

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC and)
BESINS HEALTHCARE LUXEMBOURG)
SARL,)
)
Plaintiffs,) C.A. No. _____
)
v.)
)
PERRIGO COMPANY and PERRIGO)
ISRAEL PHARMACEUTICALS LTD.,)
)
Defendants.)

**COMPLAINT AGAINST DEFENDANTS PERRIGO COMPANY
AND PERRIGO ISRAEL PHARMACEUTICALS LTD.**

Plaintiffs Unimed Pharmaceuticals, LLC (“Unimed”) and Besins Healthcare Luxembourg SARL (“Besins Luxembourg”) (collectively “Plaintiffs”) allege as follows for their complaint against Defendants Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) (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 Luxembourg SARL is a Luxembourgian company with its principal place of business at 67, Boulevard Grande-Duchesse, Charlotte, Luxembourg L-1331.

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

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

NATURE OF THE ACTION

5. This is an action for infringement of 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”; and U.S. Patent No. 8,759,329 (“the ’329 Patent”), titled “Testosterone Gel and Method of Use.” This action relates to Abbreviated New Drug Application (“ANDA”) No. 204268 submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of AbbVie’s AndroGel[®] (testosterone gel) 1.62% (Perrigo’s “Generic AndroGel[®]”), which act and of which the continued prosecution constitutes an act of infringement, including one 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 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.

10. Perrigo Company and Perrigo Israel previously did not contest that personal jurisdiction was proper in the District of Delaware with respect to ongoing litigation involving the same ANDA, same Generic AndroGel[®], and related patents (C.A. No. 13-236). Perrigo Company and Perrigo Israel filed counterclaims in that litigation and, in doing so, effectively admitted to personal jurisdiction in this District.

11. 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 is a wholly-owned subsidiary of Perrigo Company and part of Perrigo’s R_x Pharmaceuticals segment.

12. 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 and Perrigo Israel intend to sell Perrigo’s Generic AndroGel[®] through these same retail outlets in Delaware, including at least Walgreens, Wal-Mart, CVS, and Rite Aid stores.

13. On information and belief, Perrigo Company directs the activities of the other Perrigo entities, including Perrigo Israel, and is directly responsible for sales of Perrigo products

to customers in Delaware, from which Perrigo Company derives substantial revenue.

14. 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.

15. 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.

16. 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, 10-592, 13-236). Perrigo Company has further admitted to personal jurisdiction in this District (C.A. Nos. 09-758 and 10-592).

17. As further evidence of personal jurisdiction, Perrigo Israel has stipulated that it is subject to jurisdiction in the District of Delaware (C.A. Nos. 09-758 and 10-592) or otherwise not contested personal jurisdiction (C.A. No. 13-236).

18. 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.

19. On information and belief, and consistent with their practice with respect to other generic products, Perrigo Company and Perrigo Israel acted in concert to prepare and submit ANDA No. 204268. Perrigo Israel has represented that it submitted ANDA No. 204268 to the FDA through Perrigo Company, which acts as its authorized U.S. agent.

FACTUAL BACKGROUND

A. The '057 Patent

20. 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 A to this Complaint.

21. The expiration date of the '057 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.

B. The '881 Patent

22. 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 B to this Complaint.

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

C. The '070 Patent

24. 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 C to this Complaint.

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

D. The '329 Patent

26. 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 D to this Complaint.

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

E. AndroGel®

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

F. Infringement by Perrigo

33. On information and belief, Perrigo Israel, and/or Perrigo Company acting on behalf of and as agent for Perrigo Israel, has submitted ANDA No. 204268 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[®] prior to the expiration date of U.S. Patent Nos. 6,503,894, 8,466,136 ("the '136 Patent"), 8,466,137 ("the '137 Patent"), 8,466,138 ("the '138 Patent"), and 8,486,925 ("the '925 Patent").

34. Plaintiffs filed an amended complaint in this District on October 4, 2013, alleging that Perrigo's Generic AndroGel[®], if approved, would infringe the '136 Patent, '137 Patent, '138 Patent, and '925 Patent. That matter is still pending. *See Unimed Pharms., LLC v. Perrigo Co.*, C.A. No. 13-236 (RGA) (consolidated), D.I. 30 (D. Del.). By this action, Plaintiffs assert four additional, newly-issued patents against the same Generic AndroGel[®] that is at issue in the prior case. The '136 Patent, '137 Patent, '138 Patent, and '925 Patent are part of the same patent family as the '057 Patent, '881 Patent, '070 Patent, and '329 Patent.

35. On information and belief, Perrigo Company and Perrigo Israel intend to market Perrigo's Generic AndroGel[®] prior to the expiration date of the '057 Patent, '881 Patent, '070 Patent, and '329 Patent.

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

37. On information and belief, the submission of ANDA No. 204268 to the FDA and continued prosecution thereof constitutes infringement by Perrigo Company and Perrigo Israel of

the '057 Patent, '881 Patent, '070 Patent, and '329 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[®] would infringe the '057 Patent, '881 Patent, '070 Patent, and '329 Patent under 35 U.S.C. § 271(a)–(c).

CLAIMS FOR RELIEF

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

38. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204268 to the FDA and continued prosecution thereof seeking approval of Perrigo's Generic AndroGel[®] is an act of infringement of the '057 Patent by Defendants.

40. If allowed on the market, Perrigo's Generic AndroGel[®] will infringe the '057 Patent under 35 U.S.C. § 271(a).

41. Unless Defendants are enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Defendants' infringement of the '057 Patent. Unimed and Besins do not have an adequate remedy at law.

42. Defendants' infringement of the '057 Patent is willful and made with knowledge of the '057 Patent.

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

43. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 42 above as though fully restated herein.

44. Defendants have knowledge of the '057 Patent.

45. Upon FDA approval of ANDA No. 204268, Defendants will intentionally

encourage acts of direct infringement of the '057 Patent by others, with knowledge that their acts are encouraging infringement.

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

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

47. If ANDA No. 204268 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®].

48. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] is especially adapted for a use that infringes the '057 patent.

49. 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[®].

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

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

51. 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[®] prior to expiration of the '057 patent.

52. 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[®] upon receipt of final FDA approval of ANDA No. 204268, unless enjoined by the Court.

53. 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[®] will

constitute infringement of the '057 Patent under 35 U.S.C. § 271(a)–(c).

54. 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[®] would infringe the '057 Patent.

55. 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[®] according to ANDA No. 204268 will infringe one or more claims of the '057 Patent.

56. If Defendants' infringement of the '057 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. 8,741,881)

57. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 56 above as though fully restated herein.

58. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204268 to the FDA and continued prosecution thereof seeking approval of Perrigo's Generic AndroGel[®] is an act of infringement of the '881 Patent by Defendants.

59. If allowed on the market, Perrigo's Generic AndroGel[®] will infringe the '881 Patent under 35 U.S.C. § 271(a).

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

61. Defendants' infringement of the '881 Patent is willful and made with knowledge of the '881 Patent.

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

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

63. Defendants have knowledge of the '881 Patent.

64. Upon FDA approval of ANDA No. 204268, Defendants will intentionally encourage acts of direct infringement of the '881 Patent by others, with knowledge that their acts are encouraging infringement.

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

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

66. If ANDA No. 204268 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®].

67. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] is especially adapted for a use that infringes the '881 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[®].

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

69. Unimed and Besins Luxembourg 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[®] prior to expiration of the '881 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[®] upon receipt of final FDA approval of ANDA No. 204268, 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[®] will constitute infringement of the '881 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[®] would infringe the '881 Patent.

74. 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[®] according to ANDA No. 204268 will infringe one or more claims of the '881 Patent.

75. If Defendants' 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 IX
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,754,070)

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. 204268 to the FDA and continued prosecution thereof seeking approval of Perrigo's Generic AndroGel[®] is an act of infringement of the '070 Patent by Defendants.

78. If allowed on the market, Perrigo's Generic AndroGel[®] will infringe the '070 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 '070 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

80. Defendants' infringement of the '070 Patent is willful and made with knowledge of the '070 Patent.

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

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 '070 Patent.

83. Upon FDA approval of ANDA No. 204268, Defendants will intentionally encourage acts of direct infringement of the '070 Patent by others, with knowledge that their acts are encouraging infringement.

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

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

85. If ANDA No. 204268 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®].

86. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] is especially adapted for a use that infringes the '070 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[®].

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

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[®] prior to expiration of the '070 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[®] upon receipt of final FDA approval of ANDA No. 204268, 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[®] will constitute infringement of the '070 Patent under 35 U.S.C. § 271(a)–(c).

92. 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[®] would infringe the '070 Patent.

93. 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[®] according to ANDA No. 204268 will infringe one or more claims of the '070 Patent.

94. If Defendants' 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 XIII
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,759,329)

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

96. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204268 to the FDA and continued prosecution thereof seeking approval of Perrigo's Generic AndroGel[®] is an act of infringement of the '329 Patent by Defendants.

97. If allowed on the market, Perrigo's Generic AndroGel[®] will infringe the '329 Patent under 35 U.S.C. § 271(a).

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

99. Defendants' infringement of the '329 Patent is willful and made with knowledge of the '329 Patent.

COUNT XIV
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,759,329)

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

101. Defendants have knowledge of the '329 Patent.

102. Upon FDA approval of ANDA No. 204268, Defendants will intentionally encourage acts of direct infringement of the '329 Patent by others, with knowledge that their acts are encouraging infringement.

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

103. Unimed and Besins Luxembourg incorporate by reference and reallege

paragraphs 1 through 102 above as though fully restated herein.

104. If ANDA No. 204268 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel[®].

105. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel[®] is especially adapted for a use that infringes the '329 patent.

106. 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[®].

COUNT XVI

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

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

108. 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[®] prior to expiration of the '329 patent.

109. 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[®] upon receipt of final FDA approval of ANDA No. 204268, unless enjoined by the Court.

110. 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[®] will constitute infringement of the '329 Patent under 35 U.S.C. § 271(a)-(c).

111. 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[®] would infringe the '329 Patent.

112. 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[®] according to ANDA No. 204268 will infringe one or more claims of the '329 Patent.

113. If Defendants' 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a declaration that Defendants have infringed U.S. Patent Nos. 8,729,057; 8,741,881; 8,754,070; and 8,759,329;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Defendants of Perrigo's Generic AndroGel[®] will infringe U.S. Patent Nos. 8,729,057; 8,741,881; 8,754,070; and 8,759,329.

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of ANDA No. 204268 be no earlier than the expiration date of U.S. Patent Nos. 8,729,057; 8,741,881; 8,754,070; and 8,759,329, 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. 8,729,057; 8,741,881; 8,754,070; and 8,759,329;

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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