IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| MICRO LABS LTD. and MICRO LABS USA INC., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG 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 submission and amendment by Micro Labs Ltd. and Micro Labs USA Inc. of an Abbreviated New Drug Application ("ANDA") to 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 a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

## THE PARTIES

### Plaintiffs

2. 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.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

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

### Defendants

5. 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.

6. 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.

7. 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.

8. 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 drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Micro Labs Ltd., acting in concert with Micro Labs 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, Micro Labs Ltd. and Micro Labs USA Inc. acted in concert to prepare, submit, and amend ANDA No. 208334 for Micro Labs Ltd.'s 2.5 mg rivaroxaban tablets ("Micro Labs' ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Micro Labs Ltd.

10. On information and belief, Micro Labs Ltd. and Micro Labs 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 Micro Labs' ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs Ltd. and Micro Labs USA Inc. will act in concert to market, distribute, offer for sale, and sell Micro Labs' ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Micro Labs."

12. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs will market, distribute, offer for sale, and sell Micro Labs' ANDA Product throughout the United States and within Delaware.

13. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

## JURISDICTION

14. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

16. In addition, this Court has personal jurisdiction over Micro Labs because, among other things, on information and belief: (1) Micro Labs has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Micro Labs' ANDA Product in the United States, including in Delaware; and (2) Micro Labs will market, distribute, offer for sale, and/or sell Micro Labs' ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208334, and will derive substantial revenue from the use or consumption of Micro Labs' ANDA Product in the State of Delaware. On information and belief, if ANDA No. 208334 is approved, the generic Micro Labs product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

17. Alternatively, if Micro Labs Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Micro Labs Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Micro Labs Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

18. Micro Labs has consented to personal jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, including C.A. Nos. 16-cv-00242 and 17-cv-00560, and it has filed counterclaims in such cases. In addition, upon information and belief, Micro Labs will consent to personal jurisdiction in Delaware for purposes of this action.

## VENUE

19. Venue is proper in this district for Micro Labs Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Micro Labs Ltd. is a company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

20. Venue is proper in this district for Micro Labs USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Micro Labs USA is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and will consent to venue in this judicial district for purposes of this action.

## FACTUAL BACKGROUND

21. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.