

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

SHIONOGI INC.	)	
AND ANDRX LABS, L.L.C.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
AUROBINDO PHARMA LTD. and	)	
AUROBINDO PHARMA USA, INC.,	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Shionogi Inc. and Andrx Labs, L.L.C. (collectively, “Plaintiffs”), by their undersigned 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. This action relates to Abbreviated New Drug Application (“ANDA”) 20-9694 filed by Aurobindo Pharma USA, Inc. with the U.S. Food and Drug Administration (“FDA”) for approval to engage in the commercial manufacture, use or sale of Metformin Extended Release 500 mg and 1000 mg Tablets, a generic version of Shionogi’s FORTAMET® Tablets, prior to expiration of U.S. Patent Nos. 6,790,459 (the “459 Patent”) and 6,866,866 (the “866 Patent”) (collectively, the “Patents-in-Suit”).

## PARTIES

2. Shionogi Inc. (“Shionogi”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

3. Andrx Labs, L.L.C. (“Andrx”) is a Delaware limited liability company having a place of business at 4955 Orange Drive, Davie, Florida 33314.

4. Upon information and belief, Aurobindo Pharma Ltd. is a company organized and existing under the laws of India, having a registered office at Plot No. 2 Maitrivihar, Ameerpet, Hyderabad 500038, India, and a principal place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad 50084, Telangana, India. Upon information and belief, Aurobindo Pharma Ltd. itself and through its wholly-owned subsidiary and agent, Aurobindo Pharma USA, Inc., develops, manufactures and/or distributes generic drug products for marketing, sale and/or use throughout the United States, including in this judicial district.

5. Upon information and belief, Aurobindo Pharma USA, Inc. (“Aurobindo Pharma USA” and collectively with Aurobindo Pharma Ltd., “Aurobindo”) is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Aurobindo Pharma USA is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Aurobindo Pharma USA is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is controlled and/or dominated by Aurobindo Pharma Ltd. Upon information and belief, Aurobindo Pharma USA develops, manufactures, and/or distributes generic drugs for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Aurobindo Pharma Ltd.

6. Upon information and belief, Aurobindo Pharma Ltd. established Aurobindo Pharma USA for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

7. Upon information and belief, Aurobindo Pharma Ltd. operates in the United States through Aurobindo Pharma USA.

8. Upon information and belief, and consistent with their past practices, Aurobindo Pharma Ltd. and Aurobindo Pharma USA acted collaboratively in the preparation and submission of ANDA No. 20-9694.

9. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 20-9694, Aurobindo Pharma Ltd. and Aurobindo Pharma USA will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 20-9694 throughout the United States, and/or impart such generic drug products into the United States, including in this judicial district.

#### **JURISDICTION AND VENUE**

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

11. This Court has personal jurisdiction over Aurobindo Pharma Ltd. because, among other things, Aurobindo Pharma Ltd. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement in filing ANDA No. 20-9694 that has led to foreseeable harm and injury to Plaintiffs, including Shionogi, a Delaware corporation.

12. This Court also has personal jurisdiction over Aurobindo Pharma Ltd. because of, among other things, its marketing and sales activities in this judicial district, including but not

limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products in this judicial district, and the fact that it has availed itself of the rights afforded in this judicial district. On information and belief, Aurobindo Pharma Ltd. has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

13. This Court has personal jurisdiction over Aurobindo Pharma Ltd. because, on information and belief, Aurobindo Pharma Ltd. develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States, and in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary Aurobindo Pharma USA. Moreover, on information and belief, upon receiving FDA approval, Aurobindo Pharma Ltd. intends to market and sell the proposed generic products at issue in this litigation in this judicial district.

14. This Court also has personal jurisdiction over Aurobindo Pharma Ltd. because, upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharm USA work in concert for purposes of developing, formulating, manufacturing, marketing and selling its generic drug products throughout the United States, including Delaware, and Delaware is a likely destination of Aurobindo Pharma Ltd.'s generic products.

15. This Court has personal jurisdiction over Aurobindo Pharma USA because Aurobindo Pharma USA is a citizen of the State of Delaware and has engaged in systematic and continuous contacts with the State of Delaware. Upon information and belief, Aurobindo Pharma USA is in the business of, among other things, importing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, including in this judicial district.

16. Upon information and belief, Aurobindo Pharma USA holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001270. On information and belief, Aurobindo Pharma USA holds a Distributor/Manufacturer License 00006550. Moreover, on information and belief, Aurobindo Pharma USA is registered to do business in Delaware (File Number 3769913) and has appointed a registered agent in Delaware (located at The Corporation Service Company, 2711 Centerville Road Suite 400, Wilmington, DE 19808) for the receipt of service of process.

17. This Court also has personal jurisdiction over Aurobindo Pharma Ltd. and Aurobindo Pharma USA because, upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA have purposely availed itself of the rights and benefits of the laws of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Allergan Sales LLC v. Aurobindo Pharma Limited et al.*, Civil Action No. 15-1032 (D. Del.); *Reckitt Benckiser LLC v. Aurobindo Pharma Limited et al.*, Civil Action No. 14-1203 (D. Del.).

18. Upon information and belief, Aurobindo Pharma Ltd. has, directly or through its agent Aurobindo Pharma USA, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the generic drug product described in ANDA No. 20-9694 in the United States, including Delaware.

19. Upon information and belief, Aurobindo Pharma USA has filed an ANDA, and/or been actively involved in preparation and submission of an ANDA, on behalf of Aurobindo Pharma Ltd. for the purpose of seeking approval to engage in the commercial manufacture, use,

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