

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and )  
ARES TRADING SA, )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. 22-974 (GBW)  
 )  
ACCORD HEALTHCARE, INC., )  
 )  
Defendant. )

**FIRST AMENDED COMPLAINT**

Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, “Merck” or “Plaintiffs”), by their attorneys, 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 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<sup>®</sup> product prior to the expiration of U.S. Patent Nos. 7,713,947, 8,377,903, and 10,849,919.

**PARTIES**

2. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.<sup>1</sup>

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<sup>1</sup> In the United States, Plaintiff Merck KGaA conducts business under the name “Merck KGaA, Darmstadt, Germany.”

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.

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.

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.

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.

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”).

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.

#### **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.

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.

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.

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<sup>®</sup> that is at issue in this action.

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.

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.

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.

### **PATENTS-IN-SUIT**

16. United States Patent No. 7,713,947 (“the ’947 patent”), entitled “Cladribine Regimen for Treating Multiple Sclerosis” (attached as Exhibit A), was duly and legally issued on May 10, 2010.

17. United States Patent No. 8,377,903 (“the ’903 patent”), entitled “Cladribine Regimen for Treating Multiple Sclerosis” (attached as Exhibit B), was duly and legally issued on February 19, 2013.

18. United States Patent No. 10,849,919 (“the ’919 patent”), entitled Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis” (attached as Exhibit D), was duly and legally issued on December 1, 2020.

19. The ’947 and ’903 patents are owned by Merck Serono SA. The ’919 patent is owned by Ares Trading SA. The claims of the ’947, ’903, and ’919 patents are valid, enforceable, and not expired.

### **MERCK’S MAVENCLAD® PRODUCT**

20. EMD Serono, Inc. holds New Drug Application (“NDA”) No. 022561, which the FDA approved on March 29, 2019 for the marketing and sale of 10 mg strength cladribine tablets. EMD Serono, Inc. markets 10 mg strength cladribine tablets in the United States under the trade name “MAVENCLAD®.” EMD Serono, Inc. is a wholly owned subsidiary of Merck KGaA.

21. MAVENCLAD® is a purine antimetabolite. It is approved by the FDA for the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting disease and active

secondary progressive disease, in adults. A copy of the complete prescribing information for MAVENCLAD<sup>®</sup> is attached as Exhibit C.

22. The FDA's official publication of approved drugs (the "Orange Book") includes MAVENCLAD<sup>®</sup>. The Orange Book lists the '947, '903, and '919 patents as patents covering MAVENCLAD<sup>®</sup> and its use.<sup>2</sup>

### **INFRINGEMENT BY ACCORD**

23. By letter dated June 13, 2022, Accord notified Merck that it had submitted to the FDA ANDA No. 216813 seeking approval to market and sell the Accord ANDA Product in the United States prior to the expiration of the '947 and '903 patents.

24. By submitting ANDA No. 216813, Accord has represented to the FDA that the Accord ANDA Product has the same active ingredient as MAVENCLAD<sup>®</sup>, has the same dosage forms and strengths as MAVENCLAD<sup>®</sup>, and is bioequivalent to MAVENCLAD<sup>®</sup>.

25. On information and belief, Accord is seeking approval to market the Accord ANDA Product for the same approved indication as MAVENCLAD<sup>®</sup>.

26. In the Notice Letter, Accord stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) with respect to the '947 and '903 patents, and alleged that these patents are invalid. The Notice Letter did not substantively dispute the infringement of any claim of the '947 and '903 patents. The Notice Letter demonstrates that Accord seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Accord ANDA Product before the '947 and '903 patents expire.

27. Prior to filing this Complaint, Counsel for Merck obtained and reviewed portions of ANDA No. 216813 produced by Accord pursuant to an agreed Offer of Confidential Access.

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<sup>2</sup> The '919 patent was listed on the Orange Book on September 12, 2022.

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