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

OMEROS CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. _____
	)	
SANDOZ INC.,	)	
	)	
Defendant.	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Omeros Corporation, by its undersigned attorneys, brings this action against Defendant Sandoz Inc. ("Defendant" or "Sandoz"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., arises from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 207841 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendant seeks approval to market a generic version of the pharmaceutical product OMIDRIA® (phenylephrine and ketorolac injection, 1%/0.3%) prior to the expiration of United States Patent No. 8,173,707; United States Patent No. 8,586,633; United States Patent No. 9,066,856; United States Patent No. 9,278,101; United States Patent No. 9,399,040; and United States Patent No. 9,486,406. Plaintiff seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff Omeros Corporation is a corporation organized and existing under the laws of the State of Washington, and having a place of business at 201 Elliott Avenue West,

Seattle, Washington 98119. Omeros is a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule therapeutics and protein therapeutics.

3. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, and having a principal place of business at 100 College Road West, Princeton, NJ 08540.

4. On information and belief, Defendant prepared and submitted ANDA No. 207841 (the "Sandoz ANDA") and continue to collaborate in seeking FDA approval of that application.

5. On information and belief, Defendant intends to commercially manufacture, market, offer for sale, and sell the product described in the Sandoz ANDA (the "ANDA Product") throughout the United States, including in the State of New Jersey, in the event the FDA approves the Sandoz ANDA.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of United States Patent No. 8,173,707; United States Patent No. 8,586,633; United States Patent No. 9,066,856; United States Patent No. 9,278,101; United States Patent No. 9,399,040; and United States Patent No. 9,486,406. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. On information and belief, this Court has personal jurisdiction over Sandoz because it is a corporation with a principal place of business in New Jersey.

8. This Court also has personal jurisdiction over Sandoz because it has continuous and systematic contacts with New Jersey. Further, Sandoz 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 Plaintiff, which manufactures OMIDRIA for sale and use throughout the United States, including this judicial district.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1400. Venue is proper because upon information and belief, Sandoz has a regular and established principal place of business in New Jersey.

OMEROS'S APPROVED OMIDRIA DRUG PRODUCT AND PATENTS

10. Omeros makes and sells OMIDRIA, a combination product used during cataract surgery or intraocular lens replacement to maintain pupil size by preventing miosis and to reduce postoperative pain. OMIDRIA contains two active ingredients: phenylephrine hydrochloride and ketorolac tromethamine.

11. OMIDRIA is the first FDA-approved product for intraocular use during cataract surgery or intraocular lens replacement that both prevents intraoperative miosis (pupil constriction) and reduces postoperative pain.

12. Omeros is the holder of New Drug Application ("NDA") No. 205388 for OMIDRIA. The FDA approved NDA No. 205388 for OMIDRIA in May 2014, and granted OMIDRIA three years of regulatory exclusivity pursuant to 21 C.F.R. 314.108.

13. Omeros owns United States Patent No. 8,173,707 (the "'707 Patent"); United States Patent No. 8,586,633 (the "'633 Patent"); United States Patent No. 9,066,856 (the "'856 Patent"); United States Patent No. 9,278,101 (the "'101 Patent"); United States Patent No. 9,399,040 (the "'040 Patent"); and United States Patent No. 9,486,406 (the "'406 Patent").

14. The '707 Patent, the '633 Patent, the '856 Patent, the '101 Patent, the '040 Patent, and the '406 Patent are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OMIDRIA.

15. The '707 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on May 8, 2012. A true and correct copy of the '707 Patent is attached as Exhibit A.

16. The '633 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the USPTO on November 19, 2013. A true and correct copy of the '633 Patent is attached as Exhibit B.

17. The '856 Patent, entitled "Stable Preservative-Free Mydriatic and Anti-inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on June 30, 2015. A true and correct copy of the '856 Patent is attached as Exhibit C.

18. The '101 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the USPTO on March 8, 2016. A true and correct copy of the '101 Patent is attached as Exhibit D.

19. The '040 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duty and lawfully issued by the USPTO on July 26, 2016. A true and correct copy of the '040 Patent is attached as Exhibit E.

20. The '406 Patent, entitled "Stable Preservative-free Mydriatic and Anti-inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on November 8, 2016. A true and correct copy of the '406 Patent is attached as Exhibit F.

DEFENDANT'S ANDA

21. On information and belief, Defendant has submitted or caused to be submitted ANDA No. 207841 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of ketorolac tromethamine, phenylephrine hydrochloride solution, as a purported generic version of OMIDRIA, prior to the expiration of the '707, '633, '856, '101, '040, and '406 Patents.

22. On information and belief, on or about May 9, 2017, Defendant mailed Plaintiff a letter regarding "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B)) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95 Sandoz Inc.'s Ketorolac-Phenylephrine Ophthalmic Solution; 2.88 mg/mL (0.3% w/v) of Ketorolac and 10.16 mg/mL (1% w/v) of Phenylephrine Sandoz Inc.'s ANDA 207841" (the "Notice Letter"). The Notice Letter represented that Defendant has submitted to the FDA ANDA No. 207841 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Sandoz ANDA before the expiration of the patents listed in the Orange Book for OMIDRIA. Hence, Defendant's purpose in submitting the Sandoz ANDA is to manufacture and market the ANDA Product before the expiration of the '707, '633, '856, '101, '040, and '406 Patents.

23. Sandoz's Notice Letter stated that the Paragraph IV certification in the Sandoz ANDA alleges that each claim of the '707, '633, '856, '101, '040, and '406 Patents will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

24. Sandoz's Notice Letter contained "Sandoz Inc.'s Detailed Statement of the Factual and Legal Bases For Its Opinion That U.S. Patent Nos. 8,173,707, 8,586,633, 9,278,101, 9,399,040, 9,066,856, [] and 9,486,406 Are Invalid, Unenforceable and/or Not Infringed by the Manufacture, Use, Importation, Sale or Offer for Sale of the Sandoz Product" ("Detailed Statement").

25. Sandoz's Detailed Statement, however, did not identify any theory of non-infringement for the '707 Patent, the '633 Patent, claim 1-3 and 8-13 of the '101 Patent, the '040 Patent, the '856 Patent, or the '406 Patent.

26. Sandoz's Notice Letter did not include an Offer of Confidential Access ("OCA") to the Sandoz ANDA.

27. After receiving Sandoz's Notice Letter, Plaintiff wrote to Sandoz to request an OCA or, alternatively, to explain Sandoz's failure to provide an OCA. Omeros repeatedly tried to come to an agreement with Sandoz concerning an OCA but these efforts were not successful prior to the filing of this Complaint.

28. On information and belief, Defendant has participated in the preparation and submission of the Sandoz ANDA, has provided material support to the preparation and submission of the Sandoz ANDA, and intends to support the further prosecution of the Sandoz ANDA.

29. On information and belief, if the FDA approves the Sandoz ANDA, Defendant will manufacture, offer for sale, or sell the ANDA Product within the United States, including within New Jersey, or will import the ANDA Product into the United States, including New Jersey.

30. On information and belief, if the FDA approves the Sandoz ANDA, Defendant will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product.

31. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiff's receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE '707 PATENT

32. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

33. On information and belief, Defendant has submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

34. Defendant has infringed the '707 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '707 Patent.

35. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of the '707 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207841, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent.

36. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '707 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '707 Patent and knowledge that it is encouraging infringement.

37. Defendant had actual and constructive notice of the '707 Patent prior to filing the Sandoz ANDA, and was aware that the filing of the Sandoz ANDA with the request for FDA

approval prior to the expiration of the '707 Patent would constitute an act of infringement of the '707 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '707 Patent.

38. Sandoz's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '707 Patent.

39. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '707 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '707 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

40. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '707 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '707 PATENT

41. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–40 as if fully set forth herein.

42. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

43. On information and belief, if the Sandoz ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendant and its affiliates.

44. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

45. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '707 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

46. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of the '707 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

47. Plaintiff will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

48. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '633 PATENT

49. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

50. On information and belief, Defendant has submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

51. Defendant has infringed the '633 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '633 Patent.

52. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of the '633 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207841, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent.

53. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '633 Patent. In addition, on information and belief, Defendant will encourage acts of direct

infringement with knowledge of the '633 Patent and knowledge that it is encouraging infringement.

54. Defendant had actual and constructive notice of the '633 Patent prior to filing the Sandoz ANDA, and was aware that the filing of the Sandoz ANDA with the request for FDA approval prior to the expiration of the '633 Patent would constitute an act of infringement of the '633 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '633 Patent.

55. Sandoz's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '633 Patent.

56. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '633 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '633 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

57. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '633 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '633 PATENT

58. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 and 49–57 as if fully set forth herein.

59. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

60. On information and belief, if the ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendant and its affiliates.

61. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

62. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '633 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

63. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of the '633 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

64. Plaintiff will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

65. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '856 PATENT

66. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

67. On information and belief, Defendant has submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

68. Defendant has infringed the '856 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '856 Patent.

69. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, and/or would actively induce and contribute to infringement of the '856 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207841, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '856 Patent.

70. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and

belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '856 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '856 Patent and knowledge that it is encouraging infringement.

71. Defendant had actual and constructive notice of the '856 Patent prior to filing the Sandoz ANDA, and were aware that the filing of the Sandoz ANDA with the request for FDA approval prior to the expiration of the '856 Patent would constitute an act of infringement of the '856 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '856 Patent.

72. Sandoz's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '856 Patent.

73. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '856 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '856 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

74. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '856 Patent. Plaintiff does

not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '856 PATENT

75. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 and 66–74 as if fully set forth herein.

76. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. On information and belief, if the Sandoz ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendant and its affiliates. Defendant will therefore infringe one or more claims of the '856 Patent under 35 U.S.C. § 271(a).

78. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

79. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '856 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

80. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of the '856 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

81. Plaintiff will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

82. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '101 PATENT

83. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

84. On information and belief, Defendant have submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

85. Defendant has infringed at least claims 1-3 and 8-13 the '101 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '101 Patent.

86. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of one or more claims of the '101 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207841, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and

will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent.

87. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals, and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '101 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '101 Patent and knowledge that it is encouraging infringement.

88. Defendant had actual and constructive notice of the '101 Patent prior to filing the Sandoz ANDA, and was aware that the filing of the Sandoz ANDA with the request for FDA approval prior to the expiration of the '101 Patent would constitute an act of infringement of the '101 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '101 Patent.

89. Sandoz's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of claims 1-3 and 8-13 the '101 Patent.

90. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '101 Patent to be invalid, unenforceable, and/or not infringed by the commercial

manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '101 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

91. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of claims of the '101 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '101 PATENT

92. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 and 83–91 as if fully set forth herein.

93. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

94. On information and belief, if the Sandoz ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendant and its affiliates.

95. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

96. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product

complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '101 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

97. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of claims of the '101 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

98. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

99. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IX
INFRINGEMENT OF THE '040 PATENT

100. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

101. On information and belief, Defendant has submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

102. Defendant has infringed the '040 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '040 Patent.

103. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement

of the ’040 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’040 Patent.

104. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the ’040 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the ’040 Patent and knowledge that it is encouraging infringement.

105. Defendant had actual and constructive notice of the ’040 Patent prior to filing the Sandoz ANDA, and were aware that the filing of the Sandoz ANDA with the request for FDA approval prior to the expiration of the ’040 Patent would constitute an act of infringement of the ’040 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the ’040 Patent.

106. Sandoz’s Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the ’040 Patent.

107. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '040 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '040 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

108. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '040 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '040 PATENT

109. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 and 100-108 as if fully set forth herein.

110. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

111. On information and belief, if the Sandoz ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendant and its affiliates. Defendant will therefore infringe one or more claims of the '040 Patent under 35 U.S.C. § 271(a).

112. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the

infringement of one or more claims of the '040 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

113. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '040 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '040 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

114. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of the '040 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

115. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

116. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XI
INFRINGEMENT OF THE '406 PATENT

117. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 as if fully set forth herein.

118. On information and belief, Defendant has submitted or caused the submission of the Sandoz ANDA to the FDA, and continue to seek FDA approval of the Sandoz ANDA.

119. Defendant has infringed the '406 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '406 Patent.

120. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, and/or would actively induce and contribute to infringement of the '406 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207841, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '406 Patent.

121. On information and belief, upon FDA approval of ANDA No. 207841, Defendant will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendant will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '406 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '406 Patent and knowledge that it is encouraging infringement.

122. Defendant had actual and constructive notice of the '406 Patent prior to filing the Sandoz ANDA, and were aware that the filing of the Sandoz ANDA with the request for FDA approval prior to the expiration of the '406 Patent would constitute an act of infringement of the

'406 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '406 Patent.

123. Sandoz's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '406 Patent.

124. In addition, Defendant filed the Sandoz ANDA without adequate justification for asserting the '406 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '406 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

125. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '406 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '406 PATENT

126. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–31 and 117–125 as if fully set forth herein.

127. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

128. On information and belief, if the Sandoz ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the

State of New Jersey, by or through Defendant and its affiliates. Defendant will therefore infringe one or more claims of the '406 Patent under 35 U.S.C. § 271(a).

129. On information and belief, Defendant knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Sandoz ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '406 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

130. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Sandoz ANDA. Any such conduct before the '406 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '406 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

131. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant concerning liability for the infringement of the '406 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

132. Plaintiff will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

133. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '707 Patent was an act of infringement of one or more claims of the '707 Patent;

(B) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '633 Patent was an act of infringement of one or more claims of the '633 Patent;

(C) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '856 Patent was an act of infringement of one or more claims of the '856 Patent;

(D) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '101 Patent was an act of infringement of one or more claims of the '101 Patent;

(E) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA

Product before the expiration of the '040 Patent was an act of infringement of one or more claims of the '040 Patent;

(F) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to the FDA of ANDA No. 207841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '406 Patent was an act of infringement of one or more claims of the '406 Patent;

(G) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '707 Patent;

(H) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '633 Patent;

(I) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '856 Patent;

(J) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '101 Patent;

(K) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '040 Patent;

(L) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '406 Patent;

(M) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Defendant, its affiliates and subsidiaries, and all persons and entities acting in concert with Defendant from commercially manufacturing, using, offering for sale, or selling the ANDA Product within the United States, or importing the ANDA Product into the United States, until the expiration of the '707, '633, '856, '101, '040, and '406 Patents;

(N) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 207841 shall be no earlier than the last expiration date of any of the '707, '633, '856, '101,'040, and '406 Patents, or any later expiration of exclusivity for any of the '707, '633, '856, '101, '040, and '406 Patents, including any extensions or regulatory exclusivities;

(O) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '707 Patent, or induces or contributes to such conduct, prior to the expiration of the '707 Patent;

(P) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '633 Patent, or induces or contributes to such conduct, prior to the expiration of the '633 Patent;

(Q) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '856 Patent, or induces or contributes to such conduct, prior to the expiration of the '856 Patent;

(R) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '101 Patent, or induces or contributes to such conduct, prior to the expiration of the '101 Patent;

(S) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '040 Patent, or induces or contributes to such conduct, prior to the expiration of the '040 Patent;

(T) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '406 Patent, or induces or contributes to such conduct, prior to the expiration of the '406 Patent;

(U) The entry of judgment declaring that Defendant's acts render this case an exceptional case, and awarding Plaintiff its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(V) An award to Plaintiff of its costs and expenses in this action; and

(W) Such other and further relief as the Court deems just and proper.

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June 21, 2017

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of the action *Omeros Corporation v. Sandoz Inc.*, filed in the United States District Court for the District of Delaware on June 21, 2017. A case number has not yet been assigned.

Dated: June 21, 2017

Respectfully submitted,

/s/ Nicholas M. Insua

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