IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUMITOMO PHARMA SWITZERLAND GMBH, SUMITOMO PHARMA AMERICA, INC., SUMITOMO PHARMA CO., LTD., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and PFIZER INC.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et. seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, against Defendant Sandoz Inc. ("Sandoz"). This action arises out of the submission by Sandoz of Abbreviated New Drug Application ("ANDA") No. 219913 (the "Sandoz ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell 120 mg tablets of relugolix, a generic version of Orgovyx® (the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 11,795,178, 12,325,714, 12,097,198, 12,144,809, and 12,336,990 (collectively, the "Patents-in-Suit").

PARTIES

2. Plaintiff Sumitomo Pharma Switzerland GmbH ("SMPS") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Aeschengraben 27, 4051 Basel, Switzerland.

3. Plaintiff Sumitomo Pharma America, Inc. ("SMPA") is a corporation organized and

existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

4. Plaintiff Sumitomo Pharma Company Limited ("SMP") is a corporation organized and existing under the laws of Japan, with its principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka-shi, Osaka 541-0045, Japan.

5. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda") is a corporation organized and existing under the laws of Japan, with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

6. Plaintiff Takeda Pharmaceuticals International AG ("Takeda International") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Thurgauerstrasse 130, Glattpark-Opfikon, Zurich, 8152, Switzerland.

7. Plaintiff Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware and with its principal place of business at 66 Hudson Boulevard East, New York, New York 10001.

8. Plaintiffs SMPS, SMPA, SMP, Takeda, Takeda International, and Pfizer are referred to collectively herein as "Plaintiffs."

9. Upon information and belief, Sandoz is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 100 College Road West, Princeton, NJ 08540.

10. Upon information and belief, Sandoz, itself and through its subsidiaries and agents, develops, manufactures, markets, distributes, and/or imports pharmaceutical products for sale and use throughout the United States, including in Delaware.

11. Upon information and belief, Sandoz is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, including in Delaware.

12. Upon information and belief, Sandoz submitted the Sandoz ANDA to the FDA.

13. Upon information and belief, following any FDA approval of the Sandoz ANDA, Sandoz will make, use, offer to sell, and/or sell the ANDA Product that is the subject of the Sandoz ANDA throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

14. This case arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Sandoz at least because Sandoz is a corporation organized and existing under the laws of Delaware.

16. Venue is proper in this Court as to Sandoz under 28 U.S.C. § 1400(b) because, *inter alia*, Sandoz is incorporated in Delaware.

BACKGROUND

17. Orgovyx® (relugolix) is a nonpeptide GnRH receptor antagonist, for oral administration, approved by the FDA for the treatment of adult patients with advanced prostate cancer. Orgovyx® is marketed in the United States pursuant to New Drug Application (NDA) No. 214621, which was approved by the FDA on December 18, 2020. SMPS holds the NDA for Orgovyx®.

18. The Patents-in-Suit cover Orgovyx® and/or its FDA-approved methods of use, and have been properly listed in connection with Orgovyx® in the FDA's publication, *Approved Drug*

Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book."

19. U.S. Patent No. 11,795,178 (the "'178 Patent"), titled "Compositions of Thienopyrimidine Derivatives" (Ex. A), was duly and legally issued on October 24, 2023 and will expire on September 27, 2033. Takeda owns the '178 Patent.

20. U.S. Patent No. 12,325,714 (the "'714 Patent"), titled "Compositions of Thienopyrimidine Derivatives" (Ex. B), was duly and legally issued on June 10, 2025, and will expire on September 27, 2033. Takeda owns the '714 Patent.

21. U.S. Patent No. 12,097,198 (the "'198 Patent"), titled "Treatment of Prostate Cancer" (Ex. C), was duly and legally issued on September 24, 2024, and will expire on September 29, 2037. SMP and Takeda jointly own the '198 Patent.

22. U.S. Patent No. 12,144,809 (the "'809 Patent"), titled "Treatment of Prostate Cancer" (Ex. D), was duly and legally issued on November 19, 2024, and will expire on September 29, 2037. SMP and Takeda jointly own the '809 Patent.

23. U.S. Patent No. 12,336,990 (the "'990 Patent"), titled "Treatment of Prostate Cancer" (Ex. E), was duly and legally issued on June 24, 2025, and will expire on September 29, 2037. SMP and Takeda jointly own the '990 Patent.

24. Takeda International, SMP, and Pfizer are exclusive licensees of the Patents-in-Suit.

25. Orgovyx® is marketed and sold by SMPA and Pfizer throughout the United States, including in Delaware.

26. By letter dated June 20, 2025, Sandoz notified SMPS, Takeda, Takeda International and Pfizer that Sandoz had submitted the Sandoz ANDA to the FDA for approval of relugolix tablets, 120 mg, a generic version of Orgovyx®.

27. By submitting the Sandoz ANDA, Sandoz has represented to the FDA that the ANDA Product has the same active ingredient as Orgovyx®, has the same dosage form and strength as Orgovyx®, and is bioequivalent to Orgovyx®.

28. In Sandoz's Paragraph IV Notice Letter (June 20, 2025) ("Notice Letter"), Sandoz stated that the Sandoz ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the '178 Patent, the '198 Patent, and the '809 Patent, and alleged that the '178 Patent, the '198 Patent, and the '809 Patent are invalid or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product. The Notice Letter further stated that Sandoz is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product before the '178 Patent, the '198 Patent, and the '809 Patent expire.

29. In June 2025, two additional patents were listed in the Orange Book in connection with Orgovyx®. The '714 Patent was listed on June 11, 2025 and the '990 Patent was listed on June 25, 2025. The '714 Patent is related to the '178 Patent for which Sandoz submitted a Paragraph IV certification. The '990 Patent is related to the '198 Patent and the '809 Patent, for each of which Sandoz submitted a Paragraph IV certification.

30. The '178 Patent and '714 Patent each expire on September 27, 2033, and the '198 Patent, '809 Patent, and '990 Patent each expire on September 29, 2037. Based on Sandoz's representation that it is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the '178 Patent, the '198 Patent, and the '809 Patent expire, Sandoz is necessarily also seeking approval of the ANDA Product before the expirations of the '714 Patent and the '990 Patent.

31. Upon information and belief, Sandoz had knowledge of the '178 Patent, the '198 Patent, and the '809 Patent no later than when the Sandoz ANDA was submitted to the FDA.

32. Prior to the filing of this Complaint, Plaintiffs provided Sandoz copies of the '714 Patent and '990 Patent by e-mail correspondence dated July 29, 2025.

33. Sandoz knew or should have known of the '714 Patent no later than June 11, 2025, when the '714 Patent was listed in the Orange Book for Orgovyx®.

34. Sandoz knew or should have known of the '990 Patent no later than June 25, 2025, when the '990 Patent was listed in the Orange Book for Orgovyx®.

35. In the Notice Letter, Sandoz provided an Offer of Confidential Access ("OCA") to the Sandoz ANDA pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). Plaintiffs engaged in good faith negotiations with Sandoz regarding the terms of its OCA. Sandoz, however, refused to provide its ANDA under reasonable terms as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information, for example, terms governing the scope of applicable patent prosecution and FDA regulatory bars, in accordance with terms previously and widely accepted by courts.

36. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product immediately and imminently upon approval of the Sandoz ANDA.

37. This action is being commenced before the expiration of 45 days from the date of Plaintiffs' receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,795,178

38. Plaintiffs incorporate each of the preceding paragraphs 1-37 as if fully set forth herein.

39. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent constituted an act of infringement of at least claim 1 of the '178 Patent, under 35 U.S.C. § 271(e)(2)(A).

40. Sandoz's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '178 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '178 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

41. Upon FDA approval of the Sandoz ANDA, Sandoz will infringe at least claim 1 of the '178 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient and/or by actively inducing and contributing to infringement of at least claim 1 of the '178 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Sandoz has notified Plaintiffs of the submission of Sandoz's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent.

42. Upon information and belief, Sandoz will actively induce infringement of at least claim 1 of the '178 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Sandoz ANDA, Sandoz will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with

knowledge of the '178 Patent and with knowledge that its acts are encouraging infringement.

43. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Sandoz will contributorily infringe at least claim 1 of the '178 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient in the United States. The ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '178 Patent. Upon information and belief, Sandoz knows that the ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '178 Patent, and that the ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to the infringement of the '178 Patent immediately and imminently upon approval of the Sandoz ANDA.

44. A substantial and justiciable controversy exists between the parties as to the infringement of the '178 Patent.

45. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the ANDA Product will infringe the '178 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

46. Upon information and belief, Sandoz acted, and upon FDA approval of the Sandoz ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '178 Patent. This is an exceptional case.

47. Unless Sandoz is enjoined from directly or indirectly infringing the '178 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 12,325,714

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth

herein.

49. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '714 Patent constituted an act of infringement of at least claims 1, 11, and 19 of the '714 Patent, under 35 U.S.C. § 271(e)(2)(A).

50. Sandoz's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '714 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 11, and 19 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

51. Sandoz knew or should have known of the '714 Patent no later than June 11, 2025, when the '714 Patent was listed in the Orange Book for Orgovyx®. Sandoz knew of the '714 Patent by no later than July 29, 2025, when it was provided with a copy of the '714 Patent by Plaintiffs.

52. Upon FDA approval of the Sandoz ANDA, Sandoz will infringe at least claims 1, 11, and 19 of the '714 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient and/or by actively inducing and contributing to infringement of at least claims 1, 11, and 19 of the '714 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Sandoz has notified Plaintiffs of the submission of Sandoz's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '714 Patent.

53. Upon information and belief, Sandoz will actively induce infringement of at least claims 1, 11, and 19 of the '714 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Sandoz ANDA, Sandoz will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '714 Patent and with knowledge that its acts are encouraging infringement.

54. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Sandoz will contributorily infringe at least claims 1, 11, and 19 of the '714 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient in the United States. The ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '714 Patent. Upon information and belief, Sandoz knows that the ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '714 Patent, and that the ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to the infringement of the '714 Patent immediately and imminently upon approval of the Sandoz ANDA.

55. A substantial and justiciable controversy exists between the parties as to the infringement of the '714 Patent.

56. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the ANDA Product will infringe the '714 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Upon information and belief, Sandoz acted, and upon FDA approval of the Sandoz

ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '714 Patent. This is an exceptional case.

58. Unless Sandoz is enjoined from directly or indirectly infringing the '714 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 12,097,198

59. Plaintiffs incorporate each of the preceding paragraphs 1-58 as if fully set forth herein.

60. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '198 Patent constituted an act of infringement at least claims 1-2, 4-6, and 10-12 of the '198 Patent, under 35 U.S.C. § 271(e)(2)(A).

61. Sandoz's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '198 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

62. Upon FDA approval of the Sandoz ANDA, Sandoz will infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '198 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Sandoz has notified Plaintiffs of the submission of Sandoz's ANDA seeking approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '198 Patent.

63. Upon information and belief, Sandoz will actively induce infringement of at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Sandoz ANDA, Sandoz will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '198 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '198 Patent.

64. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Sandoz will contributorily infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '198 Patent and constitute a material part of those claims' inventions. Upon information and belief, Sandoz knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '198 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to the infringement of the '198 Patent immediately and imminently upon approval of the Sandoz ANDA.

65. A substantial and justiciable controversy exists between the parties as to the

infringement of the '198 Patent.

66. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the ANDA Product, inducement thereof or contribution thereto, will infringe the '198 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Upon information and belief, Sandoz acted, and upon FDA approval of the Sandoz ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '198 Patent. This is an exceptional case.

68. Unless Sandoz is enjoined from directly or indirectly infringing the '198 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 12,144,809

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

70. The claims of the '809 Patent are directed to a method of treating prostate cancer with relugolix when the patient is "in need of co-administration" of a P-glycoprotein (P-gp) inhibitor.

71. As set forth in the specification of the '809 Patent, P-gp mediates the export of drugs from certain cells. Ex. D at 85:41-43. P-gp can be affected by P-gp inducers or inhibitors which can enhance or impair P-gp mediated uptake, respectively. Ex. D at 85:43-46. P-gp inhibitors, which impair P-gp activity, can increase exposure to certain medications.

72. The specification of the '809 Patent identifies twenty-seven P-gp inhibitors. Ex. D at 85:50-56. The P-gp inhibitors identified in the '809 Patent include beta-blockers (*e.g.*, carvedilol), calcium channel blockers (*e.g.*, diltiazem, felodipine, verapamil),

immunosuppressants (*e.g.*, cyclosporine, tacrolimus), antivirals (*e.g.*, telaprevir), antiarrhythmic medications (*e.g.*, amiodarone, dronedarone, propafenone, quinidine), blood thinners (*e.g.*, ticagrelor), antiretrovirals (*e.g.*, lopinavir, ritonavir, saquinavir, tipranavir, efavirenz), antifungals (*e.g.*, itraconazole, ketoconazole), antihypertensives (*e.g.*, captopril, bosentan, reserpine), antibiotics (*e.g.*, erythromycin, clarithromycine, rifampin, nafcillin, azithromycin), and proton pump inhibitors (*e.g.*, omeprazole). Certain P-gp inhibitors are typically administered to patients for periods greater than two weeks.

73. The '809 Patent claims a method of administering relugolix to treat prostate cancer in subjects "in need of co-administration" of a P-gp inhibitor. The claimed method specifies dose separation, wherein the P-gp inhibitor is administered at least six hours apart from the daily 120 mg maintenance dose of relugolix.

74. The FDA-approved label for Orgovyx® (Ex. F) embodies the inventions claimed in the '809 Patent. As explained in the FDA-approved label for Orgovyx®, co-administration of relugolix with an oral P-gp inhibitor has been found to increase relugolix exposure. Ex. F at 6. For example, the Orgovyx® label describes a study in which co-administration of relugolix and erythromycin (a P-gp and moderate CYP3A inhibitor) increased the area under the curve (AUC) and C_{max} of relugolix by 3.5- and 2.9-fold, respectively. Ex. F at 10. Increased exposure may in turn increase the risk of adverse reactions to relugolix. Ex. F at 6. As the claims of the '809 Patent recite, however, certain patients who are being treated for prostate cancer may be "in need of co-administration" of a P-gp inhibitor. For such patients, instructing on how to avoid adverse reactions when co-administering a P-gp inhibitor is beneficial.

75. The FDA-approved label for Orgovyx® reflects the inventions claimed in the '809 Patent and specifically instructs use of the claimed dosing regimen, including in sections titled

"Drug Interactions," "Dose Modification for Use with P-gp Inhibitors," and "Effect of Other Drugs on ORGOVYX." Ex. F at 1, 2, 6. Although the label states that co-administration of relugolix and a P-gp inhibitor should be avoided and that treatment with relugolix can be interrupted for two weeks if an oral P-gp inhibitor will only be administered for up to two weeks, the label also provides specific instructions for the co-administration of relugolix with a P-gp inhibitor for patients in need of such therapy and certain P-gp inhibitors are typically administered to patients for periods greater than two weeks. Ex. F at 1, 2, 6.

76. Upon information and belief, because of Sandoz's proposed label, doctors will instruct patients in need of co-administration of the ANDA Product and a P-gp inhibitor to take the ANDA product first and wait at least 6 hours before taking the P-gp inhibitor.

77. Upon information and belief, in so doing, Sandoz will induce direct infringement of the '809 Patent by doctors and patients because Sandoz's marketing of the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '809 Patent, and they will do so based on Sandoz's proposed label.

78. Sandoz has knowledge of the '809 Patent.

79. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '809 Patent constituted an act of infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, under 35 U.S.C. § 271(e)(2)(A).

80. Sandoz's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '809 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, either literally or under the doctrine of equivalents, under

35 U.S.C. § 271(b).

81. Upon information and belief, Sandoz will actively induce infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients and, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Sandoz ANDA, Sandoz will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '809 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '809 Patent.

82. A substantial and justiciable controversy exists between the parties as to the infringement of the '809 Patent.

83. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the ANDA Product, or inducement thereof, will infringe the '809 Patent pursuant to 35 U.S.C. § 271(b).

84. Upon information and belief, Sandoz acted, and upon FDA approval of the Sandoz ANDA, will act, without a reasonable basis for believing that it would not be liable for indirectly infringing the '809 Patent. This is an exceptional case.

85. Unless Sandoz is enjoined from directly or indirectly infringing the '809 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 12,336,990

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

87. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '990 Patent constituted an act of infringement at least claims 1-2, 4-7, and 15-30 of the '990 Patent, under 35 U.S.C. § 271(e)(2)(A).

88. Sandoz's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '990 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claims 1-2, 4-7, and 15-30 of the '990 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

89. Sandoz knew or should have known of the '990 Patent no later than June 25, 2025, when the '990 Patent was listed in the Orange Book for Orgovyx®. Sandoz knew of the '990 Patent by no later than July 29, 2025, when it was provided with a copy of the '990 Patent by Plaintiffs.

90. Upon FDA approval of the Sandoz ANDA, Sandoz will infringe at least claims 1-2, 4-7, and 15-30 of the '990 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '990 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Sandoz has notified Plaintiffs of the submission of Sandoz's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '990 Patent.

91. Upon information and belief, Sandoz will actively induce infringement of at least

claims 1-2, 4-7, and 15-30 of the '990 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Sandoz ANDA, Sandoz will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '990 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '990 Patent.

92. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Sandoz will contributorily infringe at least claims 1-2, 4-7, and 15-30 of the '990 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '990 Patent and constitute a material part of those claims' inventions. Upon information and belief, Sandoz knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '990 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to the infringement of the '990 Patent immediately and imminently upon approval of the Sandoz ANDA.

93. A substantial and justiciable controversy exists between the parties as to the infringement of the '990 Patent.

94. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the ANDA Product, inducement

thereof or contribution thereto, will infringe the '990 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

95. Upon information and belief, Sandoz acted, and upon FDA approval of the Sandoz ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '990 Patent. This is an exceptional case.

96. Unless Sandoz is enjoined from directly or indirectly infringing the '990 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

(a) A judgment that the claims of the '178 Patent, the '714 Patent, the '198 Patent, the '809 Patent, and the '990 Patent were infringed by Sandoz's submission of the Sandoz ANDA under 35 U.S.C. § 271(e)(2)(A), and that Sandoz's manufacture, use, offer to sell, sale, or importation of the ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the '178 Patent, the '714 Patent, the '198 Patent, the '809 Patent, and the '990 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, will infringe the '178 Patent, the '714 Patent, the '198 Patent, the '809 Patent, and the '990 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(b) A judgment that the claims of the '178 Patent, the '714 Patent, the '198 Patent, the '809 Patent, and the '990 Patent are not invalid;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sandoz ANDA shall not be earlier than the expiration of the '178 Patent,

the ’714 Patent, the ’198 Patent, the ’809 Patent, and the ’990 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) A declaratory judgment that Sandoz’s manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the ANDA Product and/or its active ingredient prior to the expiration of the ’178 Patent, the ’714 Patent, the ’198 Patent, the ’809 Patent, and the ’990 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, would infringe the ’178 Patent, the ’714 Patent, the ’198 Patent, the ’809 Patent, and the ’990 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(e) An Order permanently enjoining Sandoz and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Sandoz, from making, using, offering to sell, selling, or importing the ANDA Product and/or its active ingredient until after the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(f) Damages or other monetary relief, including costs, attorneys’ fees, pre-judgment interest and post-judgment interest to Plaintiffs if Sandoz engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(g) Declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 entitling Plaintiffs to its attorneys’ fees and enhanced damages; and

(h) Such further and other relief as this Court deems proper and just.

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August 1, 2025

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