IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE XARELTO (RIVAROXABAN)('310) PATENT LITIGATION	C.A. No. 21-md-3017-RGA-LDH
BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC., *Plaintiffs*, v. PRINSTON PHARMACEUTICAL, INC., *Defendant.*	C.A. No. 24-336-RGA Jury Trial Demanded

PRINSTON PHARMACEUTICAL, INC.'s ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Prinston Pharmaceutical, Inc. ("Prinston"), for its Answer, Defenses and Counterclaims to the March 14, 2024 Complaint for Patent Infringement (D.I. 1) ("Complaint") of 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"), responds as follows. Every allegation not expressly admitted herein is denied.

ANSWER TO "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 Prinston Pharmaceutical, Inc. ("Prinston") 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").**

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that Plaintiffs' Complaint purports to state a claim for alleged infringement of United States Patent No. 9,539,218 (the "'218 Patent") and United States Patent No. 10,828,310 (the "'310 Patent"). Prinston admits to filing an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for rivaroxaban tablets ("Prinston's ANDA Products") prior to the expiration of the '218 and '310 patents. Prinston denies any and all remaining allegations of Paragraph 1.

ANSWER TO "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.**

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 2, and therefore denies any and all remaining allegations of Paragraph 2.

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.**

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 3, and therefore denies any and all remaining allegations of Paragraph 3.

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.**

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 4, and therefore denies any and all remaining allegations of Paragraph 4.

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.**

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 5, and therefore denies any and all remaining allegations of Paragraph 5.

Defendant

6. **Upon information and belief, Defendant Prinston is a corporation organized and existing under the laws of Delaware, with a principal place of business at 700 Atrium Dr., Somerset, New Jersey 08873.**

ANSWER: Admitted.

7. **Upon information and belief, Prinston 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, Prinston 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, Prinston 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.**

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it researches and develops generic pharmaceutical products. Prinston admits that it filed an ANDA seeking approval to manufacture and sell Prinston's ANDA Products, which included Paragraph IV Certifications for the '218 and '310 patents. Prinston denies any and all remaining allegations in Paragraph 7.

8. **Upon information and belief, Prinston prepared and submitted ANDA No. 208459 for Prinston's 2.5 mg, 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Prinston's ANDA Products"). The 10 mg, 15 mg, and 20 mg strengths of Prinston's ANDA Products are referred to collectively herein as "Prinston's 10 mg, 15 mg, and 20 mg ANDA Products." The 2.5 strength of Prinston's ANDA Products is referred to herein as "Prinston's 2.5 mg ANDA Product."**

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to manufacture and sell rivaroxaban tablets (2.5 mg, 10 mg, 15 mg, and 20 mg) ("Prinston's ANDA Products"). Prinston denies any and all remaining allegations in Paragraph 8.

9. **Upon information and belief, following any FDA approval of ANDA No. 208459, Prinston will market, distribute, offer for sale, and sell Prinston's ANDA Products throughout the United States and within Delaware.**

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to manufacture and sell Prinston's ANDA Products before the expiration of the '218 and '310 patents. Prinston denies any and all remaining allegations in Paragraph 9.

10. **Upon information and belief, following any FDA approval of ANDA No. 208459, Prinston knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.**

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '218 and '310 patents. Prinston denies any and all remaining allegations in Paragraph 10.

ANSWER TO "JURISDICTION"

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

ANSWER: Prinston incorporates by reference its responses to the preceding Paragraphs 1-10 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that subject matter jurisdiction is proper, if at all, solely for Plaintiffs' alleged infringement claims against Prinston under 35 U.S.C. § 271(e)(2)(A). Prinston denies that subject matter jurisdiction is proper for any claims asserted against Prinston under 35 U.S.C. § 271(a), (b) or (c). Prinston denies any and all remaining allegations of Paragraph 12.

13. **This Court has personal jurisdiction over Prinston because, among other things, Prinston has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Prinston is a corporation formed under the laws of the state of Delaware, and has appointed registered agents in Delaware (American Incorporators Ltd., 1013 Centre Road, Suite 403-A, Wilmington, DE) to accept service of process. It therefore has consented to general jurisdiction in Delaware.**

ANSWER: Paragraph 13 contains legal conclusions for which no answer is required. To the extent an answer is required, denied. Further answering, Prinston does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only.

14. **This Court also has personal jurisdiction over Prinston because, among other things, on information and belief: (1) Prinston 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 Prinston's ANDA Products in the United States, including in Delaware; and (2) Prinston will market, distribute, offer for sale, and/or sell Prinston's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208459, and will derive substantial revenue from the use or consumption of Prinston's ANDA Products in the State of Delaware. Upon information and belief, if ANDA No. 208459 is approved, the generic Prinston 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.**

ANSWER: Paragraph 14 contains legal conclusions for which no answer is required. To the extent an answer is required, denied. Further answering, Prinston does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only.

ANSWER TO "VENUE"

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

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, Prinston does not contest venue in this judicial district solely for the limited purpose of this action only.

ANSWER TO "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.**

ANSWER: Prinston admits that the label for XARELTO® states that the active ingredient is rivaroxaban and 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. Prinston admits that the label for XARELTO® states that XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg strengths. Prinston denies any and all remaining allegations in Paragraph 16.

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

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that, according to FDA's online records, "JANSSEN PHARMS" is the holder of NDA No. 022406 for XARELTO®, rivaroxaban tablets. Prinston denies any and all remaining allegations of Paragraph 17.

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.**

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that, according to the online records of the PTO, the '218 patent, which is titled "Prevention and Treatment of Thromboembolic Disorders," issued on or about January 10, 2017. Prinston denies that the '218 patent was duly and legally issued, as well as any suggestion that the '218 patent is valid and enforceable. Prinston denies any and all remaining allegations of Paragraph 18.

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."**

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that Claim 1 of the '218 patent recites:

> **1**. 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.

'218 Patent, Claim 1. Prinston denies any and all remaining allegations of Paragraph 19.

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

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston states that the face of the '218 patent identifies Bayer

Intellectual Property GmbH as the purported assignee. Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 20, and therefore denies any and all remaining allegations of Paragraph 20.

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

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 21, and therefore denies any and all allegations of Paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 22, and therefore denies any and all allegations of Paragraph 22.

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.**

ANSWER: Paragraph 23 contains legal conclusions for which no answer is required. To the extent an answer is required, Prinston admits that the electronic version of FDA's Orange Book currently lists the '218 patent in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg strengths. Prinston denies any and all remaining allegations of Paragraph 23.

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.**

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that, according to the online records of the PTO, the '310 patent, which is titled "Reducing the Risk of Cardiovascular Events," issued on or about

November 10, 2020. Prinston denies that the '310 patent was duly and legally issued, as well as any suggestion that the '310 patent is valid and enforceable. Prinston denies any and all remaining allegations of Paragraph 24.

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."**

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that Claim 1 of the '310 patent recites:

> **1**. 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.

'310 Patent, Claim 1. Prinston denies any and all remaining allegations of Paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston states that the face of the '310 patent Identifies Bayer Pharma Aktiengesellschaft as the purported assignee. Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 26, and therefore denies any and all remaining allegations of Paragraph 26.

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

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 27, and therefore denies any and all allegations of Paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 28, and therefore denies any and all allegations of Paragraph 28.

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®.**

ANSWER: Paragraph 29 contains legal conclusions for which no answer is required. To the extent an answer is required, Prinston admits that the electronic version of FDA's Orange Book currently lists the '310 patent in connection with XARELTO® tablets in the 2.5 mg strength. Prinston denies any and all remaining allegations of Paragraph 29.

Answer to "Infringement by Prinston"

30. **By letter dated February 1, 2024 (the "Prinston Notice Letter"), Prinston notified Bayer AG, BIP, Bayer Pharma AG, and Janssen that Prinston had submitted to the FDA ANDA No. 208459 for Prinston's ANDA Products. These products are generic versions of XARELTO®.**

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it sent a letter dated February 1, 2024, to Janssen Pharmaceuticals, Inc., Bayer Intellectual Property GmbH, Bayer AG, and Bayer Pharma AG titled "Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 9,539,218 B2 and 10,828,310 B2, Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("PIV Notice Letter"). Further answering, Prinston admits that it

submitted ANDA No. 208459 to FDA seeking approval for rivaroxaban tablets. Prinston denies any and all remaining allegations of Paragraph 30.

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

ANSWER: Prinston admits that Prinston's Notice Letter stated: "Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is rivaroxaban; the strengths of the proposed drug products are 2.5 mg, 10 mg, 15 mg, and 20 mg of rivaroxaban; and the dosage form of the proposed drug products is a tablet." Prinston denies any and all remaining allegations of Paragraph 31.

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

ANSWER: Prinston admits that Prinston's Notice Letter stated: "Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is rivaroxaban; the strengths of the proposed drug products are 2.5 mg, 10 mg, 15 mg, and 20 mg of rivaroxaban; and the dosage form of the proposed drug products is a tablet." Prinston denies any and all remaining allegations of Paragraph 32.

33. **In the Prinston Notice Letter, Prinston indicated that, in connection with its ANDA No. 208459, Prinston had filed Paragraph IV Certifications with respect to the '218 patent and to the '310 patent.**

ANSWER: Prinston admits that Prinston's Notice Letter stated that Prinston's ANDA "was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Rivaroxaban Tablets, 2.5 mg, 10 mg, 15 mg, and 20 mg, before the expiration of the 218 patent, which is listed in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") with respect to

Xarelto® (Rivaroxaban) Tablets, 10 mg, 15 mg, and 20 mg; and before the expiration of the 310 patent, which is listed in the Orange Book with respect to Xarelto® (Rivaroxaban) Tablets, 2.5 mg."

34. **Upon information and belief, the purpose of ANDA No. 208459 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 Prinston's ANDA Products with their proposed labeling prior to the expiration of the '218 patent and of the '310 patent.**

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '218 and '310 patents. Prinston denies any and all remaining allegations in Paragraph 34.

35. **Upon information and belief, Prinston intends to engage in the manufacture, use, offer for sale, and/or sale of Prinston's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208459, *i.e.*, prior to the expiration of the '218 patent and of the '310 patent.**

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '218 and '310 patents. Prinston denies any and all remaining allegations in Paragraph 35.

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

ANSWER: Prinston admits that Prinston's Notice Letter stated: "Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is rivaroxaban; the strengths of the proposed drug products are 2.5 mg, 10 mg, 15 mg, and 20 mg of rivaroxaban; and the dosage form of the proposed drug products is a tablet." Prinston denies any and all remaining allegations of Paragraph 36.

37. **Upon information and belief, the proposed labeling for Prinston's ANDA Products directs the use of Prinston'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 Prinston's ANDA Products directs the use of Prinston'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.**

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston states that the text of the proposed labeling for Prinston's ANDA Products speaks for itself. Prinston denies any and all remaining allegations of Paragraph 37.

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

ANSWER: Denied.

39. **Prinston has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Prinston has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208459. Upon information and belief, by such activities, Prinston specifically intends to infringe the '218 patent.**

ANSWER: Denied.

40. **Upon information and belief, Prinston 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.**

ANSWER: Denied.

41. **Upon information and belief, Prinston knows that Prinston's 10 mg, 15 mg, and**

20 mg ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Prinston's 10 mg, 15 mg, and 20 mg ANDA Products are not suitable for substantial noninfringing use. Prinston's 10 mg, 15 mg, and 20 mg ANDA Products are a material part of the invention. Upon information and belief, Prinston plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 208459.

ANSWER: Denied.

42. **The foregoing actions by Prinston 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.**

ANSWER: Denied.

43. **Upon information and belief, the proposed label for Prinston'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 Prinston's 2.5 mg ANDA Product further directs the administration of Prinston'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 Prinston'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.**

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston states that the text of the proposed labeling for Prinston's ANDA Products speaks for itself. Prinston denies any and all remaining allegations of Paragraph 43.

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

ANSWER: Denied.

45. **Prinston has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, Prinston has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's 2.5 mg ANDA Product with Prinston's proposed labeling immediately and imminently upon approval of ANDA No. 208459. Upon information and belief, by such activities, Prinston specifically intends to infringe the '310 patent.**

ANSWER: Denied.

46. **Upon information and belief, Prinston 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.**

ANSWER: Denied.

47. **Upon information and belief, Prinston knows that Prinston's 2.5 mg ANDA Product is especially made or adapted for use in infringing the '310 patent, and that Prinston's 2.5 mg ANDA Product is not suitable for substantial noninfringing use. Prinston's 2.5 mg ANDA Product is a material part of the invention. Upon information and belief, Prinston plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 208459.**

ANSWER: Denied.

48. **The foregoing actions by Prinston 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.**

ANSWER: Denied.

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

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it sent a PIV Notice Letter on February 1, 2024, to Janssen Pharmaceuticals, Inc., Bayer Intellectual Property GmbH, Bayer AG, and Bayer Pharma AG. Prinston denies any and all remaining allegations of Paragraph 50.

ANSWER TO "COUNT I: INFRINGEMENT OF THE '218 PATENT"

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

ANSWER: Prinston incorporates by reference its responses to the preceding Paragraphs 1-50 of the Complaint as if fully set forth herein.

52. **Prinston's submission of ANDA No. 208459 for the purpose of obtaining**

approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston'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).

ANSWER: Denied.

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

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '218 patent. Prinston denies any and all remaining allegations in Paragraph 53.

54. **Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208459, *i.e.*, prior to the expiration of the '218 patent.**

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '218 patent. Prinston denies any and all remaining allegations in Paragraph 54.

55. **The foregoing actions by Prinston 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.**

ANSWER: Denied.

56. **Unless Prinston 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.**

ANSWER: Denied.

ANSWER TO "COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '218 PATENT"

57. **Plaintiffs incorporate each of the preceding paragraphs as if fully set forth**

herein.

ANSWER: Prinston incorporates by reference its responses to the preceding Paragraphs 1-56 of the Complaint as if fully set forth herein.

58. **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 Prinston on the other regarding Prinston's liability for infringement, active inducement, and contribution to infringement of the '218 patent.**

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

60. **The Court should declare that the commercial manufacture, use, offer for sale, sale, or importation of Prinston'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.**

ANSWER: Denied.

ANSWER TO "COUNT III: INFRINGEMENT OF THE '310 PATENT"

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

ANSWER: Prinston incorporates by reference its responses to the preceding Paragraphs 1-60 of the Complaint as if fully set forth herein.

62. **Prinston's submission of ANDA No. 208459 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston'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).**

ANSWER: Denied.

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

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '310 patent. Prinston denies any and all remaining allegations in Paragraph 63.

64. **Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208459, *i.e.*, prior to the expiration of the '310 patent.**

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Prinston admits that it filed ANDA No. 208459 seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's ANDA Products before the expiration of the '310 patent. Prinston denies any and all remaining allegations in Paragraph 64.

65. **The foregoing actions by Prinston 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).**

ANSWER: Denied.

66. **Unless Prinston 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.**

ANSWER: Denied.

ANSWER TO "COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT"

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

ANSWER: Prinston incorporates by reference its responses to the preceding Paragraphs 1-66 of the Complaint as if fully set forth herein.

68. **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 Prinston on the other regarding Prinston's liability for infringement, active inducement of infringement, and/or contribution to**

infringement of the '310 patent.

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

Prinston denies that Plaintiff is entitled to any relief sought in Plaintiffs' Request for Relief in the Complaint or any relief whatsoever, including but not limited to Plaintiffs' Requests for Relief (a)-(k).

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any allegations in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Prinston asserts the following separate defenses:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

Each and every claim of the '218 patent is invalid for failure to satisfy one or more conditions of patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid for double patenting.

Third Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of Prinston's ANDA Products that are the subject of Prinston's ANDA have not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '218 patent, either literally or under the doctrine of equivalents.

Fourth Defense

Prinston has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '218 patent.

Fifth Defense

Prinston has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '218 patent.

Sixth Defense

Each and every claim of the '310 patent is invalid for failure to satisfy one or more conditions of patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid for double patenting.

Seventh Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of Prinston's ANDA Products that are the subject of Prinston's ANDA have not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '310 patent, either literally or under the doctrine of equivalents.

Eighth Defense

Prinston has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '310 patent.

Ninth Defense

Prinston has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '310 patent.

Tenth Defense

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

Eleventh Defense

The Complaint fails to state a claim for willful infringement and/or an exceptional case.

Twelfth Defense

Any additional defenses or counterclaims that discovery may reveal, including but not limited to unenforceability. Prinston reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Prinston Pharmaceutical, Inc. ("Prinston"), for its Counterclaims against Plaintiffs/Counter-Defendants Bayer Intellectual Property GmbH, Bayer Pharma AG, Bayer AG (collectively, "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Counter-Defendants"), alleges as follows:

The Parties

1. Defendant Prinston is a corporation organized and existing under the laws of Delaware, with a principal place of business at 700 Atrium Dr., Somerset, New Jersey 08873.

2. Counterclaim-Defendant Bayer Intellectual Property GmbH purports to be 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. Counterclaim-Defendant Bayer Pharma AG purports to be 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. Counterclaim-Defendant Bayer AG purports to be 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. Counterclaim-Defendant Janssen Pharmaceuticals, Inc. purports to be 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.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges—and subjected themselves to the jurisdiction—of this forum by suing Prinston in this District, and/or because Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

XARELTO ®

10. According to the United States Food and Drug Administration's ("FDA") website,

Janssen Pharmaceuticals, Inc. holds approved New Drug Application ("NDA") No. 022406, under which the FDA granted approval for XARELTO®, rivaroxaban tablets (2.5 mg, 10 mg, 15 mg, and 20 mg).

11. At the time the Complaint was filed, the electronic version of U.S. Food and Drug Administration's ("FDA") publication, Approved Drug Products with Therapeutic Equivalence Evaluations (a/k/a FDA's Orange Book) ("Orange Book"), listed U.S. Patent No. 9,539,218 ("the '218 patent") and U.S. Patent No. 10,828,310 ("the '310 patent"), in connection with NDA No. 022406.

The '218 Patent

12. On or about January 10, 2017, the PTO issued U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders."

13. The face of the '218 patent identifies Frank Misselwitz, Dagmar Kubitza Son-Mi Park, and Klaus Wehling as the purported inventors.

14. The face of the '218 patent identifies Bayer Intellectual Property GmbH as the purported assignee of the '218 patent.

15. By listing the '218 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Prinston—that attempts to seek approval for, and market, a generic version of XARELTO® before patent expiration.

The '310 Patent

16. On or about November 10, 2020, the PTO issued U.S. Patent No. 10,828,310 ("the '310 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders."

17. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020.

18. The face of the '310 patent identifies Nancy Cook Bruns, Frank Misselwitz, John William Andrew Eikelboom, Stuart J. Connolly, and Salim Yusuf as the purported inventors.

19. The face of the '310 patent identifies Bayer Pharma AG as the purported assignee of the '310 patent.

20. By listing the '310 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Prinston—that attempts to seek approval for, and market, a generic version of XARELTO® before patent expiration.

Prinston's ANDA Products

21. Prinston has filed ANDA No. 208459 ("Prinston's ANDA") with the FDA.

22. Because Prinston's ANDA seeks FDA approval to engage in the commercial manufacture, use or sale rivaroxaban tablets ("Prinston's ANDA Products") prior to the expiration of the '218 and '310 patents.

23. Prinston's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '218 and '310 patents.

24. On March 14, 2024, Plaintiffs/Counterclaim-Defendants filed the above-captioned action against Prinston, asserting infringement of the '218 and '310 patents.

COUNT I

Declaration of Invalidity of the '218 Patent

25. Prinston realleges and incorporates by reference the allegations in the preceding Paragraphs 1-24 as if fully set forth herein.

26. A present, genuine, and justiciable controversy exists between Plaintiffs and Prinston regarding, *inter alia*, the invalidity of the '218 patent.

27. The claims of the '218 patent are invalid for failure to satisfy one or more of the

conditions for patentability in Title 35 of the United States Code and/or for double patenting.

28. The claims of the '218 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the '218 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least U.S. Patent Application Publication No. 2003/0153610 Al, Sebastian Harder et al., *Effects of BAY 59-7939, an Oral, Direct Factor Xa Inhibitor, on Thrombin Generation in Healthy Volunteers*, Abstract # 3003, 102 BLOOD 811a (2003), Dagmar Kubitza et al., *Multiple Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY 59-7939, an Oral, Direct Factor Xa Inhibitor in Healthy Male Subjects*, Abstract # 3004, 102 BLOOD 811a (2003), Dagmar Kubitza et al., *Single Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY 59-7939, an Oral, Direct Factor Xa Inhibitor in Healthy Male Subjects*, Abstract # 3010, 102 BLOOD 813a (2003), Robert J. Leadley, Jr., *Coagulation Factor Xa Inhibition: Biological Background and Rationale*, 2001 CURRENT TOPICS MEDICINAL CHEMISTRY 151 (2001), Perzborn et al., In vitro *and* In Vivo *Studies of the Novel Antithrombotic Agent BAY 59-7939—An Oral, Direct Factor Xa Inhibitor*, 3 J. THROMBOSIS & HAEMOSTASIS 514 (2005), alone or in combination with other prior art.

29. Prinston reserves the right to provide additional bases for invalidity of the '310 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

30. Prinston is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not infringe any valid and enforceable claim of the '218 patent.

COUNT II
Declaration of Noninfringement of the '218 Patent

31. Prinston realleges and incorporates by reference the allegations in the preceding

Paragraphs 1-30 as if fully set forth herein.

32. A present, genuine, and justiciable controversy exists between Plaintiffs and Prinston regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Prinston's ANDA Products would infringe any valid and enforceable claim of the '218 patent.

33. The manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '218 patent, either literally or under the doctrine of equivalents.

34. Prinston is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not infringe any valid and enforceable claim of the '218 patent.

COUNT III
Declaration of Invalidity of the '310 Patent

35. Prinston realleges and incorporates by reference the allegations in the preceding Paragraphs 1-34 as if fully set forth herein.

36. A present, genuine, and justiciable controversy exists between Plaintiffs and Prinston regarding, *inter alia*, the invalidity of the '310 patent.

37. The claims of the '310 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double patenting.

38. The claims of the '310 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the '310 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least T. Raymond Foley et al., *Antithrombotic Therapy in Peripheral Artery Disease*, 21 VASCULAR MED. 156 (2016), Greg L. Plosker, *Rivaroxaban: A Review of Its Use in Acute Coronary Syndromes*, 74 DRUGS 451 (2014), European Medicines Agency, *Assessment Report, Xarelto*, EMA/CHMP/794349/2012 (2013), Dagmar Kubitza et al., *Safety, Tolerability,*

Pharmacodynamics, and Pharmacokinetics of Rivaroxaban—an Oral, Direct Factor Xa Inhibitor—Are Not Affected by Aspirin, 46 J. CLINICAL PHARMACOLOGY 981 (2006), Jennifer B. Dressman et al., *Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Acetylsalicylic Acid*, 101 J. PHARM. SCIS. 2653 (2012), alone or in combination with other prior art.

39. Prinston reserves the right to provide additional bases for invalidity of the '310 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

40. Prinston is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not infringe any valid and enforceable claim of the '310 patent.

COUNT IV
Declaration of Noninfringement of the '310 Patent

41. Prinston realleges and incorporates by reference the allegations in the preceding Paragraphs 1-40 as if fully set forth herein.

42. A present, genuine, and justiciable controversy exists between Plaintiffs and Prinston regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Prinston's ANDA Products would infringe any valid and enforceable claim of the '310 patent.

43. The manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '310 patent, either literally or under the doctrine of equivalents.

44. Prinston is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Products would not infringe any valid and enforceable claim of the '310 patent.

REQUEST FOR RELIEF

WHEREFORE, Prinston respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff as follows:

(a) declaring that the manufacture, sale, offer for sale, use or importation of Prinston's ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '218 patent;

(b) declaring that the claims of the '218 patent are invalid;

(c) declaring that the manufacture, sale, offer for sale, use or importation of Prinston's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '310 patent;

(d) declaring that the claims of the '310 patent are invalid;

(e) ordering that Plaintiff's Complaint be dismissed with prejudice and judgment entered in favor of Prinston;

(f) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Prinston its attorneys' fees, costs, and expenses in this action; and

(g) awarding Prinston any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Prinston hereby demands a jury trial on all issues so triable.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

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Dated: July 29, 2024