IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ASCENT PHARMACEUTICALS INC. and HETERO LABS LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG, Bayer AG (BIP, Bayer Pharma AG, and Bayer AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Ascent Pharmaceuticals Inc. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218 ("the '218 patent") and U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

5. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

6. Upon information and belief, Defendant Ascent Pharmaceuticals Inc. ("Ascent Pharmaceuticals") is a corporation organized and existing under the laws of New York, with a principal place of business at 400 South Technology Drive, Central Islip, New York 11722.

7. Upon information and belief, Hetero Labs Limited ("Hetero Labs") is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, Telangana, 500018, India.

8. Upon information and belief, Hetero Labs is the parent company, directly or indirectly, of Ascent Pharmaceuticals.

9. Upon information and belief, Ascent Pharmaceuticals and Hetero Labs 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, Ascent Pharmaceuticals, acting in concert with Hetero Labs, 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, Ascent Pharmaceuticals, acting in concert with Hetero Labs, 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.

10. Upon information and belief, and consistent with their practice with respect to other generic products, Ascent Pharmaceuticals and Hetero Labs acted in concert to prepare and submit ANDA No. 219332 for Ascent's 2.5 mg, 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Ascent's ANDA Products"). The 10 mg, 15 mg, and 20 mg strengths of Ascent's ANDA Products are referred to collectively herein as "Ascent's 10 mg, 15 mg, and 20 mg ANDA Products." The 2.5 mg strength of Ascent's ANDA Products is referred to herein as "Ascent's 2.5 mg ANDA Product."

11. Upon information and belief, Ascent Pharmaceuticals and Hetero Labs 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 Delaware, and including with respect to Ascent's ANDA Products at issue.

12. Upon information and belief, following any FDA approval of ANDA No. 219332, Ascent Pharmaceuticals and Hetero Labs will market, distribute, offer for sale, and sell Ascent's ANDA Products throughout the United States and within Delaware. These two entities—Ascent Pharmaceuticals and Hetero Labs—are hereafter collectively referred to as "Ascent."

13. Upon information and belief, following any FDA approval of ANDA No. 219332, Ascent knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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

16. This Court has personal jurisdiction over Ascent because, among other things, upon information and belief: (1) Ascent Pharmaceuticals, acting in concert with Hetero Labs, 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 Ascent's ANDA Products in the United States, including in Delaware; and (2) Ascent Pharmaceuticals and Hetero Labs, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Ascent's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 219332, and will derive substantial revenue from the use or consumption of Ascent's ANDA Products in the State of Delaware. Upon information and belief, if ANDA No. 219332 is approved, the generic

Ascent 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.

17. In addition, this Court has personal jurisdiction over Ascent Pharmaceuticals and Hetero Labs because they have consented to personal jurisdiction in Delaware in one or more prior cases arising out of the filing of ANDAs, and/or have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *AbbVie Inc. v. Hetero Labs Limited et al.*, 23-448-JLH (D. Del.) (Hetero Labs); *Duchesnay Inc. et al. v. Hetero Labs Limited*, 21-538-LPS (D. Del.) (Hetero Labs); *Vifor Pharma, Inc. et al. v. Alkem Laboratories Ltd. et al.*, 20-106-MN (D. Del.) (Ascent Pharmaceuticals); *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, 18-1673-LPS (D. Del.) (Ascent Pharmaceuticals); *Purdue Pharma L.P. et al. v. Ascent Pharmaceuticals, Inc.*, 18-83-RGA (D. Del.) (Ascent Pharmaceuticals). Further, upon information and belief, Ascent will consent to personal jurisdiction in Delaware for purposes of this action.

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

VENUE

19. Venue is proper in this district for Ascent Pharmaceuticals pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Ascent Pharmaceuticals is subject to personal

jurisdiction in this judicial district, has previously consented to venue in this judicial district, and, on information and belief, is subject to venue in this judicial district and/or has consented to venue for the purposes of this case. *See, e.g.*, *Vifor Pharma, Inc. et al. v. Alkem Laboratories Ltd. et al.*, 20-106-MN (D. Del.); *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, 18-1673-LPS (D. Del.); *Purdue Pharma L.P. et al. v. Ascent Pharmaceuticals, Inc.*, 18-83-RGA (D. Del.).

20. Venue is proper in this district for Hetero Labs pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Hetero Labs is not a resident in the United States and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

21. 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.

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

The '218 Patent

23. 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.

24. 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."

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

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

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

28. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

The '310 Patent

29. 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.

30. 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."

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

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

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

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

Infringement by Ascent

35. By letter dated April 1, 2024 (the "Ascent Notice Letter"), Ascent notified at least BIP, Bayer Pharma AG, and Janssen that Ascent had submitted to the FDA ANDA No. 219332 for Ascent's ANDA Products. These products are generic versions of XARELTO®.

36. In the Ascent Notice Letter, Ascent stated that Ascent's ANDA Products contain rivaroxaban.

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

38. In the Ascent Notice Letter, Ascent indicated that, in connection with its ANDA No. 219332, Ascent had filed Paragraph IV Certifications with respect to the '218 patent and to the '310 patent.

39. Upon information and belief, the purpose of ANDA No. 219332 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 Ascent's ANDA Products with their proposed labeling prior to the expiration of the '218 patent and of the '310 patent.

40. Upon information and belief, Ascent intends to engage in the manufacture, use, offer for sale, and/or sale of Ascent's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 219332, *i.e.*, prior to the expiration of the '218 patent and of the '310 patent.

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

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

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

44. Ascent has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Ascent has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of

ANDA No. 219332. Upon information and belief, by such activities, Ascent specifically intends to infringe the '218 patent.

45. Upon information and belief, Ascent 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.

46. Upon information and belief, Ascent knows that Ascent's 10 mg, 15 mg, and 20 mg ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Ascent's 10 mg, 15 mg, and 20 mg ANDA Products are not suitable for substantial noninfringing use. Ascent's 10 mg, 15 mg, and 20 mg ANDA Products are a material part of the invention. Upon information and belief, Ascent plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 219332.

47. The foregoing actions by Ascent 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.

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

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

50. Ascent has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, Ascent has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's 2.5 mg ANDA Product with Ascent's proposed labeling immediately and imminently upon approval of ANDA No. 219332. Upon information and belief, by such activities, Ascent specifically intends to infringe the '310 patent.

51. Upon information and belief, Ascent 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.

52. Upon information and belief, Ascent knows that Ascent's 2.5 mg ANDA Product is especially made or adapted for use in infringing the '310 patent, and that Ascent's 2.5 mg ANDA Product is not suitable for substantial noninfringing use. Ascent's 2.5 mg ANDA Product is a material part of the invention. Upon information and belief, Ascent plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 219332.

53. The foregoing actions by Ascent 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.

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

55. This action is being commenced before the expiration of forty-five days from the date BIP, Bayer Pharma AG, and Janssen received the Ascent Notice Letter.

COUNT I: Infringement of the ’218 Patent

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

57. Ascent’s submission of ANDA No. 219332 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Ascent’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).

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

59. Ascent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent’s 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 219332, *i.e.*, prior to the expiration of the ’218 patent.

60. The foregoing actions by Ascent 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.

61. Unless Ascent is enjoined from infringing the ’218 patent, actively inducing infringement of the ’218 patent, and contributing to the infringement by others of the ’218 patent, BIP, Bayer AG, and Janssen will suffer irreparable injury. BIP, Bayer AG, and Janssen have no adequate remedy at law.

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

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

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

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

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

COUNT III: Infringement of the ’310 Patent

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

67. Ascent’s submission of ANDA No. 219332 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Ascent’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).

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

69. Ascent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 219332, *i.e.*, prior to the expiration of the '310 patent.

70. The foregoing actions by Ascent 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).

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

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

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

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

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

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

* * *

WHEREFORE, Plaintiffs request the following relief:

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

(b) A judgment ordering that the effective date of any FDA approval for Ascent to make, use, offer for sale, sell, market, distribute, or import Ascent's 10 mg, 15 mg, and 20 mg ANDA Products, or any product or compound the use of which infringes the '218 patent, be no earlier than the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Ascent, and all persons acting in concert with Ascent, from making, using, offering for sale, selling, marketing, distributing, or importing Ascent's 10 mg, 15 mg, and 20 mg ANDA Products, or any product or compound the use of which infringes the '218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of Ascent's 10 mg, 15 mg, and 20 mg ANDA Products prior to the expiration of the '218 patent will infringe, induce the infringement, and contribute to the infringement of the '218 patent;

(e) A judgment that Ascent has infringed the ’310 patent;

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

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

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

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

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

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

OF COUNSEL:

Bruce R. Genderson
Dov P. Grossman
Alexander S. Zolan
Seth R. Bowers
Ben Picozzi
Richard Hildreth III
Dana B. Kinel
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000

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

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

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

Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

May 16, 2024

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@ morrisnichols.com
rsmith@ morrisnichols.com
dfahnestock@ morrisnichols.com

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