

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC, )  
BESINS HEALTHCARE INC., and BESINS )  
HEALTHCARE LUXEMBOURG SARL, )  
)  
Plaintiffs, ) C.A. No. \_\_\_\_\_  
)  
v. )  
)  
AMNEAL PHARMACEUTICALS, LLC, )  
)  
Defendant. )

**COMPLAINT**

Plaintiffs Unimed Pharmaceuticals, LLC (“Unimed”), Besins Healthcare Inc. (“Besins”), and Besins Healthcare Luxembourg SARL (“Besins Luxembourg”) (collectively “Plaintiffs”) allege as follows for their complaint against defendant Amneal Pharmaceuticals, LLC (“Amneal” or “Defendant”).

**THE PARTIES**

1. Plaintiff Unimed Pharmaceuticals, LLC, which is a wholly-owned subsidiary of AbbVie Inc., is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

2. Plaintiff Besins Healthcare Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 607 Herndon Parkway, Suite 110, Herndon, Virginia 20170.

3. Plaintiff Besins Healthcare Luxembourg SARL is a Luxembourgian company with its principal place of business at 2-8 rue Julien Vesque, L-2668 Luxembourg.

4. On information and belief, defendant Amneal Pharmaceuticals, LLC is a Delaware limited liability corporation with its principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, NJ 08807.

#### **NATURE OF THE ACTION**

5. This is an action for infringement of U.S. Patent No. 6,503,894 (“the ’894 Patent”), titled “Pharmaceutical Composition and Method for Treating Hypogonadism”; U.S. Patent No. 8,729,057 (“the ’057 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 8,741,881 (“the ’881 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 8,754,070 (“the ’070 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 8,759,329 (“the ’329 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 9,125,816 (“the ’816 Patent”), titled “Pharmaceutical Composition and Method for Treating Hypogonadism”; and U.S. Patent No. 9,132,089 (“the ’089 Patent”), titled “Pharmaceutical Composition and Method for Treating Hypogonadism” (collectively “the patents-in-suit”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 207373 submitted by Amneal to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of AbbVie’s AndroGel<sup>®</sup> (testosterone gel) 1.62% (Amneal’s “Generic AndroGel<sup>®</sup>”), which act constitutes an act of infringement under 35 U.S.C. § 271(e)(2) that is subject to the provisions of the Hatch Waxman Act.

#### **JURISDICTION AND VENUE**

6. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Amneal, because, *inter alia*, Amneal is a Delaware limited liability corporation and it maintains systematic and continuous contacts with Delaware.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

### **FACTUAL BACKGROUND**

#### **A. The '894 Patent**

10. On January 7, 2003, the '894 Patent was duly and legally issued to Unimed Pharmaceuticals, Inc., and Laboratoires Besins-Iscovesco as co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '894 Patent is attached as Exhibit A to this Complaint.

11. In 2007, Unimed Pharmaceuticals, Inc. changed its name to Unimed Pharmaceuticals, LLC.

12. In 2004, Laboratoires Besins-Iscovesco changed its name to Besins-Iscovesco U.S., Inc. In 2008, Besins-Iscovesco U.S., Inc. changed its name to Besins Healthcare Inc.

13. Unimed Pharmaceuticals, LLC and Besins Healthcare Inc. are the owners of all right, title, and interest in the '894 Patent.

14. The expiration date of the '894 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") is August 30, 2020.

#### **B. The '057 Patent**

15. On May 20, 2014, the '057 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-

assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '057 Patent is attached as Exhibit B to this Complaint.

16. The expiration date of the '057 Patent listed in the Orange Book is October 12, 2026.

**C. The '881 Patent**

17. On June 3, 2014, the '881 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '881 Patent is attached as Exhibit C to this Complaint.

18. The expiration date of the '881 Patent listed in the Orange Book is October 12, 2026.

**D. The '070 Patent**

19. On June 17, 2014, the '070 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '070 Patent is attached as Exhibit D to this Complaint.

20. The expiration date of the '070 Patent listed in the Orange Book is October 12, 2026.

**E. The '329 Patent**

21. On June 24, 2014, the '329 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '329 Patent is attached as Exhibit E to this Complaint.

22. The expiration date of the '329 Patent listed in the Orange Book is October 12, 2026.

**F. The '816 Patent**

23. On September 8, 2015, the '816 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Inc. as co-applicants and co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '816 Patent is attached as Exhibit F to this Complaint.

24. The expiration date of the '816 Patent listed in the Orange Book is August 30, 2020.

**G. The '089 Patent**

25. On September 15, 2015, the '089 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Inc. as co-applicants and co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '089 Patent is attached as Exhibit G to this Complaint.

26. The expiration date of the '089 Patent listed in the Orange Book is August 30, 2020.

**H. AndroGel®**

27. AbbVie is the registered holder of approved NDA No. 22-309 for the manufacture and sale of testosterone gel, 1.62%, a prescription medicine used to treat adult males for conditions associated with a deficiency or absence of endogenous testosterone. AbbVie markets and sells testosterone gel, 1.62% in the United States under the trade name AndroGel®. AndroGel® 1.62% was approved by the FDA on April 29, 2011.

28. The '894 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '894 Patent cover that product.

29. The '057 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '057 Patent cover that product.

30. The '881 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '881 Patent cover that product.

31. The '070 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '070 Patent cover that product.

32. The '329 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '329 Patent cover that product.

33. The '816 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '816 Patent cover that product.

34. The '089 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '089 Patent cover that product.

#### **I. Infringement by Amneal**

35. On information and belief, Amneal has submitted ANDA No. 207373 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market Amneal's Generic AndroGel<sup>®</sup> prior to the expiration date of the patents-in-suit.

36. On information and belief, Amneal intends to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of Amneal's Generic AndroGel<sup>®</sup> promptly upon receiving FDA approval to do so.

37. Plaintiffs received a letter dated September 10, 2015 (the “Notice Letter”) signed on behalf of Amneal stating that ANDA No. 207373 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Amneal’s Generic AndroGel<sup>®</sup> before the expiration of the ’894 Patent, the ’057 Patent, the ’881 Patent, the ’070 Patent, and the ’329 Patent. In the Notice Letter, Amneal identified the ’894 Patent, the ’057 Patent, the ’881 Patent, the ’070 Patent, or the ’329 Patent “as being unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 207373 has been submitted by Amneal.”

38. On information and belief, the submission of ANDA No. 207373 to the FDA constitutes infringement by Amneal of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Amneal’s Generic AndroGel<sup>®</sup> would infringe the patents-in-suit under 35 U.S.C. § 271(a)–(c).

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

### **CLAIMS FOR RELIEF**

#### **COUNT I**

#### **(DIRECT INFRINGEMENT OF U.S. PATENT NO. 6,503,894)**

40. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 39 above as though fully restated herein.

41. Pursuant to 35 U.S.C. § 271(e)(2), Amneal’s submission of ANDA No. 207373 to the FDA seeking approval of Amneal’s Generic AndroGel<sup>®</sup> was an act of infringement of the ’894 Patent by Amneal.

42. If allowed on the market, Amneal's Generic AndroGel<sup>®</sup> and the use thereof will infringe the '894 Patent under 35 U.S.C. § 271(a).

43. Unless Amneal is enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Amneal's infringement of the '894 Patent. Unimed and Besins do not have an adequate remedy at law.

44. Amneal's infringement of the '894 Patent is willful and made with knowledge of the '894 Patent.

**COUNT II**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 6,503,894)**

45. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

46. Amneal has knowledge of the '894 Patent.

47. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '894 patent.

48. The use of Amneal's Generic AndroGel<sup>®</sup> by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '894 patent.

49. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '894 patent.

50. Any use of Amneal's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Amneal in their proposed label for Amneal's Generic AndroGel<sup>®</sup>.

51. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '894 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '894 patent.

52. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

53. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '894 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '894 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT III**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 6,503,894)**

54. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 53 above as though fully restated herein.

55. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

56. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '894 patent.

57. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '894 patent.

58. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT IV**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 6,503,894)**

59. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 58 above as though fully restated herein.

60. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '894 patent.

61. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

62. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '894 Patent under 35 U.S.C. § 271(a)-(c).

63. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal disputes that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '894 Patent.

64. There is a justiciable case or controversy between Unimed and Besins and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '894 Patent.

65. If Amneal's infringement of the '894 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT V**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,729,057)**

66. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 65 above as though fully restated herein.

67. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '057 Patent by Amneal

68. If allowed on the market, Amneal's Generic AndroGel<sup>®</sup> will infringe the '057 Patent under 35 U.S.C. § 271(a).

69. Unless Amneal is enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Amneal's infringement of the '057 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

70. Amneal's infringement of the '057 Patent is willful and made with knowledge of the '057 Patent.

**COUNT VI**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,729,057)**

71. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 70 above as though fully restated herein.

72. Amneal has knowledge of the '057 Patent.

73. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '057 patent.

74. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '057 patent.

75. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '057 patent.

76. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '057 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '057 patent.

77. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

78. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '057 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '057 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT VII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,729,057)**

79. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 78 above as though fully restated herein.

80. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

81. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '057 patent.

82. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '057 patent.

83. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT VIII**

**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,729,057)**

84. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 83 above as though fully restated herein.

85. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '057 patent.

86. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

87. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '057 Patent under 35 U.S.C. § 271(a)–(c).

88. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal disputes that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '057 Patent.

89. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '057 Patent.

90. If Amneal's infringement of the '057 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT IX**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,741,881)**

91. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 90 above as though fully restated herein.

92. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '881 Patent by Amneal

93. If allowed on the market, the use of Amneal's Generic AndroGel<sup>®</sup> will infringe the '881 Patent under 35 U.S.C. § 271(a).

94. Unless Amneal is enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Amneal's infringement of the '881 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

95. Amneal's infringement of the '881 Patent is willful and made with knowledge of the '881 Patent.

**COUNT X**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,741,881)**

96. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 95 above as though fully restated herein.

97. Amneal has knowledge of the '881 Patent.

98. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '881 patent.

99. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '881 patent.

100. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '881 patent.

101. Any use of Amneal's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Amneal in their proposed label for Amneal's Generic AndroGel<sup>®</sup>.

102. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '881 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '881 patent.

103. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

104. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '881 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims

of the '881 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT XI**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,741,881)**

105. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 104 above as though fully restated herein.

106. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

107. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '881 patent.

108. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '881 patent.

109. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT XII**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,741,881)**

110. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 109 above as though fully restated herein.

111. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '881 Patent.

112. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

113. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '881 Patent under 35 U.S.C. § 271(a)–(c).

114. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal disputes that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '881 Patent.

115. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '881 Patent.

116. If Amneal's infringement of the '881 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XIII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,754,070)**

117. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 116 above as though fully restated herein.

118. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '070 Patent by Amneal

119. If allowed on the market, Amneal's Generic AndroGel<sup>®</sup> will infringe the '070 Patent under 35 U.S.C. § 271(a).

120. Unless Amneal is enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Amneal's infringement of the '070 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

121. Amneal's infringement of the '070 Patent is willful and made with knowledge of the '070 Patent.

**COUNT XIV**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,754,070)**

122. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 121 above as though fully restated herein.

123. Amneal has knowledge of the '070 Patent.

124. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '070 patent.

125. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '070 patent.

126. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '070 patent.

127. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '070 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '070 patent.

128. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

129. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly

infringes one or more claims of the '070 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '070 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT XV**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,754,070)**

130. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 129 above as though fully restated herein.

131. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

132. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '070 patent.

133. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '070 patent.

134. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT XVI**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,754,070)**

135. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 134 above as though fully restated herein.

136. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '070 Patent.

137. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United

States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

138. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '070 Patent under 35 U.S.C. § 271(a)–(c).

139. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal disputes that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '070 Patent.

140. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '070 Patent.

141. If Amneal's infringement of the '070 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XVII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,759,329)**

142. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 141 above as though fully restated herein.

143. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '329 Patent by Amneal

144. If allowed on the market, Amneal's Generic AndroGel<sup>®</sup> will infringe the '329 Patent under 35 U.S.C. § 271(a).

145. Unless Amneal is enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Amneal's infringement of the '329 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

146. Amneal's infringement of the '329 Patent is willful and made with knowledge of the '329 Patent.

**COUNT XVIII**

(Inducement to Infringe U.S. Patent No. 8,759,329)

147. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 146 above as though fully restated herein.

148. Amneal has knowledge of the '329 Patent.

149. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '329 patent.

150. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '329 patent.

151. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '329 patent.

152. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '329 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '329 patent.

153. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

154. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '329 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '329 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT XIX**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,759,329)**

155. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 154 above as though fully restated herein.

156. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

157. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '329 patent.

158. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '329 patent.

159. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT XX**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,759,329)**

160. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 159 above as though fully restated herein.

161. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '329 patent.

162. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

163. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '329 Patent under 35 U.S.C. § 271(a)-(c).

164. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal disputes that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '329 Patent.

165. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '329 Patent.

166. If Amneal's infringement of the '329 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXI**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,125,816)**

167. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 166 above as though fully restated herein.

168. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '816 Patent by Amneal

169. If allowed on the market, the use of Amneal's Generic AndroGel<sup>®</sup> will infringe the '816 Patent under 35 U.S.C. § 271(a).

170. Unless Amneal is enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Amneal's infringement of the '816 Patent. Unimed and Besins do not have an adequate remedy at law.

171. Amneal's infringement of the '816 Patent is willful and made with knowledge of the '816 Patent.

**COUNT XXII**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 9,125,816)**

172. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 171 above as though fully restated herein.

173. Amneal has knowledge of the '816 Patent.

174. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '816 patent.

175. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '816 patent.

176. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '816 patent.

177. Any use of Amneal's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Amneal in their proposed label for Amneal's Generic AndroGel<sup>®</sup>.

178. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '816 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '816 patent.

179. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

180. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '816 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '816 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT XXIII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 9,125,816)**

181. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 180 above as though fully restated herein.

182. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

183. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '816 patent.

184. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '816 patent.

185. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT XXIV**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 9,125,816)**

186. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 185 above as though fully restated herein.

187. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '816 patent.

188. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

189. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '816 Patent under 35 U.S.C. § 271(a)-(c).

190. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal will dispute that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '816 Patent.

191. There is a justiciable case or controversy between Unimed and Besins and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '816 Patent.

192. If Amneal's infringement of the '816 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXV**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,132,089)**

193. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 192 above as though fully restated herein.

194. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 207373 to the FDA seeking approval of Amneal's Generic AndroGel<sup>®</sup> was an act of infringement of the '089 Patent by Amneal

195. If allowed on the market, the use of Amneal's Generic AndroGel<sup>®</sup> will infringe the '089 Patent under 35 U.S.C. § 271(a).

196. Unless Amneal is enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Amneal's infringement of the '089 Patent. Unimed and Besins do not have an adequate remedy at law.

197. Amneal's infringement of the '089 Patent is willful and made with knowledge of the '089 Patent.

**COUNT XXVI**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 9,132,089)**

198. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 197 above as though fully restated herein.

199. Amneal has knowledge of the '089 Patent.

200. The use of Amneal's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '089 patent.

201. The use of Amneal's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '089 patent.

202. Amneal's proposed label for Amneal's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use Amneal's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '089 patent.

203. Any use of Amneal's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Amneal in their proposed label for Amneal's Generic AndroGel<sup>®</sup>.

204. If Amneal's Generic AndroGel<sup>®</sup> is approved by the FDA, Amneal will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '089 patent. Since at least the date of the Notice Letter, Amneal has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '089 patent.

205. Amneal intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

206. Upon FDA approval of ANDA No. 207373, Amneal will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Amneal's proposed label, to use Amneal's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '089 patent. Thus, Amneal will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims

of the '089 patent, and Amneal will affirmatively and specifically intend to cause direct infringement.

**COUNT XXVII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 9,132,089)**

207. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 206 above as though fully restated herein.

208. If ANDA No. 207373 is approved, Amneal intends to and will offer to sell, sell, or import into the United States Amneal's Generic AndroGel<sup>®</sup>.

209. Amneal's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '089 patent.

210. On information and belief, Amneal has had and continues to have knowledge that Amneal's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '089 patent.

211. On information and belief, Amneal has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic AndroGel<sup>®</sup>.

**COUNT XXVIII**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 9,132,089)**

212. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 211 above as though fully restated herein.

213. On information and belief, Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic AndroGel<sup>®</sup> prior to expiration of the '089 patent.

214. On information and belief, Amneal intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 207373, unless enjoined by the Court.

215. On information and belief, Amneal's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> will constitute infringement of the '089 Patent under 35 U.S.C. § 271(a)–(c).

216. On information and belief, based on positions taken by Amneal in the Notice Letter, Amneal will dispute that Amneal's Generic AndroGel<sup>®</sup> infringes any valid claim of the '089 Patent.

217. There is a justiciable case or controversy between Unimed and Besins and Amneal regarding whether Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic AndroGel<sup>®</sup> according to ANDA No. 207373 will infringe one or more claims of the '089 Patent.

218. If Amneal's infringement of the '089 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. For a declaration that Amneal has infringed the patents-in-suit;
- B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Amneal of Amneal's Generic AndroGel<sup>®</sup> will infringe the patents-in-suit;
- C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of ANDA No. 207373 be no earlier than the expiration date of the patents-in-suit, including any extensions or adjustments;
- D. For an order enjoining Amneal and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them

and on their behalf, or acting in concert with them directly or indirectly, from infringing the patents-in-suit;

- E. For a determination that Amneal's infringement is willful;
- F. For a determination that this is an exceptional case under 35 U.S.C. § 285; and
- G. For such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

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