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. _____
INVAGEN PHARMACEUTICALS, INC.,	)	
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 InvaGen 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.

InvaGen Pharmaceuticals, Inc.

5. On information and belief, Defendant InvaGen Pharmaceuticals, Inc. ("InvaGen") is a corporation organized and existing under the laws of the State of New York, with a place of business at 7 Oser Avenue, Hauppauge, New York 11788.

6. On information and belief, InvaGen 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, InvaGen 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, InvaGen 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, InvaGen prepared and submitted ANDA No. 208543 for InvaGen's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("InvaGen's ANDA Products").

8. On information and belief, following any FDA approval of ANDA No. 208543, InvaGen will market, distribute, offer for sale, and sell InvaGen's ANDA Products throughout the United States and within Delaware.

9. On information and belief, following any FDA approval of ANDA No. 208543, InvaGen 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 InvaGen because, among other things, on information and belief: (a) InvaGen 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 InvaGen's ANDA Products in the United States, including in Delaware; and (b) InvaGen will market, distribute, offer for sale, and/or sell InvaGen's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208543, and will derive substantial revenue from the use or consumption of InvaGen's ANDA Products in the State of Delaware. On

information and belief, if ANDA No. 208543 is approved, the generic InvaGen 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. InvaGen has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, including C.A. No. 15-902 involving the same ANDA at issue here, and it has filed counterclaims in such cases.

FACTUAL BACKGROUND

14. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (a) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (b) 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 (c) 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.

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

16. 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.

17. 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."

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

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

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

21. 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 InvaGen

22. By letter dated May 9, 2017 (the "InvaGen Notice Letter"), InvaGen notified BIP and Janssen, among others, that InvaGen had submitted to the FDA ANDA No. 208543 for InvaGen's ANDA Products. These products are generic versions of XARELTO®.

23. In the InvaGen Notice Letter, InvaGen stated that InvaGen's ANDA Products contain rivaroxaban.

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

25. On information and belief, the proposed labeling for InvaGen's ANDA Products directs the use of InvaGen's ANDA Products for one or more of the following

indications: (a) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (b) 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 (c) 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 InvaGen's ANDA Products further directs the use of InvaGen'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.

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

27. In the InvaGen Notice Letter, InvaGen indicated that, in connection with its ANDA No. 208543, InvaGen had filed Paragraph IV Certifications with respect to the '218 patent.

28. The purpose of ANDA No. 208543 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 InvaGen's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

29. InvaGen intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of InvaGen's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208543, *i.e.*, prior to the expiration of the '218 patent.

30. InvaGen has knowledge of the claims of the ’218 patent. Notwithstanding this knowledge, InvaGen has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of InvaGen’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208543. On information and belief, by such activities, InvaGen specifically intends to infringe the ’218 patent.

31. On information and belief, InvaGen 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.

32. On information and belief, InvaGen knows that InvaGen’s ANDA Products are especially made or adapted for use in infringing the ’218 patent, and that InvaGen’s ANDA Products are not suitable for substantial noninfringing use. On information and belief, InvaGen plans and intends to, and will, contribute to infringement of the ’218 patent immediately and imminently upon approval of ANDA No. 208543.

33. The foregoing actions by InvaGen 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.

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

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

CLAIM FOR RELIEF
(Infringement of the ’218 Patent)

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

37. InvaGen’s submission of ANDA No. 208543 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of InvaGen’s ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

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

39. InvaGen intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of InvaGen’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208543, *i.e.*, prior to the expiration of the ’218 patent.

40. The foregoing actions by InvaGen 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.

41. Unless InvaGen 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

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

(b) A judgment ordering that the effective date of any FDA approval for InvaGen to make, use, offer for sale, sell, market, distribute, or import InvaGen’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 InvaGen, and all persons acting in concert with InvaGen, from making, using, selling, offering for sale, marketing, distributing, or importing InvaGen’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/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiffs Bayer Intellectual Property GmbH, Bayer AG, and Janssen Pharmaceuticals, Inc.

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Dov P. Grossman
Alexander S. Zolan
Martha C. Kidd
Kathryn S. Kayali
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000
Attorneys for Plaintiffs Bayer Intellectual Property GmbH and Bayer AG

David T. Pritikin
Lisa A. Schneider
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Bindu Donovan
S. Isaac Olson
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300
Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

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