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. _____
BRECKENRIDGE PHARMACEUTICAL, 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 Breckenridge Pharmaceutical, Inc., of an Abbreviated New Drug Application ("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, *inter alia*, U.S. Patent Nos. 7,157,456 and 7,592,339.

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.

Breckenridge

5. 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.

6. 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.

7. 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").

8. 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.

9. 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.

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. Breckenridge, through its counsel, has represented that it will not contest personal jurisdiction in Delaware for purposes of this case.

13. In addition, this Court has personal jurisdiction over Breckenridge because, on information and belief, Breckenridge has registered to do business in the State of Delaware and has appointed a registered agent in Delaware to accept service of process. Breckenridge has thus consented to personal jurisdiction in Delaware.

14. This Court also has personal jurisdiction over Breckenridge because, among other things, on information and belief: (1) Breckenridge 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 Breckenridge's ANDA Products in the United States, including in Delaware; and (2) Breckenridge will market, distribute, offer for sale, and/or sell Breckenridge's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208220, and will derive substantial revenue from the use or consumption of Breckenridge's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208220 is approved, the generic Breckenridge products charged with infringing the '456 and '339 patents 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.

15. This Court also has personal jurisdiction over Breckenridge because Breckenridge has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases.

VENUE

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

17. 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.

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

The '456 Patent

19. United States Patent No. 7,157,456 ("the '456 patent"), entitled "Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation," was duly and legally issued on January 2, 2007. The '456 patent is attached as Exhibit A.

20. As set forth in greater detail in the '456 patent, the claims of the '456 patent, incorporated by reference herein, cover the compound rivaroxaban, pharmaceutical compositions containing rivaroxaban, methods of using rivaroxaban, and processes for preparing rivaroxaban.

21. BIP is the assignee of the '456 patent.

22. Bayer Pharma is an exclusive licensee under the '456 patent.

23. Janssen is an exclusive sublicensee under the '456 patent.

24. Pursuant to 21 U.S.C. § 355, the '456 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®.

The '339 Patent

25. United States Patent No. 7,592,339 ("the '339 patent"), entitled "Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation," was duly and legally issued on September 22, 2009. The '339 patent is attached as Exhibit B.

26. As set forth in greater detail in the '339 patent, the claims of the '339 patent, incorporated by reference herein, cover methods of using rivaroxaban.

27. BIP is the assignee of the '339 patent.

28. Bayer Pharma is an exclusive licensee under the '339 patent.

29. Janssen is an exclusive sublicensee under the '339 patent.

30. Pursuant to 21 U.S.C. § 355, the '339 patent is listed in the Orange Book in connection with XARELTO®.

Infringement by Breckenridge

31. By letter dated June 27, 2016 (the "June 2016 Breckenridge Notice Letter"), Breckenridge notified BIP and Janssen, among others, that Breckenridge had submitted to the FDA ANDA No. 208220 for Breckenridge's ANDA Products. These products are generic versions of XARELTO®.

32. In the June 2016 Breckenridge Notice Letter, Breckenridge stated that Breckenridge's ANDA Products contain rivaroxaban.

33. On information and belief, the proposed labeling for Breckenridge's ANDA Products directs the use of Breckenridge'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.

34. On information and belief, the manufacture, use (including in accordance with and as directed by Breckenridge's proposed labeling for Breckenridge's ANDA Products),

offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products will infringe at least claims 6 and 16 of the '456 patent, and/or at least claim 10 of the '339 patent.

35. In the June 2016 Breckenridge Notice Letter, Breckenridge indicated that, in connection with its ANDA No. 208220, Breckenridge had filed Paragraph IV Certifications with respect to each of the '456 and '339 patents.

36. The purpose of ANDA No. 208220 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge's ANDA Products with their proposed labeling prior to the expiration of the '456 and '339 patents.

37. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the '456 and '339 patents.

38. Breckenridge has knowledge of the claims of the '456 and '339 patents. Notwithstanding this knowledge, Breckenridge has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220. On information and belief, by such activities, Breckenridge specifically intends infringement of the '456 and '339 patents.

39. On information and belief, Breckenridge plans and intends to, and will, actively induce infringement of the '456 and '339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. On information and belief, Breckenridge knows that Breckenridge's ANDA Products are especially made or adapted for use in infringing the '456 and '339 patents, and that Breckenridge's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Breckenridge plans and intends to, and will, contribute to infringement of the '456 and '339 patents immediately and imminently upon approval of ANDA No. 208220.

41. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the '456 and '339 patents, active inducement of infringement of the '456 and '339 patents, and/or contribution to the infringement by others of the '456 and '339 patents.

42. An actual case or controversy exists between Plaintiffs and Breckenridge with respect to infringement of each of the '456 and '339 patents.

43. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the June 2016 Breckenridge Notice Letter.

COUNT I
(Infringement of the '456 Patent)

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

45. Breckenridge's submission of ANDA No. 208220 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge's ANDA Products was an act of infringement of the '456 patent under 35 U.S.C. § 271(e)(2).

46. On information and belief, Breckenridge has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Breckenridge's ANDA Products with their proposed labeling prior to the expiration of the '456 patent.

47. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the '456 patent.

48. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the '456 patent, active inducement of infringement of the '456 patent, and/or contribution to the infringement by others of the '456 patent.

49. Unless Breckenridge is enjoined from infringing the '456 patent, actively inducing infringement of the '456 patent, and contributing to the infringement by others of the '456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '339 Patent)

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

51. Breckenridge's submission of ANDA No. 208220 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge's ANDA Products was an act of infringement of the '339 patent under 35 U.S.C. § 271(e)(2).

52. On information and belief, Breckenridge has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Breckenridge's ANDA Products with their proposed labeling prior to the expiration of the '339 patent.

53. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their

proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the '339 patent.

54. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the '339 patent, active inducement of infringement of the '339 patent, and/or contribution to the infringement by others of the '339 patent.

55. Unless Breckenridge is enjoined from infringing the '339 patent, actively inducing infringement of the '339 patent, and contributing to the infringement by others of the '339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Breckenridge has infringed the '456 patent;

(b) A judgment that Breckenridge has infringed the '339 patent;

(c) A judgment ordering that the effective date of any FDA approval for Breckenridge to make, use, offer for sale, sell, market, distribute, or import Breckenridge's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no earlier than the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment ordering that the effective date of any FDA approval for Breckenridge to make, use, offer for sale, sell, market, distribute, or import Breckenridge's ANDA Products, or any product or compound the use of which infringes the '339 patent, be no earlier than the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Breckenridge, and all persons acting in concert with Breckenridge, from making, using, selling, offering for sale,

marketing, distributing, or importing Breckenridge's ANDA Products, or any product or compound that infringes or the use of which infringes the '456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining Breckenridge, and all persons acting in concert with Breckenridge, from making, using, selling, offering for sale, marketing, distributing, or importing Breckenridge's ANDA Products, or any product or compound the use of which infringes the '339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

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

(h) An award of Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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