IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	Civil Action No.: _____
Plaintiffs,	
v.	
AUSON PHARMACEUTICALS INC. and AUSON PHARMACEUTICALS CO., LTD.,	
Defendants.	

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 Auson Pharmaceuticals Inc. of a New Drug Application ("NDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act 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' 2.5 mg and 10 mg 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.

Auson

6. Upon information and belief, Auson Pharmaceuticals Co., Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at Room 301, Building # 2, No. 3377 Kangxin Road, SIMZ Pudong, Shanghai, China.

7. Upon information and belief, Auson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1200 Route 22 East, Suite 2000, Bridgewater, NJ 08807.

8. Upon information and belief, Auson Pharmaceuticals Inc. is a wholly owned subsidiary of Auson Pharmaceuticals Co., Ltd.

9. Upon information and belief, Auson Pharmaceuticals Co., Ltd. and Auson Pharmaceuticals Inc. are 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, Auson Pharmaceuticals Inc., acting in concert with Auson Pharmaceuticals Co., Ltd., files NDAs 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 NDAs, Auson Pharmaceuticals Inc., acting in concert with Auson Pharmaceuticals Co., Ltd., 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"), as well as Section 505(b)(2) of the Act, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of the United States patents that cover such products.

10. Upon information and belief, Auson Pharmaceuticals Inc., acting in concert with Auson Pharmaceuticals Co., Ltd., prepared and submitted NDA No. 217062 for Auson's 2.5 mg and 10 mg rivaroxaban tablet products (respectively, "Auson's 2.5 mg NDA Product" and "Auson's 10 mg NDA Product").

11. Upon information and belief, Auson Pharmaceuticals Inc. and Auson Pharmaceuticals Co., Ltd. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product at issue.

12. Upon information and belief, following any FDA approval of NDA No. 217062, Auson Pharmaceuticals Inc. and Auson Pharmaceuticals Co., Ltd. will act in concert to market, distribute, offer for sale, and sell Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product throughout the United States, including within New Jersey. These entities are hereinafter collectively referred to as "Auson."

13. Upon information and belief, following any FDA approval of NDA No. 217062, Auson knows and intends that Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product will be marketed, used, distributed, offered for sale, and sold in the United States, including within New Jersey.

JURISDICTION

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

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

16. This Court has personal jurisdiction over Auson Pharmaceuticals Inc. because, among other things, upon information and belief, Auson Pharmaceuticals Inc. is a New Jersey corporation; and, with respect to its Paragraph IV Certification for NDA No. 217062, Auson Pharmaceuticals Inc. designated as an agent for service of process a person located in this District, namely, Dr. Jin Zhu of Fox Rothschild LLP, 997 Lenox Drive, Lawrenceville, NJ 08648.

17. Upon information and belief, Auson Pharmaceuticals Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Auson Pharmaceuticals Co., Ltd.

18. Upon information and belief, Auson Pharmaceuticals Inc., acting as the agent of Auson Pharmaceuticals Co., Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Auson Pharmaceuticals Co., Ltd. or for which Auson is the named applicant on approved NDAs.

19. This Court has personal jurisdiction over Auson because, among other things, on information and belief: (1) Auson has filed an NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product in the United States, including in New Jersey; and (2) Auson will market, distribute, offer for sale, and/or sell Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product in the United States, including in New Jersey, upon approval of NDA No. 217062, and will derive substantial revenue from the use or consumption of Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product in the State of New Jersey. Upon information and belief, if NDA No. 217062 is approved, the generic Auson 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, 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.

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

VENUE

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

22. Venue is proper in this district for Auson Pharmaceuticals Inc. because, *inter alia*, Auson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district for Auson Pharmaceuticals Co., Ltd. because, *inter alia*, Auson Pharmaceuticals Co., Ltd. is not resident in the United States and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

24. 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.

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

The '218 Patent

26. 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.

27. 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."

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

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

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

31. 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 the 10 mg strength of XARELTO®, among other strengths.

The '310 Patent

32. 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.

33. 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."

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

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

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

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 Auson

37. By letter dated April 17, 2023, (the "Auson Notice Letter"), Auson notified BIP, Bayer AG and Janssen that Auson had submitted to the FDA NDA No. 217062 for Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product. These products are generic versions of XARELTO®.

38. In the Auson Notice Letter, Auson stated that Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product are rivaroxaban tablets.

39. In the Auson Notice Letter, Auson also indicated that Auson submitted to the FDA an NDA seeking approval of the 2.5 mg and 10 mg strengths of Plaintiffs' XARELTO® products.

40. Upon information and belief, the purpose of NDA No. 217062 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 Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product with their proposed labeling prior to the expiration of the '218 patent and of the '310 patent.

41. Upon information and belief, Auson intends to engage in the manufacture, use, offer for sale, and/or sale of Auson's 2.5 mg NDA Product and Auson's 10 mg NDA Product with their proposed labeling immediately and imminently upon approval of NDA No. 217062, *i.e.*, prior to the expiration of the '218 patent and of the '310 patent.

42. In the Auson Notice Letter, Auson indicated that, in connection with its NDA No. 217062, Auson had filed a Paragraph IV Certification with respect to the '218 patent.

43. In the Auson Notice Letter, Auson also stated that the dosage form of Auson's 10 mg NDA Product is tablets. Upon information and belief, the dosage form of Auson's 10 mg NDA Product satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

44. Upon information and belief, the proposed labeling for Auson's 10 mg NDA Product directs the use of Auson's 10 mg Product for at least one or more of the following indications: (i) for the treatment of deep vein thrombosis (DVT); (ii) for the treatment of pulmonary embolism (PE); (iii) 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; (iv) for the prophylaxis of DVT, which may lead to PE in adult patients undergoing knee or hip replacement surgery; and (v) 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 Auson's 10 mg NDA Products directs the use of Auson's 10 mg NDA Product 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.

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

46. In the Auson Notice Letter, Auson also indicated that the FDA had received an NDA from Auson seeking approval for generic versions of the 10 mg strength of Plaintiffs' XARELTO® products.

47. Auson has knowledge of the claims of the ’218 patent. Notwithstanding this knowledge, Auson has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Auson’s 10 mg NDA Product with their proposed labeling immediately and imminently upon approval of NDA No. 217062. Upon information and belief, by such activities, Auson specifically intends infringement of the ’218 patent.

48. Upon information and belief, Auson plans and intends to, and will, actively induce infringement of the ’218 patent when its NDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

49. Upon information and belief, Auson knows that Auson’s 10 mg NDA Product is especially made or adapted for use in infringing the ’218 patent, and that Auson’s 10 mg NDA Product is not suitable for substantial noninfringing use. Auson’s 10 mg NDA Product is a material part of the claimed invention. Upon information and belief, Auson plans and intends to, and will, contribute to infringement of the ’218 patent immediately and imminently upon approval of NDA No. 217062.

50. Upon information and belief, the foregoing actions by Auson 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.

51. Upon information and belief, Auson, by at least the offer for sale, sale, marketing, distribution, and/or importation of Auson’s 2.5 mg NDA Product and/or by the proposed labeling for Auson’s NDA 2.5 mg Product, will induce and/or contribute to the administration of Auson’s 2.5 mg NDA 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 Auson's 2.5 mg NDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

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

53. Upon information and belief, Auson has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, Auson has continued to assert its intent to engage in at least the offer for sale, sale, marketing, distribution, and/or importation of Auson's 2.5 mg NDA Product with Auson's proposed labeling immediately and imminently upon approval of NDA No. 217062. Upon information and belief, by such activities, Auson specifically intends to infringe the '310 patent.

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

55. Upon information and belief, Auson knows that Auson's 2.5 mg NDA Product is especially made or adapted for use in infringing the '310 patent, and that Auson's 2.5 mg NDA Product is not suitable for substantial noninfringing use. Auson's 2.5 mg NDA Product is a material part of the claimed invention. Upon information and belief, Auson plans and intends to, and will, contribute to the infringement of the '310 patent immediately and imminently upon approval of NDA No. 217062.

56. Upon information and belief, the foregoing actions by Auson 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.

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

58. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received the Auson Notice Letter.

COUNT I
(Infringement of the ’218 Patent)

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

60. Auson’s submission of NDA No. 217062 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Auson’s 10 mg NDA Product was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

61. Upon information and belief, Auson has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Auson’s 10 mg NDA Product with their proposed labeling prior to the expiration of the ’218 patent.

62. Auson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Auson’s 10 mg NDA Product with their proposed labeling immediately and imminently upon approval of NDA No. 217062, *i.e.*, prior to the expiration of the ’218 patent.

63. Upon information and belief, the foregoing actions by Auson 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.

64. Unless Auson 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)

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

66. 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 Auson on the other regarding Auson’s liability for infringement, active inducement of, and contribution to infringement of the ’218 patent.

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

68. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Auson’s 10 mg NDA Product will infringe, induce the infringement of, and contribute to the infringement of the ’218 patent.

COUNT III
(Infringement of the ’310 Patent)

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

70. Upon information and belief, Auson has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import

Auson's 2.5 mg NDA Product with their proposed labeling prior to the expiration of the '310 patent.

71. Upon information and belief, Auson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Auson's 2.5 mg NDA Product with their proposed labeling immediately and imminently upon approval of NDA No. 217062, *i.e.*, prior to the expiration of the '310 patent.

72. Upon information and belief, the foregoing actions by Auson 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 under 35 U.S.C. § 271(b)-(c).

73. Unless Auson 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)

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

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

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

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

* * *

WHEREFORE, Plaintiffs request the following relief:

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

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

(e) A judgment ordering that the effective date of any FDA approval for Auson to make, use, offer for sale, sell, market, distribute, or import Auson's 2.5 mg NDA 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 Auson, and all persons acting in concert with Auson, from making, using, selling, offering for sale, marketing, distributing, or importing Auson’s 2.5 mg NDA 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 of Auson’s 2.5 mg NDA 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.

Dated: June 1, 2023

s/ Keith J. Miller
Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
(973) 690-5400

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

OF COUNSEL:

Bruce R. Genderson
Dov P. Grossman
Alexander S. Zolan
Kathryn S. Kayali
Julie L. Tavares
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, and Bayer AG

Thomas D. Rein
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Andrew T. Langford
SIDLEY AUSTIN LLP
2021 McKinney Avenue, Suite 2000
Dallas, TX 75201
(214) 981-3300

Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

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.) (consolidated) (including Bayer Pharma AG et al. v. Dr. Reddy's Laboratories, Inc., Case No. 12-cv-00732 (RGA) (D. Del) and Bayer Pharma AG v. Teva Pharmaceuticals USA, Inc., No. 21-cv-01001 (RGA) (D. Del)); Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al., Case No. 21-cv-00099 (TSK) (N.D.W.V.) (subsequently designated Case No. 21-1742 (RGA) (D. Del.) in connection with MDL No. 21-md-3017); Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al., Case No. 22-cv-00063 (JPB) (N.D.W.V.) (subsequently designated Case No. 22-1228 (RGA) (D. Del.) in connection with MDL No. 21-md-3017); Mylan Pharmaceuticals Inc. v. Bayer Pharma Aktiengesellschaft, IPR2022-00517 (PTAB); Teva Pharmaceuticals USA, Inc. v. Bayer Pharma AG, IPR2022-01513 (PTAB); InvaGen Pharmaceuticals, Inc. v. Bayer Pharma AG, IPR2022-01515 (PTAB); Bayer Intellectual Property GmbH v. Mankind Pharma Limited, Case No. 3:22-cv-05599; Bayer AG et al. v. USV Private Limited, Case No. 3:22-cv-05485 (EP) (LDW) (D.N.J.) (subsequently designated Case No. 22-1492 (RGA) (D. Del.) in connection with MDL No. 21-md-3017); Bayer Pharma AG v. Apotex Inc., Case No. 22-cv-01596 (RGA) (D. Del.); Bayer Pharma AG et al. v. Dr. Reddy's Laboratories, Ltd. et al., 23-cv-00410 (RGA) (D. Del.); Bayer Pharma AG et al. v. Teva Pharmaceuticals USA, Inc., Case No. 23-cv-00551 (RGA) (D. Del.); Bayer Intellectual Property GmbH et al. v. Biocon Pharma Limited et al., Case No. 23-cv-00334 (RGA) (D. Del.).

OF COUNSEL: Bruce R. Genderson Dov P. Grossman Alexander S. Zolan Kathryn S. Kayali Julie L. Tavares WILLIAMS & CONNOLLY LLP 680 Maine Avenue SW Washington, DC 20024 (202) 434-5000 *Attorneys for Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, and Bayer AG* Thomas D. Rein SIDLEY AUSTIN LLP One South Dearborn Chicago, IL 60603 (312) 853-7000 Andrew T. Langford SIDLEY AUSTIN LLP 2021 McKinney Avenue, Suite 2000 Dallas, TX 75201 (214) 981-3300 *Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.*	*s/ Keith J. Miller* Keith J. Miller ROBINSON MILLER LLC Ironside Newark 110 Edison Place, Suite 302 Newark, NJ 07102 (973) 690-5400 *Attorney for Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, Bayer AG, and Janssen Pharmaceuticals, Inc.*