IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI MATURE IP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED, AUROMEDICS PHARMA LLC and EUGIA PHARMA SPECIALITIES LIMITED,	)	
Defendants	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter, "Sanofi U.S.") and Sanofi Mature IP (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by Eugia Pharma Specialities Limited ("Eugia") to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of cabazitaxel injection, for intravenous infusion, a generic version of Plaintiffs' JEVTANA® KIT (hereinafter "JEVTANA®"), prior to the expiration of U.S. Patent Nos. 10,583,110 ("the '110 patent"), 10,716,777 ("the '777 patent"), and 8,927,592 ("the '592 patent").

THE PARTIES

2. Plaintiff Sanofi U.S. is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Sanofi Mature IP is a company organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

4. Plaintiffs are owned by Sanofi, a global research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human health.

5. Upon information and belief, Defendant Aurobindo Pharma Limited ("APL") is a corporation organized and existing under the laws of the Republic of India, having a place of business at Plot No. 11, Survey no.9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500084, Telangana, India. Upon information and belief, APL is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Eugia Pharma Specialities Ltd. and AuroMedics Pharma LLC, throughout the United States, including in Delaware.

6. Upon information and belief, Defendant Eugia Pharma Specialities Ltd. ("Eugia") is a corporation organized and existing under the laws of the Republic of India, having a place of business at Maitrivihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India. Upon information and belief, Eugia is a wholly owned subsidiary of APL. Upon information and belief, Eugia is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including in Delaware.

7. Upon information and belief, Defendant AuroMedics Pharma LLC ("AuroMedics") is a limited liability company organized and existing under the laws of Delaware, having its corporate offices and a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Upon information and belief, AuroMedics is a wholly owned subsidiary of APL. Upon information and belief, AuroMedics is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

8. Upon information and belief, AuroMedics is a United States agent for APL and Eugia regarding ANDA No. 216733.

9. Upon information and belief, APL, Eugia, and AuroMedics (collectively referred to hereinafter as "Eugia" unless otherwise noted) collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, APL, Eugia, and AuroMedics are agents of each other and/or operate in concert as integrated parts of the same business group. Upon information and belief, APL and Eugia acted in concert to develop Eugia's Proposed ANDA Product that is the subject of ANDA No. 216733 and, with AuroMedics, to seek regulatory approval from the FDA to market and sell Eugia's Proposed ANDA Product throughout the United States, including in Delaware.

10. Upon information and belief, APL, Eugia, and AuroMedics intend to act collaboratively to obtain approval for Eugia's ANDA No. 216733, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import Eugia's Proposed ANDA Product in the United States, including in Delaware.

11. On information and belief, Eugia assembled and caused to be submitted to the FDA ANDA No. 216733 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the Eugia ANDA") concerning a proposed drug product, cabazitaxel intravenous solution, 60 mg/1.5 mL (40 mg/mL) (hereinafter "Eugia's Proposed ANDA Product"). The Eugia ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

12. By letter dated December 23, 2021, Eugia notified Plaintiffs that, as a part of its ANDA, Eugia had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '777 patent, the '110 patent, the '592 patent, and U.S. Patent No. 7,241,907 ("the '907 patent"), each of which were listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for JEVTANA®, asserting that the '777 patent, the '110 patent, the '592 patent, and the '907 patent

are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Eugia's Proposed ANDA Product.

JURISDICTION AND VENUE

13. 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 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. This Court has personal jurisdiction over APL because, *inter alia*, APL, itself and through its subsidiaries Eugia and AuroMedics, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, APL, itself and through its subsidiaries Eugia and AuroMedics, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, APL is subject to personal jurisdiction in Delaware because, upon information and belief, it controls AuroMedics, a Delaware corporation, and therefore the activities of AuroMedics in this jurisdiction are attributed to APL.

15. In addition, this Court has personal jurisdiction over APL because, among other things, on information and belief, upon approval of Eugia's ANDA, APL and its subsidiaries AuroMedics and Eugia will market, distribute, offer for sale, sell, and/or import Eugia's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Eugia's Proposed ANDA Product in Delaware. On information and belief, upon approval of Eugia's ANDA, Eugia's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware and lead to

foreseeable harm and injury to Plaintiffs, including Plaintiff Sanofi U.S., which is a Delaware company.

16. In addition, this Court has personal jurisdiction over APL because it regularly engages in patent litigation concerning Eugia's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 20-01528-CFC, D.I. 7 (D. Del. Dec. 4, 2020); *Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-00853-GMS, D.I. 10 (D. Del. Nov. 28, 2016).

17. In the alternative, APL is subject to jurisdiction throughout the United States, and specifically in the State of Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

18. For at least the above reasons, it would not be unfair or unreasonable for APL to litigate this action in this District, and APL is subject to personal jurisdiction in this District.

19. This Court has personal jurisdiction over Eugia because Eugia, itself and through its agents APL and AuroMedics, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Eugia, itself and through its agent AuroMedics and parent company APL, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, Eugia is subject to personal jurisdiction in Delaware because, upon information and belief, AuroMedics, a Delaware corporation, is an agent of Eugia, and therefore the activities of AuroMedics in this jurisdiction are attributed to Eugia.

20. In addition, this Court has personal jurisdiction over Eugia because, among other things, on information and belief: (1) Eugia and its agent AuroMedics filed Eugia's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Eugia's Proposed ANDA Product in the United States, including in Delaware; and (2) upon

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