatively, if Intas's connections with Delaware, including its connections with Accord Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Intas is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Intas in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

20. Accord Inc. and Intas have consented to jurisdiction in Delaware in multiple prior cases arising out of the filings of its ANDAs, and have filed counterclaims in some such cases. *See, e.g.*, *Purdue Pharma LP et al. v. Accord Healthcare Inc. et al.*, C.A. No. 20-1362 (D.I. 14); *Otsuka Pharmaceutical Co., Ltd. et al. v. Accord Healthcare, Inc. et al.*, C.A. No. 20-1287 (D.I. 13); *Merck Sharp & Dohme Corp. v. Accord Healthcare, Inc. et al.*, C.A. No. 19-2192 (D.I. 13); *Amgen Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-956 (D.I. 10).

VENUE

21. Venue is proper in this district as to Accord Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Accord Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district and/or will consent to venue for the purpose of

this case. *See, e.g.*, *Purdue Pharma LP et al. v. Accord Healthcare Inc. et al.*, C.A. No. 20-1362 (D.I. 14); *Amgen Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-956 (D.I. 10).

22. Venue is proper in this district for Accord Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Accord Ltd. is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district for Intas pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Intas is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

24. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

25. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

26. The ’310 patent, entitled “Reducing the Risk of Cardiovascular Events,” was duly and legally issued on November 10, 2020. The ’310 patent is attached as Exhibit A.

27. As set forth in greater detail in the ’310 patent, the claims of the ’310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, “A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that

are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

28. Bayer Pharma AG is the assignee of the '310 patent.

29. Bayer AG is an exclusive licensee under the '310 patent.

30. Janssen is an exclusive sublicensee under the '310 patent.

31. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

COUNT I: INFRINGEMENT OF THE '310 PATENT

32. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

33. By letter dated March 8, 2021 ("Accord's Notice Letter"), Accord notified, *inter alia*, Plaintiffs that Accord had submitted to the FDA ANDA No. 213340 for Accord's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

34. In Accord's Notice Letter, Accord indicated that, in connection with its ANDA No. 213340, Accord had filed a Paragraph IV Certification with respect to the '310 patent.

35. In Accord's Notice Letter, Accord stated that Accord's ANDA Product contains rivaroxaban.

36. On information and belief, the proposed labeling for Accord's ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for

Accord's ANDA Product further directs the administration of Accord's ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Accord's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

37. The purpose of ANDA No. 213340 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

38. Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 213340, *i.e.*, prior to the expiration of the '310 patent.

39. On information and belief, the manufacture, use (including in accordance with and as directed by Accord's proposed labeling for Accord's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product will infringe at least claim 1 of the '310 patent.

40. In Accord's Notice Letter, Accord did not contest that the use of Accord's ANDA Product in accordance with its proposed labeling would infringe the '310 patent.

41. Accord has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Accord has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 213340. On information and belief, by such activities, Accord specifically intends to infringe the '310 patent.

42. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

43. On information and belief, Accord knows that Accord's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Accord's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Accord plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 213340.

44. Accord's submission of ANDA No. 213340 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

45. On information and belief, Accord has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Accord's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

46. Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

47. The foregoing actions by Accord constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

48. Unless Accord is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

49. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received the Accord Notice Letter.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

50. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

51. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Accord on the other regarding Accord's liability for infringement and active inducement of infringement of the '310 patent.

52. An actual case or controversy exists between Plaintiffs and Accord with respect to Accord's liability for infringement of the '310 patent.

53. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Accord's ANDA Product will infringe and induce the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Accord has infringed the '310 patent;

(b) A judgment ordering that the effective date of any FDA approval for Accord to make, use, offer for sale, sell, market, distribute, or import Accord's ANDA Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Accord, and all persons acting in concert with Accord, from making, using, selling, offering for sale, marketing,

distributing, or importing Accord's ANDA Product, or any product or compound the use of which infringes the '310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Accord's ANDA Product prior to the expiration of the '310 patent will infringe and induce the infringement of the '310 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Rodger D. Smith (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
rsmith@morrisnichols.com
dfahnestock@morrisnichols.com

Attorneys for Plaintiffs Bayer Pharma AG, Bayer AG and Janssen Pharmaceuticals, Inc.

OF COUNSEL:

Bruce R. Genderson
Dov P. Grossman
Alexander S. Zolan
Kathryn S. Kayali
Julie L. Tavares
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs Bayer Pharma AG and Bayer AG

S. Isaac Olson
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

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