UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MYLAN INSTITUTIONAL LLC, *Plaintiff*, v. ALORA PHARMACEUTICALS, LLC, *Defendant*.	Civil Action No.: _____

MYLAN INSTITUTIONAL LLC'S COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiff Mylan Institutional LLC ("Mylan Institutional" or "Plaintiff") brings this Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement against Defendant Alora Pharmaceuticals, LLC ("Alora" or "Defendant"), and Plaintiff alleges, on personal knowledge as to its own actions and on information and belief as to the actions of others, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and a declaratory judgment of patent infringement arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, 35 U.S.C. § 1 et seq., involving U.S. Patent Nos. 7,662,992 (the "'992 Patent"); 8,969,616 (the "'616

Patent"); 9,353,050 (the "'050 Patent"); 10,464,888 (the "'888 Patent"); 10,508,080 (the "'080 Patent"); 10,590,071 (the "'071 Patent"); 10,626,086 (the "'086 Patent"); and 10,752,580 (the "'580 Patent") (collectively, the "Patents-in-Suit").

2. On information and belief, Defendant has submitted to the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application for an isosulfan blue ("ISB") injection product ("Defendant's ANDA Application").

3. On information and belief, Defendant has made, used, offered to sell, sold, and/or imported into the United States and intends to continue to make, use, offer to sell, sell, and/or import into the United States an ISB injection product ("Defendant's ANDA Product") prior to the expiration of the Patents-in-Suit.

THE PARTIES

4. Mylan Institutional is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 3711 Collins Ferry Road, Morgantown, WV 26505.

5. Mylan Institutional is a pharmaceutical company that develops and commercializes injectable and other pharmaceutical products.

6. On information and belief, Alora is a company organized and existing under the laws of the State of Delaware. On information and belief, Alora has a

principal place of business at 1880 McFarland Parkway, Suite 110, Alpharetta, Georgia 30005.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

8. Certain of the claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States of America, 35 U.S.C. § 1 et seq.

9. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this case involves an actual controversy within the Court's jurisdiction and seeks a declaratory judgment that the Patents-in-Suit have been and will be infringed.

10. This Court has personal jurisdiction over Defendant under the Georgia state long arm statute and consistent with due process of law because Defendant uses and possesses real property in the state, including by maintaining its principal place of business in Alpharetta, Georgia.

11. This Court has personal jurisdiction over Defendant under the Georgia state long arm statute and consistent with due process of law because Defendant has extensive contacts with the State of Georgia and regularly transacts business in this judicial district.

12. Defendant is registered to do business in the State of Georgia under Control Number 11094875. Moreover, on information and belief, Defendant has appointed a registered agent in Georgia for the receipt of service of process.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Defendant has committed acts in this judicial district giving rise to the claims asserted herein and Defendant has a regular and established place of business within this judicial district.

PATENTS-IN-SUIT

14. After years of significant effort and expense, a superior process of manufacturing ISB was developed that allowed for the commercial synthesis of ISB at a purity level far greater than previously achieved by others. That superior process and the resulting highly pure ISB is the basis for the claims of the Patents-in-Suit.

15. Mylan Institutional's highly pure ISB product ("Mylan Institutional's ISB Product") is designated by FDA as the Reference Standard product for all ISB products. As such, Mylan Institutional's ISB Product is used as the benchmark for analytical testing of all other ISB products. *See* Exhibit A (FDA webpage showing that Mylan Institutional's ISB Product is the Reference Standard).

16. FDA regulations provide that a "[r]eference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use

in conducting an *in vivo* bioequivalence study required for approval." 21 CFR 314.3(b).

17. The '992 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 16, 2010. The named inventors of the '992 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '992 Patent. A true and correct copy of the '992 Patent is attached hereto as Exhibit B.

18. The '616 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on March 3, 2015. The named inventors of the '616 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '616 Patent. A true and correct copy of the '616 Patent is attached hereto as Exhibit C.

19. The '050 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on May 31, 2016. The named inventors of the '050 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '050 Patent. A true and correct copy of the '050 Patent is attached hereto as Exhibit D.

20. The '888 Patent, entitled "Process for the Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on November 5, 2019. The named

inventors of the ’888 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the ’888 Patent. A true and correct copy of the ’888 Patent is attached hereto as Exhibit E.

21. The ’080 Patent, entitled “Process for the Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on December 17, 2019. The named inventors of the ’080 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the ’080 Patent. A true and correct copy of the ’080 Patent is attached hereto as Exhibit F.

22. The ’071 Patent, entitled “Process for the Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on March 17, 2020. The named inventors of the ’071 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the ’071 Patent. A true and correct copy of the ’071 Patent is attached hereto as Exhibit G.

23. The ’086 Patent, entitled “Process for the Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on April 21, 2020. The named inventors of the ’086 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the ’086 Patent. A true and correct copy of the ’086 Patent is attached hereto as Exhibit H.

24. The ’580 Patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on August 25, 2020. The named

inventors of the ’580 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the ’580 Patent. A true and correct copy of the ’580 Patent is attached hereto as Exhibit I.

25. Mylan Institutional is the lawful owner of the Patents-in-Suit and has all right, title, and interest in and to the Patents-in-Suit.

26. Currently, no other FDA-approved generic version of Mylan Institutional’s ISB Product is commercially sold in the United States. Mylan Institutional has previously asserted the Patents-in-Suit against potential generic competitors, and the validity of the Patents-in-Suit is now well established.

27. Mylan Institutional has previously obtained a preliminary injunction based on certain of the Patents-in-Suit, preventing a company from making, using, selling, offering for sale or importing into the United States an infringing ISB product. The preliminary injunction was affirmed by the United States Court of Appeals for the Federal Circuit. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, No. 2:16-cv-00491, 2017 WL 497593 (E.D. Tex. Feb. 7, 2017) (“Order Adopting R&R”), *aff’d*, 857 F.3d 858 (Fed. Cir. 2017).

28. The validity of the Patents-in-Suit has also been acknowledged by several companies that submitted an ANDA for an ISB product. *Apicore US LLC v. Beloteca, Inc.*, No. 1:19-cv-02638, D.I. 162 (N.D. Ill. July 19, 2019); *Mylan API US LLC & Mylan Institutional LLC v. Am. Regent, Inc.*, No. 2:19-cv-05675, D.I. 18

(E.D.N.Y. Mar. 16, 2020) (asserting the ’050 Patent and voluntarily dismissed); *Mylan Institutional LLC & Apicore US LLC v. BPI Labs LLC*, No. 8:22-cv-02155, D.I. 23 (M.D. Fla. Nov. 30, 2022) (asserting the ’050, ’086, and ’580 Patents and voluntarily dismissed); *Mylan Institutional LLC & Apicore US LLC v. Hong Kong King-Friend Indus. Co. Ltd.*, No. 2:21-cv-00419, D.I. 68 (E.D. Tex. Dec. 13, 2021) (asserting the ’050, ’086, and ’580 Patents and entering Consent Judgment and Permanent Injunction admitting infringement of the asserted patents and stipulating to the validity and enforceability of the asserted patents).

29. The validity of the Patents-in-Suit is further established by the USPTO’s Patent Trial and Appeal Board’s decision in 2019 denying institution of an *inter partes* review challenging the ’050 Patent. The Board found that Petitioner Luitpold Pharmaceuticals, Inc. “ha[d] not demonstrated a reasonable likelihood of prevailing with respect to at least one claim of the ’050 patent.” *Luitpold Pharms., Inc. v. Apicore US LLC et al.*, No. IPR2018-01640, Paper 19 at 2 (P.T.A.B. Mar. 6, 2019).

ACTS GIVING RISE TO THIS ACTION

30. Mylan Institutional has not authorized or licensed Defendant to make, use, sell, offer for sale, and/or import into the United States any of the inventions claimed in the Patents-in-Suit.

31. On information and belief, Defendant submitted Defendant's ANDA Application to the FDA seeking approval to engage in the commercial manufacture, use, marketing, offer for sale, and sale of an ISB product in the United States.

32. On information and belief, Defendant plans to launch Defendant's ANDA Product in the United States upon receipt of FDA approval before expiry of the Patents-in-Suit.

33. On information and belief, Defendant intends to launch Defendant's ANDA Product in January 2026.

34. On September 16, 2025, counsel for Mylan Institutional sent a letter to Defendant at its principal place of business, care of its General Counsel, identifying the Patents-in-Suit. The letter requested additional information related to the manufacture of Defendant's ANDA Product by no later than September 26, 2025. The letter also requested Defendant agree to refrain from making, using, selling, offering to sell, and/or importing Defendant's ANDA Product while the parties resolve Mylan Institutional's rights with respect to the Patents-in-Suit.

35. Upon information and belief, Defendant received the letter on September 17, 2025.

36. Defendant has provided no response to the letter.

37. Defendant's refusal to communicate with Mylan Institutional concerning Mylan Institutional's patent rights has left Mylan Institutional no choice

but to file the instant Complaint directed to Defendant's infringement of the Patents-in-Suit.

38. Defendant was aware of the Patents-in-Suit prior to the commencement of this action.

CLAIMS FOR RELIEF

COUNT I
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the '992 Patent

39. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

40. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '992 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

41. Upon information and belief, Defendant's ANDA Application was submitted to FDA while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

42. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

43. Mylan Institutional's ISB active pharmaceutical ingredient ("API") and Mylan Institutional's ISB Product are at least 99% pure as determined by high-performance liquid chromatography ("HPLC") testing, as defined by the Patents-in-Suit.

44. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

45. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to Mylan Institutional's ISB Product as the Reference Standard.

46. On information and belief, Defendant infringes at least claim 1 of the '992 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

47. On information and belief, the ISB API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid in a polar solvent with 2.0 to 3.0 equivalents of silver oxide, recovering ISB acid, and treating the ISB acid with a sodium solution.

48. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as the polar solvent.

49. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using an aqueous inorganic or organic derivative of sodium or a combination thereof.

50. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using sodium bicarbonate solution.

51. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid using a solvent selected from the group consisting of a polar solvent, a non-polar solvent, and a combination thereof to afford HPLC purity greater than 99.5%.

52. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid from an aqueous acetone medium and 80% aqueous isopropanol/acetone.

53. On information and belief, Defendant had knowledge of the '992 Patent at least by on or about September 17, 2025.

54. Defendant has had constructive notice of the '992 Patent as of its date of issuance on February 16, 2010.

55. On information and belief, Defendant is and was aware of the existence of the ’992 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’992 Patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

56. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’992 Patent is not enjoined by this Court.

57. Defendant’s infringement of the ’992 Patent has caused Mylan Institutional substantial harm.

COUNT II
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the ’616 Patent

58. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

59. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’616 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

60. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

61. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA

Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

62. Mylan Institutional's ISB API and Mylan Institutional's ISB Product are at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

63. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

64. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to Mylan Institutional's ISB Product as the Reference Standard.

65. On information and belief, Defendant infringes at least claim 1 of the '616 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

66. On information and belief, the API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid in a polar solvent with silver oxide, recovering ISB acid, and treating the ISB acid with a sodium solution.

67. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as the polar solvent.

68. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using an aqueous inorganic or organic derivative of sodium or a combination thereof.

69. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using sodium bicarbonate solution.

70. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid using a solvent selected from the group consisting of a polar solvent, a non-polar solvent, and a combination thereof to afford HPLC purity greater than 99.5%.

71. On information and belief, Defendant had knowledge of the '616 Patent at least by on or about September 17, 2025.

72. Defendant has had constructive notice of the '616 Patent as of its date of issuance on March 3, 2015.

73. On information and belief, Defendant is and was aware of the existence of the '616 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '616 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

74. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '616 Patent is not enjoined by this Court.

75. Defendant's infringement of the '616 Patent has caused Mylan Institutional substantial harm.

COUNT III
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the '050 Patent

76. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

77. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '050 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

78. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

79. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

80. Mylan Institutional's ISB API and Mylan Institutional's ISB Product are at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

81. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

82. Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

83. On information and belief, Defendant infringes at least claim 1 of the '050 Patent because the API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

84. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

85. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

86. On information and belief, Defendant had knowledge of the '050 Patent at least by on or about September 17, 2025.

87. Defendant has had constructive notice of the '050 Patent as of its date of issuance on May 31, 2016.

88. On information and belief, Defendant is and was aware of the existence of the ’050 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’050 Patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

89. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’050 Patent is not enjoined by this Court.

90. Defendant’s infringement of the ’050 Patent has caused Mylan Institutional substantial harm.

COUNT IV
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the ’888 Patent

91. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

92. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’888 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

93. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

94. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA

Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

95. Mylan Institutional's ISB API and Mylan Institutional's ISB Product are at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

96. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

97. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

98. On information and belief, Defendant infringes at least claim 1 of the '888 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

99. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent to provide an ISB acid.

100. On information and belief, the API used in Defendant's ANDA Product is prepared by recovering ISB acid.

101. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid.

102. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through recrystallization.

103. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through crystallization using a solvent comprising an alcohol.

104. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB through crystallization using aqueous isopropyl alcohol as a solvent.

105. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent in the absence of a strong acid.

106. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is not lead oxide, chloranil, or iron phthalocyanine/oxone.

107. On information and belief, the API used in Defendant's ANDA Product is prepared by using silver oxide as an oxidizing agent.

108. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

109. On information and belief, the API used in Defendant's ANDA Product is prepared by using a polar solvent that is selected from a group consisting of water, alcohol, and mixtures thereof.

110. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent to provide an ISB acid, recovering said ISB acid, combining said ISB acid with a solvent to prepare an ISB acid mixture, and adjusting the pH of said ISB acid mixture.

111. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using a base.

112. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted to a pH greater than 6.0.

113. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using an aqueous carbonate base.

114. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using aqueous sodium carbonate.

115. On information and belief, Defendant had knowledge of the ’888 Patent at least by on or about September 17, 2025.

116. Defendant has had constructive notice of the ’888 Patent as of its date of issuance on November 5, 2019.

117. On information and belief, Defendant is and was aware of the existence of the ’888 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’888 Patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

118. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’888 Patent is not enjoined by this Court.

119. Defendant’s infringement of the ’888 Patent has caused Mylan Institutional substantial harm.

COUNT V
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the ’080 Patent

120. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

121. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’080 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

122. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

123. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

124. Mylan Institutional's ISB API and Mylan Institutional's ISB Product are at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

125. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

126. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to Mylan Institutional's ISB Product as the Reference Standard.

127. On information and belief, Defendant infringes at least claim 1 of the ’080 Patent because the manufacture and/or preparation of Defendant’s ANDA Product includes the process described in claim 1.

128. On information and belief, the API used in Defendant’s ANDA Product is prepared by combining isoleuco acid with an oxidizing agent, recovering ISB acid, and obtaining ISB sodium salt therefrom.

129. On information and belief, the API used in Defendant’s ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

130. On information and belief, the API used in Defendant’s ANDA Product is prepared by using a polar solvent that is selected from a group consisting of water, alcohol, and mixtures thereof.

131. On information and belief, the API used in Defendant’s ANDA Product is prepared by using methanol as a polar solvent.

132. On information and belief, the API used in Defendant’s ANDA Product is prepared by using silver oxide as an oxidizing agent.

133. On information and belief, the API used in Defendant’s ANDA Product is prepared by combining ISB acid with a sodium solution.

134. On information and belief, the API used in Defendant’s ANDA Product is prepared by combining ISB acid with an aqueous sodium solution.

135. On information and belief, the API used in Defendant's ANDA Product is prepared by obtaining a purity of at least 99% as measured by HPLC.

136. On information and belief, Defendant had knowledge of the '080 Patent at least by on or about September 17, 2025.

137. Defendant has had constructive notice of the '080 Patent as of its date of issuance on December 17, 2019.

138. On information and belief, Defendant is and was aware of the existence of the '080 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '080 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

139. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '080 Patent is not enjoined by this Court.

140. Defendant's infringement of the '080 Patent has caused Mylan Institutional substantial harm.

COUNT VI
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the '071 Patent

141. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

142. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '071 Patent, including

at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

143. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

144. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

145. Mylan Institutional's ISB API and Mylan Institutional's ISB Product are at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

146. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

147. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to Mylan Institutional's ISB Product as the Reference Standard.

148. On information and belief, Defendant infringes at least claim 1 of the ’071 Patent because the manufacture and/or preparation of Defendant’s ANDA Product includes the process described in claim 1.

149. On information and belief, the API used in Defendant’s ANDA Product is prepared by combining isoleuco acid with an oxidizing agent to provide ISB acid, wherein said isoleuco acid is combined with said oxidizing agent in the absence of a strong acid.

150. On information and belief, the API used in Defendant’s ANDA Product is prepared by recovering ISB acid.

151. On information and belief, the API used in Defendant’s ANDA Product is prepared by purifying recovered ISB acid.

152. On information and belief, the API used in Defendant’s ANDA Product is prepared by purifying recovered ISB acid through recrystallization.

153. On information and belief, the API used in Defendant’s ANDA Product is prepared by purifying recovered ISB acid through recrystallization in a solvent comprising an alcohol.

154. On information and belief, the API used in Defendant’s ANDA Product is prepared by purifying recovered ISB acid through recrystallization in a solvent comprising an alcohol that is aqueous isopropyl alcohol.

155. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is not lead oxide, chloranil, or iron phthalocyanine/oxone.

156. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is silver oxide.

157. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

158. On information and belief, the API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid with an oxidizing agent to provide ISB acid, wherein said isoleuco acid is combined with said oxidizing agent in the absence of a strong acid, recovering said ISB, combining said ISB acid with a solvent to prepare an ISB acid mixture, and adjusting the pH of said ISB acid mixture.

159. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using a base.

160. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted to a pH greater than 6.0.

161. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted using an aqueous carbonate base.

162. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted using aqueous sodium carbonate.

163. On information and belief, Defendant had knowledge of the '071 Patent at least by on or about September 17, 2025.

164. Defendant has had constructive notice of the '071 Patent as of its date of issuance on March 17, 2020.

165. On information and belief, Defendant is and was aware of the existence of the '071 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '071 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

166. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '071 Patent is not enjoined by this Court.

167. Defendant's infringement of the '071 Patent has caused Mylan Institutional substantial harm.

COUNT VII
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the '086 Patent

168. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

169. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '086 Patent, including

at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

170. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

171. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

172. Mylan Institutional's ISB API and Mylan Institutional's ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

173. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

174. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

175. On information and belief, Defendant infringes at least claim 1 of the '086 Patent because the API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

176. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

177. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

178. On information and belief, the API used in Defendant's ANDA Product contains between 0.5% and 1% impurities by HPLC.

179. On information and belief, the API used in Defendant's ANDA Product contains less than about 0.5% impurities by HPLC.

180. On information and belief, Defendant had knowledge of the '086 Patent at least by on or about September 17, 2025.

181. Defendant has had constructive notice of the '086 Patent as of its date of issuance on April 21, 2020.

182. On information and belief, Defendant is and was aware of the existence of the '086 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '086 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

183. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '086 Patent is not enjoined by this Court.

184. Defendant's infringement of the '086 Patent causes Mylan Institutional substantial harm.

COUNT VIII
35 U.S.C. §§ 271(a), (b), (c) and/or (g) Infringement of the '580 Patent

185. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

186. Defendant has infringed under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '580 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

187. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

188. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

189. Mylan Institutional's ISB API and Mylan Institutional's ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

190. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

191. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

192. On information and belief, Defendant infringes at least claim 1 of the '580 Patent because the ISB API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

193. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

194. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

195. On information and belief, the API used in Defendant's ANDA Product has a purity of at least 99.5% by HPLC.

196. On information and belief, Defendant had knowledge of the '580 Patent at least by on or about September 17, 2025.

197. Defendant has had constructive notice of the '580 Patent as of its date of issuance on August 25, 2020.

198. On information and belief, Defendant is and was aware of the existence of the '580 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '580 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

199. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '580 Patent is not enjoined by this Court.

200. Defendant's infringement of the '580 Patent causes Mylan Institutional substantial harm.

COUNT IX
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the '992 Patent

201. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

202. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '992 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

203. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

204. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

205. Mylan Institutional's ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

206. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

207. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

208. On information and belief, Defendant infringes at least claim 1 of the '992 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

209. On information and belief, the API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid in a polar solvent with 2.0 to 3.0 equivalents of silver oxide, recovering ISB acid, and treating the ISB acid with a sodium solution.

210. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as the polar solvent.

211. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using an aqueous inorganic or organic derivative of sodium or a combination thereof.

212. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6 using sodium bicarbonate solution.

213. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid from the group consisting of a polar solvent, a non-polar solvent and a combination thereof to afford HPLC purity greater than 99.5%.

214. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid from an aqueous acetone medium and 80% aqueous isopropanol/acetone.

215. On information and belief, Defendant had knowledge of the '992 Patent at least by on or about September 17, 2025.

216. Defendant has had constructive notice of the '992 Patent as of its date of issuance on February 16, 2010.

217. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '992 Patent is not enjoined by this Court.

218. Defendant's infringement of the '992 Patent will cause Mylan Institutional substantial harm.

COUNT X
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the '616 Patent

219. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

220. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '616 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

221. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

222. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all isosulfan blue products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

223. Mylan Institutional's ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

224. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

225. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

226. On information and belief, Defendant infringes at least claim 1 of the '616 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

227. On information and belief, the API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid in a polar solvent with silver oxide, recovering ISB acid, and treating the ISB acid with a sodium solution.

228. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as the polar solvent.

229. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6.0 using an aqueous inorganic or organic derivative of sodium or a combination thereof.

230. On information and belief, the API used in Defendant's ANDA Product is prepared by adjusting ISB acid to a pH greater than 6 using sodium bicarbonate solution.

231. On information and belief, the API used in Defendant's ANDA Product is prepared by recrystallizing ISB acid from the group consisting of a polar solvent, a non-polar solvent and a combination thereof to afford HPLC purity greater than 99.5%.

232. On information and belief, Defendant had knowledge of the '616 Patent at least by on or about September 17, 2025.

233. Defendant has had constructive notice of the '616 Patent as of its date of issuance on March 3, 2015.

234. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '616 Patent is not enjoined by this Court.

235. Defendant's infringement of the '616 Patent will cause Mylan Institutional substantial harm.

COUNT XI
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the '050 Patent

236. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

237. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’050 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

238. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

239. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA Product, must be compared to Mylan Institutional’s ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

240. Mylan Institutional’s ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

241. Because comparison to Mylan Institutional’s ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant’s ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional’s ISB Product.

242. On information and belief, Defendant’s ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional’s ISB Product.

243. On information and belief, Defendant infringes at least claim 1 of the ’050 Patent because the API used in Defendant’s ANDA Product has a purity of at least 99.0% by HPLC.

244. On information and belief, the API used in Defendant’s ANDA Product has a purity between 99.0% and 99.5% by HPLC.

245. On information and belief, the API used in Defendant’s ANDA Product has less than 20 ppm silver.

246. On information and belief, Defendant had knowledge of the ’050 Patent at least by on or about September 17, 2025.

247. Defendant has had constructive notice of the ’050 Patent as of its date of issuance on May 31, 2016.

248. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’050 Patent is not enjoined by this Court.

249. Defendant’s infringement of the ’050 Patent will cause Mylan Institutional substantial harm.

COUNT XII
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the ’888 Patent

250. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

251. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’888 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

252. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

253. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA Product, must be compared to Mylan Institutional’s ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

254. Mylan Institutional’s ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

255. Because comparison to Mylan Institutional’s ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant’s ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional’s ISB Product.

256. On information and belief, Defendant’s ANDA Product is manufactured by the same or similar process as Mylan Institutional’s ISB Product

to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

257. On information and belief, Defendant infringes at least claim 1 of the '888 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

258. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent to provide an ISB acid.

259. On information and belief, the API used in Defendant's ANDA Product is prepared by recovering ISB acid.

260. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid.

261. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through recrystallization.

262. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through crystallization using a solvent comprising an alcohol.

263. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB through crystallization using aqueous isopropyl alcohol as a solvent.

264. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent in the absence of a strong acid.

265. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is not lead oxide, chloranil, or iron phthalocyanine/oxone.

266. On information and belief, the API used in Defendant's ANDA Product is prepared by using silver oxide as an oxidizing agent.

267. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

268. On information and belief, the API used in Defendant's ANDA Product is prepared by using a polar solvent that is selected from a group consisting of water, alcohol, and mixtures thereof.

269. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with a mild oxidizing agent to provide an ISB acid, recovering said ISB acid, combining said ISB acid with a solvent to prepare an ISB acid mixture, and adjusting the pH of said ISB acid mixture.

270. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using a base.

271. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted to a pH greater than 6.0.

272. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using an aqueous carbonate base.

273. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using aqueous sodium carbonate.

274. On information and belief, Defendant had knowledge of the '888 Patent at least by on or about September 17, 2025.

275. Defendant has had constructive notice of the '888 Patent as of its date of issuance on November 5, 2019.

276. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '888 Patent is not enjoined by this Court.

277. Defendant's infringement of the '888 Patent will cause Mylan Institutional substantial harm.

COUNT XIII
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the '080 Patent

278. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

279. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’080 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

280. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

281. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA Product, must be compared to Mylan Institutional’s ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

282. Mylan Institutional’s ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

283. Because comparison to Mylan Institutional’s ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant’s ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional’s ISB Product.

284. On information and belief, Defendant’s ANDA Product is manufactured by the same or similar process as Mylan Institutional’s ISB Product

to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

285. On information and belief, Defendant infringes at least claim 1 of the '080 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

286. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent, recovering ISB acid, and obtaining ISB sodium salt therefrom.

287. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

288. On information and belief, the API used in Defendant's ANDA Product is prepared by using a polar solvent that is selected from a group consisting of water, alcohol, and mixtures thereof.

289. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as a polar solvent.

290. On information and belief, the API used in Defendant's ANDA Product is prepared by using silver oxide as an oxidizing agent.

291. On information and belief, the API used in Defendant's ANDA Product is prepared by combining ISB acid with a sodium solution.

292. On information and belief, the API used in Defendant's ANDA Product is prepared by combining ISB acid with an aqueous sodium solution.

293. On information and belief, the API used in Defendant's ANDA Product is prepared by obtaining a purity of at least 99% as measured by HPLC.

294. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent, forming ISB acid, and obtaining ISB sodium salt therefrom.

295. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

296. On information and belief, the API used in Defendant's ANDA Product is prepared by using a polar solvent that is selected from a group consisting of water, alcohol, and mixtures thereof.

297. On information and belief, the API used in Defendant's ANDA Product is prepared by using methanol as a polar solvent.

298. On information and belief, the API used in Defendant's ANDA Product is prepared by using silver oxide as an oxidizing agent.

299. On information and belief, the API used in Defendant's ANDA Product is prepared by obtaining ISB by combining ISB acid with a sodium solution.

300. On information and belief, the API used in Defendant's ANDA Product is prepared by combining ISB acid with an aqueous sodium solution.

301. On information and belief, Defendant had knowledge of the ’080 Patent at least by on or about September 17, 2025.

302. Defendant has had constructive notice of the ’080 Patent as of its date of issuance on December 17, 2019.

303. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’080 Patent is not enjoined by this Court.

304. Defendant’s infringement of the ’080 Patent will cause Mylan Institutional substantial harm.

COUNT XIV
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the ’071 Patent

305. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

306. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’071 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

307. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

308. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

309. Mylan Institutional's ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

310. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

311. On information and belief, Defendant's ANDA Product is manufactured by the same or similar process as Mylan Institutional's ISB Product to produce a product comparable to the Mylan Institutional's ISB Product as the Reference Standard.

312. On information and belief, Defendant infringes at least claim 1 of the '071 Patent because the manufacture and/or preparation of Defendant's ANDA Product includes the process described in claim 1.

313. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent to provide ISB acid,

wherein said isoleuco acid is combined with said oxidizing agent in the absence of a strong acid.

314. On information and belief, the API used in Defendant's ANDA Product is prepared by recovering ISB acid.

315. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid.

316. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through recrystallization.

317. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through recrystallization in a solvent comprising an alcohol.

318. On information and belief, the API used in Defendant's ANDA Product is prepared by purifying recovered ISB acid through recrystallization in a solvent comprising an alcohol that is aqueous isopropyl alcohol.

319. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is not lead oxide, chloranil, or iron phthalocyanine/oxone.

320. On information and belief, the API used in Defendant's ANDA Product is prepared by using an oxidizing agent that is silver oxide.

321. On information and belief, the API used in Defendant's ANDA Product is prepared by combining isoleuco acid with an oxidizing agent in a polar solvent.

322. On information and belief, the API used in Defendant's ANDA Product is prepared by combining a suspension of isoleuco acid with an oxidizing agent to provide ISB acid, wherein said isoleuco acid is combined with said oxidizing agent in the absence of a strong acid, recovering said ISB, combining said ISB acid with a solvent to prepare an ISB acid mixture, and adjusting the pH of said ISB acid mixture.

323. On information and belief, the pH of the ISB acid mixture used to make the API used in in Defendant's ANDA Product is adjusted using a base.

324. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted to a pH greater than 6.0.

325. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted using an aqueous carbonate base.

326. On information and belief, the pH of the ISB acid mixture used to make the API used in Defendant's ANDA Product is adjusted using aqueous sodium carbonate.

327. On information and belief, Defendant had knowledge of the '071 Patent at least by on or about September 17, 2025.

328. Defendant has had constructive notice of the ’071 Patent as of its date of issuance on March 17, 2020.

329. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’071 Patent is not enjoined by this Court.

330. Defendant’s infringement of the ’071 Patent will cause Mylan Institutional substantial harm.

COUNT XV
Declaratory Judgment of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the ’086 Patent

331. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

332. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the ’086 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant’s ANDA Product.

333. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

334. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant’s ANDA

Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

335. Mylan Institutional's ISB API and Mylan Institutional's ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

336. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

337. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

338. On information and belief, Defendant infringes at least claim 1 of the '086 Patent because the API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

339. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

340. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

341. On information and belief, the API used in Defendant's ANDA Product contains between 0.5% and 1% impurities by HPLC.

342. On information and belief, the API used in Defendant's ANDA Product contains less than about 0.5% impurities by HPLC.

343. On information and belief, Defendant had knowledge of the '086 Patent at least by on or about September 17, 2025.

344. Defendant has had constructive notice of the '086 Patent as of its date of issuance on April 21, 2020.

345. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '086 Patent is not enjoined by this Court.

346. Defendant's infringement of the '086 Patent will cause Mylan Institutional substantial harm.

COUNT XVI
Declaratory Judgement of 35 U.S.C. §§ 271(a), (b), (c) and/or (g)
Infringement of the '580 Patent

347. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

348. Defendant infringes and/or will infringe under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) (either literally and/or under the doctrine of equivalents) the '580 Patent, including at least claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States Defendant's ANDA Product.

349. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

350. Because Mylan Institutional's ISB Product is listed as the Reference Standard for all ISB products, any new ISB product, including Defendant's ANDA Product, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

351. Mylan Institutional's ISB API and Mylan Institutional's ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

352. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

353. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

354. On information and belief, Defendant infringes at least claim 1 of the '580 Patent because the ISB API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

355. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

356. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

357. On information and belief, the API used in Defendant's ANDA Product has a purity of at least 99.5% by HPLC.

358. On information and belief, Defendant had knowledge of the '580 Patent at least by on or about September 17, 2025.

359. Defendant has had constructive notice of the '580 Patent as of its date of issuance on August 25, 2020.

360. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '580 Patent is not enjoined by this Court.

361. Defendant's infringement of the '580 Patent will cause Mylan Institutional substantial harm.

COUNT XVII
35 U.S.C. § 271(e) Infringement of the '050 Patent

362. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

363. Defendant has infringed under 35 U.S.C. § 271(e) (either literally and/or under the doctrine of equivalents) the '050 Patent, including at least claim 1, by submitting an ANDA to FDA for the drug claimed in the '050 Patent.

364. Upon receiving FDA approval for its ANDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation

into the United States of the ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '050 Patent unless enjoined by the Court.

365. Upon information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

366. Because Mylan Institutional's ISB Product is listed as the Reference Standard for ISB, any new ANDA for ISB, including Defendant's ANDA, must be compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

367. Mylan Institutional's ISB Product is at least 99% pure as determined by HPLC testing, as defined by the Patents-in-Suit.

368. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

369. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

370. On information and belief, Defendant infringes at least claim 1 of the ’050 Patent because the API used in Defendant’s ANDA Product has a purity of at least 99.0% by HPLC.

371. On information and belief, the API used in Defendant’s ANDA Product has a purity between 99.0% and 99.5% by HPLC.

372. On information and belief, the API used in Defendant’s ANDA Product has less than 20 ppm silver.

373. On information and belief, Defendant had knowledge of the ’050 Patent at least by on or about September 17, 2025.

374. Defendant has had constructive notice of the ’050 Patent as of its date of issuance on May 31, 2016.

375. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’050 Patent is not enjoined by this Court.

376. Defendant’s infringement of the ’050 Patent will cause Mylan Institutional substantial harm.

COUNT XVIII
35 U.S.C. § 271(e) Infringement of the ’086 Patent

377. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

378. Defendant has infringed under 35 U.S.C. § 271(e) (literally and/or under the doctrine of equivalents) the ’086 Patent, including at least claim 1, by submitting an ANDA to FDA for the drug claimed in the ’086 Patent.

379. Upon receiving FDA approval for its ANDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the ’086 Patent unless enjoined by the Court.

380. Upon information and belief, Defendant’s ANDA Application was submitted while Mylan Institutional’s ISB Product was listed as the Reference Standard for all ISB products.

381. Because Mylan Institutional’s ISB Product is listed as the Reference Standard for ISB, any new ANDA for ISB, including Defendant’s ANDA, must be compared to Mylan Institutional’s ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

382. Mylan Institutional’s ISB API and Mylan Institutional’s ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

383. Because comparison to Mylan Institutional’s ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in

Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

384. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

385. On information and belief, Defendant infringes at least claim 1 of the '086 Patent because the API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

386. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

387. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

388. On information and belief, the API used in Defendant's ANDA Product contains between 0.5% and 1% impurities by HPLC.

389. On information and belief, the API used in Defendant's ANDA Product contains less than about 0.5% impurities by HPLC.

390. On information and belief, Defendant had knowledge of the '086 Patent at least by on or about September 17, 2025.

391. Defendant has had constructive notice of the '086 Patent as of its date of issuance on April 21, 2020.

392. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant's infringement of the '086 Patent is not enjoined by this Court.

393. Defendant's infringement of the '086 Patent will cause Mylan Institutional substantial harm.

COUNT XIX
35 U.S.C. § 271(e) Infringement of the '580 Patent

394. Mylan Institutional repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

395. Defendant has infringed under 35 U.S.C. § 271(e) (literally and/or under the doctrine of equivalents) the '580 Patent, including at least claim 1, by submitting an ANDA to FDA for the drug claimed in the '580 Patent.

396. Upon receiving FDA approval for its ANDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '580 Patent unless enjoined by the Court.

397. On information and belief, Defendant's ANDA Application was submitted while Mylan Institutional's ISB Product was listed as the Reference Standard for all ISB products.

398. Because Mylan Institutional's ISB Product is listed as the Reference Standard for ISB, any new ANDA for ISB, including Defendant's ANDA, must be

compared to Mylan Institutional's ISB Product in *in vivo* bioequivalence studies required by FDA. *See* 21 CFR § 314.3(b).

399. Mylan Institutional's ISB API and Mylan Institutional's ISB Product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

400. Because comparison to Mylan Institutional's ISB Product as the Reference Standard product is required for FDA approval, the ISB API used in Defendant's ANDA Application for an ISB product is most likely to have at least the same purity as the ISB API used in Mylan Institutional's ISB Product.

401. On information and belief, Defendant's ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB Product.

402. On information and belief, Defendant infringes at least claim 1 of the '580 Patent because the ISB API used in Defendant's ANDA Product has a purity of at least 99.0% by HPLC.

403. On information and belief, the API used in Defendant's ANDA Product has a purity between 99.0% and 99.5% by HPLC.

404. On information and belief, the API used in Defendant's ANDA Product has less than 20 ppm silver.

405. On information and belief, the API used in Defendant's ANDA Product has a purity of at least 99.5% by HPLC.

406. On information and belief, Defendant had knowledge of the ’580 Patent at least by on or about September 17, 2025.

407. Defendant has had constructive notice of the ’580 Patent as of its date of issuance on August 25, 2020.

408. Mylan Institutional will be substantially and irreparably damaged and harmed if Defendant’s infringement of the ’580 Patent is not enjoined by this Court.

409. Defendant’s infringement of the ’580 Patent will cause Mylan Institutional substantial harm.

PRAYER FOR RELIEF

WHEREFORE, Mylan Institutional prays that the Court enter judgment in its favor and against Defendant as follows:

A. A judgment that Defendant has infringed or will infringe the ’992 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

B. A judgment that Defendant has infringed or will infringe the ’616 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

C. A judgment that Defendant has infringed or will infringe the ’050 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

D. A judgment that Defendant has infringed or will infringe the ’888 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

E. A judgment that Defendant has infringed or will infringe the ’080 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

F. A judgment that Defendant has infringed or will infringe the ’071 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

G. A judgment that Defendant has infringed or will infringe the ’086 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

H. A judgment that Defendant has infringed or will infringe the ’580 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendant’s ANDA Product;

I. A judgment that Defendant has infringed or will infringe the ’050 Patent under 35 U.S.C. § 271(e) by submitting Defendant’s ANDA Application;

J. A judgment that Defendant has infringed or will infringe the ’086 Patent under 35 U.S.C. § 271(e) by submitting Defendant’s ANDA Application;

K. A judgment that Defendant has infringed or will infringe the ’580 Patent under 35 U.S.C. § 271(e) by submitting Defendant’s ANDA Application;

L. A judgment that the ’992 Patent is valid and enforceable;

M. A judgment that the ’616 Patent is valid and enforceable;

N. A judgment that the ’050 Patent is valid and enforceable;

O. A judgment that the ’888 Patent is valid and enforceable;

P. A judgment that the ’080 Patent is valid and enforceable;

Q. A judgment that the ’071 Patent is valid and enforceable;

R. A judgment that the ’086 Patent is valid and enforceable;

S. A judgment that the ’580 Patent is valid and enforceable;

T. A judgment ordering that the effective date of any FDA approval of Defendant’s ANDA shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity to which Mylan Institutional is or may become entitled;

U. An order preliminarily and/or permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from infringing, contributorily infringing, or inducing others to infringe the Patents-in-Suit, including engaging in the manufacture, use, offer to sell, and selling in the United States, and/or importation into the United States, of Defendant’s ANDA Product until the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity to which Mylan Institutional is or may become entitled;

V. A judgment awarding Mylan Institutional damages or other monetary relief under 35 U.S.C. § 281 as appropriate;

W. A judgment ordering Defendant to pay damages to Mylan Institutional to compensate for its infringement of each of the Patents-in-Suit, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with pre-judgment and post-judgment interest on the damages awarded, with all of these damages to be enhanced in an amount up to treble the amount of the calculated compensatory damages as justified under 35 U.S.C. § 284 as appropriate;

X. A judgment declaring that infringement of the Patents-in-Suit was willful, and awarding treble damages under 35 U.S.C. § 284 as appropriate;

Y. A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Mylan Institutional be awarded reasonable attorneys' fees and costs; and

Z. Such further and other relief as this Court may deem just and proper.

Dated: October 13, 2025

Respectfully submitted,

/s/ Steven G. Hill

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