Keith J. Miller, Esq.
Michael J. Gesualdo, 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
mgesualdo@rwmlegal.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and The Regents of the University of California

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

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiffs,

v.

HETERO LABS LIMITED UNIT V, and HETERO USA, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), and The Regents of the University of California ("Regents") (collectively, "Plaintiffs"), for their Complaint against Defendants Hetero Labs Limited Unit V ("Hetero Labs") and Hetero USA, Inc. ("Hetero USA") (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 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. 217185 ("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. On information and belief, Hetero Labs is a corporation organized under the laws of India, having its principal place of business at Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Jadcherla Mandal, Polepally Village, Mahabubnagar, Telangana, India 509301.

7. On information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

JURISDICTION AND VENUE

8. 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).

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

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

11. 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.

12. On information and belief, Hetero Labs has substantial, continuous, and systematic contacts with New Jersey.

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

14. On information and belief, Hetero Labs, alone or together with Hetero USA, 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.

15. On information and belief, Hetero Labs consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-20-cv-14389; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-15449; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-05797; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-17463; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-14111; *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-22-cv-03212.

16. This Court has personal jurisdiction over Hetero Labs 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, Hetero USA.

17. This Court has personal jurisdiction over Hetero Labs because, *inter alia*, this action arises from actions of Hetero Labs 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.

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

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

20. Venue is proper under 28 U.S.C. § 1391(c)(3) because Hetero Labs is a foreign corporation.

21. On information and belief, Hetero USA has substantial, continuous, and systematic contacts with New Jersey.

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

23. On information and belief, Hetero USA has substantial, continuous, and systematic contacts with New Jersey, including that it is registered to do business in New Jersey

(Entity Id. No. 0400362826) and is registered as a drug wholesaler in New Jersey (Registration No. 5004050).

24. On information and belief, Hetero USA has a regular and established business at 1035 Centennial Avenue, Piscataway, New Jersey 08854 and has registered this address with the New Jersey Department of Health.

25. On information and belief, Hetero USA, alone or together with Hetero Labs, 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, Hetero USA consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-20-cv-14389; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-15449; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-05797; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-17463; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-14111; *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-22-cv-03212.

27. This Court has personal jurisdiction over Hetero USA 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, Hetero Labs.

28. This Court has personal jurisdiction over Hetero USA because, *inter alia*, this action arises from actions of Hetero USA 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 Hetero USA in this district would not be unreasonable given Hetero USA's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

30. On information and belief, Hetero USA has committed an act of infringement in this judicial district by submitting the ANDA with the FDA on or about February 14, 2022, and subsequently amending its ANDA on or about April 26, 2024, to contain a Paragraph IV certification for the 689 Patent, the 159 Patent, and the 261 Patent.

31. 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.

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

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

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

ERLEADA®

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

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

37. 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.

38. 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

39. 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 A.

40. 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 B.

41. 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 C.

42. 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®.

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

DEFENDANTS' NOTICE LETTERS AND THE ANDA

44. By letter dated April 18, 2022, addressed to JBI, Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering"),[1] Aragon and Regents ("2022 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217185 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2022 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 2022 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the 8,445,507 ("507 Patent"), 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"), which are asserted in *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, Civil Action No. 2:22-cv-03212 (D.N.J.) ("2022 Matter").

45. The 2022 Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

46. The ANDA includes a Paragraph IV Certification that the claims of the 507 Patent, the 663 Patent, the 054 Patent, the 314 Patent, the 508 Patent, and the 888 Patent are invalid, unenforceable, or not infringed.

47. The 2022 Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On May 6, 2022, Defendants produced documents that Defendants purported to be the ANDA.

48. Plaintiffs commenced an action within 45 days of the date of receipt of the 2022 Notice Letter. *See* 2022 Matter at D.I. 1.

[1] Sloan-Kettering is not a party to the filing of the present complaint.

49. On January 3, 2023, the RE353 Patent issued as a reissue of the 314 Patent. Accordingly, Plaintiffs submitted Form 3542 identifying the RE353 Patent for listing in the Orange Book.

50. On January 27, 2023, Plaintiffs notified Defendants of the RE353 Patent.

51. By letter dated September 11, 2023, addressed to JBI, Sloan-Kettering, Aragon, and Regents ("2023 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217185 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2023 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 2023 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the RE353 Patent.

52. The 2023 Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

53. The ANDA includes a Paragraph IV Certification that the claims of the RE353 Patent are invalid, unenforceable, and/or will not be infringed.

54. The 2023 Notice Letter included an OCA to the ANDA.

55. Plaintiffs timely amended the pleadings in the 2022 Matter to include allegations of infringement of the RE353 Patent. *See* 2022 Matter at D.I. 68.

56. By letter dated April 26, 2024, addressed to JBI, Aragon, and Regents ("2024 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217185 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2024 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 2024 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the 689 Patent, the 159 Patent, and the 261 Patent. The 689 Patent, the 159 Patent, and the 261 Patent have each been listed in the Orange Book as covering Erleada® since before the date of Defendants' 2022 Notice Letter.

57. The 2024 Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

58. The ANDA includes a Paragraph IV Certification that the claims of the 689 Patent, the 159 Patent, and the 261 Patent are invalid, unenforceable, and/or will not be infringed.

59. The 2024 Notice Letter included an OCA to the ANDA. Defendants agreed that Plaintiffs could access the ANDA documents produced in the 2022 Matter.

60. On information and belief, Defendants have actual knowledge of each of the Patents-In-Suit, at least as shown by the discussion of the Orange Book listing for Erleada® in the 2022 Notice Letter, 2023 Notice Letter, and 2024 Notice Letter.

61. On information and belief, Defendants seek to obtain FDA approval to manufacture, use, import, offer to sell, and sell its Proposed ANDA Product in the United States before the expiration of the Patents-In-Suit.

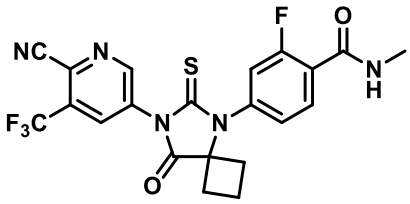
62. Plaintiffs are commencing this action within 45 days of the date of receipt of the 2024 Notice Letter.

COUNT I – CLAIM FOR INFRINGEMENT OF THE 689 PATENT

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

64. 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.

65. On information and belief, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



, which will infringe the genus of compounds claimed in at least claim 2 of the 689 Patent.

66. 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.

67. 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.

68. 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.

69. 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.

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

71. 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.

72. 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).

73. 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.

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

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

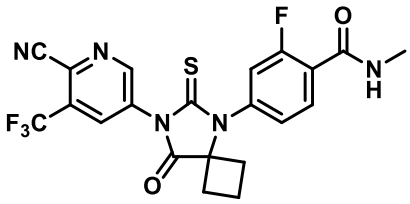
COUNT II – CLAIM FOR INFRINGEMENT OF THE 159 PATENT

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

81. 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.

82. 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.

83. On information and belief, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



, which will infringe the genus of compounds claimed in at least claim 1 of the 159 Patent.

84. 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.

85. 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.

86. 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.

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

88. 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.

89. 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).

90. 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.

91. 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 the use of the Proposed ANDA Product upon approval.

92. 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.

93. 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.

94. 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.

95. 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.

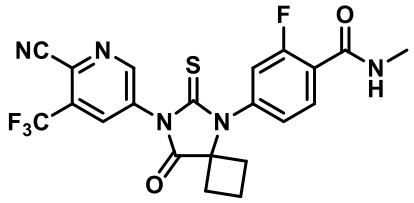
96. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III – CLAIM FOR INFRINGEMENT OF THE 261 PATENT

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

98. 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 10 and 12.

99. On information and belief, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



. Thus, the Proposed ANDA Product and the use of the Proposed ANDA Product will infringe at least claims 10 and 12 of the 261 Patent.

100. On information and belief, the Proposed ANDA Product infringes at least claims 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.

101. 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 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 10 and 12, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

102. 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.

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

104. 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 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.

105. 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 10 and 12, under at least one of 35 U.S.C. § 271(a), (b), or (c).

106. 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 10 and 12.

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

108. 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 10 and 12, for the pecuniary benefit of Defendants.

109. 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 10 and 12. On information and belief, Defendants will actively induce the infringement of the claims of the 261 Patent, including at least claims 10 and 12.

110. 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 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 10 and 12.

111. 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.

112. 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: June 6, 2024

s/ Keith J. Miller
Keith J. Miller, Esq.
Michael J. Gesualdo, 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
mgesualdo@rwmlegal.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and The Regents of the University of California

Of Counsel:

Steven D. Maslowski
Matthew A. Pearson
Jonathan J. Underwood
Anthony D. Sierra
Vincent P. Jones
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
jonesv@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

Caitlin E. Olwell
AKIN GUMP STRAUSS HAUER & FELD LLP
Bank of America Tower
1 Bryant Park
New York, NY 10036
Tel: (212) 872-1000
Fax: (202) 872-1002
colwell@akingump.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and The Regents of the University of California

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, 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. Zydus Worldwide DMCC et al.*, Civil Action No. 2:22-cv-02964-SRC-LDW (Consolidated), *Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, Civil Action No. 2:22-cv-03044-SRC-LDW. 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: June 6, 2024

Respectfully Submitted,

s/ Keith J. Miller

Keith J. Miller, Esq.
Michael J. Gesualdo, 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
mgesualdo@rwmlegal.com

Attorneys for Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and The Regents of the University of California