IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON THERAPEUTICS U.S. HOLDING LLC and HORIZON THERAPEUTICS USA, INC.,	)	C. A. No.: _____
Plaintiffs,	)	
v.	)	
TEVA PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Therapeutics U.S. Holding LLC and Horizon Therapeutics USA, Inc. (collectively, "Horizon"), by their undersigned attorneys, bring this action against Defendant Teva Pharmaceuticals, Inc. ("Teva"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.* This action relates to Teva's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or import of a generic version of Horizon's pharmaceutical product RAVICTI® (glycerol phenylbutyrate oral liquid) ("RAVICTI®") prior to the expiration of United States Patent Nos. 8,642,012 ("'012 patent"), 9,254,278 ("'278 Patent"), 9,326,966 ("'966 patent"), 9,561,197 ("'197 patent"), 9,962,359 ("'359 patent"), 9,999,608 ("'608 patent"), 10,045,958 ("'958 patent"), 10,045,959 ("'959 patent"), 10,183,002 ("'002 patent"), 10,183,003 ("'003 patent"), 10,183,004 ("'004

patent"), 10,183,005 ("'005 patent"), 10,183,006 ("'006 patent"), and 10,668,040 ("'040 patent") (collectively, "the Patents-in-Suit"), including any applicable exclusivities or extensions.

THE PARTIES

2. Horizon Therapeutics U.S. Holding LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Horizon Way, Deerfield, IL 60015.

3. Horizon Therapeutics USA, Inc. is a publicly traded corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Horizon Way, Deerfield, IL 60015.

4. Horizon Therapeutics U.S. Holding LLC is a wholly owned subsidiary of Horizon Therapeutics USA, Inc.

5. Horizon is a global biotechnology company focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by autoimmune, inflammatory, and rare diseases, including the urea cycle disorders that are the subject of the Patents-in-Suit.

6. Upon information and belief, Teva is a company organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Upon information and belief, Teva, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

8. Upon information and belief, Teva filed ANDA No. 218738 ("Teva's ANDA") for glycerol phenylbutyrate oral liquid, 1.1 gm/ml ("Teva's ANDA Product"), continues to participate and seek FDA approval of that application, and intends to participate in the commercial manufacture, use, offer for sale, and/or sale throughout the United States, and/or importation into the United States, of Teva's ANDA Product, including in the State of Delaware, in the event FDA approves Teva's ANDA.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Teva because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware and has a registered agent for service of process in Delaware.

11. This Court has personal jurisdiction over Teva by virtue of the fact that, upon information and belief, Teva 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, upon information and belief, Teva 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.

12. This Court also has personal jurisdiction over Teva because, *inter alia*, Teva has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of

patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Horizon Therapeutics U.S. Holding LLC and Horizon Therapeutics USA, Inc., both Delaware corporations.

13. Upon information and belief, if Teva's ANDA is approved, Teva's ANDA Product will, *inter alia*, be marketed and distributed by Teva in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

14. Upon information and belief, Teva has been sued previously in this Judicial District and has not challenged personal jurisdiction and has availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *AbbVie Inc. v. Teva Pharmaceuticals, Inc.*, C.A. No. 23-362-RGA (D. Del.) (filed Mar. 30, 2023); *AbbVie Inc. v. Teva Pharmaceuticals, Inc.*, C.A. No. 23-133-RGA (D. Del.) (filed Feb. 3, 2023); *Amicus Therapeutics US, LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 22-1462-CFC (D. Del.) (filed Nov. 7, 2022); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals, Inc. et al.*, C.A. No. 22-513-RGA (D. Del.) (filed Apr. 22, 2022); *Journey Medical Corp. et al. v. Teva Pharmaceuticals, Inc. et al.*, C.A. No. 22-288-CFC (D. Del.) (filed Mar. 4, 2022); *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, C.A. No. 211043-MN (D. Del.) (filed July 16, 2021).

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

U.S. PATENT NO. 8,642,012

16. On February 4, 2014, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '012 patent entitled "Methods of Treatment Using Ammonia-Scavenging Drugs."

17. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '012 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '012 patent.

18. A true and correct copy of the '012 patent is attached hereto as Exhibit A.

U.S. PATENT NO. 9,254,278

19. On February 9, 2016, the USPTO duly and legally issued the '278 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

20. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '278 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '278 patent.

21. A true and correct copy of the '278 patent is attached hereto as Exhibit B.

U.S. PATENT NO. 9,326,966

22. On May 3, 2016, the USPTO duly and legally issued the '966 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

23. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '966 patent, which discloses and claims, *inter alia*, a method of

treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '966 patent.

24. A true and correct copy of the '966 patent is attached hereto as Exhibit C.

U.S. PATENT NO. 9,561,197

25. On February 7, 2017, the USPTO duly and legally issued the '197 patent entitled "Methods of Therapeutic Monitoring of Phenylacetic Acid Prodrugs."

26. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '197 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '197 patent.

27. A true and correct copy of the '197 patent is attached hereto as Exhibit D.

U.S. PATENT NO. 9,962,359

28. On May 8, 2018, the USPTO duly and legally issued the '359 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

29. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '359 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '359 patent.

30. A true and correct copy of the '359 patent is attached hereto as Exhibit E.

U.S. PATENT NO. 9,999,608

31. On June 19, 2018, the USPTO duly and legally issued the '608 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

32. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '608 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '608 patent.

33. A true and correct copy of the '608 patent is attached hereto as Exhibit F.

U.S. PATENT NO. 10,045,958

34. On August 14, 2018, the USPTO duly and legally issued the '958 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

35. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '958 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '958 patent.

36. A true and correct copy of the '958 patent is attached hereto as Exhibit G.

U.S. PATENT NO. 10,045,959

37. On August 14, 2018, the USPTO duly and legally issued the '959 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

38. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '959 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '959 patent.

39. A true and correct copy of the ’959 patent is attached hereto as Exhibit H.

U.S. PATENT NO. 10,183,002

40. On January 22, 2019, the USPTO duly and legally issued the ’002 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.”

41. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the ’002 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the ’002 patent.

42. A true and correct copy of the ’002 patent is attached hereto as Exhibit I.

U.S. PATENT NO. 10,183,003

43. On January 22, 2019, the USPTO duly and legally issued the ’003 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.”

44. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the ’003 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the ’003 patent.

45. A true and correct copy of the ’003 patent is attached hereto as Exhibit J.

U.S. PATENT NO. 10,183,004

46. On January 22, 2019, the USPTO duly and legally issued the ’004 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.”

47. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the ’004 patent, which discloses and claims, *inter alia*, a method of

treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '004 patent.

48. A true and correct copy of the '004 patent is attached hereto as Exhibit K.

U.S. PATENT NO. 10,183,005

49. On January 22, 2019, the USPTO duly and legally issued the '005 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

50. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '005 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '005 patent.

51. A true and correct copy of the '005 patent is attached hereto as Exhibit L.

U.S. PATENT NO. 10,183,006

52. On January 22, 2019, the USPTO duly and legally issued the '006 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs."

53. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '006 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '006 patent.

54. A true and correct copy of the '006 patent is attached hereto as Exhibit M.

U.S. PATENT NO. 10,668,040

55. On June 2, 2020, the USPTO duly and legally issued the '040 patent entitled "Treatment of Urea Cycle Disorders in Neonates and Infants."

56. Horizon Therapeutics U.S. Holding LLC is the assignee and owns all legal right, title, and interest in and to the '040 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. Horizon Therapeutics USA, Inc. is an exclusive licensee of the '040 patent.

57. A true and correct copy of the '040 patent is attached hereto as Exhibit N.

RAVICTI®

58. Horizon Therapeutics U.S. Holding LLC is the owner of FDA-approved New Drug Application No. 203284 ("the RAVICTI® NDA") for glycerol phenylbutyrate oral liquid 1.1gm/ml in the United States, which is sold by Horizon Therapeutics USA, Inc. in the United States under the trademark RAVICTI®.

59. RAVICTI® is currently approved by FDA for use as a nitrogen-binding agent indicated for chronic management of patients with urea cycle disorders who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

60. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the RAVICTI® NDA.

61. The Patents-in-Suit qualify for listing in the Orange Book in connection with NDA No. 203284 because each claims, *inter alia*, an approved use of RAVICTI®.

62. The use of RAVICTI® in accordance with its FDA-approved labeling is covered by one or more claims of each of the Patents-in-Suit.

TEVA'S ANDA

63. By a letter dated February 20, 2024 ("Teva's Notice Letter"), Teva notified Horizon that Teva had submitted to the FDA Teva's ANDA for Teva's ANDA Product.

64. Horizon first received Teva's Notice Letter on February 22, 2024.

65. In Teva's Notice Letter, Teva notified Horizon that, as a part of its ANDA, Teva had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV Certification"), with respect to each of the Patents-in-Suit alleging that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

66. Teva was aware of the Patents-in-Suit when it submitted Teva's ANDA with a Paragraph IV Certification.

67. Upon information and belief, Teva included the Paragraph IV Certification in its ANDA for the purpose of obtaining approval from FDA to engage in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Teva's ANDA Product before the expiration of the Patents-in-Suit. And upon information and belief, upon approval of Teva's ANDA, Teva will be involved, directly and/or indirectly, in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Teva's ANDA Product.

68. Upon information and belief, by filing Teva's ANDA, Teva has necessarily represented to FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as RAVICTI®, and will be bioequivalent to RAVICTI®.

69. Upon information and belief, Teva's proposed labeling for Teva's ANDA Product copies the FDA-approved label for RAVICTI®.

70. Upon information and belief, Teva's ANDA seeks FDA approval of Teva's ANDA Product for the indication included in the FDA-approved label for RAVICTI®, for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Upon information and belief, Teva intends, conditioned upon FDA approval of Teva's ANDA, to market Teva's ANDA Product for the indication included in the FDA-approved label for RAVICTI®. Upon information and belief, Teva also intends for medical practitioners and/or physicians to prescribe, and for patients to use, Teva's ANDA Product in accordance with, and as directed by, Teva's proposed labeling for Teva's ANDA Product.

71. Upon information and belief, Teva intends to engage in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of Teva's ANDA.

72. Horizon is timely commencing this action within 45 days of receiving Teva's Notice Letter pursuant to 21 U.S.C. § 255 (j)(5)(B)(iii).

COUNT I
(Infringement of the '012 Patent)

73. Horizon incorporates each of the preceding paragraphs 1–72 as if fully set forth herein.

74. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '012 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

75. Teva has, and will have, actual knowledge of the '012 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

76. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '012 patent.

77. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '012 patent within the United States.

78. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '012 patent, including through the labeling of Teva's ANDA Product.

79. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '012 patent, and will specifically intend that they do the same.

80. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '012 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '012 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '012 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

81. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

82. Teva's infringement of the '012 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '012 patent.

COUNT II
(Declaration of Infringement of the '012 Patent)

83. Horizon incorporates each of the preceding paragraphs 1–82 as if fully set forth herein.

84. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

85. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

86. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '012 patent, including any applicable exclusivities or extensions.

87. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '012 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

88. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '012 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '012 patent under 35 U.S.C. § 271(b) and (c).

89. Teva's infringement of the '012 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '012 patent.

COUNT III
(Infringement of the '278 Patent)

90. Horizon incorporates each of the preceding paragraphs 1–89 as if fully set forth herein.

91. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '278 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

92. Teva has, and will have, actual knowledge of the ’278 patent, as evidenced by Teva’s Notice Letter and Teva’s ANDA with a Paragraph IV Certification.

93. Upon information and belief, the use of Teva’s ANDA Product within the United States according to the instructions included in the proposed labeling of Teva’s ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the ’278 patent.

94. Upon information and belief, upon FDA approval of Teva’s ANDA, Teva will include within the packaging of Teva’s ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the ’278 patent within the United States.

95. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva’s ANDA Product with the specific intent to induce infringement of the ’278 patent, including through the labeling of Teva’s ANDA Product.

96. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva’s ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the ’278 patent, and will specifically intend that they do the same.

97. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva’s ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the ’278 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '278 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '278 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

98. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '278 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

99. Teva's infringement of the '278 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '278 patent.

COUNT IV
(Declaration of Infringement of the '278 Patent)

100. Horizon incorporates each of the preceding paragraphs 1–99 as if fully set forth herein.

101. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '278 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

102. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

103. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '278 patent, including any applicable exclusivities or extensions.

104. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '278 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

105. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '278 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '278 patent under 35 U.S.C. § 271(b) and (c).

106. Teva's infringement of the '278 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '278 patent.

COUNT V
(Infringement of the '966 Patent)

107. Horizon incorporates each of the preceding paragraphs 1–106 as if fully set forth herein.

108. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '966 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

109. Teva has, and will have, actual knowledge of the '966 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

110. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '966 patent.

111. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '966 patent within the United States.

112. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '966 patent, including through the labeling of Teva's ANDA Product.

113. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '966 patent, and will specifically intend that they do the same.

114. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '966 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '966 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '966 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

115. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '966 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

116. Teva's infringement of the '966 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '966 patent.

COUNT VI
(Declaration of Infringement of the '966 Patent)

117. Horizon incorporates each of the preceding paragraphs 1–116 as if fully set forth herein.

118. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '966 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

119. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

120. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '966 patent, including any applicable exclusivities or extensions.

121. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '966 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

122. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '966 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '966 patent under 35 U.S.C. § 271(b) and (c).

123. Teva's infringement of the '966 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '966 patent.

COUNT VII
(Infringement of the '197 Patent)

124. Horizon incorporates each of the preceding paragraphs 1–123 as if fully set forth herein.

125. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '197 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

126. Teva has, and will have, actual knowledge of the '197 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

127. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '197 patent.

128. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '197 patent within the United States.

129. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '197 patent, including through the labeling of Teva's ANDA Product.

130. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '197 patent, and will specifically intend that they do the same.

131. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '197 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '197 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '197 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

132. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '197 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

133. Teva's infringement of the '197 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '197 patent.

COUNT VIII
(Declaration of Infringement of the '197 Patent)

134. Horizon incorporates each of the preceding paragraphs 1–133 as if fully set forth herein.

135. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '197 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

136. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

137. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '197 patent, including any applicable exclusivities or extensions.

138. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '197 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

139. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '197 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '197 patent under 35 U.S.C. § 271(b) and (c).

140. Teva's infringement of the '197 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '197 patent.

COUNT IX
(Infringement of the '359 Patent)

141. Horizon incorporates each of the preceding paragraphs 1–140 as if fully set forth herein.

142. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '359 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

143. Teva has, and will have, actual knowledge of the '359 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

144. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '359 patent.

145. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '359 patent within the United States.

146. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '359 patent, including through the labeling of Teva's ANDA Product.

147. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '359 patent, and will specifically intend that they do the same.

148. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '359 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '359 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '359 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

149. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '359 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

150. Teva's infringement of the '359 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '359 patent.

COUNT X
(Declaration of Infringement of the '359 Patent)

151. Horizon incorporates each of the preceding paragraphs 1–150 as if fully set forth herein.

152. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '359 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

153. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

154. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '359 patent, including any applicable exclusivities or extensions.

155. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '359 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

156. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '359 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '359 patent under 35 U.S.C. § 271(b) and (c).

157. Teva's infringement of the '359 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '359 patent.

COUNT XI
(Infringement of the '608 Patent)

158. Horizon incorporates each of the preceding paragraphs 1–157 as if fully set forth herein.

159. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '608 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

160. Teva has, and will have, actual knowledge of the '608 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

161. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '608 patent.

162. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '608 patent within the United States.

163. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '608 patent, including through the labeling of Teva's ANDA Product.

164. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '608 patent, and will specifically intend that they do the same.

165. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '608 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '608 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '608 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

166. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '608 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

167. Teva's infringement of the '608 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '608 patent.

COUNT XII
(Declaration of Infringement of the '608 Patent)

168. Horizon incorporates each of the preceding paragraphs 1–167 as if fully set forth herein.

169. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '608 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

170. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

171. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '608 patent, including any applicable exclusivities or extensions.

172. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '608 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

173. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '608 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '608 patent under 35 U.S.C. § 271(b) and (c).

174. Teva's infringement of the '608 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '608 patent.

COUNT XIII
(Infringement of the '958 Patent)

175. Horizon incorporates each of the preceding paragraphs 1–174 as if fully set forth herein.

176. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '958 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

177. Teva has, and will have, actual knowledge of the '958 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

178. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '958 patent.

179. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '958 patent within the United States.

180. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '958 patent, including through the labeling of Teva's ANDA Product.

181. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '958 patent, and will specifically intend that they do the same.

182. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '958 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '958 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '958 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

183. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '958 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

184. Teva's infringement of the '958 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '958 patent.

COUNT XIV
(Declaration of Infringement of the '958 Patent)

185. Horizon incorporates each of the preceding paragraphs 1–184 as if fully set forth herein.

186. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '958 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

187. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

188. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '958 patent, including any applicable exclusivities or extensions.

189. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '958 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

190. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '958 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '958 patent under 35 U.S.C. § 271(b) and (c).

191. Teva's infringement of the '958 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '958 patent.

COUNT XV
(Infringement of the '959 Patent)

192. Horizon incorporates each of the preceding paragraphs 1–191 as if fully set forth herein.

193. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '959 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

194. Teva has, and will have, actual knowledge of the '959 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

195. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '959 patent.

196. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '959 patent within the United States.

197. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '959 patent, including through the labeling of Teva's ANDA Product.

198. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '959 patent, and will specifically intend that they do the same.

199. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '959 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '959 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '959 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

200. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '959 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

201. Teva's infringement of the '959 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '959 patent.

COUNT XVI
(Declaration of Infringement of the '959 Patent)

202. Horizon incorporates each of the preceding paragraphs 1–201 as if fully set forth herein.

203. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '959 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

204. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

205. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '959 patent, including any applicable exclusivities or extensions.

206. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '959 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

207. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '959 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '959 patent under 35 U.S.C. § 271(b) and (c).

208. Teva's infringement of the '959 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '959 patent.

COUNT XVII
(Infringement of the '002 Patent)

209. Horizon incorporates each of the preceding paragraphs 1–208 as if fully set forth herein.

210. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '002 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

211. Teva has, and will have, actual knowledge of the '002 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

212. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '002 patent.

213. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '002 patent within the United States.

214. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '002 patent, including through the labeling of Teva's ANDA Product.

215. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '002 patent, and will specifically intend that they do the same.

216. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '002 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '002 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '002 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

217. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '002 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

218. Teva's infringement of the '002 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '002 patent.

COUNT XVIII
(Declaration of Infringement of the '002 Patent)

219. Horizon incorporates each of the preceding paragraphs 1–218 as if fully set forth herein.

220. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '002 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

221. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

222. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '002 patent, including any applicable exclusivities or extensions.

223. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '002 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

224. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '002 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '002 patent under 35 U.S.C. § 271(b) and (c).

225. Teva's infringement of the '002 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '002 patent.

COUNT XIX
(Infringement of the '003 Patent)

226. Horizon incorporates each of the preceding paragraphs 1–225 as if fully set forth herein.

227. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '003 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

228. Teva has, and will have, actual knowledge of the '003 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

229. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '003 patent.

230. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '003 patent within the United States.

231. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '003 patent, including through the labeling of Teva's ANDA Product.

232. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '003 patent, and will specifically intend that they do the same.

233. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '003 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '003 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '003 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

234. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

235. Teva's infringement of the '003 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '003 patent.

COUNT XX
(Declaration of Infringement of the '003 Patent)

236. Horizon incorporates each of the preceding paragraphs 1—235 as if fully set forth herein.

237. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

238. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

239. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '003 patent, including any applicable exclusivities or extensions.

240. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '003 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

241. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '003 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '003 patent under 35 U.S.C. § 271(b) and (c).

242. Teva's infringement of the '003 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '003 patent.

COUNT XXI
(Infringement of the '004 Patent)

243. Horizon incorporates each of the preceding paragraphs 1–242 as if fully set forth herein.

244. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '004 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

245. Teva has, and will have, actual knowledge of the '004 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

246. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '004 patent.

247. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '004 patent within the United States.

248. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '004 patent, including through the labeling of Teva's ANDA Product.

249. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '004 patent, and will specifically intend that they do the same.

250. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '004 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '004 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '004 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

251. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '004 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

252. Teva's infringement of the '004 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '004 patent.

COUNT XXII
(Declaration of Infringement of the '004 Patent)

253. Horizon incorporates each of the preceding paragraphs 1–252 as if fully set forth herein.

254. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '004 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

255. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

256. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '004 patent, including any applicable exclusivities or extensions.

257. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '004 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

258. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '004 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '004 patent under 35 U.S.C. § 271(b) and (c).

259. Teva's infringement of the '004 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '004 patent.

COUNT XXIII
(Infringement of the '005 Patent)

260. Horizon incorporates each of the preceding paragraphs 1–259 as if fully set forth herein.

261. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '005 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

262. Teva has, and will have, actual knowledge of the '005 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

263. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '005 patent.

264. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '005 patent within the United States.

265. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '005 patent, including through the labeling of Teva's ANDA Product.

266. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '005 patent, and will specifically intend that they do the same.

267. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '005 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '005 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '005 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

268. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '005 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

269. Teva's infringement of the '005 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '005 patent.

COUNT XXIV
(Declaration of Infringement of the '005 Patent)

270. Horizon incorporates each of the preceding paragraphs 1–269 as if fully set forth herein.

271. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '005 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

272. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

273. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '005 patent, including any applicable exclusivities or extensions.

274. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '005 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

275. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '005 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '005 patent under 35 U.S.C. § 271(b) and (c).

276. Teva's infringement of the '005 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '005 patent.

COUNT XXV
(Infringement of the '006 Patent)

277. Horizon incorporates each of the preceding paragraphs 1–276 as if fully set forth herein.

278. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '006 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

279. Teva has, and will have, actual knowledge of the '006 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

280. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '006 patent.

281. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '006 patent within the United States.

282. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '006 patent, including through the labeling of Teva's ANDA Product.

283. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '006 patent, and will specifically intend that they do the same.

284. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '006 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '006 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '006 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

285. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '006 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

286. Teva's infringement of the '006 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '006 patent.

COUNT XXVI
(Declaration of Infringement of the '006 Patent)

287. Horizon incorporates each of the preceding paragraphs 1–286 as if fully set forth herein.

288. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '006 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

289. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

290. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '006 patent, including any applicable exclusivities or extensions.

291. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '006 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

292. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '006 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '006 patent under 35 U.S.C. § 271(b) and (c).

293. Teva's infringement of the '006 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '006 patent.

COUNT XXVII
(Infringement of the '040 Patent)

294. Horizon incorporates each of the preceding paragraphs 1–293 as if fully set forth herein.

295. By submitting Teva's ANDA with a Paragraph IV Certification to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product throughout the United States prior to the expiration of the '040 patent, including any applicable

exclusivities or extensions, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

296. Teva has, and will have, actual knowledge of the '040 patent, as evidenced by Teva's Notice Letter and Teva's ANDA with a Paragraph IV Certification.

297. Upon information and belief, the use of Teva's ANDA Product within the United States according to the instructions included in the proposed labeling of Teva's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '040 patent.

298. Upon information and belief, upon FDA approval of Teva's ANDA, Teva will include within the packaging of Teva's ANDA Product, or will otherwise make available to third parties, including, for example, patients and healthcare providers, labeling that instructs and encourages those third parties to perform one or more of the methods claimed in the '040 patent within the United States.

299. Upon information and belief, Teva will commercially make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with the specific intent to induce infringement of the '040 patent, including through the labeling of Teva's ANDA Product.

300. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product, Teva will knowingly induce third parties, including, for example, patients and healthcare providers, to infringe one or more claims of the '040 patent, and will specifically intend that they do the same.

301. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product and its corresponding labeling, Teva will contribute to infringement of one or more claims of the '040 patent by third

parties because: (i) Teva's ANDA Product constitutes a material part of one or more methods of treatment claimed in the '040 patent; (ii) Teva knows or should know that Teva's ANDA Product will be especially made and adapted for uses that directly infringe one or more methods claimed in the '040 patent; and (iii) Teva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

302. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '040 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

303. Teva's infringement of the '040 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '040 patent.

COUNT XXVIII
(Declaration of Infringement of the '040 Patent)

304. Horizon incorporates each of the preceding paragraphs 1–303 as if fully set forth herein.

305. Upon information and belief, by commercially making, using, offering for sale, selling, importing, distributing, and/or marketing Teva's ANDA Product for use according to Teva's proposed label, Teva will induce and/or contribute to infringement of one or more claims of the '040 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

306. Upon information and belief, Teva intends to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling immediately and imminently upon final approval of Teva's ANDA.

307. Upon information and belief, Teva has made, and will continue to make, substantial preparation in the United States to make, use, offer for sale, sell, import, distribute, and/or market Teva's ANDA Product with its proposed labeling prior to the expiration of the '040 patent, including any applicable exclusivities or extensions.

308. Therefore, a case or controversy exists between Horizon and Teva as to infringement of the '040 patent such that the Court may enter Horizon's request for declaratory relief consistent with Article III of the United States Constitution.

309. Horizon is entitled to a declaratory judgment that by commercially making, using, offering for sale, selling, distributing, and/or marketing within the United States, and/or importing into the United States, Teva's ANDA Product prior to the expiration of the '040 patent, including any applicable exclusivities or extensions, Teva would induce and or contribute to infringement of the '040 patent under 35 U.S.C. § 271(b) and (c).

310. Teva's infringement of the '040 patent will cause Horizon to suffer irreparable harm. Teva's infringement will continue unless enjoined by the Court. Horizon has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Teva from infringing the '040 patent.

PRAYER FOR RELIEF

WHEREFORE, Horizon respectfully requests the following relief:

A. A judgment that Teva has infringed one or more claims of each of the Patents-in-Suit by submitting ANDA No. 218738 seeking FDA approval for the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product within the United States, or importation into the United States, prior to the expiration of any of the Patents-in-Suit, including any applicable exclusivities or extensions, under 35 U.S.C. § 271(e)(2)(A);

B. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 218738 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of any of the Patents-in-Suit, including any applicable exclusivities or extensions;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Teva, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, from engaging in the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Teva's ANDA Product prior to the expiration of any of the Patents-in-Suit, including any applicable exclusivities or extensions;

D. A declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that if Teva, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, commercially manufacture, use, offer for sale, sell, market, and/or distribute within the United States, and/or import into the United States, Teva's ANDA Product prior to the expiration of any of the Patents-in-Suit, including any applicable exclusivities or extensions, it will constitute an act of infringement under 35 U.S.C. § 271(b) and/or (c);

E. A judgment awarding Horizon monetary relief together with interest if Teva commercially manufactures, uses, offers for sale, and/or sells within the United States, and/or imports into the United States, Teva's ANDA Product prior to the expiration of any of the Patents-in-Suit, including any applicable exclusivities or extensions;

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

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

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

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**Pro hac vice* admission to be filed

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