IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., BRECKENRIDGE PHARMACEUTICAL, INC., MICRO LABS LTD., MICRO LABS USA INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., PRINSTON PHARMACEUTICAL INC., SIGMAPHARM LABORATORIES, LLC, TORRENT PHARMACEUTICALS, LIMITED, and TORRENT PHARMA INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG ("Bayer Pharma") (Bayer Pharma and BIP are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, 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 filing by various defendants of Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration

of one or more of U.S. Patent Nos. 7,157,456 ("the '456 patent"), 7,585,860 ("the '860 patent"), and 7,592,339 ("the '339 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Aurobindo

5. On information and belief, Defendant Aurobindo Pharma Limited is a company organized and existing under the laws of India, with a place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 6 Wheeling Road, Dayton, New Jersey.

7. On information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited, and is controlled and dominated by Aurobindo Pharma Limited.

8. On information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, and consistent with their practice with respect to other generic products, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit ANDA No. 208544 for Aurobindo Pharma Limited's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Aurobindo's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Aurobindo Pharma Limited.

10. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Aurobindo's ANDA Products at issue.

11. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to market, distribute, offer for sale, and sell Aurobindo's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Aurobindo."

12. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Breckenridge

13. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation organized and existing under the laws of the State of Florida, with a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida.

14. On information and belief, Breckenridge is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Breckenridge files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Breckenridge files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

15. On information and belief, Breckenridge prepared and submitted ANDA No. 208220 for Breckenridge's 10 mg, 15 mg, and 20 mg rivaroxaban tablets, oral ("Breckenridge's ANDA Products").

16. On information and belief, following any FDA approval of ANDA No. 208220, Breckenridge will market, distribute, offer for sale, and sell Breckendridge's ANDA Products throughout the United States and within Delaware.

17. On information and belief, following any FDA approval of ANDA No. 208220, Breckenridge knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Micro Labs

18. On information and belief, Defendant Micro Labs Ltd. is a corporation organized and existing under the laws of India, with a place of business at 27 Race Course Road, Bangalore 560 001, India.

19. On information and belief, Defendant Micro Labs USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a place of business at 104 Carnegie Ctr., Suite 216, Princeton, New Jersey.

20. On information and belief, Defendant Micro Labs USA Inc. is a wholly-owned subsidiary of Micro Labs Ltd., and is controlled and dominated by Micro Labs Ltd.

21. On information and belief, Micro Labs Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Micro Labs Ltd., acting in concert with Micro Labs USA Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of

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