IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SIGMAPHARM LABORATORIES, LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer AG (Bayer AG 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 submission by Sigmapharm Laboratories, LLC 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 generic versions of Plaintiffs' XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218.

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 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 place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Sigmapharm Laboratories, LLC

5. On information and belief, Defendant Sigmapharm Laboratories LLC ("Sigmapharm") is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 3375 Progress Drive, Bensalem, Pennsylvania.

6. On information and belief, Sigmapharm 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, Sigmapharm 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, Sigmapharm 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.

7. On information and belief, Sigmapharm prepared and submitted ANDA No. 208546 for Sigmapharm's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Sigmapharm's ANDA Products").

8. On information and belief, following any FDA approval of ANDA No. 208546, Sigmapharm will market, distribute, offer for sale, and sell Sigmapharm's ANDA Products throughout the United States and within Delaware.

9. On information and belief, following any FDA approval of ANDA No. 208546, Sigmapharm knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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

12. This Court has personal jurisdiction over Sigmapharm because, among other things, on information and belief: (1) Sigmapharm 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 Sigmapharm's ANDA Products in the United States, including in Delaware; and (2) Sigmapharm will market, distribute, offer for sale, and/or sell Sigmapharm's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208546, and will

derive substantial revenue from the use or consumption of Sigmapharm's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208546 is approved, the generic Sigmpharm products charged with infringing the '218 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.

13. Sigmapharm has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, including Case No. 15-902 involving the same ANDA at issue here, and it has filed counterclaims in such cases.

VENUE

14. Sigmapharm, through its counsel, has represented that it consents to venue in the District of Delaware for purposes of this case.

FACTUAL BACKGROUND

15. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. XARELTO® is available as tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

16. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

17. U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders," was duly and legally issued on January 10, 2017. The '218 patent is attached as Exhibit A.

18. As set forth in greater detail in the '218 patent, the claims of the '218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, "A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke."

19. BIP is the assignee of the '218 patent.

20. Bayer AG is an exclusive licensee under the '218 patent.

21. Janssen is an exclusive sublicensee under the '218 patent.

22. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®.

Infringement by Sigmapharm

23. By letter dated April 12, 2017 (the "Sigmapharm Notice Letter"), Sigmapharm notified BIP and Janssen, among others, that Sigmapharm had submitted to the FDA ANDA No. 208546 for Sigmapharm's ANDA Products. These products are generic versions of XARELTO®.

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