IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION, INC.; MEDIVATION PROSTATE THERAPEUTICS, INC.; and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS LABORATORIES FL, INC. and ACTAVIS LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas"), Medivation, Inc. and Medivation Prostate Therapeutics, Inc. (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (collectively, "Plaintiffs"), for their Complaint against Defendants Actavis Laboratories FL, Inc. and Actavis LLC (collectively, "Actavis"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. 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 Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

3. Plaintiff Astellas Pharma US, Inc. is a is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

4. Plaintiff Medivation, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 525 Market St. 36th Floor, San Francisco, California 94105, United States.

5. Plaintiff Medivation Prostate Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 525 Market St. 36th Floor, San Francisco, California 94105, United States.

6. Plaintiff The Regents of the University of California 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, Actavis Laboratories FL, Inc. is a corporation organized and existing under the laws of the State of Florida, having a place of business at 2945 W. Corporate Lakes Boulevard, Weston, Florida 33331.

8. On information and belief, Actavis Laboratories FL, Inc., 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 Delaware and throughout the United States.

9. On information and belief, Actavis LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

10. On information and belief, Actavis LLC, 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 Delaware and throughout the United States.

11. On information and belief, Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of Actavis LLC.

12. On information and belief, Actavis LLC and Actavis Laboratories FL, Inc. have at least on officer and/or director in common.

13. On information and belief, Defendants Actavis Laboratories FL, Inc. and Actavis LLC have cooperated and assisted in the preparation and filing of Actavis's Abbreviated New Drug Application ("ANDA") No. 209614 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 209614 if it is approved.

NATURE OF THE ACTION

14. 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 9,126,941 ("the '941 patent") (collectively, "the Xtandi® patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Actavis's filing of an ANDA with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product Xtandi® before the expiration of Plaintiffs' patents covering Xtandi® and its use.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

16. This Court has personal jurisdiction over Actavis by virtue of the fact that, *inter alia*, Actavis 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 Delaware, and throughout the United States.

17. This Court has personal jurisdiction over Actavis LLC. On information and belief, Actavis LLC is a Delaware company.

18. This Court also has personal jurisdiction over Actavis by virtue of the fact that Actavis is at home in Delaware as reflected by the fact that, on information and belief, it regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Actavis conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic. On information and belief, if Actavis's ANDA No. 209614 is approved, it will market and sell its generic version of Xtandi® in Delaware.

19. This Court also has personal jurisdiction over Actavis by virtue of the fact that Actavis previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*, *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-905-SLR, D.I. 11 (D. Del. Oct. 31, 2016); *Salix Pharm., Ltd. v. Actavis Laboratories FL, Inc.*, No. 16-cv-00188-GMS, D.I. 21 (D. Del. July 1, 2016); *Millennium Pharmaceuticals, Inc. v.*

Actavis LLC, No. 16-cv-00223-GMS, D.I. 7 (D. Del. Apr. 25, 2016); *Recro Tech. LLC v. Actavis Laboratories FL, Inc.*, No. 15-cv-413-GMS, D.I. 6 (D. Del. June 16, 2015); *Cosmo Tech. Ltd. v. Actavis Laboratories FL, Inc.*, No. 15-cv-1046-LPS, D.I. 9 (D. Del. Dec. 7, 2015); *Purdue Pharma L.P. v. Alvogen Pine Brook, LLC*, No. 15-cv-687-GMS, D.I. 27 (D. Del. Nov. 30, 2015); *Takeda Pharm. Co. v. Actavis Laboratories FL, Inc.*, No. 15- cv-451-RGA, D.I. 11 (D. Del. July 27, 2015); *Acorda Therapeutics, Inc. v. Actavis Laboratories FL, Inc.*, No. 15-cv-77-LPS, D.I. 7 (D. Del. Feb. 17, 2015); *Tris Pharma, Inc. v. Actavis Laboratories FL, Inc.*, No. 14-cv-1309-GMS, D.I. 16 (D. Del. Dec. 5, 2014); *Daravita Ltd. v. Actavis Laboratories FL, Inc.*, No. 14-cv-1118-GMS, D.I. 75 (D. Del. Jan. 14, 2016).

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

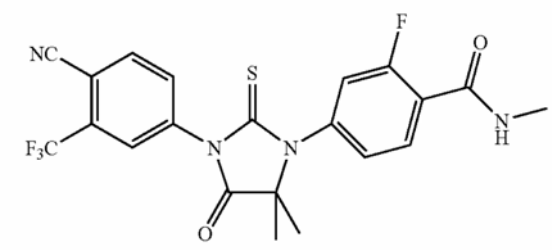
THE XTANDI® NDA

21. 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.

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

23. 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

24. 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.

25. 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.

26. On September 8, 2015, the ’941 patent, entitled “Treatment of Hyperproliferative Disorders with Diarylhydantoin Compounds,” was duly and legally issued to The Regents. A true and correct copy of the ’941 patent is attached hereto as Exhibit C.

27. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the Xtandi® 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.

28. Pursuant to an agreement, as amended, entered into between Medivation and The Regents, Medivation was granted an exclusive license to the ’517, ’274, and ’941 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

29. Pursuant to an agreement entered into between Astellas Pharma Inc. and Medivation, Astellas Pharma Inc. was granted an exclusive sublicense to the ’517, ’274, and ’941 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

30. Pursuant to an agreement entered into between Astellas Pharma Inc. and Astellas US LLC, Astellas US LLC was granted a sublicense to the ’517, ’274, and ’941 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

31. By a letter dated October 24, 2016 (the “Actavis Notice Letter”), Actavis advised Astellas Pharma US, Inc. and The Regents that it had submitted ANDA No. 209614 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg capsules (“Actavis’s Generic Product”) prior to the expiration of the Xtandi® patents.

32. On information and belief, Actavis submitted ANDA No. 209614 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 Actavis’s Generic Product as a generic version of Xtandi® 40 mg capsules.

33. On information and belief, ANDA No. 209614 seeks FDA approval of Actavis’s Generic Product for the indication of treatment of metastatic castration-resistant prostate cancer.

34. The Actavis Notice Letter also advised Astellas Pharma US, Inc. and The Regents that Actavis’s ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

that, in Actavis's opinion, certain claims of the Xtandi® patents are invalid, unenforceable, and/or not infringed.

35. The Actavis Notice Letter does not allege non-infringement of certain claims of the '517, '274, and '941 patents.

36. By not identifying non-infringement defenses for certain claims of the '517, '274, and '941 patents in the Actavis Notice Letter, Actavis admits Actavis's Generic Product meets all limitations of those claims.

37. The Actavis Notice Letter does not allege invalidity of certain claims of the '517, '274, and '941 patents.

38. By not identifying invalidity defenses for certain claims of the '517, '274, and '941 patents in the Actavis Notice Letter, Actavis admits the claims of the '517, '274, and '941patents for which invalidity defenses have not been raised are valid.

39. The Actavis Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or § 112, or unenforceability of any claim of the '517, '274, and '941 patents.

40. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for any of the '517, '274, and '941 patents in the Actavis Notice Letter, Actavis admits the claims of those patents are valid under 35 U.S.C. §§ 101, 102, and 112 and are enforceable.

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

42. Plaintiffs are commencing this action within 45 days of receiving the Actavis Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement Of The ’517 Patent)

43. Plaintiffs incorporate each of the preceding paragraphs 1 to 42 as if fully set forth herein.

44. By submitting ANDA No. 209614 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 Actavis’s Generic Product throughout the United States, including Delaware, prior to expiration of the ’517 patent, Actavis committed an act of infringement of the ’517 patent under 35 U.S.C. § 271(e)(2)(A).

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

46. On information and belief, Actavis’s Generic Product, 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.

47. On information and belief, Actavis’s manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis’s Generic Product 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). Actavis will infringe one or more of the claims of the ’517 patent.

48. On information and belief, Actavis’s Generic Product 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, Actavis’s Generic Product will infringe Claim 1 of the ’517 patent because Actavis’s Generic Product will contain enzalutamide.

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

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

51. On information and belief, Actavis’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.

52. 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)

53. Plaintiffs incorporate each of the preceding paragraphs 1 to 52 as if fully set forth herein.

54. By submitting ANDA No. 209614 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 Actavis’s Generic Product throughout the United States, including Delaware, prior to expiration of the ’274 patent, Actavis committed an act of infringement of the ’274 patent under 35 U.S.C. § 271(e)(2)(A).

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

56. On information and belief, Actavis's Generic Product, if approved by the FDA, will be prescribed and administered to human patients to treat metastatic castration-resistant prostate cancer, which will constitute infringement of claims of the '274 patent.

57. On information and belief, Actavis's manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's Generic Product 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). Actavis will aid another in the infringement of one or more of the claims of the '274 patent.

58. On information and belief, Actavis 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 prostate cancer." On information and belief, Actavis will infringe at least Claim 1 of the '274 patent because Actavis's Generic Product will contain enzalutamide and will be used to treat prostate cancer.

59. On information and belief, Actavis's Generic Product will have instructions for use that substantially copy the instructions for Xtandi®. Upon information and belief, the proposed labeling for Actavis's Generic Product will direct the use of the Actavis's Generic Product for the following indication: treatment of patients with metastatic castration-resistant prostate cancer.

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

61. On information and belief, Actavis 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.

62. On information and belief, Actavis knows or should know Actavis's Generic Product 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.

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

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

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

66. On information and belief, Actavis's statement of the 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.

67. 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 '941 Patent)

68. Plaintiffs incorporate each of the preceding paragraphs 1 to 67 as if fully set forth herein.

69. By submitting ANDA No. 209614 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 Actavis's Generic Product throughout the United States, including Delaware, prior to expiration of the '941 patent, Actavis committed an act of infringement of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

70. The '941 patent claims, *inter alia*, methods of treating cancer with enzalutamide.

71. On information and belief, Actavis's Generic Product, if approved by the FDA, will be prescribed and administered to human patients to treat metastatic castration-resistant prostate cancer, which will constitute infringement of claims of the '941 patent.

72. On information and belief, Actavis's manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's Generic Product prior to the expiration of the '941 patent, including any applicable exclusivities or extensions, will actively induce infringement of the '941 patent under 35 U.S.C. § 271(b) and will constitute contributory infringement of the '941 patent under 35 U.S.C. § 271(c). Actavis will aid another in the infringement of one or more of the claims of the '941 patent.

73. On information and belief, Actavis will infringe at least Claim 1 of the '941 patent which claims a "method for treating a 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 cancer." On information and belief, Actavis will infringe at least Claim 1 of the '941 patent because Actavis's Generic Product will contain enzalutamide and will be used to treat cancer.

74. On information and belief, Actavis's Generic Product will have instructions for use that substantially copy the instructions for Xtandi®. Upon information and belief, the proposed labeling for Actavis's Generic Product will direct the use of the Actavis's Generic Product for the following indication: treatment of patients with metastatic castration-resistant prostate cancer.

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

76. On information and belief, Actavis 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 '941 patent.

77. On information and belief, Actavis knows or should know Actavis's Generic Product will be especially made or especially adapted for use in a manner that will constitute infringement of the '941 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

78. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '941 patent.

79. On information and belief, Actavis's acts will be performed with knowledge of the '941 patent and with intent to encourage infringement prior to patent expiry.

80. On information and belief, Actavis was aware of the existence of the '941 patent and its listing in the Orange Book as demonstrated by Actavis's reference to the '941 patent in the Actavis Notice Letter.

81. On information and belief, Actavis's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '941 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

82. 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 Actavis has infringed one or more claims of United States Patent Nos. 7,709,517, 8,183,274, and 9,126,941 by submitting ANDA No. 209614 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's Generic Product before the expiration of the Xtandi® patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Actavis's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Actavis's Generic Product will infringe one or more claims of United States Patent Nos. 7,709,517, 8,183,274, and 9,126,941 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 Actavis, 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 Actavis's Generic Product prior to the expiration dates of United States Patent Nos. 7,709,517, 8,183,274, and 9,126,941, 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. 209614 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 dates of United States Patent Nos. 7,709,517, 8,183,274, and 9,126,941, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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