IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
USV PRIVATE LIMITED	)	
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 USV Private Limited ("USV") 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 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 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.

USV

6. Upon information and belief, Defendant USV Private Limited ("USV") is a corporation organized and existing under the laws of India, having a place of business at Arvind Vithal Gandhi Chowk, B.S.D. Marg, Station Road, Govandi East, Mumbai, Maharashtra, 400 088 India.

7. Upon information and belief, USV 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, USV 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, USV 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, USV prepared and submitted ANDA No. 217336 for USV's 2.5 mg, 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("USV's ANDA Products"). The 10 mg, 15 mg, and 20 mg strengths of USV's ANDA Products are referred to collectively herein as "USV's 10 mg, 15 mg, and 20 mg ANDA Products." The 2.5 strength of USV's ANDA Products is referred to herein as "USV's 2.5 mg ANDA Product."

9. Upon information and belief, following any FDA approval of ANDA No. 217336, USV will market, distribute, offer for sale, and sell USV's ANDA Products throughout the United States and within New Jersey.

10. Upon information and belief, following any FDA approval of ANDA No. 217336, USV knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

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. In addition, this Court has personal jurisdiction over USV because, among other things, on information and belief: (1) USV 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 USV's ANDA Products in the United States, including in New Jersey; and (2) USV will market, distribute, offer for sale, and/or sell USV's ANDA Products in the United States, including in New Jersey, upon approval of ANDA No. 217336, and will derive substantial revenue from the use or consumption of USV's ANDA Products in the State of New Jersey. Upon information and belief, if ANDA No. 217336 is approved, the generic USV 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 New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

14. If USV's connections with New Jersey are found to be insufficient to confer personal jurisdiction, then, upon information and belief, USV is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over USV in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2). Relatedly, USV sent the USV Notice Letter (defined below) to Janssen and BIP in the United States, specifically in this district.

VENUE

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

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

FACTUAL BACKGROUND

17. 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; (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.

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

The '218 Patent

19. 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.

20. 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."

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

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

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

24. 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

25. 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.

26. 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."

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

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

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

30. 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 USV

31. By letter dated July 28, 2022, (the "USV Notice Letter"), USV notified BIP and Janssen, among others, that USV had submitted to the FDA ANDA No. 217336 for USV's ANDA Products. These products are generic versions of XARELTO®.

32. In the USV Notice Letter, USV stated that USV's ANDA Products contain rivaroxaban.

33. In the USV Notice Letter, USV stated that the dosage form of USV's ANDA Products is tablets. Upon information and belief, the dosage form of USV's 10 mg, 15

mg, and 20 mg ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

34. Upon information and belief, the proposed labeling for USV's ANDA Products directs the use of USV'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 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. Upon information and belief, the proposed labeling for USV's ANDA Products directs the use of USV'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.

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

36. Upon information and belief, USV, by at least the offer for sale, sale, marketing, distribution, and/or importation of USV's 2.5 mg ANDA Product and/or by the

proposed labeling for USV's ANDA Products, will induce and/or contribute to the administration of USV's 2.5 mg ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein USV's 2.5 mg ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

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

38. In the USV Notice Letter, USV indicated that, in connection with its ANDA No. 217336, USV had filed Paragraph IV Certifications with respect to the '218 patent.

39. In the USV Notice Letter, USV also indicated that the FDA had received an ANDA from USV seeking approval of all four strengths of Plaintiffs' XARELTO® products.

40. The purpose of ANDA No. 217336 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 USV's ANDA Products with their proposed labeling prior to the expiration of the '218 patent and the '310 patent.

41. USV intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of USV's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 217336, *i.e.*, prior to the expiration of the '218 patent and of the '310 patent.

42. USV has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, USV has continued to assert its intent to engage in the manufacture, use, offer for sale,

sale, marketing, distribution, and/or importation of USV's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 217336. Upon information and belief, by such activities, USV specifically intends to infringe the '218 patent.

43. Upon information and belief, USV 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.

44. Upon information and belief, USV knows that USV's 10 mg, 15 mg, and 20 mg ANDA Products are especially made or adapted for use in infringing the '218 patent, and that USV's 10 mg, 15 mg, and 20 mg ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, USV plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 217336.

45. The foregoing actions by USV 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.

46. USV has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, USV has continued to assert its intent to engage in at least the offer for sale, sale, marketing, distribution, and/or importation of USV's 2.5 mg ANDA Product with USV's proposed labeling immediately and imminently upon approval of ANDA No. 217336. Upon information and belief, by such activities, USV specifically intends to infringe the '310 patent.

47. Upon information and belief, USV 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.

48. Upon information and belief, USV knows that USV’s 2.5 mg ANDA Product is especially made or adapted for use in infringing the ’310 patent, and that USV’s 2.5 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, USV plans and intends to, and will, contribute to infringement of the ’310 patent immediately and imminently upon approval of ANDA No. 217336.

49. The foregoing actions by USV constitute and/or will constitute active inducement of infringement of the ’310 patent and/or contribution to the infringement by others of the ’310 patent.

50. An actual case or controversy exists between Plaintiffs and USV with respect to infringement of the ’218 patent and the ’310 patent.

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

COUNT I: Infringement of the ’218 Patent

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

53. USV’s submission of ANDA No. 217336 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of USV’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).

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

55. USV intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of USV's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 217336, *i.e.*, prior to the expiration of the '218 patent.

56. The foregoing actions by USV 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.

57. Unless USV 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

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

59. 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 USV on the other regarding USV's liability for infringement, active inducement of, and contribution to infringement of the '218 patent.

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

61. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of USV'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

62. Bayer Pharma AG, Bayer AG and Janssen incorporate each of the preceding paragraphs as if fully set forth herein.

63. USV intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of USV's 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217336, *i.e.*, prior to the expiration of the '310 patent.

64. The foregoing actions by USV will constitute 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).

65. Unless USV is enjoined from 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

66. Bayer Pharma AG, Bayer AG and Janssen incorporate each of the preceding paragraphs as if fully set forth herein.

67. 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 USV on the other regarding USV's liability for active inducement of and/or contribution to infringement of the '310 patent.

68. An actual case or controversy exists between Bayer Pharma AG, Bayer AG, and Janssen and USV with respect to USV's liability for inducing and/or contributing to the infringement of the '310 patent.

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

* * *

WHEREFORE, Plaintiffs request the following relief:

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

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

(e) A judgment ordering that the effective date of any FDA approval for USV to make, use, offer for sale, sell, market, distribute, or import USV’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;

(f) A preliminary and permanent injunction enjoining USV, and all persons acting in concert with USV, from making, using, selling, offering for sale, marketing, distributing, or importing USV’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;

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

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

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

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

September 9, 2022

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned, attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon the information available to me, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, except for: Bayer Pharma AG et al. v. Lupin Limited et al., Case No. 21-cv-00314 (JLH) (Consolidated) (D. Del.); In Re: Xarelto (rivaroxaban) ('310) Patent Litigation, MDL No. 21-md-3017 (RGA)(D. Del.); Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al., Case No. 21-cv-00099 (TSK) (NDWV); 21-cv-01742 (RGA) (D. Del.); Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al., Case No. 22-cv-00063 (JPB) (NDWV); Mylan Pharmaceuticals Inc. v. Bayer Pharma Aktiengesellschaft, IPR2022-00517 (PTAB); and InvaGen Pharmaceuticals, Inc. v. Bayer Pharma Aktiengesellschaft, IPR2022-01515 (PTAB).

Dated: September 9, 2022

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