Keith J. Miller, Esq.
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761
Email: kmiller@rwmlegal.com

Attorneys for Plaintiffs
Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research

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

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), and Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") (collectively, "Plaintiffs"), for their Complaint against Defendants Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharms."), and Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) ("Zydus Lifesciences") (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), 10,052,314 ("the 314 Patent"), 10,702,508 ("the 508 Patent"), and 10,849,888 ("the 888 Patent") (collectively, the "Patents-In-Suit").

2. This action relates to the submission of Abbreviated New Drug Application No. 217113 ("the ANDA") by Defendants to the United States Food and Drug Administration ("FDA") seeking approval to market a proposed generic version of Erleada® ("Proposed ANDA Product") prior to the expiration of the Patents-In-Suit.

THE PARTIES

3. Aragon is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 10990 Wilshire Boulevard, Suite 440, Los Angeles, California 90024.

4. JBI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

5. Sloan-Kettering is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

6. On information and belief, Zydus Worldwide is a corporation organized under the laws of the United Arab Emirates, having its principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeirah Lakes Towers P.O. BOX-113536 Dubai, United Arab Emirates 340100.

7. On information and belief, Zydus Pharms. is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 73-B, Route 31 North, Pennington, New Jersey 08534.

8. On information and belief, Zydus Lifesciences is a corporation organized under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India.

9. On information and belief, Zydus Worldwide and Zydus Pharms. are wholly-owned subsidiaries of Zydus Lifesciences.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including § 271(e)(2), and also including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 for patent infringement arising under 35 U.S.C. § 100 *et seq.*, including § 271(a)-(c).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

13. On information and belief, Defendants cooperate, collaborate, or act in concert for the purposes of manufacturing, selling, marketing, distributing, and importing generic drug products in New Jersey and throughout the United States.

14. On information and belief, Zydus Worldwide has substantial, continuous, and systematic contacts with New Jersey.

15. On information and belief, Zydus Worldwide develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

16. On information and belief, Zydus Worldwide, alone or together with Zydus Pharms. and/or Zydus Lifesciences, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in New Jersey.

17. On information and belief, Zydus Worldwide consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Almirall, LLC v. Zydus Pharms. (USA) Inc.*, No. 3-20-cv-00343, and *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2-18-cv-13635.

18. This Court has personal jurisdiction over Zydus Worldwide by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial

volume of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Zydus Pharms. and/or Zydus Lifesciences.

19. This Court has personal jurisdiction over Zydus Worldwide because, *inter alia*, this action arises from actions of Zydus Worldwide directed toward New Jersey. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the Patents-In-Suit. If FDA approval is obtained, the Proposed ANDA Product would be sold in New Jersey, causing injury to Plaintiffs in New Jersey.

20. Exercising personal jurisdiction over Zydus Worldwide in this district would not be unreasonable given Zydus Worldwide's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

21. In the alternative, this Court has personal jurisdiction over Zydus Worldwide because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met because: (a) Plaintiffs' claims arise under federal law; (b) Zydus Worldwide is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Worldwide has sufficient contacts with the United States as a whole, including, but not limited to, filing Abbreviated New Drug Applications with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Worldwide satisfies due process, and is consistent with the United States Constitution and Laws.

22. Venue is proper under 28 U.S.C. § 1391(c)(3) because Zydus Worldwide is a foreign corporation.

23. On information and belief, Zydus Lifesciences has substantial, continuous, and systematic contacts with New Jersey.

24. On information and belief, Zydus Lifesciences develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

25. On information and belief, Zydus Lifesciences, alone or together with Zydus Pharms. and/or Zydus Worldwide, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in New Jersey.

26. On information and belief, Zydus Lifesciences consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2-18-cv-13635, *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3-18-cv-11792, and *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3-18-cv-01994.

27. This Court has personal jurisdiction over Zydus Lifesciences by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Zydus Pharms. and/or Zydus Worldwide.

28. This Court has personal jurisdiction over Zydus Lifesciences because, *inter alia*, this action arises from actions of Zydus Lifesciences directed toward New Jersey. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer

for sale, or import the Proposed ANDA Product prior to the expiration of the Patents-In-Suit. If FDA approval is obtained, the Proposed ANDA Product would be sold in New Jersey, causing injury to Plaintiffs in New Jersey.

29. Exercising personal jurisdiction over Zydus Lifesciences in this district would not be unreasonable given Zydus Lifesciences' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

30. In the alternative, this Court has personal jurisdiction over Zydus Lifesciences because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met because: (a) Plaintiffs' claims arise under federal law; (b) Zydus Lifesciences is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Lifesciences has sufficient contacts with the United States as a whole, including, but not limited to, acts relating to filing Abbreviated New Drug Applications with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Lifesciences satisfies due process, and is consistent with the United States Constitution and Laws.

31. Venue is proper under 28 U.S.C. § 1391(c)(3) because Zydus Lifesciences is a foreign corporation.

32. On information and belief, Zydus Pharms. has substantial, continuous, and systematic contacts with New Jersey.

33. On information and belief, Zydus Pharms. develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

34. On information and belief, Zydus Pharms. has substantial, continuous, and systematic contacts with New Jersey, including that it is incorporated in New Jersey (Filing No. 0100915422), it is registered to do business in New Jersey (Entity Id. No. 01000915422), and is registered as a drug manufacturer and wholesaler in New Jersey (Registration No. 5003171).

35. On information and belief, Zydus Pharms. has a regular and established business at 73-B, Route 31 North, Pennington, New Jersey 08534 and has registered this address with the New Jersey Department of Health.

36. On information and belief, Zydus Pharms., alone or together with Zydus Worldwide and/or Zydus Lifesciences, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in New Jersey.

37. On information and belief, Zydus Pharms. consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Almirall, LLC v. Zydus Pharms. (USA) Inc.*, No. 3-20-cv-00343, *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2-18-cv-13635, *Shionogi Inc. v. Zydus Pharms. (USA) Inc.*, No. 3-18-cv-12898, *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3-18-cv-11792, and *Impax Labs., Inc. v. Zydus Pharms. (USA) Inc.*, No. 2-17-cv-13476.

38. This Court has personal jurisdiction over Zydus Pharms. by virtue of, among other things, (1) its incorporation in New Jersey; (2) its continuous and systematic contacts with New Jersey; (3) its acts of patent infringement that will result in foreseeable harm in New Jersey;

(4) its sale of a substantial volume of prescription drugs in New Jersey; and (5) its conduct by and through, and in concert with, Zydus Worldwide and/or Zydus Lifesciences.

39. This Court has personal jurisdiction over Zydus Pharms. because, *inter alia*, this action arises from actions of Zydus Pharms. directed toward New Jersey. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the Patents-In-Suit. If FDA approval is obtained, the Proposed ANDA Product would be sold in New Jersey, causing injury to Plaintiffs in New Jersey.

40. Exercising personal jurisdiction over Zydus Pharms. in this district would not be unreasonable given Zydus Pharms.' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

41. On information and belief, Zydus Pharms. has committed an act of infringement in this judicial district by submitting the ANDA with the FDA on or about February 14, 2022.

42. On information and belief, Defendants are cooperating, collaborating, or acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, or selling with respect to the Proposed ANDA Product.

43. On information and belief, Zydus Pharms. has committed acts or caused acts to be committed in preparation for and submission of the ANDA in this judicial district.

44. On information and belief, Zydus Pharms. will directly benefit if the ANDA is approved by participating in the distribution, offer for sale, or sale of the Proposed ANDA Product.

45. Venue is proper under 28 U.S.C. § 1400(b) because Zydus Pharms. is incorporated in New Jersey and thus resides in this judicial district.

ERLEADA®

46. JBI holds approved New Drug Application No. 210951 for apalutamide, which is prescribed and sold as Erleada®.

47. On information and belief, Defendants know that JBI holds approved New Drug Application No. 210951.

48. Erleada® is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Erleada® is supplied as tablets for oral administration containing the active pharmaceutical ingredient apalutamide.

49. The International Union of Pure and Applied Chemistry (IUPAC) name for apalutamide is 4-[7-(6-Cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide.

THE PATENTS-IN-SUIT

50. On November 1, 2016, the 663 Patent, titled "Crystalline Forms of an Androgen Receptor Modulator" was duly and legally issued to Aragon and Sloan-Kettering as assignees. A copy of the 663 Patent is attached as Exhibit A.

51. On February 6, 2018, the 054 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 054 Patent is attached as Exhibit B.

52. On August 21, 2018, the 314 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 314 Patent is attached as Exhibit C.

53. On July 7, 2020, the 508 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 508 Patent is attached as Exhibit D.

54. On December 1, 2020, the 888 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 888 Patent is attached as Exhibit E.

55. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-In-Suit are listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering Erleada®.

56. On information and belief, Defendants know that the Patents-In-Suit are listed in the Orange Book as covering Erleada®.

DEFENDANTS' NOTICE LETTER AND THE ANDA

57. By letter dated April 11, 2022, addressed to JBI, Sloan-Kettering, Aragon, and Johnson & Johnson ("Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217113 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that the ANDA seeks the FDA approval necessary to engage in activities that constitute or require the commercial manufacture, use, sale, offer for sale in, or importation into the United States, of the Proposed ANDA Product, described in the Notice Letter as "apalutamide tablets, 60 mg" prior to the expiration of the Patents-In-Suit.

58. The Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

59. The ANDA includes a Paragraph IV Certification that the claims of the Patents-In-Suit are invalid, unenforceable, or not infringed.

60. The Notice Letter stated that the Proposed ANDA Product will not literally infringe the claims of the 663 Patent because the Proposed ANDA Product does not contain crystalline Form B of apalutamide.

61. The Notice Letter stated that the Proposed ANDA Product will not infringe the claims of the 663 Patent under the doctrine of equivalents because the Proposed ANDA Product does not contain crystalline Form B of apalutamide.

62. The Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On April 29, 2022, Defendants produced documents that Defendants purported were the ANDA.

63. On May 11, 2022, Plaintiffs requested technical information regarding the Proposed ANDA Product. Defendants did not respond. By failing to provide information, Defendants impeded Plaintiffs' ability to evaluate infringement of the 663 Patent. On information and belief, if Defendants had a good faith basis to contest infringement of the 663 Patent, they would have provided the requested information.

64. Plaintiffs are not aware of any other means by which to obtain technical information regarding the Proposed ANDA Product.

65. On information and belief, the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

66. On information and belief, the drug substance in and used for the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

67. Plaintiffs are commencing this action within 45 days of the date of receipt of the Notice Letter.

COUNT I – CLAIM FOR INFRINGEMENT OF THE 663 PATENT

68. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

69. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 663 Patent, including at least claims 1, 13, and 17.

70. On information and belief, because the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product contain some amount of crystalline Form B of apalutamide, the Proposed ANDA Product and the drug substance infringe at least claims 1, 13, and 17.

71. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe claim 1 because they contain crystalline Form B of apalutamide that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

72. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe claim 13 because they are a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

73. On information and belief, the use of the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product will infringe claim 17 because physicians and/or patients will practice a method of treating prostate cancer in a mammal, said method comprising administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

74. On information and belief, Defendants will induce infringement of claim 17 by actively inducing the use of the Proposed ANDA Product to practice a method of treating prostate cancer in a mammal, said method comprising administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

75. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims

of the 663 Patent, including at least claims 1, 13, and 17, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 663 Patent, including at least claims 1, 13, and 17, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

76. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 663 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 663 Patent.

77. On information and belief, Defendants have actual knowledge of the 663 Patent, at least as shown by the Notice Letter.

78. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 663 Patent, including at least claims 1, 13, and 17, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 663 Patent.

79. On information and belief, the Proposed ANDA Product and its use, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 663 Patent, including at least claims 1, 13, and 17, under at least one of 35 U.S.C. § 271(a), (b), or (c).

80. On information and belief, the manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17.

81. On information and belief, physicians and/or patients will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17, by the use of the Proposed ANDA Product upon approval.

82. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17, for the pecuniary benefit of Defendants.

83. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will actively induce the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

84. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will thus contribute to the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

85. On information and belief, the actions described in this Complaint relating to the ANDA and the 663 Patent were done by and for the benefit of Defendants.

86. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT II – CLAIM FOR INFRINGEMENT OF THE 054 PATENT

87. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

88. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 054 Patent, including at least claims 6 and 15.

89. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 6 and 15 of the 054 Patent because physicians and/or patients will practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of a therapeutically effective amount of an anti-androgen to a male human in need of such treatment, wherein the anti-androgen is apalutamide that is administered orally to the male human at a dose of about 240 mg per day.

90. On information and belief, Defendants will induce infringement of at least claims 6 and 15 of the 054 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of a therapeutically effective amount of an anti-androgen to a male human in need of such treatment, wherein the anti-androgen is apalutamide that is administered orally to the male human at a dose of about 240 mg per day.

91. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 054 Patent, including at least claims 6 and 15, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 054 Patent, including at least claims 6 and

15, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

92. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 054 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 054 Patent.

93. On information and belief, Defendants have actual knowledge of the 054 Patent, at least as shown by the Notice Letter.

94. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 054 Patent, including at least claims 6 and 15, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 054 Patent.

95. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 054 Patent, including at least claims 6 and 15, under at least one of 35 U.S.C. § 271(a), (b), or (c).

96. On information and belief, physicians and/or patients will directly infringe the claims of the 054 Patent, including at least claims 6 and 15, by their use of the Proposed ANDA Product upon approval.

97. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or

patients, in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15, for the pecuniary benefit of Defendants.

98. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15. On information and belief, Defendants will actively induce the infringement of the claims of the 054 Patent, including at least claims 6 and 15.

99. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15. On information and belief, Defendants will thus contribute to the infringement of the claims of the 054 Patent, including at least claims 6 and 15.

100. On information and belief, the actions described in this Complaint relating to the ANDA and the 054 Patent were done by and for the benefit of Defendants.

101. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III – CLAIM FOR INFRINGEMENT OF THE 314 PATENT

102. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

103. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 314 Patent, including at least claims 3 and 19.

104. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 3 and 19 of the 314 Patent because physicians and/or patients will practice a method of treating a male human with non-metastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of an anti-

androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide, wherein said method further comprises administering a gonadotropin releasing hormone (GnRH) agonist.

105. Defendants will induce infringement of at least claims 3 and 19 of the 314 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating a male human with non-metastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide, wherein said method further comprises administering a gonadotropin releasing hormone (GnRH) agonist.

106. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 314 Patent, including at least claims 3 and 19, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 314 Patent, including at least claims 3 and 19, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

107. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 314 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 314 Patent.

108. On information and belief, Defendants have actual knowledge of the 314 Patent, at least as shown by the Notice Letter.

109. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 314 Patent, including at least claims 3 and 19, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 314 Patent.

110. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 314 Patent, including at least claims 3 and 19, under at least one of 35 U.S.C. § 271(a), (b), or (c).

111. On information and belief, physicians and/or patients will directly infringe the claims of the 314 Patent, including at least claims 3 and 19, by their use of the Proposed ANDA Product upon approval.

112. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 314 Patent, including at least claims 3 and 19, for the pecuniary benefit of Defendants.

113. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 314 Patent, including at least claims 3 and 19. On information and belief, Defendants will actively induce the infringement of the claims of the 314 Patent, including at least claims 3 and 19.

114. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 314 Patent, including at least claims 3 and 19. On information and belief, Defendants will thus contribute to the infringement of the claims of the 314 Patent, including at least claims 3 and 19.

115. On information and belief, the actions described in this Complaint relating to the ANDA and the 314 Patent were done by and for the benefit of Defendants.

116. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT IV – CLAIM FOR INFRINGEMENT OF THE 508 PATENT

117. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

118. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

119. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 1 and 2 of the 508 Patent because physicians and/or patients will practice a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein the median metastasis free survival is about 40.5 months.

120. On information and belief, Defendants will induce infringement of at least claims 1 and 2 of the 508 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of improving metastasis free survival in a male human with nonmetastatic castration-

resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein the median metastasis free survival is about 40.5 months.

121. On information and belief, the use of the Proposed ANDA Product will infringe claims at least 5 and 7 of the 508 Patent because physicians and/or patients will practice a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein a drug product label for a reference listed drug for such approved drug product comprises metastasis free survival data, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.

122. On information and belief, Defendants will induce infringement of at least claims 5 and 7 of the 508 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein a drug product label for a reference listed drug for such approved drug product comprises metastasis free survival data, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.

123. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

124. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 508 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 508 Patent.

125. On information and belief, Defendants have actual knowledge of the 508 Patent, at least as shown by the Notice Letter.

126. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 508 Patent.

127. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 508 Patent, including at least claims 1, 2, 5, and 7, under at least one of 35 U.S.C. § 271(a), (b), or (c).

128. On information and belief, physicians and/or patients will directly infringe the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, by their use of the Proposed ANDA Product upon approval.

129. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, for the pecuniary benefit of Defendants.

130. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7. On information and belief, Defendants will actively induce the infringement of the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

131. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7. On information and belief, Defendants will thus contribute to the infringement of the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

132. On information and belief, the actions described in this Complaint relating to the ANDA and the 508 Patent were done by and for the benefit of Defendants.

133. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT V – CLAIM FOR INFRINGEMENT OF THE 888 PATENT

134. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

135. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 888 Patent, including at least claims 1 and 8.

136. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 1 and 8 of the 888 Patent because physicians and/or patients will practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide and wherein said method further comprises orchiectomy.

137. On information and belief, Defendants will induce infringement of at least claims 1 and 8 of the 888 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating non-metastatic castration-resistant prostate cancer in a male human by administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide and wherein said method further comprises orchiectomy.

138. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 888 Patent, including at least claims 1 and 8, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 888 Patent, including at least claims 1 and 8, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

139. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 888 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 888 Patent.

140. On information and belief, Defendants have actual knowledge of the 888 Patent, at least as shown by the Notice Letter.

141. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 888 Patent, including at least claims 1 and 8, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 888 Patent.

142. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 888 Patent, including at least claims 1 and 8, under at least one of 35 U.S.C. § 271(a), (b), or (c).

143. On information and belief, physicians and/or patients will directly infringe the claims of the 888 Patent, including at least claims 1 and 8, by their use of the Proposed ANDA Product upon approval.

144. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8, for the pecuniary benefit of Defendants.

145. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8. On information and belief, Defendants will actively induce the infringement of the claims of the 888 Patent, including at least claims 1 and 8.

146. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8. On information and belief, Defendants will thus contribute to the infringement of the claims of the 888 Patent, including at least claims 1 and 8.

147. On information and belief, the actions described in this Complaint relating to the ANDA and the 888 Patent were done by and for the benefit of Defendants.

148. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed one or more claims of the Patents-In-Suit through the submission of the ANDA to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell the Proposed ANDA Product in the United States before the expiration of the Patents-In-Suit;

B. Enter a declaratory judgment that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed ANDA Product, prior to the expiration of the

Patents-In-Suit, would constitute infringement of one or more claims of the Patents-In-Suit under 35 U.S.C. § 271 (a), (b), and/or (c);

C. Order that pursuant to 35 U.S.C. § 271(e)(4)(A) the effective date of any approval of the ANDA be a date that is not earlier than the expiration date of the Patents-In-Suit, or such later date as the Court may determine;

D. Order that Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with Defendants, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling the Proposed ANDA Product, and any other product that infringes or induces or contributes to the infringement of the Patents-In-Suit, prior to the expiration of the Patents-In-Suit, or such later date as the Court may determine;

E. If Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product prior to the expiration of the Patents-In-Suit, a judgment awarding damages to Plaintiffs resulting from such infringement together with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees; and

G. Award such further and other relief as this Court deems proper and just.

Respectfully Submitted,

Dated: May 20, 2022

s/ Keith J. Miller
Keith J. Miller, Esq.
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302

Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761
Email: kmiller@rwmlegal.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research

Of Counsel:

Steven D. Maslowski
Matthew A. Pearson
Jonathan J. Underwood
Anthony D. Sierra
AKIN GUMP STRAUSS HAUER & FELD LLP
1735 Market Street, 12th Floor
Philadelphia, PA 19103
Tel: (215) 965-1200
Fax: (215) 965-1210
smaslowski@akingump.com
mpearson@akingump.com
underwoodj@akingump.com
asierra@akingump.com

Golda Lai
AKIN GUMP STRAUSS HAUER & FELD LLP
Robert S. Strauss Tower
2001 K Street, N.W.
Washington, D.C. 20006
Tel: (202) 887-4000
Fax: (202) 887-4288
laig@akingump.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research

CERTIFICATE PURSUANT TO RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same plaintiffs have asserted one of the patents in this case (663 patent) in the pending matters *Aragon Pharmaceuticals, Inc. et al. v. Lupin Limited et al.*, Civil Action No. 2:22-cv-02825-JXN-LDW in this Judicial District, and *Aragon Pharmaceuticals, Inc. et al. v. Lupin Limited et al.*, Civil Action No. 1:22-cv-00637-CFC in the United States District Court for the District of Delaware. Further, there are not any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 20, 2022

Respectfully Submitted,

s/ Keith J. Miller
Keith J. Miller, Esq.
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2761
Email: kmiller@rwmlegal.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research