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®.

24. In the Sigmapharm Notice Letter, Sigmapharm stated that Sigmapharm's ANDA Products contain rivaroxaban.

25. In the Sigmapharm Notice Letter, Sigmapharm stated that the dosage form of Sigmapharm's ANDA Products is tablets. On information and belief, the dosage form of Sigmapharm's ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

26. On information and belief, the proposed labeling for Sigmapharm's ANDA Products directs the use of Sigmpharm's ANDA Products for one or more of the following indications: (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. On information and belief, the proposed labeling for Sigmapharm's ANDA Products further directs the use of Sigmapharm's ANDA Products in a manner that satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

27. On information and belief, the manufacture, use (including in accordance with and as directed by Sigmapharm's proposed labeling for Sigmapharm's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products will infringe at least claim 1 of the '218 patent.

28. In the Sigmapharm Notice Letter, Sigmapharm indicated that, in connection with its ANDA No. 208546, Sigmapharm had filed Paragraph IV Certifications with respect to the '218 patent.

29. The purpose of ANDA No. 208546 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Sigmapharm's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

30. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the '218 patent.

31. Sigmapharm has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Sigmapharm has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546. On information and belief, by such activities, Sigmapharm specifically intends to infringe the '218 patent.

32. On information and belief, Sigmapharm plans and intends to, and will, actively induce infringement of the '218 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

33. On information and belief, Sigmapharm knows that Sigmapharm's ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Sigmapharm's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Sigmapharm plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 208546.

34. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the ’218 patent, active inducement of infringement of the ’218 patent, and/or contribution to the infringement by others of the ’218 patent.

35. An actual case or controversy exists between Plaintiffs and Sigmapharm with respect to infringement of the ’218 patent.

36. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Sigmapharm Notice Letter.

CLAIM FOR RELIEF
(Infringement of the ’218 Patent)

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

38. Sigmapharm’s submission of ANDA No. 208546 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sigmapharm’s ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

39. On information and belief, Sigmapharm has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sigmapharm’s ANDA Products with their proposed labeling prior to the expiration of the ’218 patent.

40. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the ’218 patent.

41. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the ’218 patent, active inducement of infringement of the ’218 patent, and/or contribution to the infringement by others of the ’218 patent.

42. Unless Sigmapharm is enjoined from infringing the ’218 patent, actively inducing infringement of the ’218 patent, and contributing to the infringement by others of the ’218 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Sigmapharm has infringed the ’218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Sigmapharm to make, use, offer for sale, sell, market, distribute, or import Sigmapharm’s ANDA Products, or any product or compound the use of which infringes the ’218 patent, be no earlier than the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sigmapharm, and all persons acting in concert with Sigmapharm, from making, using, selling, offering for sale, marketing, distributing, or importing Sigmapharm’s ANDA Products, or any product or compound the use of which infringes the ’218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A declaration that this is an exceptional case and an award of attorneys’ fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(e) An award of Plaintiffs’ costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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May 26, 2017