IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
UMEDICA LABORATORIES PVT. LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG, Bayer AG (BIP, Bayer Pharma AG, and Bayer 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 by Umedica Laboratories Pvt. Ltd. ("Umedica") 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 '218 patent") and U.S. Patent No. 10,828,310 ("the '310 patent").

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 50, 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 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.

5. 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.

Umedica

6. Upon information and belief, Defendant Umedica Laboratories Pvt. Ltd. is a corporation organized and existing under the laws of India, with a place of business at 3rd Floor, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai Maharashtra 400021, India.

7. Upon information and belief, Umedica 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, upon information and belief, Umedica 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. Upon

information and belief, as part of these ANDAs, Umedica 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.

8. Upon information and belief, Umedica prepared and submitted ANDA No. 218340 for Umedica's 2.5 mg, 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Umedica's ANDA Products"). The 10 mg, 15 mg, and 20 mg strengths of Umedica's ANDA Products are referred to collectively herein as "Umedica's 10 mg, 15 mg, and 20 mg ANDA Products." The 2.5 strength of Umedica's ANDA Products is referred to herein as "Umedica's 2.5 mg ANDA Product."

9. Upon information and belief, following any FDA approval of ANDA No. 218340, Umedica will market, distribute, offer for sale, and sell Umedica's ANDA Products throughout the United States and within Delaware.

10. Upon information and belief, following any FDA approval of ANDA No. 218340, Umedica 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

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

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

13. This Court has personal jurisdiction over Umedica because, among other things, on information and belief: (1) Umedica 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 Umedica's ANDA Products in the United States, including in Delaware; and (2) Umedica will market, distribute, offer for sale, and/or sell Umedica's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 218340, and will derive substantial revenue from the use or consumption of Umedica's ANDA Products in the State of Delaware. Upon information and belief, if ANDA No. 218340 is approved, the generic Umedica products charged with infringing the '218 patent and the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

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

VENUE

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

FACTUAL BACKGROUND

16. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis ("DVT"); (iii) for the treatment of

pulmonary embolism ("PE"); (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in adult patients undergoing knee or hip replacement surgery; (vi) for the prophylaxis of venous thromboembolism ("VTE") and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding; (vii) in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease ("CAD"); (viii) in combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease ("PAD"), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD; (ix) for the treatment of VTE and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment; and (x) for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure. XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

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

The '218 Patent

18. 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.

19. 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."

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

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

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

23. 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® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

The '310 Patent

24. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020. The '310 patent is attached as Exhibit B.

25. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example,

independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

26. Bayer Pharma AG is the assignee of the '310 patent.

27. Bayer AG is an exclusive licensee under the '310 patent.

28. Janssen is an exclusive sublicensee under the '310 patent.

29. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in the Orange Book in connection with the 2.5 mg strength of XARELTO®.

Infringement by Umedica

30. By letter dated November 13, 2023 (the "Umedica Notice Letter"), Umedica notified BIP, Bayer Pharma AG, and Janssens that Umedica had submitted to the FDA ANDA No. 218340 for Umedica's ANDA Products. These products are generic versions of XARELTO®.

31. In the Umedica Notice Letter, Umedica stated that Umedica's ANDA Products contain rivaroxaban.

32. In the Umedica Notice Letter, Umedica also indicated that Umedica submitted to the FDA an ANDA seeking approval of all four strengths of Plaintiffs' XARELTO® products.

33. In the Umedica Notice Letter, Umedica indicated that, in connection with its ANDA No. 218340, Umedica had filed Paragraph IV Certifications with respect to the '218 patent and to the '310 patent.

34. Upon information and belief, the purpose of ANDA No. 218340 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 Umedica's ANDA Products with their proposed labeling prior to the expiration of the '218 patent and of the '310 patent.

35. Upon information and belief, Umedica intends to engage in the manufacture, use, offer for sale, and/or sale of Umedica's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218340, *i.e.*, prior to the expiration of the '218 patent and of the '310 patent.

36. In the Umedica Notice Letter, Umedica stated that the dosage form of Umedica's ANDA Products is oral tablets. Upon information and belief, the dosage form of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

37. Upon information and belief, the proposed labeling for Umedica's ANDA Products directs the use of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for the treatment of DVT; (iii) for the treatment of PE; (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in adult patients undergoing knee or hip replacement surgery; and (vi) for the prophylaxis of VTE and VTE related death during hospitalization and

post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding. Upon information and belief, the proposed labeling for Umedica's ANDA Products directs the use of Umedica's 10 mg, 15 mg, and 20 mg 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.

38. Upon information and belief, the manufacture, use (including in accordance with and as directed by Umedica's proposed labeling for Umedica's 10 mg, 15 mg, and 20 mg ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products will infringe at least claim 1 of the '218 patent.

39. In the Umedica Notice Letter, Umedica did not substantively contest infringement of any claim of the '218 patent.

40. Umedica has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Umedica has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218340. Upon information and belief, by such activities, Umedica specifically intends to infringe the '218 patent.

41. Upon information and belief, Umedica 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.

42. Upon information and belief, Umedica knows that Umedica's 10 mg, 15 mg, and 20 mg ANDA Products are especially made or adapted for use in infringing the '218

patent, and that Umedica's 10 mg, 15 mg, and 20 mg ANDA Products are not suitable for substantial noninfringing use. Umedica's 10 mg, 15 mg, and 20 mg ANDA Products are a material part of the invention. Upon information and belief, Umedica plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 218340.

43. The foregoing actions by Umedica 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.

44. Upon information and belief, the proposed label for Umedica's 2.5 mg ANDA Product directs a method of reducing the risk of myocardial infarction, stroke or cardiovascular death in human patients with CAD and/or PAD. Upon information and belief, the proposed labeling for Umedica's 2.5 mg ANDA Product further directs the administration of Umedica's 2.5 mg ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with CAD and/or PAD, wherein Umedica's 2.5 mg ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily, just as in claim 1 of the '310 patent.

45. Upon information and belief, the manufacture, use (including in accordance with and as directed by Umedica's proposed labeling for Umedica's 2.5 mg ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Umedica's 2.5 mg ANDA Product will infringe at least claim 1 of the '310 patent.

46. In the Notice Umedica Letter, Umedica did not substantively contest infringement of claim 1 of the '310 patent.

47. Umedica has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, Umedica has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Umedica's 2.5 mg ANDA Product with Umedica's proposed labeling immediately and imminently upon approval of ANDA No. 218340. Upon information and belief, by such activities, Umedica specifically intends to infringe the '310 patent.

48. Upon information and belief, Umedica plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

49. Upon information and belief, Umedica knows that Umedica's 2.5 mg ANDA Product is especially made or adapted for use in infringing the '310 patent, and that Umedica's 2.5 mg ANDA Product is not suitable for substantial noninfringing use. Umedica's 2.5 mg ANDA Product is a material part of the invention. Upon information and belief, Umedica plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 218340.

50. The foregoing actions by Umedica constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

51. An actual case or controversy exists between Plaintiffs and Umedica with respect to infringement of the '218 patent and of the '310 patent.

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

COUNT I: Infringement of the '218 Patent

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

54. Umedica's submission of ANDA No. 218340 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

55. Upon information and belief, Umedica has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Umedica's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

56. Umedica intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218340, *i.e.*, prior to the expiration of the '218 patent.

57. The foregoing actions by Umedica 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.

58. Unless Umedica 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, BIP, Bayer AG, and Janssen will suffer irreparable injury. BIP, Bayer AG, and Janssen have no adequate remedy at law.

COUNT II: Declaratory Judgment of Infringement of the '218 Patent

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

60. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between BIP, Bayer AG, and Janssen on the one hand and Umedica on the other regarding Umedica's liability for infringement, active inducement, and contribution to infringement of the '218 patent.

61. An actual case or controversy exists between BIP, Bayer AG, and Janssen and Umedica with respect to Umedica's liability for infringement of the '218 patent.

62. The Court should declare that the commercial manufacture, use, offer for sale, sale, or importation of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products will infringe, induce the infringement of, and contribute to the infringement of the '218 patent.

COUNT III: Infringement of the '310 Patent

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

64. Umedica's submission of ANDA No. 218340 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Umedica's 2.5 mg ANDA Product with its proposed labeling was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

65. Upon information and belief, Umedica has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Umedica's 2.5 mg ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

66. Umedica intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Umedica's 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218340, *i.e.*, prior to the expiration of the '310 patent.

67. The foregoing actions by Umedica constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent under 35 U.S.C. § 271(b)-(c).

68. Unless Umedica is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and/or contributing to the infringement by others of the '310 patent, Bayer Pharma AG, Bayer AG, and Janssen will suffer irreparable injury. Bayer Pharma AG, Bayer AG, and Janssen have no adequate remedy at law.

COUNT IV: Declaratory Judgment of Infringement of the '310 Patent

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

70. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Bayer Pharma AG, Bayer AG, and Janssen on the one hand and Umedica on the other regarding Umedica's liability for infringement, active inducement of infringement, and/or contribution to infringement of the '310 patent.

71. An actual case or controversy exists between Bayer Pharma AG, Bayer AG, and Janssen and Umedica with respect to Umedica's liability for infringement of the '310 patent.

72. The Court should declare that the commercial manufacture, use, offer for sale, sale, or importation of Umedica's 2.5 mg ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Umedica has infringed the '218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Umedica to make, use, offer for sale, sell, market, distribute, or import Umedica's 10 mg, 15 mg, and 20 mg 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 Umedica, and all persons acting in concert with Umedica, from making, using, offering for sale, selling, marketing, distributing, or importing Umedica's 10 mg, 15 mg, and 20 mg 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 judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of Umedica's 10 mg, 15 mg, and 20 mg ANDA Products prior to the expiration of the '218 patent will infringe, induce the infringement, and contribute to the infringement of the '218 patent;

(e) A judgment that Umedica has infringed the '310 patent;

(f) A judgment ordering that the effective date of any FDA approval for Umedica to make, use, offer for sale, sell, market, distribute, or import Umedica's 2.5 mg ANDA Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A preliminary and permanent injunction enjoining Umedica, and all persons acting in concert with Umedica, from making, using, offering for sale, selling, marketing, distributing, or importing Umedica's 2.5 mg ANDA Product, or any product or compound the use of which infringes the '310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of Umedica's 2.5 mg ANDA Product prior to the expiration of the '310 patent will infringe and will induce and contribute to the infringement of the '310 patent;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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December 21, 2023