

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC,)	
BESINS HEALTHCARE INC., and BESINS)	
HEALTHCARE LUXEMBOURG SARL,)	
)	
Plaintiffs,)	
v.)	C.A. No. _____
)	
TWi PHARMACEUTICALS, INC.,)	
)	
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 TWi Pharmaceuticals, Inc. (“TWi” 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 TWi Pharmaceuticals, Inc. is a Taiwan corporation with its principal place of business at 4F, No. 41, Lane 221, Kang Chien Rd., Nei Hu Dis., Taipei 114, Taiwan.

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. 209390 submitted by TWi to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of AbbVie’s AndroGel[®] (testosterone gel) 1.62% (TWi’s “Generic AndroGel[®]”), 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.

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

PERSONAL JURISDICTION

9. This Court has personal jurisdiction over TWi by virtue of, *inter alia*, its systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of their ANDA, as set forth below, and for other reasons that will be developed and presented to the Court if personal jurisdiction is challenged.

10. On information and belief, TWi intends to sell TWi's Generic AndroGel[®] through retail drug outlets in Delaware.

11. On information and belief, TWi, directly or through related companies, is responsible for sales of TWi products to customers in Delaware, from which TWi derives substantial revenue.

12. On information and belief, TWi, directly or through related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over TWi in Delaware on the basis of general jurisdiction.

13. On information and belief, TWi develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products, including generic versions of Aricept[®], Megace[®], and ProCardia[®] XL. On information and belief, TWi derives substantial revenue from the sale of products to customers in Delaware.

14. On information and belief, TWi's wholly owned subsidiary TWI Pharmaceuticals, USA, Inc. ("TWi-USA") is a corporation organized and existing under the laws of the State of Delaware. On information and belief, TWi-USA acts at the direction, under the control, and for the benefit of TWi, and on this basis TWi has systematic contact with Delaware which satisfies

due process and confers personal jurisdiction over TWi in Delaware on the basis of general jurisdiction.

15. On information and belief, TWi sent to Plaintiffs a letter dated August 3, 2016 (the “Notice Letter”) stating that ANDA No. 209390 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale, or importation of TWi’s Generic AndroGel[®] before the expiration of the patents-in-suit. The act of sending this letter to AbbVie Inc., a Delaware corporation, and Besins Healthcare Inc., also a Delaware corporation, confers personal jurisdiction over TWi in Delaware on the basis of specific jurisdiction.

16. On information and belief, TWi’s filing of ANDA No. 209390 is tightly tied, in purpose and planned effect, to the deliberate making of sales of TWi’s Generic AndroGel[®] in Delaware, and on this basis satisfies due process and confers personal jurisdiction over TWi in Delaware on the basis of specific jurisdiction. *See Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016).

17. As further evidence of personal jurisdiction, TWi has previously availed itself of this forum by submitting to the jurisdiction of this court and asserting counterclaims in this judicial district. *See Endo Pharmaceuticals Inc.. et al. v. TWi Pharmaceuticals, Inc. et al.*, C.A. No. 12-848-GMS (D. Del.).

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over TWi, this Court may exercise jurisdiction over TWi pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs’ claims arise under federal law; (b) TWi is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) TWi has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products

distributed throughout the United States, such that this Court's exercise of jurisdiction over TWI satisfies due process.

FACTUAL BACKGROUND

A. The '894 Patent

19. 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.

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

21. 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.

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

23. 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

24. 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.

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

C. The '881 Patent

26. 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.

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

D. The '070 Patent

28. 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.

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

E. The '329 Patent

30. 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.

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

F. The '816 Patent

32. 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.

33. The expiration date of the '816 Patent listed in the Orange Book is August 30, 2020. AndroGel[®] has received pediatric exclusivity of six months beginning from the expiration of the '816 patent.

G. The '089 Patent

34. 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.

35. The expiration date of the '089 Patent listed in the Orange Book is August 30, 2020. AndroGel[®] has received pediatric exclusivity of six months beginning from the expiration of the '089 patent.

H. AndroGel[®]

36. 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.

37. The '894 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '894 Patent cover that product.

38. The '057 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '057 Patent cover that product.

39. The '881 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '881 Patent cover that product.

40. The '070 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '070 Patent cover that product.

41. The '329 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '329 Patent cover that product.

42. The '816 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '816 Patent cover that product.

43. The '089 Patent is listed in the Orange Book in conjunction with AndroGel[®] (testosterone gel) 1.62%, and the claims of the '089 Patent cover that product.

I. Infringement by TWi

44. On information and belief, TWi has submitted ANDA No. 209390 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market TWi's Generic AndroGel[®] prior to the expiration date of the patents-in-suit.

45. On information and belief, TWi intends to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of TWi's Generic AndroGel[®] promptly upon receiving FDA approval to do so.

46. Plaintiffs received a letter dated August 3, 2016 (the "Notice Letter") signed on behalf of TWi stating that ANDA No. 209390 includes a Paragraph IV Certification to obtain

approval to engage in the commercial manufacture, use, sale or importation of TWi's Generic AndroGel[®] before the expiration of the patents-in-suit. In the Notice Letter, TWi identified the patents-in-sit "as being unenforceable, invalid, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in [ANDA No. 209390]."

47. On information and belief, the submission of ANDA No. 209390 to the FDA constitutes infringement by TWi 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 TWi's Generic AndroGel[®] would infringe the patents-in-suit under 35 U.S.C. § 271(a)–(c).

48. 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)

49. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '894 Patent by TWi.

51. If allowed on the market, TWi's Generic AndroGel[®] and the use thereof will infringe the '894 Patent under 35 U.S.C. § 271(a), including, at least, claim 31, which recites, *inter alia*, a method comprising administering a pharmaceutical composition containing testosterone to a human subject in need thereof.

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

53. TWi'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)

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

55. TWi has knowledge of the '894 Patent.

56. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '894 patent, including, at least, claim 31.

57. The use of TWi's Generic AndroGel[®] 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.

58. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '894 patent.

59. Any use of TWi's Generic AndroGel[®] by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by TWi in its proposed label for TWi's Generic AndroGel[®].

60. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or

at least with willful blindness, of the fact that the induced acts would constitute infringement of the '894 patent.

61. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

62. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '894 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

63. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 62 above as though fully restated herein.

64. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel[®].

65. TWi's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '894 patent, including, at least, claim 31.

66. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel[®] is especially adapted for a use that infringes the '894 patent.

67. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel[®].

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

68. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 67 above as though fully restated herein.

69. On information and belief, TWi has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic AndroGel[®] prior to expiration of the '894 patent.

70. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

71. On information and belief, TWi's commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic AndroGel[®] will constitute infringement of the '894 Patent under 35 U.S.C. § 271(a)–(c).

72. On information and belief, based on positions taken by TWi in the Notice Letter, TWi disputes that TWi's Generic AndroGel[®] infringes any valid claim of the '894 Patent.

73. There is a justiciable case or controversy between Unimed and Besins and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '894 Patent.

74. If TWi'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)

75. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 74 above as though fully restated herein.

76. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '057 Patent by TWi.

77. If allowed on the market, TWi's Generic AndroGel[®] will infringe the '057 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a gel pharmaceutical composition containing testosterone.

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

79. TWi'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)

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

81. TWi has knowledge of the '057 Patent.

82. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '057 patent, including, at least, claim 1.

83. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '057 patent.

84. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '057 patent.

85. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '057 patent.

86. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

87. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '057 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

88. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 87 above as though fully restated herein.

89. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel[®].

90. TWi's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '057 patent, including, at least, claim 1.

91. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel[®] is especially adapted for a use that infringes the '057 patent.

92. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel[®].

COUNT VIII

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

93. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 92 above as though fully restated herein.

94. On information and belief, TWi has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic AndroGel[®] prior to expiration of the '057 patent.

95. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

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

97. On information and belief, based on positions taken by TWi in the Notice Letter, TWi disputes that TWi's Generic AndroGel[®] infringes any valid claim of the '057 Patent.

98. There is a justiciable case or controversy between Unimed and Besins Luxembourg and TWi regarding whether TWi's commercial manufacture, use, sale, offer for

sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '057 Patent.

99. If TWi'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)

100. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 99 above as though fully restated herein.

101. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '881 Patent by TWi.

102. If allowed on the market, the use of TWi's Generic AndroGel[®] will infringe the '881 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a method comprising treating hypogonadism in a human male with a pharmaceutical composition containing testosterone.

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

104. TWi'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)

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

106. TWi has knowledge of the '881 Patent.

107. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '881 patent.

108. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '881 patent, including, at least, claim 1.

109. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '881 patent.

110. Any use of TWi's Generic AndroGel[®] by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by TWi in its proposed label for TWi's Generic AndroGel[®].

111. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '881 patent.

112. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

113. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '881 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

114. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 113 above as though fully restated herein.

115. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel®.

116. TWi's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '881 patent, including, at least, claim 1.

117. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel® is especially adapted for a use that infringes the '881 patent.

118. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel®.

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

119. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 118 above as though fully restated herein.

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

121. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

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

123. On information and belief, based on positions taken by TWi in the Notice Letter, TWi disputes that TWi's Generic AndroGel[®] infringes any valid claim of the '881 Patent.

124. There is a justiciable case or controversy between Unimed and Besins Luxembourg and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '881 Patent.

125. If TWi'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)

126. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 125 above as though fully restated herein.

127. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '070 Patent by TWi.

128. If allowed on the market, TWi's Generic AndroGel[®] will infringe the '070 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a gel pharmaceutical composition containing testosterone.

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

130. TWi'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)

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

132. TWi has knowledge of the '070 Patent.

133. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '070 patent, including, at least, claim 1.

134. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '070 patent.

135. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '070 patent.

136. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '070 patent.

137. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

138. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly

infringes one or more claims of the '070 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

139. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 138 above as though fully restated herein.

140. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel®.

141. TWi's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '070 patent, including, at least, claim 1.

142. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel® is especially adapted for a use that infringes the '070 patent.

143. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel®.

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

144. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 143 above as though fully restated herein.

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

146. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's

Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

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

148. On information and belief, based on positions taken by TWi in the Notice Letter, TWi disputes that TWi's Generic AndroGel[®] infringes any valid claim of the '070 Patent.

149. There is a justiciable case or controversy between Unimed and Besins Luxembourg and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '070 Patent.

150. If TWi'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)

151. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 150 above as though fully restated herein.

152. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '329 Patent by TWi.

153. If allowed on the market, TWi's Generic AndroGel[®] will infringe the '329 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a gel pharmaceutical composition containing testosterone.

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

155. TWi'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)

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

157. TWi has knowledge of the '329 Patent.

158. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '329 patent, including, at least, claim 1.

159. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '329 patent.

160. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '329 patent.

161. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '329 patent.

162. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

163. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '329 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

164. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 163 above as though fully restated herein.

165. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel[®].

166. TWi's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '329 patent, including, at least, claim 1.

167. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel[®] is especially adapted for a use that infringes the '329 patent.

168. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel[®].

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

169. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 168 above as though fully restated herein.

170. On information and belief, TWi has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic AndroGel[®] prior to expiration of the '329 patent.

171. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

172. On information and belief, TWi's commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic AndroGel[®] will constitute infringement of the '329 Patent under 35 U.S.C. § 271(a)–(c).

173. On information and belief, based on positions taken by TWi in the Notice Letter, TWi disputes that TWi's Generic AndroGel[®] infringes any valid claim of the '329 Patent.

174. There is a justiciable case or controversy between Unimed and Besins Luxembourg and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '329 Patent.

175. If TWi'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)

176. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 175 above as though fully restated herein.

177. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '816 Patent by TWi.

178. If allowed on the market, the use of TWi's Generic AndroGel[®] will infringe the '816 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a method of administering testosterone to human males for treating hypogonadism wherein the administration is sufficient to reach the bloodstream of human males to achieve the claimed pharmacokinetic profile.

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

180. TWi'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)

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

182. TWi has knowledge of the '816 Patent.

183. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '816 patent, including, at least, claim 1.

184. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '816 patent.

185. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '816 patent.

186. Any use of TWi's Generic AndroGel[®] by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by TWi in its proposed label for TWi's Generic AndroGel[®].

187. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '816 patent.

188. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

189. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through TWi's proposed label, to use TWi's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '816 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

190. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 189 above as though fully restated herein.

191. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel®.

192. TWi's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '816 patent, including, at least, claim 1.

193. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel® is especially adapted for a use that infringes the '816 patent.

194. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel®.

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

195. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 194 above as though fully restated herein.

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

197. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

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

199. On information and belief, based on positions taken by TWi in the Notice Letter, TWi will dispute that TWi's Generic AndroGel® infringes any valid claim of the '816 Patent.

200. There is a justiciable case or controversy between Unimed and Besins and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '816 Patent.

201. If TWi'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)

202. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 201 above as though fully restated herein.

203. Pursuant to 35 U.S.C. § 271(e)(2), TWi's submission of ANDA No. 209390 to the FDA seeking approval of TWi's Generic AndroGel[®] was an act of infringement of the '089 Patent by TWi.

204. If allowed on the market, the use of TWi's Generic AndroGel[®] will infringe the '089 Patent under 35 U.S.C. § 271(a), including, at least, claim 1, which recites, *inter alia*, a method of treating hypogonadism in a human male by once a day application of a pharmaceutical composition containing testosterone.

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

206. TWi'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)

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

208. TWi has knowledge of the '089 Patent.

209. The use of TWi's Generic AndroGel[®] is covered by one or more claims of the '089 patent, including, at least, claim 1.

210. The use of TWi's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '089 patent.

211. TWi's proposed label for TWi's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use TWi's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '089 patent.

212. Any use of TWi's Generic AndroGel[®] by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by TWi in its proposed label for TWi's Generic AndroGel[®].

213. If TWi's Generic AndroGel[®] is approved by the FDA, TWi 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, TWi has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '089 patent.

214. TWi intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

215. Upon FDA approval of ANDA No. 209390, TWi will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients,

through TWi's proposed label, to use TWi's Generic AndroGel® in a manner that directly infringes one or more claims of the '089 patent. Thus, TWi 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 TWi will affirmatively and specifically intend to cause direct infringement.

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

216. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 215 above as though fully restated herein.

217. If ANDA No. 209390 is approved, TWi intends to and will offer to sell, sell, or import into the United States TWi's Generic AndroGel®.

218. TWi's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '089 patent, including, at least, claim 1.

219. On information and belief, TWi has had and continues to have knowledge that TWi's Generic AndroGel® is especially adapted for a use that infringes the '089 patent.

220. On information and belief, TWi has had and continues to have knowledge that there is no substantial non-infringing use for TWi's Generic AndroGel®.

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

221. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 220 above as though fully restated herein.

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

223. On information and belief, TWi intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 209390, unless enjoined by the Court.

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

225. On information and belief, based on positions taken by TWi in the Notice Letter, TWi will dispute that TWi's Generic AndroGel[®] infringes any valid claim of the '089 Patent.

226. There is a justiciable case or controversy between Unimed and Besins and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic AndroGel[®] according to ANDA No. 209390 will infringe one or more claims of the '089 Patent.

227. If TWi'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 TWi has infringed the patents-in-suit;
- B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by TWi of TWi's Generic AndroGel[®] 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. 209390 be no earlier than the expiration date of the patents-in-suit, including any extensions or adjustments;

D. For an order enjoining TWi 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 TWi'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

OF COUNSEL:

Calvin P. Griffith
JONES DAY
North Point
901 Lakeside Ave.
Cleveland, OH 44114

Jason G. Winchester
JONES DAY
77 W. Wacker Dr.
Chicago, IL 60601

Gaspar J. La Rosa
Kenneth S. Canfield
JONES DAY
250 Vesey St.
New York, NY 10281
*Attorneys for Unimed
Pharmaceuticals, LLC*

Liane M. Peterson
Andrew R. Cheslock
FOLEY & LARDNER LLP
3000 K Street, N.W., Suite 600
Washington, DC 20007-5109
*Attorneys for Besins Healthcare Inc. and
Besins Healthcare Luxembourg SARL*

/s/ Mary B. Graham

Mary B. Graham (#2256)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
skraftschik@mnat.com

*Attorneys for Unimed Pharmaceuticals, LLC,
Besins Healthcare Inc., and Besins Healthcare
Luxembourg SARL*

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