

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. _____
)	
SANDOZ 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 Sandoz Inc. (“Sandoz” 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 Sandoz Inc. is a Colorado company with its principal place of business at 100 College Road West, Princeton, NJ 08540.

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. 8,466,136 (“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”; U.S. Patent No. 8,486,925 (“the ’925 Patent”), titled “Testosterone Gel and Method of Use,” 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. 207287 submitted in the name of Sandoz Inc. to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of AbbVie’s AndroGel[®] (testosterone gel) 1.62% (Sandoz’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 the Defendant by virtue of, *inter alia*, Sandoz's systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of its 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, Sandoz has availed itself of this forum by maintaining lawsuits in this judicial district as a plaintiff, including, for example, *Sandoz Inc. v. Pfizer, Inc. et al.*, 10-cv-00104-LPS.

11. Further, on information and belief, Sandoz will manufacture, market, and/or sell within the United States the generic product described in its ANDA if FDA approval is granted. If Sandoz's ANDA is approved, on information and belief, Sandoz's Generic AndroGel[®] would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

12. On information and belief, Sandoz holds a pharmacy wholesale license for the state of Delaware under License No. A4-0000260 and a distributor/manufacturer license for controlled substances for the state of Delaware under License No. DS0131.

13. On information and belief, Sandoz sent to Plaintiffs a letter dated October 20, 2015 (the "Notice Letter") stating that ANDA No. 207287 includes a Paragraph IV Certification

to obtain approval to engage in the commercial manufacture, use, sale, or importation of Sandoz'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 Sandoz in Delaware on the basis of specific jurisdiction.

14. As further evidence of personal jurisdiction, Sandoz has previously consented to being sued in this jurisdiction numerous times and has availed itself of Delaware courts through the assertion of counterclaims. *See, e.g., Cephalon Inc. v. Sandoz Inc. et al.*, C.A. No. 15-cv-00178; *Forest Labs. LLC et al. v. Apotex Corp. et al.*, C.A. No. 15-cv-00018; *Sanofi et al. v. Sandoz Inc.*, C.A. No. 14-cv-01434; *Teva Pharms. USA, Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 14-cv-01171; *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, C.A. No. 14-cv-00916; *Allos Therapeutics, Inc. et al. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 14-cv-00778; *ALZA Corp. et al. v. Sandoz Inc.*, C.A. No. 14-cv-00744; *Cephalon, Inc. v. Hetero Labs Ltd. et al.*, C.A. No. 13-cv-02046; *Genzyme Corp. et al. v. Sandoz Inc.*, C.A. No. 13-cv-01507; *UCB Inc. et al. v. Sandoz Inc.*, C.A. No. 13-cv-01216; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 13-cv-01111; *Kissei Pharm. Co. Ltd. et al. v. Sandoz Inc.*, C.A. No. 13-cv-01092; *Avanir Pharms. Inc. et al. v. Sandoz Inc.*, C.A. No. 13-cv-00961; *Acura Pharms. Inc. v. Sandoz Inc.*, C.A. No. 12-cv-01373; *Abbott Labs. et al. v. Sandoz Inc.*, C.A. No. 12-cv-00836; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 12-cv-00814; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 12-cv-00654; *Cephalon Inc. v. Sandoz Inc.*, C.A. No. 12-cv-00248; *Abbott Labs. et al. v. Sandoz Inc.*, C.A. No. 12-cv-00103; *Cephalon Inc. v. Sandoz Inc.*, C.A. No. 12-cv-00074; *GlaxoSmithKline Intellectual Property Mgmt. Ltd. et al. v. Sandoz Inc.*, C.A. No. 11-cv-01284; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 11-cv-01252; *AbbVie Inc. et al. v. Sandoz Inc.*, C.A. No. 11-cv-01113; *Cephalon Inc. et al.*

v. Sandoz Inc., C.A. No. 11-cv-00821; *Cephalon Inc. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00782; *Abbott Labs. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00424; *Research Found. of State Univ. of New York et al. v. Sandoz Inc.*, C.A. No. 11-cv-00162; *Abbott Labs. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00145; *Aventis Pharma S.A. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00043; *Allergan Inc. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00042; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 11-cv-00023; *AbbVie Inc. et al. v. Sandoz Inc.*, C.A. No. 10-cv-00538; *Genzyme Corp. v. Sandoz Inc.*, C.A. No. 10-cv-00429; *Cephalon Inc. et al. v. Sandoz Inc.*, C.A. No. 10-cv-00123; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 10-cv-00103; *Cephalon Inc. et al. v. Sandoz Inc.*, C.A. No. 10-cv-00055; *Allergan Inc. v. Sandoz Inc.*, C.A. No. 10-cv-00024; *Abbott Labs. v. Sandoz Inc.*, C.A. No. 09-cv-00972; *Wyeth Holdings Corp. et al. v. Sandoz Inc.*, C.A. No. 09-cv-00955; *Daiichi Sankyo Co. Ltd. et al. v. Sandoz Inc.*, C.A. No. 09-cv-00898; *Allergan Inc. et al. v. Sandoz Inc.*, C.A. No. 09-00882; *Aventis Pharma S.A. et al. v. Sandoz Inc.*, C.A. No. 09-cv-00810; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 09-cv-00742; *Bone Care Int'l LLC et al. v. Sandoz Inc.*, C.A. No. 09-cv-00524; *Pfizer Inc. et al. v. Sandoz Inc.*, C.A. No. 09-cv-00310; *Abbott Labs. et al. v. Sandoz Inc. et al.*, C.A. No. 09-cv-00215; *Medicis Pharm. Corp. v. Mylan Inc. et al.*, C.A. No. 09-cv-00033; *Endo Pharms. Inc. et al. v. Sandoz Inc.*, C.A. No. 08-cv-00970; *Wyeth v. Sandoz Inc.*, C.A. No. 08-cv-00317; and *AstraZeneca Pharms. LP et al. v. Sandoz Inc.*, C.A. No. 07-cv-00807.

FACTUAL BACKGROUND

A. The '894 Patent

15. 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.

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

17. 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.

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

19. 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 '136 Patent

20. 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.

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

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

23. The expiration date of the '136 Patent listed in the Orange Book is October 12, 2026.

C. The '137 Patent

24. 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.

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

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

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

D. The '138 Patent

28. 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.

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

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

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

E. The '925 Patent

32. 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.

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

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

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

F. The '057 Patent

36. 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 F to this Complaint.

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

G. The '881 Patent

38. 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 G to this Complaint.

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

H. The '070 Patent

40. 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 H to this Complaint.

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

I. The '329 Patent

42. 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 I to this Complaint.

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

J. The '816 Patent

44. 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 J to this Complaint.

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

K. The '089 Patent

46. 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 K to this Complaint.

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

L. AndroGel®

48. 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.

49. 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.

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

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

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

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

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

M. Infringement by Sandoz

60. On information and belief, Sandoz has submitted ANDA No. 207287 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market Sandoz's Generic AndroGel[®] prior to the expiration date of the patents-in-suit.

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

62. Plaintiffs received the Notice Letter signed on behalf of Sandoz stating that ANDA No. 207287 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Sandoz's Generic AndroGel[®] before the

expiration of the patents-in-suit. In the Notice Letter, Sandoz also states that, “the claims of the [patents-in-suit] are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of [Sandoz’s Generic AndroGel[®]].”

63. Under applicable regulations, Sandoz was required in its Notice Letter to set forth “a full and detailed explanation” to support any non-infringement arguments on a patent-by-patent, claim-by-claim basis. *See* 21 C.F.R. 314.52(c). Sandoz is a sophisticated generic pharmaceutical company that is knowledgeable about the requirements applicable to ANDAs, including Notice Letters. Sandoz did not provide in its Notice Letter any argument, much less a “full and detailed explanation,” to suggest that its proposed generic version of AndroGel[®] 1.62% would not infringe all or any of the patents-in-suit.

64. Plaintiffs requested access to ANDA No. 207287 for pre-suit evaluation within the 45-day statutory period after receiving the Notice Letter, but Sandoz refused to provide any portion of the ANDA for review, even pursuant to a confidentiality agreement.

65. On information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(iv), Sandoz’s Generic AndroGel[®] is bioequivalent to AbbVie’s AndroGel[®] 1.62%.

66. On information and belief, Sandoz’s Generic AndroGel[®] contains substantially the same ingredients in substantially the same amounts as AbbVie’s AndroGel[®] 1.62%.

67. On information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(v), Sandoz’s proposed label contains the same instructions for use as the approved label for AbbVie’s AndroGel[®] 1.62%.

68. The submission of ANDA No. 207287 to the FDA constitutes infringement by Sandoz 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 Sandoz's Generic AndroGel[®] would infringe the patents-in-suit under 35 U.S.C. § 271(a)–(c).

69. 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)

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

71. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel^{1®} was an act of infringement of the '894 Patent by Defendant.

72. If allowed on the market, Sandoz's Generic AndroGel[®] and the use thereof will infringe the '894 Patent under 35 U.S.C. § 271(a).

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

74. Defendant'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)

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

76. Defendant has knowledge of the '894 Patent.

77. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '894 patent.

78. On information and belief, the use of Sandoz'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.

79. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '894 patent.

80. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

81. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '894 patent.

82. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

83. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '894 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

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

85. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel®.

86. On information and belief, Sandoz's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '894 patent.

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

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

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

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

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

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

States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

93. There is a justiciable case or controversy between Unimed and Besins and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '894 Patent.

94. If Defendant'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. 8,466,136)

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), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '136 Patent by Defendant.

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

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

99. Defendant's 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)

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

101. Defendant has knowledge of the '136 Patent.

102. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '136 patent.

103. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '136 patent.

104. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '136 patent.

105. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '136 patent. Since at least the date of the Notice Letter, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '136 patent.

106. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

107. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®]

in a manner that directly infringes one or more claims of the '136 patent. Thus, Defendant will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '136 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

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

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

109. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

110. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '136 patent.

111. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic AndroGel[®] is especially adapted for a use that infringes the '136 patent.

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

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

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

114. On information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic AndroGel[®] prior to expiration of the '136 Patent.

115. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

117. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '136 Patent.

118. If Defendant's 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)

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

120. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '137 Patent by Defendant.

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

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

123. Defendant's 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)

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

125. Defendant has knowledge of the '137 Patent.

126. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '137 patent.

127. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '137 patent.

128. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '137 patent.

129. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

130. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '137 patent. Since at least the date of the Notice

Letter, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '137 patent.

131. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

132. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '137 patent. Thus, Defendant will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '137 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

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

133. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 132 above as though fully restated herein.

134. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

135. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '137 patent.

136. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic AndroGel[®] is especially adapted for a use that infringes the '137 patent.

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

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

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

139. On information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic AndroGel[®] prior to expiration of the '137 Patent.

140. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

142. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '137 Patent.

143. If Defendant's 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)

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

145. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '138 Patent by Defendant.

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

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

148. Defendant's 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)

149. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 148 above as though fully restated herein.

150. Defendant has knowledge of the '138 Patent.

151. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '138 patent.

152. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '138 patent.

153. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '138 patent.

154. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

155. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '138 patent. Since at least the date of the Notice Letter, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '138 patent.

156. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

157. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '138 patent. Thus, Defendant will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '138 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

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

158. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 157 above as though fully restated herein.

159. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel®.

160. On information and belief, Sandoz's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '138 patent.

161. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic AndroGel® is especially adapted for a use that infringes the '138 patent.

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

COUNT XVI

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

163. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 162 above as though fully restated herein.

164. On information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic AndroGel® prior to expiration of the '138 patent.

165. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

167. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale,

offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '138 Patent.

168. If Defendant's 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)

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

170. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '925 Patent by Defendant.

171. If allowed on the market, Sandoz's Generic AndroGel[®] will infringe the '925 Patent under 35 U.S.C. § 271(a).

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

173. Defendant's 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)

174. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 173 above as though fully restated herein.

175. Defendant has knowledge of the '925 Patent.

176. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '925 patent.

177. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '925 patent.

178. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '925 patent.

179. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '925 patent. Since at least the date of the Notice Letter, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '925 patent.

180. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

181. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '925 patent. Thus, Defendant will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '925 patent, and Defendant will affirmatively and specifically intend to cause direct infringement.

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

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

183. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel®.

184. On information and belief, Sandoz's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '925 patent.

185. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic AndroGel® is especially adapted for a use that infringes the '925 patent.

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

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

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

188. On information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic AndroGel® prior to expiration of the '925 patent.

189. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

191. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '925 Patent.

192. If Defendant's 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.

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

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

194. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '057 Patent by Defendant.

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

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

197. Defendant's infringement of the '057 Patent is willful and made with knowledge of the '057 Patent.

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

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

199. Defendant has knowledge of the '057 Patent.

200. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '057 patent.

201. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '057 patent.

202. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '057 patent.

203. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '057 patent.

204. ON information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

205. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '057 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

206. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 205 above as though fully restated herein.

207. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

208. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '057 patent.

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

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

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

211. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 210 above as though fully restated herein.

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

213. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

215. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '057 Patent.

216. If Defendant'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 XXV
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,741,881)

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

218. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '881 Patent by Defendant.

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

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

221. Defendant's infringement of the '881 Patent is willful and made with knowledge of the '881 Patent.

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

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

223. Defendant has knowledge of the '881 Patent.

224. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '881 patent.

225. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '881 patent.

226. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '881 patent.

227. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

228. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '881 patent.

229. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

230. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare

Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '881 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

231. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 230 above as though fully restated herein.

232. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

233. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '881 patent.

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

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

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

236. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 235 above as though fully restated herein.

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

238. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

240. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '881 Patent.

241. If Defendant'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 XXIX
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,754,070)

242. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 241 above as though fully restated herein.

243. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '070 Patent by Defendant.

244. If allowed on the market, Sandoz's Generic AndroGel[®] will infringe the '070 Patent under 35 U.S.C. § 271(a).

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

246. Defendant's infringement of the '070 Patent is willful and made with knowledge of the '070 Patent.

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

247. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 246 above as though fully restated herein.

248. Defendant has knowledge of the '070 Patent.

249. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '070 patent.

250. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '070 patent.

251. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '070 patent.

252. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '070 patent.

253. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

254. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '070 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

255. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 254 above as though fully restated herein.

256. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

257. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '070 patent.

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

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

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

260. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 259 above as though fully restated herein.

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

262. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

264. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '070 Patent.

265. If Defendant'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 XXXIII
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,759,329)

266. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 265 above as though fully restated herein.

267. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '329 Patent by Defendant.

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

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

270. Defendant's infringement of the '329 Patent is willful and made with knowledge of the '329 Patent.

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

271. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 270 above as though fully restated herein.

272. Defendant has knowledge of the '329 Patent.

273. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '329 patent.

274. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '329 patent.

275. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '329 patent.

276. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '329 patent.

277. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

278. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '329 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

279. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 278 above as though fully restated herein.

280. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

281. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '329 patent.

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

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

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

284. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 283 above as though fully restated herein.

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

286. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

288. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '329 Patent.

289. If Defendant'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 XXXVII
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,125,816)

290. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 289 above as though fully restated herein.

291. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '816 Patent by Defendant.

292. If allowed on the market, the use of Sandoz's Generic AndroGel[®] will infringe the '816 Patent under 35 U.S.C. § 271(a).

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

294. Defendant's infringement of the '816 Patent is willful and made with knowledge of the '816 Patent.

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

295. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 294 above as though fully restated herein.

296. Defendant has knowledge of the '816 Patent.

297. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '816 patent.

298. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '816 patent.

299. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '816 patent.

300. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

301. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '816 patent.

302. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

303. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '816 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

304. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 303 above as though fully restated herein.

305. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

306. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '816 patent.

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

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

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

309. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 308 above as though fully restated herein.

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

311. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

313. There is a justiciable case or controversy between Unimed and Besins and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '816 Patent.

314. If Defendant'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 XLI
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,132,089)

315. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 314 above as though fully restated herein.

316. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207287 to the FDA seeking approval of Sandoz's Generic AndroGel[®] was an act of infringement of the '089 Patent by Defendant.

317. If allowed on the market, the use of Sandoz's Generic AndroGel[®] will infringe the '089 Patent under 35 U.S.C. § 271(a).

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

319. Defendant's infringement of the '089 Patent is willful and made with knowledge of the '089 Patent.

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

320. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 319 above as though fully restated herein.

321. Defendant has knowledge of the '089 Patent.

322. On information and belief, the use of Sandoz's Generic AndroGel[®] is covered by one or more claims of the '089 patent.

323. On information and belief, the use of Sandoz's Generic AndroGel[®] by any Healthcare Providers and patients, will directly infringe one or more claims of the '089 patent.

324. On information and belief, Defendant's proposed label for Sandoz's Generic AndroGel[®] will explicitly instruct Healthcare Providers and patients to use Sandoz's Generic AndroGel[®] in a manner that will directly infringe one or more claims of the '089 patent.

325. Any use of Sandoz'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 Defendant in its proposed label for Sandoz's Generic AndroGel[®].

326. On information and belief, if Sandoz's Generic AndroGel[®] is approved by the FDA, Defendant 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, Defendant has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '089 patent.

327. On information and belief, Defendant intends to cause direct infringement by others, e.g. Healthcare Providers and patients.

328. On information and belief, upon FDA approval of ANDA No. 207287, Defendant will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendant's proposed label, to use Sandoz's Generic AndroGel[®] in a manner that directly infringes one or more claims of the '089 patent. Thus, Defendant 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 Defendant will affirmatively and specifically intend to cause direct infringement.

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

329. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 328 above as though fully restated herein.

330. If ANDA No. 207287 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic AndroGel[®].

331. On information and belief, Sandoz's Generic AndroGel[®] constitutes a material part of the inventions covered by the claims of the '089 patent.

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

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

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

334. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 333 above as though fully restated herein.

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

336. On information and belief, Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic AndroGel[®] upon receipt of final FDA approval of ANDA No. 207287, unless enjoined by the Court.

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

338. There is a justiciable case or controversy between Unimed and Besins and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic AndroGel[®] according to ANDA No. 207287 will infringe one or more claims of the '089 Patent.

339. If Defendant'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 Defendant has infringed the patents-in-suit;
- B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Defendant of Sandoz'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. 207287 be no earlier than the expiration date of the last to expire of the patents-in-suit, including any extensions or adjustments;
- D. For an order enjoining Defendant 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 Defendant's infringement is willful;
- F. For a determination that this is an exceptional case under 35 U.S.C. § 285; and
- G. For such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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