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

ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; MEDIVATION PROSTATE THERAPEUTICS LLC; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, v. ASCENT PHARMACEUTICALS, INC. Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc. ("API"), Astellas US LLC ("AUS"), and Astellas Pharma US, Inc. ("APUS") (collectively, "Astellas"), Medivation LLC ("Medivation") and Medivation Prostate Therapeutics LLC ("MPT") (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (all collectively, "Plaintiffs"), for their Complaint against Defendant Ascent Pharmaceuticals, Inc. ("Ascent"), hereby allege as follows:

THE PARTIES

1. Plaintiff API is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. Plaintiff AUS is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

3. Plaintiff APUS is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

4. Plaintiff Medivation is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

5. Plaintiff MPT is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

6. Plaintiff The Regents is a public corporation organized and existing under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its corporate offices located at 1111 Franklin Street, Oakland, California 94607-5200, United States.

7. On information and belief, Defendant Ascent is a corporation organized and existing under the laws of the State of New York having a principal place of business at 400 South Technology Drive, Central Islip, New York 11722, United States.

8. On information and belief, Ascent, by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent Nos. 7,709,517 ("the '517 patent"), 8,183,274 ("the '274 patent"), and 12,161,628 ("the '628 patent") (collectively, "the Xtandi® patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Ascent's filing of ANDA No. 220025 with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of the pharmaceutical product Xtandi® capsules before the expiration of Plaintiffs' patents covering Xtandi® and its use.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Ascent by virtue of the fact that, *inter alia*, Ascent has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

12. This Court has personal jurisdiction over Ascent by virtue of the fact that Ascent is at home in New Jersey as reflected by the fact that, on information and belief, Ascent regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably

expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Ascent conducts marketing and sales activities in the State of New Jersey, including but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if Ascent's ANDA No. 220025 is approved, Ascent will market and sell its generic version of Xtandi® capsules in New Jersey.

13. This Court has personal jurisdiction over Ascent by virtue of the fact that, on information and belief, Ascent regularly conducts business in New Jersey and has registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5005459.

14. This Court has personal jurisdiction over Ascent by virtue of the fact that, on information and belief, Ascent regularly and continuously transacts business within New Jersey, either directly or through its affiliates, including by selling pharmaceutical products in New Jersey.

15. This Court also has personal jurisdiction over Ascent by virtue of the fact that Ascent has previously submitted to the jurisdiction of this Court and availed itself of this Court by asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, e.g., *Tris Pharma, Inc. v. Ascent Pharms., Inc.*, No. 2:21-cv-12867 (D.N.J.). Ascent has acknowledged the Court's personal jurisdiction by consenting or agreeing not to contest jurisdiction in civil actions initiated in this Court, including, but not limited to *e.g.*, *Impax Lab'ys, LLC v. Ascent Pharms., Inc.*, No. 1:24-cv-05299 (D.N.J.); *Supernus Pharms., Inc. v. Ascent Pharms., Inc. et al.*, No. 3:23-cv-04015 (D.N.J.); and *Jazz Pharms., Inc. et al. v. Ascent Pharms., Inc.*, No. 2:17-cv-05487 (D.N.J.).

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

17. Venue is proper in this Judicial District for Ascent. On information and belief, Ascent has registered as a drug wholesaler and manufacturer (registration number 5005459) in the State of New Jersey. On information and belief, Ascent has a regular and established place of business and employees in the State of New Jersey. On information and belief, based on Ascent's presence in and connections to New Jersey, discoverable information in Ascent's possession, custody, or control regarding Ascent's ANDA No. 220025 will likely show that Ascent engaged in activities in New Jersey relevant to the preparation and/or submission of Ascent's ANDA No. 220025.

18. Venue is also proper in this Judicial District as to Ascent because, among other things, Ascent has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Xtandi® for sale and use throughout the United States, including within the State of New Jersey.

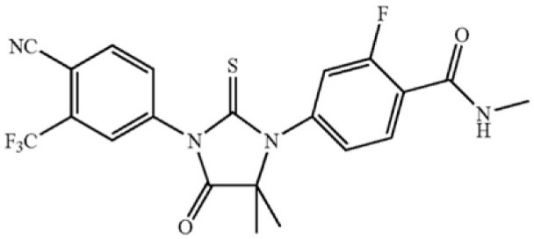
THE XTANDI® CAPSULE NDA

19. Medivation, Inc. filed New Drug Application ("NDA") No. 203415 for Xtandi® (enzalutamide) capsules, 40 mg. The FDA approved NDA No. 203415 for Xtandi® 40 mg capsules on August 31, 2012, for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. On September 10, 2014, the FDA approved an expanded indication for the use of Xtandi® 40 mg capsules to treat patients with metastatic castration-resistant prostate cancer. On July 13, 2018, the FDA approved an expanded indication for the use of Xtandi® 40 mg capsules to treat patients with castration-resistant prostate cancer. On December 16, 2019, the FDA approved an additional indication for the use of Xtandi® 40 mg capsules to treat patients with metastatic castration-sensitive prostate cancer. On November

16, 2023, the FDA approved an additional indication for the use of Xtandi® 40 mg capsules to treat patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

20. Effective September 13, 2012, Medivation, Inc. assigned all rights, title, and interest to NDA No. 203415 to Astellas Pharma US, Inc. Xtandi® capsules are sold and co-promoted by Astellas Pharma US, Inc. and Pfizer Inc. in the United States.

21. Enzalutamide is a compound that can be referred to by any of several chemical names, including 4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-{3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-4-keto-5,5-dimethyl-2-thioxo-imidazolidin-1-yl]-2-fluoro-N-methyl-benzamide, and 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylidene-1-imidazolidinyl]-2-fluoro-N-methylbenzamide, and which has the following chemical structure:



THE PATENTS-IN-SUIT

22. On May 4, 2010, the ’517 patent, entitled “Diarylhydantoin Compounds,” was duly and legally issued to The Regents. A true and correct copy of the ’517 patent is attached hereto as Exhibit A.

23. On May 22, 2012, the ’274 patent, entitled “Treatment of Hyperproliferative Disorders with Diarylhydantoin Compounds,” was duly and legally issued to The Regents. A true and correct copy of the ’274 patent is attached hereto as Exhibit B.

24. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the ’517 and ’274 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the “Orange Book”) for Xtandi® 40 mg capsules.

25. Pursuant to an agreement, as amended, entered into between Medivation, Inc., Medivation Prostate Therapeutics, Inc., and The Regents, Medivation, Inc. and Medivation Prostate Therapeutics, Inc. were granted an exclusive license to the ’517 and ’274 patents, with the right to sue for infringement of the ’517 and ’274 patents in the United States.

26. Pursuant to an agreement entered into between API, AUS, Medivation, Inc., and Medivation Prostate Therapeutics, Inc., API was granted an exclusive sublicense to the ’517 and ’274 patents, with the right to sue for infringement of the ’517 and ’274 patents in the United States.

27. Pursuant to an agreement entered into between API and AUS, AUS was granted a sublicense to the ’517 and ’274 patents, with the right to sue for infringement of the ’517 and ’274 patents in the United States.

28. Pursuant to an agreement entered into between AUS and APUS, APUS was granted a sublicense to the ’517 and ’274 patents, with the right to sue for infringement of the ’517 and ’274 patents in the United States.

29. On September 28, 2016, Pfizer Inc. acquired Medivation, Inc. and its wholly owned subsidiary Medivation Prostate Therapeutics, Inc.

30. On August 28, 2017, Medivation, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation, Inc. converted from a corporation to a limited liability company and changed its name to Medivation LLC.

31. On August 28, 2017, Medivation Prostate Therapeutics, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation Prostate Therapeutics, Inc. converted from a corporation to a limited liability company and changed its name to Medivation Prostate Therapeutics LLC.

32. On December 10, 2024, the ’628 patent, entitled “Combination Therapy,” was duly and legally issued to MPT and API. A true and correct copy of the ’628 patent is attached hereto as Exhibit C.

33. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the ’628 patent will be timely listed in the Orange Book for Xtandi® 40 mg capsules.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

34. By a letter dated November 18, 2024 (“Ascent’s Notice Letter”), Ascent advised The Regents and APUS that Ascent had submitted ANDA No. 220025 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg capsules (“Ascent’s Generic Products”) prior to the expiration of the ’517 and ’274 patents. The ’628 patent will expire after the ’517 and ’274 patents.

35. On information and belief, Ascent submitted ANDA No. 220025 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the

commercial manufacture, use, and sale of Ascent's Generic Products as generic versions of Xtandi® 40 mg capsules before expiration of the Xtandi® patents.

36. On information and belief, ANDA No. 220025 seeks FDA approval of Ascent's Generic Products for the indications of treatment of castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

37. Ascent's Notice Letter also advised The Regents and APUS that Ascent's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Ascent's opinion, certain claims of the '517 and '274 patents are invalid, unenforceable, and/or not infringed.

38. Ascent's Notice Letter does not allege non-infringement of certain claims of the '517 or '274 patents.

39. By not identifying non-infringement defenses for certain claims of the '517 and '274 patents in Ascent's Notice Letter, Ascent admits Ascent's Generic Products meet all limitations of those claims.

40. Ascent's Notice Letter does not allege invalidity under 35 U.S.C. § 101 or unenforceability of any claim of the '517 or '274 patents.

41. By not identifying invalidity defenses under 35 U.S.C. § 101 or unenforceability defenses for any claim of the '517 and '274 patents in Ascent's Notice Letter, Ascent admits all claims of the '517 and '274 patents are valid under 35 U.S.C. § 101 and are enforceable.

42. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Ascent regarding the infringement, validity, and enforceability of the Xtandi® patents.

43. Plaintiffs are commencing this action within 45 days of receiving Ascent's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '517 Patent)

44. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

45. By submitting ANDA No. 220025 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Ascent's Generic Products throughout the United States, including New Jersey, prior to expiration of the '517 patent, Ascent committed an act of infringement of the '517 patent under 35 U.S.C. § 271(e)(2)(A).

46. The '517 patent claims, *inter alia*, the compound, and pharmaceutical compositions of, enzalutamide.

47. On information and belief, Ascent's Generic Products, if approved by the FDA, will contain the compound enzalutamide and/or pharmaceutical compositions thereof, which will constitute infringement of claims of the '517 patent.

48. On information and belief, Ascent's manufacture, use, sale, offer for sale, and/or importation into the United States of Ascent's Generic Products prior to the expiration of the '517 patent, including any applicable exclusivities or extensions, will directly infringe the '517 patent under 35 U.S.C. § 271(a). Ascent will infringe one or more of the claims of the '517 patent.

49. On information and belief, Ascent's Generic Products will infringe at least Claim 1 of the '517 patent which recites "[a] compound selected from the group consisting of" a group of compounds including enzalutamide. On information and belief, Ascent's Generic Products will infringe Claim 1 of the '517 patent because Ascent's Generic Products will contain enzalutamide.

50. On information and belief, Ascent was aware of the existence of the ’517 patent and its listing in the Orange Book as demonstrated by Ascent’s reference to the ’517 patent in Ascent’s Notice Letter.

51. On information and belief, Ascent copied the claimed invention of the ’517 patent.

52. On information and belief, Ascent knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Ascent’s Generic Products prior to patent expiry will infringe one or more claims of the ’517 patent.

53. On information and belief, Ascent’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’517 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

54. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’274 Patent)

55. Plaintiffs incorporate each of the preceding paragraphs 1 to 54 as if fully set forth herein.

56. By submitting ANDA No. 220025 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Ascent’s Generic Products throughout the United States, including New Jersey, prior to expiration of the ’274 patent, Ascent committed an act of infringement of the ’274 patent under 35 U.S.C. § 271(e)(2)(A).

57. The ’274 patent claims, *inter alia*, methods of treating prostate cancer with enzalutamide.

58. On information and belief, Ascent's Generic Products, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis, which will constitute infringement of claims of the '274 patent.

59. On information and belief, Ascent's manufacture, use, sale, offer for sale, and/or importation into the United States of Ascent's Generic Products prior to the expiration of the '274 patent, including any applicable exclusivities or extensions, will actively induce infringement of the '274 patent under 35 U.S.C. § 271(b) and will constitute contributory infringement of the '274 patent under 35 U.S.C. § 271(c). Ascent will aid another in the infringement of one or more of the claims of the '274 patent.

60. On information and belief, Ascent will infringe at least Claim 1 of the '274 patent which claims a "method for treating prostate cancer comprising administering a therapeutically effective amount of a compound" selected from a group of compounds including enzalutamide "or a pharmaceutically acceptable salt thereof to a subject in need of such treatment, thereby treating the prostate cancer." On information and belief, Ascent will infringe at least Claim 1 of the '274 patent because Ascent's Generic Products will contain enzalutamide and will be used to treat prostate cancer.

61. On information and belief, Ascent's Generic Products will have instructions for use that substantially copy the instructions for Xtandi® capsules, which disclose all the elements of Claim 1 of the '274 patent. Upon information and belief, the proposed labeling for Ascent's Generic Products will direct the use of Ascent's Generic Products for the following indications: treatment of patients with castration-resistant prostate cancer, treatment of patients with metastatic

castration-sensitive prostate cancer, and treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

62. On information and belief, this directly infringing use will occur with Ascent's specific intent and encouragement and will be a use that Ascent knows or should know will occur.

63. On information and belief, Ascent will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '274 patent.

64. On information and belief, Ascent knows or should know Ascent's Generic Products will be especially made or especially adapted for use in a manner that will constitute infringement of the '274 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

65. On information and belief, Ascent knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Ascent's Generic Products prior to patent expiry will contribute to the direct infringement of one or more claims of the '274 patent.

66. On information and belief, Ascent's acts will be performed with knowledge of the '274 patent and with intent to encourage infringement prior to patent expiry.

67. On information and belief, Ascent was aware of the existence of the '274 patent and its listing in the Orange Book as demonstrated by Ascent's reference to the '274 patent in Ascent's Notice Letter.

68. On information and belief, Ascent copied the claimed invention of the '274 patent.

69. On information and belief, Ascent's statement of factual and legal bases for its opinions regarding non-infringement and invalidity of the '274 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

70. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '628 Patent)

71. Plaintiffs incorporate each of the preceding paragraphs 1 to 70 as if fully set forth herein.

72. Ascent, by filing Ascent's Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's Generic Products prior to the expiration of the '517 and '274 patents, and therefore prior to the expiration of the '628 patent.

73. Ascent has been aware of the '628 patent since at least December 10, 2024, when it was notified by Plaintiffs' counsel.

74. The submission of Ascent's ANDA seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Ascent's Generic Products, prior to the expiration of the '628 patent, constitutes infringement of one or more of the claims of the '628 patent under 35 U.S.C. § 271(e)(2)(A).

75. On information and belief, Ascent intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's Generic Products with the proposed labeling immediately and imminently upon final approval of Ascent's ANDA No. 220025.

76. The '628 patent claims, *inter alia*, methods of treating prostate cancer in patients to whom rifampin is administered. Claim 1 recites a "method of treating prostate cancer in a patient

to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg of enzalutamide."

77. On information and belief, Ascent's manufacture, use, sale, offer for sale, and/or importation into the United States of Ascent's Generic Products prior to the expiration of the '628 patent, including any applicable exclusivities or extensions, will actively induce infringement of at least Claim 1 of the '628 patent under 35 U.S.C. § 271(b). Ascent will aid another in the infringement of one or more of the claims of the '628 patent.

78. On information and belief, Ascent's Generic Products will have instructions for use that substantially copy the instructions for Xtandi® capsules, which disclose and encourage the practice of all the elements of Claim 1 of the '628 patent. On information and belief, the proposed labeling for Ascent's Generic Products will direct the use of Ascent's Generic Products for the following indications: treatment of patients with castration-resistant prostate cancer, treatment of patients with metastatic castration-sensitive prostate cancer, and treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. On information and belief, the proposed labeling for Ascent's Generic Products will identify rifampin as a strong CYP3A4 inducer that decreases plasma concentrations of enzalutamide and its active metabolite and direct the co-administration of Ascent's Generic Products at a dose of 240 mg orally once daily in patients who are receiving rifampin.

79. On information and belief, Ascent's Generic Products, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and/or non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis, who are also receiving rifampin, at

a daily dose of 240 mg/day, which will constitute infringement of at least Claim 1 of the '628 patent.

80. On information and belief, this directly infringing use will occur with Ascent's specific intent and encouragement and will be a use that Ascent knows or should know will occur.

81. On information and belief, Ascent copied the claimed invention of the '628 patent.

82. On information and belief, Ascent will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '628 patent.

83. On information and belief, Ascent's acts will be performed with knowledge of the '628 patent and with intent to encourage infringement prior to patent expiry.

84. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
(Declaratory Judgment of Infringement of the '628 Patent Under 35 U.S.C. § 271(b))

85. Plaintiffs incorporate each of the preceding paragraphs 1 to 84 as if fully set forth herein.

86. On information and belief, Ascent intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ascent's Generic Products with the proposed labeling immediately and imminently upon final approval of Ascent's ANDA No. 220025 and prior to the expiration of the '628 patent. Therefore, a case or controversy exists between Ascent and Plaintiffs as to infringement of the '628 patent.

87. Ascent has been aware of the '628 patent since at least December 10, 2024, when it was notified by Plaintiffs' counsel.

88. The '628 patent claims, *inter alia*, methods of treating prostate cancer in patients to whom rifampin is administered. Claim 1 recites a "method of treating prostate cancer in a patient to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg of enzalutamide."

89. On information and belief, Ascent's manufacture, use, sale, offer for sale, and/or importation into the United States of Ascent's Generic Products prior to the expiration of the '628 patent, including any applicable exclusivities or extensions, will actively induce infringement of at least Claim 1 of the '628 patent under 35 U.S.C. § 271(b). Ascent will aid another in the infringement of one or more of the claims of the '628 patent.

90. On information and belief, Ascent's Generic Products will have instructions for use that substantially copy the instructions for Xtandi® capsules, which disclose and encourage the practice of all the elements of Claim 1 of the '628 patent. On information and belief, the proposed labeling for Ascent's Generic Products will direct the use of Ascent's Generic Products for the following indications: treatment of patients with castration-resistant prostate cancer, treatment of patients with metastatic castration-sensitive prostate cancer, and treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. On information and belief, the proposed labeling for Ascent's Generic Products will identify rifampin as a strong CYP3A4 inducer that decreases plasma concentrations of enzalutamide and its active metabolite and direct the co-administration of Ascent's Generic Products at a dose of 240 mg orally once daily in patients who are receiving rifampin.

91. On information and belief, Ascent's Generic Products, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and/or non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis, who are also receiving rifampin, at a daily dose of 240 mg/day, which will constitute infringement of at least Claim 1 of the '628 patent.

92. On information and belief, this directly infringing use will occur with Ascent's specific intent and encouragement and will be a use that Ascent knows or should know will occur.

93. On information and belief, Ascent copied the claimed invention of the '628 patent.

94. On information and belief, Ascent will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '628 patent.

95. On information and belief, Ascent's acts will be performed with knowledge of the '628 patent and with intent to encourage infringement prior to patent expiry.

96. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Ascent has infringed one or more claims of United States Patent Nos. 7,709,517, 8,183,274, and 12,161,628 by submitting and maintaining ANDA No. 220025 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Ascent's Generic Products before the expiration of the patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment (or a declaration) that Ascent's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Ascent's Generic Products will infringe one or more claims of United States Patent Nos. 7,709,517, 8,183,274, and 12,161,628 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Ascent, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Ascent's Generic Products prior to the expiration date of United States Patent Nos. 7,709,517, 8,183,274, and 12,161,628, inclusive of any extensions;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 220025 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent Nos. 7,709,517, 8,183,274, and 12,161,628, inclusive of any extensions;

E. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: January 2, 2025

/s/Liza M. Walsh

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action, but this action is related to the following actions:

- *Astellas Pharma Inc., et al. v. Haimen Pharma Inc., et al.*, Case No. 3:24-cv-09403 (MAS), pending in the United States District Court for the District of New Jersey;
- *Astellas Pharma Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, Case No. 3:24-cv-09748 (MAS), pending in the United States District Court for the District of New Jersey.

Dated: January 2, 2025

/s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: January 2, 2025

/s/Liza M. Walsh

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