IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT

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 Defendant Sandoz Inc. ("Sandoz" or "Defendant"), 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. 216431 ("the ANDA") by Defendant 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, Sandoz is a corporation organized under the laws of the State of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

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. § 1400(b).

11. On information and belief, Defendant has substantial, continuous, and systematic contacts with Delaware.

12. On information and belief, Defendant develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

13. On information and belief, Defendant 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 Delaware.

14. On information and belief, Defendant consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in Delaware in one or more prior litigations, for example: *Acerta Pharma BV et al. v. Sandoz Inc.*, No. 22-164; *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, No. 20-1589; *Sanofi-Aventis US LLC et al. v. Actavis LLC et al.*, No. 20-804; *Novo Nordisk Inc. et al. v. Sandoz, Inc.*, No. 20-747; *Pharmacyclics LLC et al. v. Sun Pharma Global FZE et al.*, No. 20-403; *Otsuka Pharmaceutical Co., Ltd. et al. v. Sandoz, Inc. et al.*, No. 19-2080; *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 19-312; *Genentech, Inc. et al. v. Sandoz, Inc.*, No. 19-203; *Genentech, Inc. et al. v. Sandoz, Inc.*, No. 19-202; *Astellas US LLC et al. v. Sandoz Inc.*, No. 18-1676.

15. This Court has personal jurisdiction over Defendant by virtue of, among other things, (1) its incorporation in Delaware, (2) its continuous and systematic contacts with Delaware; (3) its acts of patent infringement that will result in foreseeable harm in Delaware; and (4) its sale of a substantial volume of prescription drugs in Delaware.

16. This Court has personal jurisdiction over Defendant because, *inter alia*, this action arises from actions of Defendant directed toward Delaware. For example, Defendant 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 Delaware, causing injury to Plaintiffs in Delaware.

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

18. Venue is proper under 28 U.S.C. § 1400(b) because Defendant is incorporated in Delaware and thus resides in this judicial district.

ERLEADA®

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

20. On information and belief, Defendant knows that JBI holds approved New Drug Application No. 210951.

21. 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.

22. 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

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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®.

29. On information and belief, Defendant knows that the Patents-In-Suit are listed in the Orange Book as covering Erleada®.

DEFENDANT'S NOTICE LETTER AND THE ANDA

30. By letter dated April 13, 2022, addressed to JBI, Sloan-Kettering, Aragon, Regents, and Johnson & Johnson, and received by Johnson & Johnson on April 14, 2022 ("Notice Letter"), Defendant notified Plaintiffs that it had submitted ANDA No. 216431 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.

31. The Notice Letter did not state that Defendant 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).

32. The Notice Letter did not state that the FDA had received an ANDA submitted by Defendant containing any required bioavailability or bioequivalence data or information, despite the requirement to do so under 21 C.F.R. § 314.95(c)(1).

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

34. 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.

35. 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 patent owner had disclosed but did not claim alternatives to crystalline Form B of apalutamide.

36. The Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On May 4, 2022, Defendant produced documents that Defendant purported to be the ANDA.

37. On May 13, 2022, Plaintiffs requested technical information regarding the Proposed ANDA Product. Defendant did not provide any further information. By failing to provide information, Defendant impeded Plaintiffs' ability to evaluate infringement of the 663 Patent. On information and belief, if Defendant had a good faith basis to contest infringement of the 663 Patent, it would have provided the requested information.

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

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

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

41. 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

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

43. An actual controversy exists between the parties as to whether Defendant's 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.

44. 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.

45. 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.

46. 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.

47. 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 patient in need of such treatment, thereby treating the prostate cancer.

48. On information and belief, Defendant 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 patient in need of such treatment, thereby treating the prostate cancer.

49. On information and belief, if the FDA approves the ANDA, Defendant 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 Defendant knows that physicians will

prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendant 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.

50. 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.

51. On information and belief, Defendant has actual knowledge of the 507 Patent, at least as shown by the Notice Letter.

52. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has 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.

53. 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).

54. 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.

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

56. On information and belief, upon approval, Defendant 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 Defendant.

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

58. 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, Defendant will thus contribute to the infringement of the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

59. 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 Defendant.

60. 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

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

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

63. 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.

64. 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.

65. On information and belief, Defendant 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.

66. On information and belief, if the FDA approves the ANDA, Defendant 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 Defendant knows that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendant 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.

67. 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.

68. On information and belief, Defendant has actual knowledge of 689 Patent, at least as shown by the Notice Letter.

69. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has 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.

70. 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).

71. 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.

72. 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.

73. On information and belief, upon approval, Defendant 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 Defendant.

74. On information and belief, Defendant specifically intends 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, Defendant will actively induce the infringement of the claims of the 689 Patent, including at least claim 2.

75. 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, Defendant will thus contribute to the infringement of the claims of the 689 Patent, including at least claim 2.

76. 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 Defendant.

77. 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

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

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

80. 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.

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

82. 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.

83. On information and belief, if the FDA approves the ANDA, Defendant 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 Defendant knows that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendant 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.

84. 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.

85. On information and belief, Defendant has actual knowledge of the 159 Patent, at least as shown by the Notice Letter.

86. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has 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.

87. 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).

88. 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.

89. 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.

90. On information and belief, upon approval, Defendant 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 Defendant.

91. On information and belief, Defendant specifically intends 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, Defendant will actively induce the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

92. 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, Defendant will thus contribute to the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

93. 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 Defendant.

94. 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

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

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

97. 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.

98. 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.

99. 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.

100. 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.

101. On information and belief, Defendant 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.

102. On information and belief, if the FDA approves the ANDA, Defendant 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 Defendant knows that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendant 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.

103. 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.

104. On information and belief, Defendant has actual knowledge of the 663 Patent, at least as shown by the Notice Letter.

105. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has 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.

106. 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).

107. 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.

108. 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.

109. On information and belief, upon approval, Defendant 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 Defendant.

110. On information and belief, Defendant specifically intends 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, Defendant will actively induce the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

111. 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, Defendant will thus contribute to the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

112. 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 Defendant.

113. 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

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

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

116. 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.

117. 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.

118. On information and belief, if the FDA approves the ANDA, Defendant 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 Defendant knows that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendant 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.

119. 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.

120. On information and belief, Defendant has actual knowledge of the 261 Patent, at least as shown by the Notice Letter.

121. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has 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.

122. 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).

123. 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.

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

125. On information and belief, upon approval, Defendant 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 Defendant.

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

127. 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, Defendant will thus contribute to the infringement of the claims of the 261 Patent, including at least claims 8, 10, and 12.

128. 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 Defendant.

129. 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 Defendant 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 Defendant has 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 Defendant, its officers, agents, servants, and employees, and those persons in active concert or participation with Defendant, 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 Defendant engages 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.

MORRIS, NICHOLS, ARSHT &TUNNELL LLP

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