

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. _____
)
PERRIGO COMPANY, PERRIGO ISRAEL)
PHARMACEUTICALS LTD., and PERRIGO)
UK FINCO LIMITED PARTNERSHIP)
)
Defendants.)
)

**COMPLAINT AGAINST DEFENDANTS PERRIGO COMPANY, PERRIGO ISRAEL
PHARMACEUTICALS LTD., AND PERRIGO UK FINCO LIMITED PARTNERSHIP**

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 Defendants Perrigo Company, Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”), and Perrigo UK FINCO Limited Partnership (“Perrigo UK”) (collectively “Perrigo” or “Defendants”).

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 210, Herndon, Virginia 20170.

3. Plaintiff Besins Healthcare Luxembourg SARL is a Luxembourgian company with its principal place of business at 67, Boulevard Grande-Duchesse, Charlotte, Luxembourg L-1331.

4. Defendant Perrigo Company is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan, 49010.

5. Defendant Perrigo Israel is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak, 51200, Israel.

6. On information and belief, Defendant Perrigo UK Finco Limited Partnership is a United Kingdom company with its principal place of business at Braunton, EX33 2DL.

NATURE OF THE ACTION

7. 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. 8,466,136 (“the ’136 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 8,466,137 (“the ’137 Patent”), titled “Testosterone Gel and Method of Use”; U.S. Patent No. 8,466,138 (“the ’138 Patent”), titled “Testosterone Gel and Method of Use”; and U.S. Patent No. 8,486,925 (“the ’925 Patent”), titled “Testosterone Gel and Method of Use.” This action relates to Abbreviated New Drug Application (“ANDA”) No. 205781 submitted in the name of Perrigo UK Finco Limited Partnership to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of AbbVie’s AndroGel[®] (testosterone gel) 1.62% in packet form (Perrigo’s “Generic AndroGel[®] Packets”), 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

8. 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.

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

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

PERSONAL JURISDICTION

11. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their 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.

12. Perrigo Company and Perrigo Israel previously did not contest that personal jurisdiction was proper in the District of Delaware with respect to litigation involving ANDA No. 204268, which is also an application for a generic version of AbbVie's AndroGel[®] 1.62%. That litigation, C.A. No. 13-236, is currently ongoing in this District. Perrigo Company and Perrigo Israel filed counterclaims in that litigation and, in doing so, effectively admitted to personal jurisdiction in this District.

13. As reported in its 2012 Annual Report on behalf of itself and its subsidiaries, Perrigo operates as a "leading global provider" that "develops, manufactures and distributes," *inter alia*, over-the-counter and generic prescription pharmaceutical products. As described in that Annual Report, one of Perrigo's business segments is "R_x Pharmaceuticals," which "markets a portfolio of generic prescription drug products for the U.S. market" that is

focused on “topical dosage forms.” On information and belief, Perrigo Israel and Perrigo UK are wholly-owned subsidiaries of Perrigo Company and part of Perrigo’s R_x Pharmaceuticals segment.

14. According to Perrigo’s 2010 Annual Report, its “U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Wal-Mart, CVS, Rite Aid” and others. Perrigo’s “[g]eneric prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as [over the counter] pharmaceuticals and nutritional products.” On information and belief, Perrigo Company, Perrigo Israel, and Perrigo UK intend to sell Perrigo’s Generic AndroGel[®] Packets through these same retail outlets in Delaware, including at least Walgreens, Wal-Mart, CVS, and Rite Aid stores.

15. On information and belief, Perrigo Company directs the activities of the other Perrigo entities, including Perrigo Israel and Perrigo UK, and is directly responsible for sales of Perrigo products to customers in Delaware, from which Perrigo Company derives substantial revenue.

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

17. On information and belief, Perrigo Israel develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products, including cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and

cream, imiquimod cream, and mesalamine rectal suspension enema, which are all among Perrigo's major pharmaceutical products according to its Annual Reports. On information and belief, Perrigo Israel derives substantial revenue from the sale of products to customers in Delaware.

18. On information and belief, Perrigo UK develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products, including clindamycin phosphate, which is among Perrigo's major pharmaceutical products according to its Annual Reports. On information and belief, Perrigo UK derives substantial revenue from the sale of products to customers in Delaware.

19. As further evidence of personal jurisdiction, Perrigo Company has been sued for patent infringement in this district and has not contested personal jurisdiction (see, e.g., C.A. Nos. 04-107, 09-167, 09-758, and 10-592). Perrigo Company has further admitted to personal jurisdiction in this District (C.A. Nos. 09-758 and 10-592).

20. As further evidence of personal jurisdiction, Perrigo Israel has stipulated that it is subject to jurisdiction in the District of Delaware (C.A. No. 09-758 and 10-592).

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

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

23. On information and belief, and consistent with their practice with respect to other generic products, Perrigo Company, Perrigo Israel, and Perrigo UK acted in concert to prepare and submit ANDA No. 205781. Perrigo UK has represented that it submitted ANDA No. 205781 to the FDA through Perrigo Company, which acts as its authorized U.S. agent.

FACTUAL BACKGROUND

A. The '894 Patent

24. 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.

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

26. 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.

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

28. The expiration date of the '894 Patent is August 30, 2020.

B. The '136 Patent

29. On June 18, 2013, the '136 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '136 Patent is attached as Exhibit B to this Complaint.

30. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '136 Patent to Besins Healthcare Luxembourg SARL.

31. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '136 Patent.

32. The expiration date of the '136 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") is October 12, 2026.

C. The '137 Patent

33. On June 18, 2013, the '137 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '137 Patent is attached as Exhibit C to this Complaint.

34. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '137 Patent to Besins Healthcare Luxembourg SARL.

35. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '137 Patent.

36. The expiration date of the '137 Patent listed in the Orange Book is October 12, 2026.

D. The '138 Patent

37. On June 18, 2013, the '138 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '138 Patent is attached as Exhibit D to this Complaint.

38. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '138 Patent to Besins Healthcare Luxembourg SARL.

39. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '138 patent.

40. The expiration date of the '138 Patent listed in the Orange Book is October 12, 2026.

E. The '925 Patent

41. On July 16, 2013, the '925 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '925 Patent is attached as Exhibit E to this Complaint.

42. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '925 Patent to Besins Healthcare Luxembourg SARL.

43. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '925 Patent.

44. The expiration date of the '925 Patent listed in the Orange Book is October 12, 2026.

F. AndroGel®

45. 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.

46. 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.

47. The '136 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62% packets, and the claims of the '136 Patent cover that product.

48. The '137 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62% packets, and the claims of the '137 Patent cover that product.

49. The '138 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62% packets, and the claims of the '138 Patent cover that product.

50. The '925 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62% packets, and the claims of the '925 Patent cover that product.

G. Infringement by Perrigo

51. On information and belief, Perrigo UK, and/or Perrigo Company acting on behalf of and as agent for Perrigo UK, has submitted ANDA No. 205781 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market Perrigo's Generic AndroGel® Packets prior to the expiration date of the '136 Patent, the '137 Patent, the '138 Patent, and the '925 Patent.

52. On information and belief, Perrigo Company, Perrigo Israel, and Perrigo UK also intend to market Perrigo's Generic AndroGel® Packets prior to the expiration date of the '894 Patent.

53. On information and belief, Perrigo Company, Perrigo Israel, and Perrigo UK intend to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of Perrigo's Generic AndroGel[®] Packets promptly upon receiving FDA approval to do so.

54. Plaintiffs received a letter dated June 11, 2014 (the "Notice Letter") signed on behalf of Perrigo UK and stating that ANDA No. 205781 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Perrigo's Generic AndroGel[®] Packets before the expiration of the '136 Patent, the '137 Patent, the '138 Patent, and the '925 Patent. The Notice Letter also states that, "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '136, '137, '138, and '925 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation" of Perrigo's Generic AndroGel[®] Packets.

55. On information and belief, the submission of ANDA No. 205781 to the FDA constitutes infringement by Perrigo Company, Perrigo Israel, and Perrigo UK of the '894 Patent, the '136 Patent, the '137 Patent, the '138 Patent, and the '925 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Perrigo's Generic AndroGel[®] Packets would infringe the '894 Patent, the '136 Patent, the '137 Patent, the '138 Patent, and the '925 Patent under 35 U.S.C. § 271(a)-(c).

56. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter as required by 21 U.S.C. § 355(j)(5)(B)(iii).

CLAIMS FOR RELIEF

COUNT I

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

57. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 55 above as though fully restated herein.

58. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205781 to the FDA seeking approval of Perrigo's Generic AndroGel[®] Packets was an act of infringement of the '894 Patent by Defendants.

59. If allowed on the market, Perrigo's Generic AndroGel[®] Packets will infringe the '894 Patent under 35 U.S.C. § 271(a).

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

61. Defendants' 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)

62. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 61 above as though fully restated herein.

63. Defendants have knowledge of the '894 Patent.

64. Upon FDA approval of ANDA No. 205781, Defendants will intentionally encourage acts of direct infringement of the '894 Patent by others, with knowledge that their acts are encouraging infringement.

COUNT III

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

65. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 64 above as though fully restated herein.

66. If ANDA No. 205781 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®] Packets.

67. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] Packets is especially adapted for a use that infringes the '894 patent.

68. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel[®] Packets.

COUNT IV

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

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

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

71. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel[®] Packets upon receipt of final FDA approval of ANDA No. 205781, unless enjoined by the Court.

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

73. On information and belief, based on positions taken by Perrigo Company and Perrigo Israel in C.A. No. 13-236, Defendants dispute that Perrigo's Generic AndroGel[®] Packets infringe the '894 Patent.

74. There is a justiciable case or controversy between Unimed and Besins and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel[®] Packets according to ANDA No. 205781 will infringe one or more claims of the '894 Patent.

75. If Defendants' 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. 8,466,136)

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

77. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205781 to the FDA seeking approval of Perrigo's Generic AndroGel[®] Packets was an act of infringement of the '136 Patent by Defendants.

78. If allowed on the market, Perrigo's Generic AndroGel[®] Packets will infringe the '136 Patent under 35 U.S.C. § 271(a).

79. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '136 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

80. Defendants' infringement of the '136 Patent is willful and made with knowledge of the '136 Patent.

COUNT VI
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,136)

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

82. Defendants have knowledge of the '136 Patent.

83. Upon FDA approval of ANDA No. 205781, Defendants will intentionally encourage acts of direct infringement of the '136 Patent by others, with knowledge that their acts are encouraging infringement.

COUNT VII
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,136)

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

85. If ANDA No. 205781 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®] Packets.

86. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] Packets is especially adapted for a use that infringes the '136 patent.

87. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel[®] Packets.

COUNT VIII

(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,136)

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

89. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic AndroGel[®] Packets prior to expiration of the '136 Patent.

90. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel[®] Packets upon receipt of final FDA approval of ANDA No. 205781, unless enjoined by the Court.

91. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic AndroGel[®] Packets will constitute infringement of the '136 Patent under 35 U.S.C. § 271(a)-(c).

92. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel[®] Packets according to ANDA No. 205781 will infringe one or more claims of the '136 Patent.

93. If Defendants' infringement of the '136 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. 8,466,137)

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

95. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205781 to the FDA seeking approval of Perrigo's Generic AndroGel[®] Packets was an act of infringement of the '137 Patent by Defendants.

96. If allowed on the market, Perrigo's Generic AndroGel[®] Packets will infringe the '137 Patent under 35 U.S.C. § 271(a).

97. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '137 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

98. Defendants' infringement of the '137 Patent is willful and made with knowledge of the '137 Patent.

COUNT X
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,137)

99. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 98 above as though fully restated herein.

100. Defendants have knowledge of the '137 Patent.

101. Upon FDA approval of ANDA No. 205781, Defendants will intentionally encourage acts of direct infringement of the '137 Patent by others, with knowledge that their acts are encouraging infringement.

COUNT XI

(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,137)

102. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 101 above as though fully restated herein.

103. If ANDA No. 205781 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®] Packets.

104. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] Packets is especially adapted for a use that infringes the '137 patent.

105. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel[®] Packets.

COUNT XII

(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,137)

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

107. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic AndroGel[®] Packets prior to expiration of the '137 Patent.

108. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel[®] Packets upon receipt of final FDA approval of ANDA No. 205781, unless enjoined by the Court.

109. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic AndroGel[®] Packets will constitute infringement of the '137 Patent under 35 U.S.C. § 271(a)–(c).

110. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel[®] Packets according to ANDA No. 205781 will infringe one or more claims of the '137 Patent.

111. If Defendants' infringement of the '137 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. 8,466,138)

112. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 111 above as though fully restated herein.

113. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205781 to the FDA seeking approval of Perrigo's Generic AndroGel[®] Packets was an act of infringement of the '138 Patent by Defendants.

114. If allowed on the market, Perrigo's Generic AndroGel[®] Packets will infringe the '138 Patent under 35 U.S.C. § 271(a).

115. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '138 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

116. Defendants' infringement of the '138 Patent is willful and made with knowledge of the '138 Patent.

COUNT XIV
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,138)

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

118. Defendants have knowledge of the '138 Patent.

119. Upon FDA approval of ANDA No. 205781, Defendants will intentionally encourage acts of direct infringement of the '138 Patent by others, with knowledge that their acts are encouraging infringement.

COUNT XV
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,138)

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

121. If ANDA No. 205781 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®] Packets.

122. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] Packets is especially adapted for a use that infringes the '138 patent.

123. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel[®] Packets.

COUNT XVI
(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,138)

124. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 123 above as though fully restated herein.

125. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic AndroGel[®] Packets prior to expiration of the '138 patent.

126. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel[®] Packets upon receipt of final FDA approval of ANDA No. 205781, unless enjoined by the Court.

127. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic AndroGel[®] Packets will constitute infringement of the '138 Patent under 35 U.S.C. § 271(a)-(c).

128. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel[®] Packets according to ANDA No. 205781 will infringe one or more claims of the '138 Patent.

129. If Defendants' infringement of the '138 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. 8,486,925)

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

131. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205781 to the FDA seeking approval of Perrigo's Generic AndroGel[®] Packets was an act of infringement of the '925 Patent by Defendants.

132. If allowed on the market, Perrigo's Generic AndroGel® Packets will infringe the '925 Patent under 35 U.S.C. § 271(a).

133. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '925 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

134. Defendants' infringement of the '925 Patent is willful and made with knowledge of the '925 Patent.

COUNT XVIII
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,486,925)

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

136. Defendants have knowledge of the '925 Patent.

137. Upon FDA approval of ANDA No. 205781, Defendants will intentionally encourage acts of direct infringement of the '925 Patent by others, with knowledge that their acts are encouraging infringement.

COUNT XIX
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,486,925)

138. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 137 above as though fully restated herein.

139. If ANDA No. 205781 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel® Packets.

140. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel® Packets is especially adapted for a use that infringes the '925 patent.

141. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel[®] Packets.

COUNT XX
(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,486,925)

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

143. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic AndroGel[®] Packets prior to expiration of the '925 patent.

144. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel[®] Packets upon receipt of final FDA approval of ANDA No. 205781, unless enjoined by the Court.

145. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic AndroGel[®] Packets will constitute infringement of the '925 Patent under 35 U.S.C. § 271(a)–(c).

146. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel[®] Packets according to ANDA No. 205781 will infringe one or more claims of the '925 Patent.

147. If Defendants' infringement of the '925 Patent is not enjoined, Unimed and Besins Luxembourg 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 Defendants have infringed U.S. Patent Nos. 6,503,894; 8,466,136; 8,466,137; 8,466,138; and 8,486,925;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Defendants of Perrigo's Generic AndroGel[®] Packets will infringe U.S. Patent Nos. 6,503,894; 8,466,136; 8,466,137; 8,466,138; and 8,486,925;

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of ANDA No. 205781 be no earlier than the expiration date of U.S. Patent Nos. 6,503,894; 8,466,136; 8,466,137; 8,466,138; and 8,486,925, including any extensions or adjustments;

D. For an order enjoining Defendants and their 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 U.S. Patent Nos. 6,503,894; 8,466,136; 8,466,137; 8,466,138; and 8,486,925;

E. For a determination that this is an exceptional case under 35 U.S.C. § 285; and

F. 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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