

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MERCK KGaA, MERCK SERONO SA, and
ARES TRADING SA,

Plaintiffs,

v.

ACCORD HEALTHCARE INC.,

Defendant.

C.A. No. 22-974 (GBW)

**ACCORD HEALTHCARE INC.'S ANSWER AND AFFIRMATIVE DEFENSES
TO PLAINTIFFS' FIRST AMENDED COMPLAINT**

Defendant Accord Healthcare Inc. (“Accord”) responds to the First Amended Complaint (“Complaint,” D.I. 15) by Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, “Merck” or “Plaintiffs”) 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 Defendant Accord Healthcare, Inc. of Abbreviated New Drug Application (“ANDA”) No. 216813 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Merck’s MAVENCLAD® product prior to the expiration of U.S. Patent Nos. 7,713,947, 8,377,903, and 10,849,919.

ANSWER: Accord admits that Plaintiffs purport to bring this action for alleged infringement of the ’947, ’903, and ’919 patents under the patent laws of the United States, Title

35, United States Code. Accord admits that it submitted ANDA No. 216813 in the name of Accord Healthcare Inc. Accord denies any remaining allegations in this paragraph.

PARTIES

2. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.

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

3. Plaintiff Merck Serono SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Merck Serono SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

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

4. Plaintiff Ares Trading SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Ares Trading SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

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

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

ANSWER: Admitted.

6. On information and belief, Accord Healthcare's business includes marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Accord Healthcare submits ANDAs to the FDA seeking approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic versions of drug products covered by United States patents.

ANSWER: Defendant admits that Accord Healthcare Inc. markets and distributes generic pharmaceutical products in the United States and submits ANDAs to the FDA seeking approval to market generic pharmaceutical products in the United States. Defendant denies any remaining allegations in this paragraph.

7. On information and belief, Accord Healthcare prepared and submitted ANDA No. 216813 for Accord Healthcare's cladribine 10 mg tablets (the "Accord ANDA Product").

ANSWER: Admitted.

8. On information and belief, following any FDA approval of ANDA No. 216813, Accord Healthcare will market, distribute, offer for sale, and/or sell the Accord ANDA Product throughout the United States including in Delaware.

ANSWER: Defendant admits that Accord Healthcare Inc. filed ANDA No. 216813 with a Paragraph IV certification with respect to the '947 and '903 patents seeking FDA approval to market the Accord ANDA product in the United States. Defendant denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 9 states a legal conclusion to which no answer is required. To the extent an answer is required, Defendant 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, 1338(a), 2201, and 2202. Defendant denies any remaining allegations in this paragraph.

10. Venue is proper in this Court under 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b), and this Court has personal jurisdiction over Accord Healthcare. Accord Healthcare, through its counsel, by e-mail dated July 6, 2022, agreed that it does not contest personal jurisdiction or venue in this Court in this matter.

ANSWER: Defendant admits that it agreed not to contest personal jurisdiction or venue in the District of Delaware for the purposes of this case only. Defendant denies any remaining allegations in this paragraph.

11. Moreover, this Court has personal jurisdiction over Accord Healthcare because, on information and belief, Accord Healthcare has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in Delaware, and deriving substantial revenue from such activities.

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

12. On information and belief, Accord Healthcare has purposefully conducted business in the State of Delaware and continues to conduct business in Delaware, and Delaware is a likely destination of Accord's products, including its proposed generic version of MAVENCLAD® that is at issue in this action.

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

13. On information and belief, upon approval of ANDA No. 216813, Accord Healthcare will market and sell the Accord ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

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

14. On information and belief, upon approval of Accord's ANDA No. 216813, Accord Healthcare will place the Accord ANDA Product into the stream of commerce with the expectation or knowledge and the intent that such product will be purchased and used by consumers in Delaware and throughout the United States.

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

15. Accord Healthcare has consented to jurisdiction in the District of Delaware in multiple previous cases. *See, e.g., Eagle Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-704; *Teva Pharmaceuticals Int'l GmbH et al., v. Accord Healthcare, Inc. et al.*, C.A. No. 21-952; *Merck Sharp & Dohme Corp. v. Accord Healthcare, Inc. et al.*, C.A. No. 19-2192; *Amgen Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-956.

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

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