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*Attorneys for Defendants Auson Pharmaceuticals Inc. and Shanghai Auson Pharmaceuticals Co., Ltd.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

BAYER INTELLECTUAL PROPERTY GMBH,  
BAYER PHARMA AG, BAYER AG, AND  
JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

AUSON PHARMACEUTICALS INC. AND  
AUSON PHARMACEUTICALS CO., LTD.,

Defendants.

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Civil Action No. 2:23-cv-03020-EP-  
LDW

*(Document filed electronically)*

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AUSON PHARMACEUTICALS INC. AND  
SHANGHAI AUSON PHARMACEUTICALS CO.,  
LTD.,

Counterclaim-Plaintiffs

v.

BAYER INTELLECTUAL PROPERTY GMBH,  
BAYER PHARMA AG, BAYER AG, AND  
JANSSEN PHARMACEUTICALS, INC.,

Counterclaim-Defendants.

**AUSON PHARMACEUTICALS INC. AND SHANGHAI AUSON PHARMACEUTICALS CO., LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Auson Pharmaceutical, Inc. (“Auson US”) and Shanghai Auson Pharmaceuticals Co., Ltd. (“Shanghai Auson”) (collectively, “Auson” or “Defendants”) hereby answer the Complaint filed by Bayer Intellectual Property GmbH (“BIP”), Bayer Pharma AG, Bayer AG (collectively, “Bayer”), and Janssen Pharmaceuticals, Inc. (“Janssen”) (collectively, “Plaintiffs”). Additionally, Defendants hereby assert counterclaims for declaratory judgment of noninfringement and invalidity of U.S. Patent No. 9,539,218 (“the ’218 patent”) and U.S. Patent No. 10,828,310 (“the ’310 patent”) (collectively, the “Patents-in-Suit”) against Bayer and Janssen (collectively, the “Counterclaim-Defendants”). Defendants deny all allegations in the Complaint except those admitted specifically below. With respect to the allegations made in the Complaint, upon knowledge with respect to Defendants’ own acts, and upon information and belief as to other matters, Defendants respond and 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”).

**Defendants’ Response:** Defendants admit that Plaintiffs purport to bring this action for patent infringement of the Patents-in-Suit under the patent laws of the United States, 35 U.S.C. §100, et seq. Defendants admit that Auson US holds the rights, title, and ownership to an NDA filed with the FDA seeking, in part, approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Auson’s 2.5 mg and 10 mg strength NDA products. The

remaining allegations in Paragraph 1 constitute conclusions of law to which no answer is required.

To the extent an answer is required, Defendants deny the remaining allegations of Paragraph 1.

**The Parties**

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.

**Defendants' Response:** Paragraph 2 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and on that basis deny them.

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.

**Defendants' Response:** Paragraph 3 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and on that basis deny them.

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.

**Defendants' Response:** Paragraph 4 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and on that basis deny them.

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.

**Defendants' Response:** Paragraph 5 is not directed to Defendants and therefore does not

require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 and on that basis deny them.

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.

**Defendants' Response:** Denied.

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

**Defendants' Response:** Defendants admit the allegations of Paragraph 7.

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

**Defendants' Response:** Denied. Defendant Auson Pharmaceuticals Inc. (“Auson US”) is a wholly owned subsidiary of Shanghai Auson Pharmaceuticals Co., Ltd. (“Shanghai Auson”).

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.

**Defendants' Response:** Denied. Defendants admit that Shanghai Auson and Auson US collaborate in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. The remaining allegations in Paragraph 9 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants

deny the remaining allegations of Paragraph 9.

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").

**Defendants' Response:** Denied. Defendants admit that Shanghai Auson and Auson US collaborated to prepare and submit NDA No. 217062 for Auson's 2.5 mg NDA product and 10 mg NDA product, which are both intended to be administered as oral suspensions. Defendants deny the remaining allegations in Paragraph 10.

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

**Defendants' Response:** The allegations in Paragraph 11 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 11.

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."

**Defendants' Response:** Denied. Defendants admit that, following FDA approval of NDA No. 217062, Auson US and Shanghai Auson (collectively, "Auson") may collaborate to market, distribute, offer for sale, and sell Auson's NDA products in the United States. Defendants deny the remaining allegations in Paragraph 12.

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.

**Defendants' Response:** Denied. Defendants admit that, following FDA approval of NDA No. 217062, Auson's NDA products may be marketed, distributed, offered for sale, and sold in the United States. Defendants deny the remaining allegations in Paragraph 13.

**Jurisdiction**

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

**Defendants' Response:** Defendants incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

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

**Defendants' Response:** Defendants admit that this action purports to arise under the patent laws of the United States. The remaining allegations in Paragraph 15 constitute conclusions of law to which no answer is required.

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.

**Defendants' Response:** Denied. The allegations in Paragraph 16 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only.

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

**Defendants' Response:** Denied.

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.

**Defendants' Response:** Denied. The allegations in Paragraph 18 constitute conclusions of law to which no answer is required.

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.

**Defendants' Response:** Denied. The allegations in Paragraph 19 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only and deny the remaining allegations of Paragraph 19.

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).

**Defendants' Response:** Denied. The allegations in Paragraph 20 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only and deny the remaining allegations of Paragraph 20.

### Venue

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

**Defendants' Response:** The allegations of Paragraph 21 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

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.

**Defendants' Response:** The allegations of Paragraph 22 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

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.

**Defendants' Response:** The allegations of Paragraph 23 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

### **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.

**Defendants' Response:** Paragraph 24 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 and on that basis deny them.

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

**Defendants' Response:** Paragraph 25 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 and on that basis deny them.

### **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.

**Defendants' Response:** Paragraph 26 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants deny that the ‘218 Patent was “duly and legally issued.” Exhibit A speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 26 and on that basis deny them.

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.”

**Defendants’ Response:** Paragraph 27 is not directed to Defendants and therefore does not require a response. To the extent a response is required, the ’218 Patent speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 27 and on that basis deny them.

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

**Defendants’ Response:** Paragraph 28 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 and on that basis deny them.

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

**Defendants’ Response:** Paragraph 29 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 and on that basis deny them.

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

**Defendants’ Response:** Paragraph 30 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and on that basis deny them.

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.

**Defendants' Response:** Paragraph 31 is not directed to Defendants and therefore does not require a response. To the extent a response is required, the Orange Book speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 31 and on that basis deny them.

**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.

**Defendants' Response:** Paragraph 32 is not directed to Defendants and therefore does not require a response. Exhibit B speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 32 and on that basis deny them.

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."

**Defendants' Response:** Paragraph 33 is not directed to Defendants and therefore does not require a response. To the extent a response is required, the '310 Patent speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 33 and on that basis deny them.

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

**Defendants' Response:** Paragraph 34 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 and on that basis deny them.

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

**Defendants' Response:** Paragraph 35 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 and on that basis deny them.

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

**Defendants' Response:** Paragraph 36 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 and on that basis deny them.

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®.<sup>1</sup>

**Defendants' Response:** The above sentence is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the above sentence and on that basis deny them.

#### 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

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<sup>1</sup> This allegation does not have a separate paragraph number in Plaintiffs' Complaint (ECF 1, p. 8).

XARELTO®

**Defendants' Response:** Denied. Defendants admit that Auson sent a Notice Letter to BIP, Bayer AG, and Janssen on April 17, 2023. Auson's Notice Letter otherwise speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 37.

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.

**Defendants' Response:** Denied. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations in Paragraph 38.

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.

**Defendants' Response:** Denied. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations in Paragraph 39.

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.

**Defendants' Response:** Denied. Defendants admit submitting NDA No. 217062 to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, offer for sale, and/or sale of Auson's 2.5 mg NDA product and Auson's 10 mg NDA product with their respective proposed labeling. Defendants deny the remaining allegations in Paragraph 40.

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.

**Defendants' Response:** Denied. Defendants admit that Auson intends to engage in the manufacture, offer for sale, and/or sale of Auson's 2.5 mg NDA product and Auson's 10 mg NDA product with their respective proposed labeling following FDA approval of NDA No. 217062. The remaining allegations in Paragraph 41 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the remainder of the allegations in Paragraph 41.

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.

**Defendants' Response:** Denied. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 42.

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.

**Defendants' Response:** Denied. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. The remaining allegations in Paragraph 43 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the remainder of the allegations in Paragraph 43.

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.

**Defendants' Response:** Denied. The allegations in Paragraph 44 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 44.

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.

**Defendants' Response:** Denied. The allegations in Paragraph 45 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 45.

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.

**Defendants' Response:** Denied. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations in Paragraph 46.

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.

**Defendants' Response:** Denied. Defendants admit having knowledge of the claims of the '218 Patent. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. The remaining allegations of Paragraph 47 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 47.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 48 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 48.

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

**Defendants' Response:** Denied. The allegations of Paragraph 49 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 49.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 50 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 50.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 51 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 51.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 52 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 52.

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.

**Defendants' Response:** Denied. Defendants admit having knowledge of the claims of the '310 Patent. Auson's Notice Letter speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. The remaining allegations of Paragraph 53 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 53.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 54 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 54.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 55 constitute conclusions of

law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 55.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 56 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 56.

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

**Defendants' Response:** Denied. The allegations of Paragraph 57 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 57.

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

**Defendants' Response:** Denied. Paragraph 58 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 58 and on that basis deny them.

**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.

**Defendants' Response:** Defendants incorporate by reference the preceding paragraphs of this Answer 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).

**Defendants' Response:** Denied. The allegations of Paragraph 60 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 60.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 61 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 61.

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.

**Defendants' Response:** Denied. Defendants admit that Auson intends to engage in the manufacture, offer for sale, sale, marketing, distribution, and/or importation of Auson's 10 mg NDA product with its proposed labeling following FDA approval of NDA No. 217062. The remaining allegations in Paragraph 62 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the remainder of the allegations in Paragraph 62.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 63 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 63.

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.

**Defendants' Response:** Denied. Paragraph 64 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 64 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64 and on that basis deny them.

**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.

**Defendants' Response:** Defendants incorporate by reference the preceding paragraphs of this Answer 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.

**Defendants' Response:** Denied. The allegations of Paragraph 66 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 66.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 67 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 67.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 68 constitute conclusions of

law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 68.

**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.

**Defendants' Response:** Defendants incorporate by reference the preceding paragraphs of this Answer 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.

**Defendants' Response:** Denied. The allegations of Paragraph 70 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 70.

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.

**Defendants' Response:** Denied. Defendants admit that Auson intends to engage in the manufacture, offer for sale, sale, marketing, distribution, and/or importation of Auson's 2.5 mg NDA product with its proposed labeling following FDA approval of NDA No. 217062. The remaining allegations in Paragraph 71 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the remainder of the allegations in Paragraph 71.

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).

**Defendants' Response:** Denied. The allegations of Paragraph 72 constitute conclusions of

law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 72.

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.

**Defendants' Response:** Denied. Paragraph 73 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 73 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73 and on that basis deny them.

**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.

**Defendants' Response:** Defendants incorporate by reference the preceding paragraphs of this Answer 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.

**Defendants' Response:** Denied. The allegations of Paragraph 75 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 75.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 76 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the

allegations of Paragraph 76.

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.

**Defendants' Response:** Denied. The allegations of Paragraph 1<sup>2</sup> constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 1.

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**THE REMAINDER OF THE COMPLAINT IS A PRAYER FOR RELIEF AND DOES NOT REQUIRE A RESPONSE. TO THE EXTENT ANY RESPONSE IS REQUIRED, DEFENDANTS DENY THAT PLAINTIFFS ARE ENTITLED TO ANY REMEDY OR RELIEF.**

**DEFENDANTS' AFFIRMATIVE DEFENSES**

**DEFENDANTS ASSERT THE FOLLOWING DEFENSES WITHOUT PREJUDICE TO THE DENIALS IN THIS ANSWER, AND WITHOUT ADMITTING ANY ALLEGATIONS OF THE COMPLAINT NOT OTHERWISE ADMITTED. DEFENDANTS RESERVE THE RIGHT TO ASSERT ADDITIONAL DEFENSES AS WARRANTED BY FACTS LEARNED THROUGH INVESTIGATION AND DISCOVERY.**

**First Affirmative Defense – Non-infringement of the '218 Patent**

Defendants' 2.5 mg and 10 mg NDA products have not infringed, do not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '218 Patent, literally or under the Doctrine of Equivalents, and in relation to any allegations of Declaratory Judgment of Infringement of the '218 Patent.

**Second Affirmative Defense – Invalidity of the '218 Patent**

Each claim of the '218 Patent is invalid for failure to comply with one or more conditions

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<sup>2</sup> Plaintiff's Complaint (ECF 1, p. 16) numbers this paragraph as "1." Defendants follow this numbering scheme accordingly.

and requirements for patentability, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or is invalid for obvious-type double patenting or under other judicially created bases for invalidity.

**Third Affirmative Defense – Non-infringement of the '310 Patent**

Defendants' 2.5 mg and 10 mg NDA products have not infringed, do not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '310 Patent, literally or under the Doctrine of Equivalents, and in relation to any allegations of Declaratory Judgment of Infringement of the '310 Patent.

**Fourth Affirmative Defense – Invalidity of the '310 Patent**

Each claim of the '310 Patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or is invalid for obvious-type double patenting or under other judicially created bases for invalidity, consistent with the PTAB's recent invalidation of the '310 Patent.

**Fifth Affirmative Defense – No Relief Available**

Plaintiffs are barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1 et seq., including but not limited to §§ 286 and 287. Plaintiffs have not suffered any damages. Plaintiff is not suffering an irreparable injury.

**Sixth Affirmative Defense – Failure to State a Claim**

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

**Seventh Affirmative Defense – No Exceptional Case**

Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

**Eighth Affirmative Defense – Estoppel**

Plaintiffs are estopped from asserting infringement by the doctrines of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

**Ninth Affirmative Defense – Damages**

Plaintiffs' damages, if any, are limited pursuant to 35 U.S.C. §§ 286-287.

**Tenth Affirmative Defense – Lack of Subject Matter Jurisdiction**

Plaintiffs' Counts for infringement and declaratory judgment of infringement based on the '310 patent lack subject matter jurisdiction.

**RESERVATION OF DEFENSES**

Defendants reserve the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

**DEFENDANTS' COUNTERCLAIMS**

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer *supra*, and without prejudice to Defendants/Counterclaim-Plaintiffs' right to plead additional counterclaims as the facts of the matter warrant, Defendants/Counterclaim-Plaintiffs, Auson Pharmaceutical, Inc. ("Auson US") and Shanghai Auson Pharmaceuticals Co., Ltd. ("Shanghai Auson") (collectively, "Auson" or "Counterclaim-Plaintiffs") for their Counterclaims against Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG, Bayer AG (collectively, "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "Counterclaim-Defendants"), state as follows:

**NATURE AND SUMMARY OF COUNTERCLAIMS**

1. These counterclaims include claims for declaratory judgment that U.S. Patent No. 9,539,218 (the "'218 patent") and U.S. Patent No. 10,828,310 (the "'310 patent") (together, "the Counterclaim Patents-in-Suit") are invalid and/or not infringed.

2. Defendants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer and Affirmative Defenses to Plaintiffs' Complaint.

### **THE PARTIES**

3. Counterclaim-Plaintiff Auson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its corporate office at 1200 Route 22 East, Suite 2000, Bridgewater, NJ 08807, USA.

4. Counterclaim-Plaintiff Shanghai 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.

5. Upon information and belief, Counterclaim-Defendant 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.

6. Upon information and belief, Counterclaim-Defendant 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.

7. Upon information and belief, Counterclaim-Defendant 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.

8. Upon information and belief, Counterclaim-Defendant 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.

### **JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual,

substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

10. This Court has personal jurisdiction over Counterclaim-Defendants because, among other reasons, Counterclaim-Defendants subjected themselves to the jurisdiction of this Court by filing their Complaint here.

11. Venue is proper in this District with respect to Counterclaim-Defendants as to these Counterclaims under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because the assertion of Counterclaim-Defendants' infringement action against Counterclaim-Plaintiffs in this District gave rise to these Counterclaims. Counterclaim-Defendants assert in their Complaint that venue is proper in this District.

12. In the alternative, this Court has personal jurisdiction over Bayer because the requirements of Fed. R. Civ. P. 4(k)(2) are met as: (1) Counterclaim-Plaintiffs' claims arise under federal law; (2) Bayer are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (3) Bayer has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting NDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Bayer satisfies due process.

13. At least because, on information and belief, Bayer are foreign companies, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c).

#### **PATENTS-IN-SUIT**

##### ***Auson's Paragraph IV Patent Certification***

14. In accordance with 21 U.S.C. § 355(b)(2), Auson notified Counterclaim-Defendants in writing that Auson's NDA No. 217062 was filed with a certification provided for

in 21 U.S.C. § 355(b)(2)(A)(iv) that inter alia, the '218 Patent and the '053 Patent are invalid, unenforceable, and/or will not be infringed by Auson's NDA products ("Auson's Notice Letter").

**COUNT I**  
**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '218 PATENT**

15. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

16. Counterclaim-Plaintiffs and the Auson NDA products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '218 Patent directly or indirectly, either literally or by the doctrine of equivalents.

17. Counterclaim-Plaintiffs deny infringement of the '218 Patent at least for the reasons set forth in Auson's Notice Letter, including at least that Auson's Proposed Label does not induce the infringement of the claims of the '218 Patent.

18. In particular, all of the claims of the '218 patent cover methods 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 "in a rapid-release tablet to a patient in need thereof."

19. In fact, the claims of the '218 patent were specifically limited during prosecution to administration "in a rapid-release tablet to a patient in need thereof" in order to overcome prior art that invalidated the claimed methods by disclosing the same method of treatment in rapid-release oral dosage forms. *See* Notice of Allowance, dated August 20, 2016; Decision on Appeal, Appeal 2014-004087, Application 11/883,218 (PTAB June 3, 2016) at 8-9 ("Decision on Appeal").

20. As indicated in Auson's Notice Letter, the Auson NDA product label indicates that the Auson NDA product will be administered not "in a rapid-release tablet" to a patient in need

thereof,” but instead administered as an oral liquid **suspension** to a patient in need thereof.

21. Nothing in the label of the Auson NDA product encourages, recommends, or promotes the practice of the claimed methods by third-party physicians or patients since the label clearly does not instruct the physician or patient to administer rivaroxaban as a rapid-release tablet. Thus, for at least these reasons, the use of the Auson NDA product will not directly infringe the claims of the ’218 patent, and Auson’s proposed label does not induce the infringement of any claim of the ’218 patent.

22. This is shown in the following claim chart:

'218 Patent Claims	Non-Infringement Position
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 <b>in a rapid-release tablet</b> to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke (emphasis added).	<p>The proposed label of the Auson 10 mg rivaroxaban product indicates that it will be <b>administered to the patient as an oral suspension and not a rapid-release tablet.</b></p> <p>Thus, the use of the Auson product will not directly infringe this claim and the proposed label of the Auson product will not induce the infringement of this claim.</p>
2. The method of claim 1, wherein the thromboembolic disorder is pulmonary embolisms.	See response to claim 1.
3. The method of claim 1, wherein the thromboembolic disorder is deep vein thromboses.	See response to claim 1.
4. The method of claim 1, wherein the thromboembolic disorder is stroke.	See response to claim 1. In addition, the proposed label for the Auson 10 mg rivaroxaban product is not indicated for stroke, but for (1) Nonvalvular Atrial Fibrillation; (2) treatment of deep vein thrombosis (“DVT”) and/or pulmonary

	embolism (“PE”); (3) the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for DVT and/or PE, (4) the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery, (5) the prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; (6) treatment of Venous Thromboembolism (“VTE”) and reduction in risk of recurrent VTE in pediatric patients; and (7) thromboprophylaxis in Pediatric Patients with Congenital Heart Disease after the Fontan Procedure.
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23. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’218 Patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

**COUNT II**  
**DECLARATORY JUDGMENT OF INVALIDITY OF THE ’218 PATENT**

24. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

25. The ’218 Patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, is invalid for obvious-type double patenting, or is invalid under other judicially created bases for invalidation, and invalid at least for the reasons as set forth in Auson’s Notice Letter.

26. For example, as discussed in Auson’s Notice Letter, all of the claims of the ’218 patent are invalid for being obvious over at least Straub et al., U.S. 2003/0153610 A1 (“Straub”),

Kubitza et al., Blood, Vol. 102:11, 16 Nov. 2003, p. 811a, Abstract #3004 (“Kubitza 1”) and Kubitza et al., Blood, Vol. 102:11, 16 Nov. 2003, p. 813a, Abstract #3010, (“Kubitza 2”), and Forsman et al., WO 00/13671 (“Forsman”).

27. Claim 1 of the ’218 patent is directed to 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. As recognized during prosecution, Straub in combination with the Kubitza abstracts discloses all of the elements of claim 1 of the ’218 patent except for the use of a “rapid-release tablet.” Both the PTAB’s Decision on Appeal and the Patent Office concluded that Straub along with the Kubitza abstracts disclose:

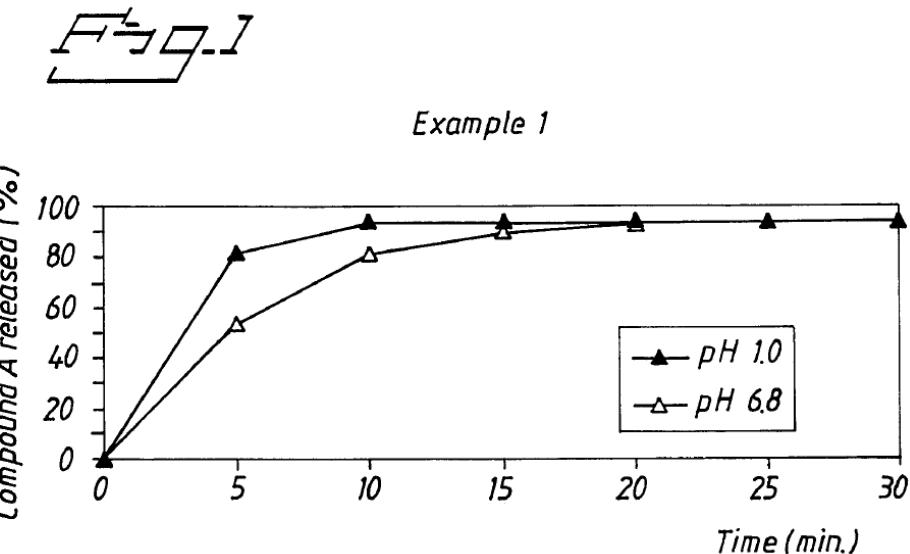
- method of treating a thromboembolic disorder comprising
- administering a direct factor Xa inhibitor that is 5-Chloro-N-((5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl)methyl)-2-thiophenecarboxamide
- no more than once daily for at least five consecutive days in a rapid-release oral dosage [in contrast to 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.

*See* PTAB Decision on Appeal at 8-9.

29. As discussed above, the combined teachings of Straub and the Kubitza abstracts disclose all of the elements of claim 1 of the ’218 patent, except for the administration of

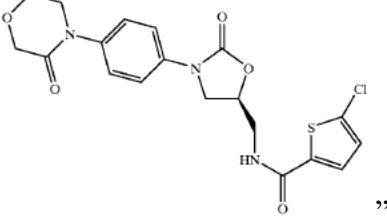
rivaroxaban as a rapid-release tablet. Forsman fills that gap by additionally teaching that immediate/rapid-release tablets have utility in the prophylaxis and/or treatment of thromboembolism. Forsman at 3:16-17 (“The particularly preferred low molecular weight thrombin inhibitor Compound A is effective for the treatment of thrombo-embolism.”) (emphasis added). Forsman thus discloses methods for formulating immediate/rapid-release oral tablets for low molecular weight anticoagulant thrombin inhibitors. In view of Kubitz 2, which teaches a rapid-release liquid oral dosage form of rivaroxaban achieving maximum blood concentrations at 0.5 hours, a person of ordinary skill before January 2005 would have been motivated to formulate rivaroxaban with the rapid-release tablets disclosed in Forsman.

30. Notably, the tablets disclosed in Forsman meet the definition of a “rapid-release tablet” specified in the ’218 patent and adopted by the Patent Office and the PTAB’s Decision on Appeal, as “those [tablets] which, according to the USP release method using apparatus 2 (paddle), have a Q value (30 minutes) of 75%.” PTAB Decision of Appeal at 7, dated June 3, 2016. Forsman’s rapid release tablets released “more than 85% [of the thrombin inhibitor] within 30 minutes in acidic as well as neutral environment.” *Id.* at 3:29-4:2. Moreover, Example 1a of Forsman shows that 94% of anticoagulant is released after 30 minutes at pH 1 and at pH 6.8. *Id.* at 7:1-8:2. This is also shown in Figure 1 (below), which shows that virtually all of the thrombin inhibitor is rapidly released from the tablet after 30 minutes.



31. Thus, there would have been a reasonable expectation of success that combining the Straub and Kubitz abstracts would allow the skilled worker to practice the method of treatment of claim 1, as well as all of the other claims of the '218 patent, as demonstrated below in the following claim chart.

'218 Patent Claims	Obvious over Straub, the Kubitz Abstracts, and Forsman
<p>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 ...</p> <p>...wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke.</p>	<p>"The compounds of general formula (I) ...act in particular as anticoagulants and can therefore preferably be employed in medicaments <b>for the prophylaxis and/or therapy of thromboembolic disorders such as...stroke, ... pulmonary embolism, or deep venous thrombosis.</b>" Straub. at ¶356; <i>see also id.</i>, Abstract, ¶364 (emphasis added).</p> <p>"Example 44: <b>5-Chloro-N-((5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide.</b>" Straub at ¶617.</p> <p>"Very particular preference is also given here to the compound having the following formula</p>

	 <p>”</p> <p><i>Id.</i> at ¶145 (emphasis added), <i>see also</i> Claim 7.</p> <p>“<b>BAY 59-7939</b> is an innovative, oral, direct <b>Factor Xa inhibitor</b> in development for the prevention and treatment of thromboembolic diseases[.]” Kubitza 1 abstract at 811a, Kubitza 2 abstract at 813a (emphasis added).</p> <p>These data suggest that <b>BAY 59-7939</b> offers predictable anticoagulation with an excellent safety profile.” Kubitza 2 abstract at 813a (emphasis added).</p>
no more than once daily for at least five consecutive days	“64 subjects received multiple oral doses of <b>BAY 59-7939: 5 mg od [once daily]</b> , bid, or tid, or 10 mg, 20 mg, or 30 mg bid <b>for 5 days</b> with food....There were no differences between the PD effects on day 1 versus day 7 at any dose step. Comparable profiles were observed for all PD parameters. Relevant changes in the PD parameters were <b>still present after 12 hours</b> . ...In conclusion, oral administration of BAY 59-7939 was safe and well tolerated in doses up to 30 mg bid.” Kubitza 1 abstract at 811a (emphasis added).
in a rapid-release tablet to a patient in need thereof.	“The invention relates to a solid dosage form of a low molecular weight thrombin inhibitor <b>formulated as immediate release (IR) tablets</b> as well as a process for manufacture thereof. The invention also relates to <b>the medical use of the formulation in the prophylaxis and/or treatment of thromboembolism</b> .” Forsman at 1:6-9.
	“ <b>Tablets must release 85% or more of stated amount within 30 min.</b> ” <i>Id.</i> at 2:4-5, Example 1a,

	<p>Figure 1.</p> <table border="1"> <caption>Data points estimated from Figure 1</caption> <thead> <tr> <th>Time (min)</th> <th>pH 1.0 (%)</th> <th>pH 6.8 (%)</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>5</td><td>85</td><td>50</td></tr> <tr><td>10</td><td>95</td><td>75</td></tr> <tr><td>15</td><td>95</td><td>85</td></tr> <tr><td>20</td><td>95</td><td>88</td></tr> <tr><td>25</td><td>95</td><td>90</td></tr> <tr><td>30</td><td>95</td><td>90</td></tr> </tbody> </table> <p><i>Id.</i> at Figure 1.</p>	Time (min)	pH 1.0 (%)	pH 6.8 (%)	0	0	0	5	85	50	10	95	75	15	95	85	20	95	88	25	95	90	30	95	90
Time (min)	pH 1.0 (%)	pH 6.8 (%)																							
0	0	0																							
5	85	50																							
10	95	75																							
15	95	85																							
20	95	88																							
25	95	90																							
30	95	90																							
2. The method of claim 1, wherein the thromboembolic disorder is pulmonary embolisms.	See response to claim 1.																								
3. The method of claim 1, wherein the thromboembolic disorder is deep vein thromboses.	See response to claim 1.																								
4. The method of claim 1, wherein the thromboembolic disorder is stroke.	See response to claim 1.																								

32. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the '218 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

**COUNT III**  
**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '310 PATENT**

33. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

34. Counterclaim-Plaintiffs and the Auson NDA products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '310 Patent directly or indirectly, either literally or by the doctrine of equivalents.

35. Counterclaim-Plaintiffs deny infringement of the '310 Patent for at least the following reason. Auson's Notice Letter did not indicate that Auson certified the '310 patent under paragraph IV of the applicable section under the Hatch-Waxman Act dealing with Section 505(b)(2) applications. As a result, there is no subject matter jurisdiction to raise an infringement action against Auson under the Hatch-Waxman Act.

36. Moreover, all of the claims of the '310 patent are directed to 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 a human patient rivaroxaban "and aspirin" where "aspirin is administered in an amount of 75-100 mg daily."

37. The proposed label for Auson's NDA product does not indicate that it will be prescribed for reducing the risk of the claimed conditions "in a human patient with coronary artery disease and/or peripheral artery disease," and/or that this patient would be administered rivaroxaban and aspirin, let alone the daily amounts of aspirin claimed in the '310 patent.

38. As such, the methods prescribed by the proposed label of the Auson NDA product do not directly infringe any of the claims of the '310 patent. Moreover, nothing in the proposed label encourages, recommends, or promotes the practice of the claimed methods by third-party physicians or patients. Thus, Auson's proposed label does not induce the infringement of any claim of the '310 patent.

39. For at least these reasons, Auson does not infringe or induce the infringement of any of the claims of the '310 patent, as demonstrated below in the following claim charts:

'310 Patent Claims	Auson's NDA Product
1. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death <u>in a human patient with coronary artery disease and/or</u>	The proposed label of the Auson's NDA product does not indicate that it will be used in a human patient with coronary artery disease and/or peripheral artery

<p><b><u>peripheral artery disease</u></b>, comprising administering to the human patient rivaroxaban <b><u>and aspirin</u></b> 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 <b><u>and aspirin is administered in an amount of 75-100 mg daily.</u></b></p>	<p>disease. The label also does not prescribe that rivaroxaban be administered with aspirin for the claimed indications. As a result, the use of the Auson product will not directly infringe this claim and the proposed label of the Auson product will not induce the infringement of this claim.</p>
<p>2. The method of claim 1, wherein <b><u>aspirin</u></b> is administered in an amount of 100 mg daily.</p>	<p>See response to claim 1.</p>
<p>3. The method of claim 1, wherein <b><u>aspirin</u></b> is administered in an amount of 81 mg daily.</p>	<p>See response to claim 1.</p>
<p>4. The method of claim 1, wherein <b><u>aspirin</u></b> is administered in an amount of 75 mg daily.</p>	<p>See response to claim 1.</p>
<p>5. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death <b><u>in a human patient with coronary artery disease and/or peripheral artery disease</u></b>, the method comprising administering to the human patient rivaroxaban <b><u>and aspirin</u></b> 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 the method comprises once daily administration of a first product comprising rivaroxaban <b><u>and aspirin</u></b> and a second product comprising rivaroxaban, and further wherein the first product comprises 2.5 mg rivaroxaban <b><u>and 75-100 mg aspirin</u></b> and the second product comprises 2.5 mg rivaroxaban.</p>	<p>The proposed label of the Auson's NDA product does not indicate that it will be used in a human patient with coronary artery disease and/or peripheral artery disease. The label also does not prescribe that rivaroxaban be administered with aspirin for the claimed indications. As a result, the use of the Auson product will not directly infringe this claim and the proposed label of the Auson product will not induce the infringement of this claim.</p>

6. The method of claim 5, wherein the first product comprises <u>75 mg aspirin.</u>	See response to claim 5.
7. The method of claim 5, wherein the first product comprises <u>81 mg aspirin.</u>	See response to claim 5.
8. The method of claim 5, wherein the first product comprises <u>100 mg aspirin</u>	See response to claim 5.

40. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '310 Patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

**COUNT IV**  
**DECLARATORY JUDGMENT OF INVALIDITY OF THE '310 PATENT**

41. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

42. The '310 Patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, is invalid for obvious-type double patenting, or is invalid under other judicially created bases for invalidation, and invalid at least for the reasons as set forth in the PTAB's Judgment and Final Written Description in IPR2022-00517, dated July 28, 2023 ("PTAB Decision"), where the PTAB invalidated all of the claims of the '310 patent for being anticipated and/or obvious. The PTAB Decision is attached hereto as Exhibit A.

43. In particular, the PTAB decided that Foley et al., *Antithrombotic Therapy in Peripheral Artery Disease*, 21 VASCULAR MED. 156–69 (2016) ("Foley") anticipated claims 1 and 2 of the '310 patent. The PTAB Decision states that:

Petitioner asserts that Foley discloses each limitation of claims 1 and 2. Pet. 52–57. We agree. We find that Foley’s disclosure of the COMPASS clinical trial (i.e., Rivaroxaban for the Prevention of Major Cardiovascular Events in Coronary or Peripheral Artery Disease) and its protocol of administering to patients with CAD or PAD 2.5 mg rivaroxaban twice daily and 100 mg aspirin once daily discloses each limitation of claims 1 and 2. *See* Ex. 1006, 166–67.

That is, we are persuaded that a POSA would have understood that COMPASS’s study of preventing major cardiovascular events such as myocardial infarction, stroke, or cardiovascular death in coronary or peripheral artery disease constitutes a method of reducing the risk of those events in human patients with CAD and/or PAD, as required by the preamble.<sup>12</sup> Ex. 1006, 166–67; Ex. 1002 ¶¶ 250–254. We also find that Foley’s disclosure of administering 2.5 mg of rivaroxaban twice daily and 100 mg aspirin once daily discloses the step of “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 [CAD and/or PAD], wherein the rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75–100 mg daily.” Ex. 1006, 166–67; Ex. 1002 ¶¶ 256, 257, 268–283.

PTAB Decision at 24-25.

44. The PTAB further concluded that the Foley reference was sufficient to show that the natural result of the disclosed dosing regimen would be “clinically proven effective” by the COMPASS study detailed in the Foley reference, since that claimed process was confirmed by that same COMPASS study. *Id.* at 26. Thus, the PTAB found that Foley inherently discloses “clinically proven effective” amounts of rivaroxaban and aspirin.

45. As to the remaining claims of the ’310 patent, claims 3-8, the PTAB found that these claims are rendered obvious by Foley or in combination with Plosker, *Rivaroxaban: A Review of Its Use in Acute Coronary Syndromes*, 74 DRUGS 451–64 (2014) (“Plosker”).

46. As to claims 5 and 8, the PTAB noted that the only difference between these claims and claims 1 and 2 (which were found to be anticipated by Foley) was that claims 5 and 8

recites that the “first product comprises 2.5 mg rivaroxaban and 75–100 mg aspirin” (or 100 mg aspirin for claim 8) and the “second product comprises 2.5 mg rivaroxaban.” *Id.* at 29. The PTAB concluded that the person of ordinary skill in the art (“POSA”), reading Foley, would have found it obvious to administer aspirin together with one of the rivaroxaban doses and therefore “Foley teaches or suggests each limitation of claims 5 and 8, and that a POSA would have had a reason to modify Foley to administer rivaroxaban together with aspirin with a reasonable expectation of success.” *Id.* at 30.

47. As to the remaining claims, the PTAB found these to be invalid for being obvious over Foley in combination with Plosker. In particular, the PTAB stated that:

Claims 3 and 7 depend from independent claims 1 and 5, respectively, and recite 81 mg aspirin, whereas claims 4 and 6 depend from independent claims 1 and 5, respectively, and recite 75 mg aspirin daily. Petitioner asserts that Foley teaches administering 100 mg aspirin, and Plosker teaches administering 75–100 mg aspirin to patients with ACS. Pet. 70 (citing Ex. 1006, 166–67; Ex. 1007, 460). Petitioner asserts that from these teachings, a POSA “would have had good reason to administer to a human patient with CAD or PAD a dosage of aspirin that falls within the 75–100 mg range of aspirin taught by Plosker.” *Id.* at 70–71 (citing Ex. 1002 ¶¶ 353–355, 359–361). As noted by Petitioner, Dr. Zusman also explains that “no clinical difference exists between administering 100 mg daily aspirin, as expressly taught by Foley, and 81 or 75 mg daily aspirin” and that these dosages “just represent the strength of commercially available dosage units in different areas of the world.” *Id.* at 71 (citing Ex. 1002 ¶¶ 351–362; Ex. 1013, 2656)...

... We are persuaded that a POSA would have had a reason to use 75 mg and 81 mg aspirin daily instead of 100 mg aspirin taught by Foley with a reasonable expectation of success, because those dosages simply represent the dosage amounts of aspirin available throughout the world (i.e., aspirin is available in Germany in 75 and 100 mg dosages, and 81 mg is more common in the United States)—hence, obvious variant dosages. *See* Ex. 1013, 2656; *see also* Ex. 1002 ¶ 355; Ex. 1001, 9:21–22 (stating the individual active ingredients “are commercially available”). Moreover, those dosages are consistent with the dosage range taught by Plosker. *See* Ex. 1007, 460.

Accordingly, having considered the arguments and evidence presented at trial, we find Foley alone or the combination of Foley and Plosker teach or suggest each limitation of claims 1–8 and a POSA would have had a reasonable expectation of success in reaching the claimed invention.

PTAB Decision at 32-34.

48. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the '310 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

**PRAYER FOR RELIEF FOR COUNTERCLAIMS**

**(COUNTS I THROUGH IV)**

WHEREFORE, Defendants/Counterclaim-Plaintiffs request that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

- (A) Adjudging that Defendants/Counterclaim-Plaintiffs have not and will not infringe any patent asserted by Plaintiffs;
- (B) Adjudging that no patent asserted by Plaintiffs is valid;
- (C) Enjoining Counterclaim-Defendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Counterclaim-Plaintiffs or their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Counterclaim-Plaintiffs, or charging them either orally or in writing with infringement of any patent asserted herein against Counterclaim-Plaintiffs;
- (D) Granting Counterclaim-Plaintiffs judgment in their favor on the Complaint;

- (E) Denying Plaintiffs' request for injunctive relief;
- (F) Dismissing the Complaint with prejudice;
- (G) Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Defendants their costs and reasonable attorneys' fees; and
- (H) Awarding any other such relief as is just and proper.

Dated: September 22, 2023

**FOX ROTHSCHILD LLP**

s/ Paul W. Kalish

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendants certify that, to the best of their knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding, except for: *Bayer Pharma AG et al. v. Lupin Limited et al.*, Case No. 1:21-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. 1:21-cv-00732 (RGA) (D. Del); *Bayer Pharma AG v. Teva Pharmaceuticals USA, Inc.*, No. 1:21-cv-01001 (RGA) (D. Del)); *Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:21-cv-00099 (TSK) (N.D.W.V.) (subsequently designated Case No. 1:21-01742 (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. 1:22-01228 (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. 1:22-01492 (RGA) (D. Del.) in connection with MDL No. 21-md-3017); *Bayer Pharma AG v. Apotex Inc.*, Case No. 1:22-cv-01596 (RGA) (D. Del.); *Bayer Pharma AG et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, 1:23-cv-00410 (RGA) (D. Del.); *Bayer Pharma AG et al. v. Teva Pharmaceuticals USA, Inc.*, Case No. 1:23-cv-00551 (RGA) (D. Del.); *Bayer Pharma AG et al. v. Macleods Pharmaceuticals Ltd. et al.*, 1:23-cv-00665 (RGA) (D. Del.); *Bayer Pharma AG et al. v. Apotex Inc. et al.*, 1:23-cv-00327 (RGA) (D. Del.).

Del.); *Bayer Pharma AG et al. v. Indoco Remedies Limited et al.*, 1:23-cv-00690 (RGA) (D. Del.).

Dated: September 22, 2023

/s/ Paul W. Kalish  
Paul W. Kalish

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that the causes of action as asserted herein as its counterclaims seek primarily declaratory judgment relief. This action is, therefore, not appropriate for compulsory arbitration.

Dated: September 22, 2023

/s/ Paul W. Kalish  
Paul W. Kalish

**CERTIFICATE OF SERVICE**

I hereby certify pursuant to Fed. R. Civ. P. 5 that on September 22, 2023, I electronically filed and served the foregoing ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS with the Clerk of the United States District Court for the District of New Jersey using the CMF/ECF system, which will automatically notify and serve all counsel of record.

/s/ Paul W. Kalish  
Paul W. Kalish