

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VELOXIS PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
ACCORD HEALTHCARE, INC. and)	
INTAS PHARMACEUTICALS LTD.,)	
)	
Defendants.)	

COMPLAINT

Plaintiff Veloxis Pharmaceuticals, Inc. (“Veloxis”), by its undersigned attorneys, for its Complaint against Defendants Accord Healthcare, Inc. (“Accord Healthcare”) and Intas Pharmaceuticals Ltd. (“Intas”) (collectively “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, arising from Defendants’ submission of Abbreviated New Drug Application (“ANDA”) No. 217255 to the United States Food and Drug Administration (“FDA”). Defendants’ ANDA seeks FDA approval to market and sell 0.75 mg, 1 mg, and 4 mg extended-release tablets of tacrolimus (“Defendants’ ANDA Products”) prior to the expiration of U.S. Patent Nos. 8,685,998 (“the ’998 Patent”); 9,549,918 (“the ’918 Patent”); 10,166,190 (“the ’190 Patent”); 10,864,199 (“the ’199 Patent”); 11,110,081 (“the ’081 Patent”); and 11,123,331 (“the ’331 Patent”).

2. Veloxis owns the patents-in-suit and is the holder of FDA approved New Drug Application (“NDA”) No. 206406 for the brand name drug ENVARUSUS XR[®] (tacrolimus). The patents-in-suit generally cover oral dosage forms and methods of use and administration of

tacrolimus, including ENVARSUS XR[®]. Defendants' ANDA Products are generic versions of ENVARSUS XR[®].

THE PARTIES

3. Plaintiff Veloxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

4. Upon information and belief, Defendant Accord Healthcare is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210 Durham, North Carolina 27703. Upon information and belief, Accord Healthcare is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

5. Upon information and belief, Defendant Intas is a corporation organized and existing under the laws of India, having a principal place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India. Upon information and belief, Intas is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

6. Upon information and belief, Accord Healthcare is a wholly-owned subsidiary of Intas and is controlled and/or dominated by Intas. Upon information and belief, Accord Healthcare is the commercial arm of Intas. Upon information and belief, Accord Healthcare and Intas are agents of each other and/or operate in concert as integrated parts of the same business group.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and this Court has personal jurisdiction over Defendants.

9. Accord Healthcare, through their counsel, by email dated June 23, 2022, have consented to personal jurisdiction and venue in this Court for purposes of this matter.

10. This Court also has personal jurisdiction over Accord Healthcare because Accord Healthcare, itself and/or through its parent Intas, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Accord Healthcare, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, prepared and filed ANDA No. 217255 with the FDA. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

11. This Court also has personal jurisdiction over Intas because Intas, itself and/or through its subsidiary Accord Healthcare, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Intas, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, prepared and

submitted ANDA No. 217255 to the FDA. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

12. In the alternative, this Court also has personal jurisdiction over Intas pursuant to Rule 4(k)(2), Fed. R. Civ. P. This action arises from actions of Intas directed toward Delaware, and Intas has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Intas regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Intas derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

13. Venue is also proper in this Court with respect to Intas because, upon information and belief, Intas is a foreign corporation that may be sued in any judicial district where it is subject to the personal jurisdiction of the Court.

14. Personal jurisdiction and venue are also proper in this Judicial District because Defendants have availed themselves of the legal protections of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in this Court. *See e.g., Celgene Corp. et al. v. Accord Healthcare Inc.*, No. 21-1795 (D. Del. Dec. 22, 2021); *Teva Pharmaceuticals International GmbH et al v. Accord Healthcare Inc.*, No. 21-952 (D. Del. June 29, 2021); *Taiho Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc. et al*, No. 21-838 (D. Del. June 9, 2021); *Bayer Pharma AG et al v. Accord Healthcare Inc. et al*, No. 21-566 (D. Del. Apr. 22, 2021);

Purdue Pharma L.P. et al v. Accord Healthcare Inc., No. 20-1362 (D. Del. Oct. 8, 2020); *Otsuka Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc.*, No. 20-1287 (D. Del. Sep. 25, 2020); *Sanofi-Aventis U.S. LLC et al v. Accord Healthcare Inc.*, No. 20-803 (D. Del. Jun. 12, 2020). *Merck Sharp & Dohme Corp. v. Accord Healthcare Inc. et al.*, No. 19-2192 (D. Del. Jan. 24, 2020); *Novartis Pharm. Co. v. Accord Healthcare Inc. et al.*, No. 18-1043 (D. Del. Aug. 8, 2018); *Amgen Inc. v. Accord Healthcare et al.*, No. 18-956 (D. Del. June 28, 2018).

PATENTS-IN-SUIT

15. On April 1, 2014, the '998 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Veloxis is the assignee of the '998 Patent. A true copy of the '998 Patent is attached hereto as **Exhibit A**.

16. On January 24, 2017, the '918 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '918 Patent. A true copy of the '918 Patent is attached hereto as **Exhibit B**.

17. On January 1, 2019, the '190 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '190 Patent. A true copy of the '190 Patent is attached hereto as **Exhibit C**.

18. On December 15, 2020, the '199 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '199 Patent. A true copy of the '199 Patent is attached hereto as **Exhibit D**.

19. On September 7, 2021, the '081 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '081 Patent. A true copy of the '081 Patent is attached hereto as **Exhibit E**.

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