IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA and MERCK SERONO SA, Plaintiffs, v. ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Merck KGaA and Merck Serono 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® product prior to the expiration of U.S. Patent Nos. 7,713,947 and 8,377,903.

PARTIES

1. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.[1]

2. 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.

[1] In the United States, Plaintiff Merck KGaA conducts business under the name "Merck KGaA, Darmstadt, Germany."

3. On information and belief, Defendant Accord Healthcare, Inc. ("Accord Healthcare") 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.

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

5. On information and belief, Accord Healthcare is a wholly-owned subsidiary of Intas, and is controlled and/or dominated by Intas.

6. On information and belief, Intas's business includes manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Accord Healthcare, in concert with Intas, 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 and Intas acted in concert to prepare and submit ANDA No. 216813 for Accord Healthcare's cladribine 10 mg tablets (the "Accord ANDA Product"). On information and belief, ANDA No. 216813 was submitted at the direction of, under the control of, and for the direct benefit of, Intas.

8. On information and belief, Accord Healthcare and Intas are agents of each other, operate in concert as integrated parts of the same business group, and/or enter into agreements with each other that are nearer than arm's length. On information and belief, these agreements include developing, obtaining regulatory approval for, marketing, selling, offering for sale, and

distributing generic pharmaceutical products throughout the United States, including in Delaware, and including with respect to the Accord ANDA Product.

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

10. Hereinafter, Accord Healthcare and Intas are collectively referred to as "Accord" or "Defendants."

JURISDICTION AND VENUE

11. 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.

12. 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 and Intas. 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. Intas is a foreign corporation not residing in any United States district and, thus, may be sued in any judicial district. *See* 28 U.S.C. § 1391(c).

13. Moreover, this Court has personal jurisdiction over Accord Healthcare and Intas because, on information and belief, Accord Healthcare and Intas, acting in concert with one another, have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed themselves 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.

14. On information and belief, Accord Healthcare and Intas, acting in concert with one another, have purposefully conducted business in the State of Delaware and continue 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.

15. On information and belief, upon approval of ANDA No. 216813, Accord Healthcare, acting in concert with and/or on behalf of Intas, will market and sell the Accord ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

16. On information and belief, upon approval of Accord's ANDA No. 216813, Accord Healthcare and Intas 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.

17. Accord Healthcare and Intas have 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

18. 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.

19. 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.

20. The '947 and '903 patents are owned by Merck Serono SA. The claims of the '947 and '903 patents are valid, enforceable, and not expired.

MERCK'S MAVENCLAD® PRODUCT

21. 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.

22. 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® is attached as Exhibit C.

23. The FDA's official publication of approved drugs (the "Orange Book") includes MAVENCLAD®. The Orange Book lists the '947 and '903 patents as patents covering MAVENCLAD® and its use.

INFRINGEMENT BY ACCORD

24. 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.

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

26. On information and belief, Accord is seeking approval to market the Accord ANDA Product for the same approved indication as MAVENCLAD®.

27. 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

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