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

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs,

v.

EUGIA PHARMA SPECIALITIES LIMITED (A.K.A. EUGIA PHARMA SPECIALTIES LIMITED), AUROBINDO PHARMA USA, INC., and AUROMEDICS PHARMA LLC,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), The Regents of the University of California ("Regents"), and Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") (collectively, "Plaintiffs"), for their Complaint against Defendants Eugia Pharma Specialities Limited (also known as Eugia Pharma Specialties Limited) ("Eugia"), Aurobindo Pharma USA, Inc. ("Aurobindo"), and AuroMedics Pharma LLC ("AuroMedics") (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,445,507 ("the 507 Patent"), 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), 9,481,663 ("the 663 Patent"), and 9,987,261 ("the 261 Patent") (collectively, the "Patents-In-Suit").

2. This action relates to the submission of Abbreviated New Drug Application No. 217104 ("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. Regents is a California non-profit constitutional corporation and the governing body of an educational institution, having its principal place of business at 1111 Franklin Street, Oakland, California 94607.

6. 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.

7. On information and belief, Eugia is a corporation organized under the laws of India, having its principal place of business at either its registered office at Maitrivihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India ("Maitrivihar" address) or its corporate office at Galaxy, Floors: 22-24, Plot No.1, Sy No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India ("Galaxy" address).

8. On information and belief, Eugia has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for example, in Answers that Eugia filed in the following cases: *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al.*, No. 20-cv-01528, Answer (D. Del. Dec 4, 2020) ("Eugia Pharma Specialities Ltd."; principal place of business at the "Maitrivihar" address), *Medicure International, Inc. v. Aurobindo Pharma Limited et al.,* No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Galaxy" address), and *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al.*, No. 22-cv-00227, Answer (D. Del. Mar 17, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Maitrivihar" address).

9. On information and belief, Aurobindo is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520.

10. On information and belief, AuroMedics is a corporation organized under the laws of the State of Delaware, having its principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520.

JURISDICTION AND VENUE

11. 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).

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

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

14. 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.

15. On information and belief, Eugia has substantial, continuous, and systematic contacts with New Jersey.

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

17. On information and belief, Eugia, alone or together with Aurobindo and/or AuroMedics, 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.

18. On information and belief, Eugia consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Medicure International, Inc. v. Aurobindo Pharma Limited et al.*, No. 2:21-cv-17534; *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-00624; *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2:20-cv-00315; *Celgene Corporation v. Aurobindo Pharma Limited et al.*, No. 2:19-cv-05799; *Celgene Corporation v. Aurobindo Pharma Limited et al.*, No. 2:19-cv-00143; *Celgene Corporation v. Hetero Labs Limited et al.*, No. 2:17-cv-03387.

19. This Court has personal jurisdiction over Eugia 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, Aurobindo and/or AuroMedics.

20. This Court has personal jurisdiction over Eugia because, *inter alia*, this action arises from actions of Eugia 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.

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

22. In the alternative, this Court has personal jurisdiction over Eugia because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met: (a) Plaintiffs' claims arise under federal law; (b) Eugia is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Eugia 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 Eugia satisfies due process, and is consistent with the United States Constitution and Laws.

23. Venue is proper under 28 U.S.C. § 1391(c)(3) because Eugia is a foreign corporation.

24. On information and belief, AuroMedics has substantial, continuous, and systematic contacts with New Jersey.

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

26. On information and belief, AuroMedics has substantial, continuous, and systematic contacts with New Jersey, including that it is registered to do business in New Jersey (Entity Id. No. 0400485691) and is registered as a drug manufacturer and drug wholesaler in New Jersey (Registration No. 5004299).

27. On information and belief, AuroMedics has a regular and established business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520.

28. On information and belief, AuroMedics, alone or together with Aurobindo and/or Eugia, 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.

29. On information and belief, AuroMedics consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Medicure International, Inc. v. Aurobindo Pharma Limited et al.*, No. 2:21-cv-17534; *Merck Sharp & Dohme Corp. v. Aurobindo Pharma USA, Inc. et al*., No. 3:20-cv-10444.

30. This Court has personal jurisdiction over AuroMedics 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, Aurobindo and/or Eugia.

31. This Court has personal jurisdiction over AuroMedics because, *inter alia*, this action arises from actions of AuroMedics 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.

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

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

34. 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.

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

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

37. Venue is proper under 28 U.S.C. § 1400(b) because AuroMedics has committed an act of infringement and has a regular and established place of business in this judicial district.

38. On information and belief, Aurobindo has substantial, continuous, and systematic contacts with New Jersey.

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

40. On information and belief, Aurobindo has substantial, continuous, and systematic contacts with New Jersey, including that it is registered to do business in New Jersey (Entity Id. No. 01000921223) and is registered as a drug wholesaler in New Jersey (Registration No. 5005256).

41. On information and belief, Aurobindo has a regular and established business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520. On information and belief, Aurobindo has a regular and established business at 203 Windsor Center Dr, East Windsor, NJ 08520 and has registered this address with the New Jersey Department of Health.

42. On information and belief, Aurobindo, alone or together with Eugia and/or AuroMedics, 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.

43. On information and belief, Aurobindo consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Medicure International, Inc. v. Aurobindo Pharma Limited et al.*, No. 2:21-cv-17534; *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-00624; *Merck Sharp & Dohme Corp. v. Aurobindo Pharma USA, Inc. et al.*, No. 3:20-cv-10444; *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2:20-cv-00315; *Celgene Corporation v. Aurobindo Pharma Limited et al.*, No. 2:19-cv-05799; *Celgene Corporation v. Aurobindo Pharma Limited et al.*, No. 2:19-cv-00143; *Celgene Corporation v. Hetero Labs Limited et al.*, No. 2:17-cv-03387.

44. This Court has personal jurisdiction over Aurobindo 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, Eugia and/or AuroMedics.

45. This Court has personal jurisdiction over Aurobindo because, *inter alia*, this action arises from actions of Aurobindo 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.

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

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

48. 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.

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

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

51. Venue is proper under 28 U.S.C. § 1400(b) because Aurobindo has committed an act of infringement and has a regular and established place of business in this judicial district.

ERLEADA®

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

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

54. 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.

55. 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

56. On May 21, 2013, the 507 Patent, titled "Androgen Receptor Modulator for the Treatment of Prostate Cancer and Androgen Receptor-Associated Diseases" was duly and legally issued to Regents as assignee. A copy of the 507 Patent is attached as Exhibit A.

57. On August 12, 2014, the 689 Patent, titled "Androgen Receptor Modulator for the Treatment of Prostate Cancer and Androgen Receptor-Associated Diseases" was duly and legally issued to Regents as assignee. A copy of the 689 Patent is attached as Exhibit B.

58. On July 12, 2016, the 159 Patent, titled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators" was duly and legally issued to Regents as assignee. A copy of the 159 Patent is attached as Exhibit C.

59. 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 D.

60. On June 5, 2018, the 261 Patent, titled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators" was duly and legally issued to Regents as assignee. A copy of the 261 Patent is attached as Exhibit E.

61. 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®.

62. 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

63. By letter dated April 16, 2022, addressed to JBI, Sloan-Kettering, Aragon, and Regents ("Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217104 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.

64. The Notice Letter stated that "Eugia Pharma Specialties Limited and U.S. Agent AuroMedics Pharma LLC" were providing notice in relation to the submission of the ANDA.

65. On information and belief, Aurobindo is a U.S. Agent connected to the filing of the ANDA.

66. The Notice Letter did not cite section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, despite the requirement to do so under 21 C.F.R. § 314.95(c).

67. The Notice Letter did not state that Defendants had received a Paragraph IV acknowledgement letter from the FDA, despite the requirement to do so under 21 C.F.R. § 314.95(c)(3).

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

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

70. The Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA.

71. The OCA referred to a drug called "pomalidomide" but did not refer to apalutamide.

72. Counsel for Plaintiffs telephoned and/or emailed counsel for Defendants regarding the OCA on at least April 26, April 28, April 29, May 2, May 9, and May 11, but counsel for Defendants did not respond until the evening of May 11.

73. On May 19, 2022, Defendants produced documents that Defendants purported to be the ANDA.

74. On May 23, 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.

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

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

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

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

COUNT I – CLAIM FOR INFRINGEMENT OF THE 507 PATENT

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

80. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

81. On information and belief, because the Proposed ANDA Product contains apalutamide, the Proposed ANDA Product and the use of the Proposed ANDA Product infringe at least claims 1, 2, 3, 11, 19, and 22 of the 507 Patent.

82. On information and belief, the Proposed ANDA Product infringes at least claims 1 and 22 of the 507 Patent because it contains the compound apalutamide.

83. On information and belief, the Proposed ANDA Product infringes at least claims 2 and 11 of the 507 Patent because it is a pharmaceutical composition comprising a therapeutically effective amount of the compound apalutamide and a pharmaceutically acceptable carrier, diluent, or adjuvant.

84. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 3 and 19 of the 507 Patent because physicians and/or patients will practice a method for treating a hyperproliferative disorder, specifically prostate cancer, said method comprising administering, causing to be administered, or directing the administration of the compound

apalutamide to a subject, specifically a patient, in need of such treatment, thereby treating the prostate cancer.

85. On information and belief, Defendants will induce infringement of at least claims 3 and 19 of the 507 Patent by actively inducing the use of the Proposed ANDA Product to practice a method for treating a hyperproliferative disorder, specifically prostate cancer, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to a subject, specifically a patient, in need of such treatment, thereby treating the prostate cancer.

86. 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 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, 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 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

87. 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 507 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 507 Patent.

88. On information and belief, Defendants have actual knowledge of the 507 Patent, at least as shown by the Notice Letter.

89. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, 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 507 Patent.

90. 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 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, under at least one of 35 U.S.C. § 271(a), (b), or (c).

91. 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 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

92. On information and belief, physicians and/or patients will directly infringe the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, by their use of the Proposed ANDA Product upon approval.

93. 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 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, for the pecuniary benefit of Defendants.

94. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 507 Patent, including at least

claims 1, 2, 3, 11, 19, and 22. On information and belief, Defendants will actively induce the infringement of the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

95. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22. On information and belief, Defendants will thus contribute to the infringement of the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

96. On information and belief, the actions described in this Complaint relating to the ANDA and the 507 Patent were done by and for the benefit of Defendants.

97. 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 689 PATENT

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

99. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 689 Patent, including at least claim 2.

100. On information and belief, because the Proposed ANDA Product contains apalutamide, the use of the Proposed ANDA Product infringes at least claim 2 of the 689 Patent.

101. On information and belief, the use of the Proposed ANDA Product will infringe at least claim 2 of the 689 Patent because physicians and/or patients will practice a method for treating prostate cancer in a subject, specifically a patient, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to the patient in need of such treatment.

102. On information and belief, Defendants will induce infringement of at least claim 2 of the 689 Patent by actively inducing the use of the Proposed ANDA Product to practice a method for treating prostate cancer in a subject, specifically a patient, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to the patient in need of such treatment.

103. 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 689 Patent, including at least claim 2, 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 689 Patent, including at least claim 2, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

104. 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 689 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 689 Patent.

105. On information and belief, Defendants have actual knowledge of 689 Patent, at least as shown by the Notice Letter.

106. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 689 Patent, including at least claim 2, 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 689 Patent.

107. 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 689 Patent, including at least claim 2, under at least one of 35 U.S.C. § 271(a), (b), or (c).

108. 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 689 Patent, including at least claim 2.

109. On information and belief, physicians and/or patients will directly infringe the claims of the 689 Patent, including at least claim 2, by their use of the Proposed ANDA Product upon approval.

110. 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 689 Patent, including at least claim 2, for the pecuniary benefit of Defendants.

111. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 689 Patent, including at least claim 2. On information and belief, Defendants will actively induce the infringement of the claims of the 689 Patent, including at least claim 2.

112. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 689 Patent, including at least claim 2. On information and belief, Defendants will thus contribute to the infringement of the claims of the 689 Patent, including at least claim 2.

113. On information and belief, the actions described in this Complaint relating to the ANDA and the 689 Patent were done by and for the benefit of Defendants.

114. 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 159 PATENT

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

116. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 159 Patent, including at least claims 1, 12, and 17.

117. On information and belief, because the Proposed ANDA Product contains apalutamide, the Proposed ANDA Product and the use of the Proposed ANDA Product infringe at least claims 1, 12, and 17 of the 159 Patent.

118. On information and belief, the Proposed ANDA Product infringes at least claim 1 of the 159 Patent because it contains the compound apalutamide.

119. On information and belief, the Proposed ANDA Product infringes at least claims 12 and 17 of the 159 Patent because it is a pharmaceutical composition comprising a therapeutically effective amount of the compound apalutamide formulated in an oral dosage form and a pharmaceutically acceptable carrier, diluent, or adjuvant.

120. 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 159 Patent, including at least claims 1, 12, 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 159 Patent, including at least claims 1, 12, and 17, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

121. 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 159 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 159 Patent.

122. On information and belief, Defendants have actual knowledge of the 159 Patent, at least as shown by the Notice Letter.

123. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 159 Patent, including at least claims 1, 12, 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 159 Patent.

124. 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 159 Patent, including at least claims 1, 12, and 17, under at least one of 35 U.S.C. § 271(a), (b), or (c).

125. 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 159 Patent, including at least claims 1, 12, and 17.

126. On information and belief, physicians and/or patients will directly infringe the claims of the 159 Patent, including at least claims 1, 12, and 17, by their use of the Proposed ANDA Product upon approval.

127. 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 159 Patent, including at least claims 1, 12, and 17, for the pecuniary benefit of Defendants.

128. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 159 Patent, including at least claims 1, 12, and 17. On information and belief, Defendants will actively induce the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

129. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 159 Patent, including at least claims 1, 12, and 17. On information and belief, Defendants will thus contribute to the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

130. On information and belief, the actions described in this Complaint relating to the ANDA and the 159 Patent were done by and for the benefit of Defendants.

131. 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 663 PATENT

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

133. 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.

134. 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 of the 663 Patent.

135. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe at least claim 1 of the 663 Patent 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.

136. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe at least claim 13 of the 663 Patent 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.

137. 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 at least claim 17 of the 663 Patent because physicians and/or patients will practice a method of treating prostate cancer in a mammal, specifically a patient, 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.

138. On information and belief, Defendants will induce infringement of at least claim 17 of the 663 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating prostate cancer in a mammal, specifically a patient, 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.

139. 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.

140. 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.

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

142. 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.

143. 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).

144. 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.

145. 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 their use of the Proposed ANDA Product upon approval.

146. 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.

147. 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.

148. On information and belief, the 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.

149. 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.

150. 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 261 PATENT

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

152. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 261 Patent, including at least claims 8, 10, and 12.

153. On information and belief, because the Proposed ANDA Product contains apalutamide, the Proposed ANDA Product and the use of the Proposed ANDA Product infringe at least claims 8, 10, and 12 of the 261 Patent.

154. On information and belief, the Proposed ANDA Product infringes claims at least claims 8, 10, and 12 of the 261 Patent because it is a tablet comprising the compound apalutamide in a range of from 0.0005 to 500 mg and a pharmaceutically acceptable carrier, diluent, or adjuvant.

155. 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 261 Patent, including at least claims 8, 10, and 12, 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 261 Patent, including at least claims 8, 10, and 12, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

156. 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 261 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 261 Patent.

157. On information and belief, Defendants have actual knowledge of the 261 Patent, at least as shown by the Notice Letter.

158. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 261 Patent, including at least claims 8, 10, and 12, 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 261 Patent.

159. 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 261 Patent, including at least claims 8, 10, and 12, under at least one of 35 U.S.C. § 271(a), (b), or (c).

160. 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 261 Patent, including at least claims 8, 10, and 12.

161. On information and belief, physicians and/or patients will directly infringe the claims of the 261 Patent, including at least claims 8, 10, and 12, by their use of the Proposed ANDA Product upon approval.

162. 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 261 Patent, including at least claims 8, 10, and 12, for the pecuniary benefit of Defendants.

163. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 261 Patent, including at least

claims 8, 10, and 12. On information and belief, Defendants will actively induce the infringement of the claims of the 261 Patent, including at least claims 8, 10, and 12.

164. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 261 Patent, including at least claims 8, 10, and 12. On information and belief, Defendants will thus contribute to the infringement of the claims of the 261 Patent, including at least claims 8, 10, and 12.

165. On information and belief, the actions described in this Complaint relating to the ANDA and the 261 Patent were done by and for the benefit of Defendants.

166. 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 each 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 each 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 dates 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 26, 2022

s/ Keith J. Miller
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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 Aragon, JBI, Sloan-Kettering, and/or Regents have asserted one or more of the patents in this case in the pending matters in this Judicial District: *Aragon Pharmaceuticals, Inc. et al. v. Lupin Limited et al.*, Civil Action No. 2:22-cv-02825-JXN-LDW (663 Patent), *Aragon Pharmaceuticals, Inc. et al. v. Zydus Worldwide DMCC et al.*, Civil Action No. 2:22-cv-02964-JXN-LDW (663 Patent), *Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, Civil Action No. 2:22-cv-03044-JXN-LDW (507 Patent, 689 Patent, 159 Patent, 663 Patent, 261 Patent); and in the pending matters in the United States District Court for the District of Delaware: *Aragon Pharmaceuticals, Inc. et al. v. Lupin Limited et al.*, Civil Action No. 1:22-cv-00637-CFC (663 Patent), *Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, Civil Action No. 1:22-cv-00678 (507 Patent, 689 Patent, 159 Patent, 663 Patent, 261 Patent). 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 26, 2022

Respectfully Submitted,

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