

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC. et al.,

Defendants.

Case No. 14-cv-5151

BESINS HEALTHCARE, INC.’S ANSWER TO THE COMPLAINT

Defendant Besins Healthcare, Inc. (“Besins”) hereby submits its Answer to the Complaint.

I. Nature of the Case

1. Some of the allegations in paragraph 1 purport to summarize and characterize the FDA-approved label for AndroGel, to which Besins refers for a true and complete statement of its contents. Besins denies the remaining allegations in paragraph 1.

2. Besins admits that it co-owns U.S. Patent No. 6,503,894 (the ‘894 Patent’) and that AbbVie, Inc. is the ultimate parent of Unimed, the entity with which Besins originally co-owned the ‘894 Patent. Besins further admits that the ‘894 Patent relates to AndroGel, and that the term “penetration enhancer” can be used to refer to a chemical moiety used to to enhance the transport of delivery of an active pharmaceutical ingredient across the skin for topical or systemic therapeutic effects. Some of the further allegations in paragraph 2 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies the allegations in paragraph 2.

3. Besins admits that, according to Perrigo and Teva, those entities filed applications with the FDA to market testosterone gels containing, respectively, isostearic acid and isopropyl palmitate. Besins denies the remaining allegations in paragraph 3.

4. Besins admits that in 2009, Besins was not a party to a lawsuit asserting claims against Perrigo for infringement of the '894 Patent. The selected quotations by the FTC to an "internal business document" are not attributed to Besins and, therefore, Besins can neither admit nor deny the allegation contained in the second sentence of paragraph 4. To the extent a further response is required, Besins denies all remaining allegations in paragraph 4.

5. Besins admits that, in 2011, along with Unimed, the co-owner of the '894 Patent, Besins separately sued Teva and Perrigo for infringement of the '894 Patent. Besins denies the remaining allegations in paragraph 5.

6. Besins admits that the lawsuits against, respectively, Teva and Perrigo did not allege literal infringement of the '894 Patent. Besins denies that it had no reasonable basis to assert that Teva's and Perrigo's penetration enhancers infringed the '894 Patent under the doctrine of equivalents. Besins further denies the allegations against it stated in the third and fourth sentences of paragraph 6. The fifth sentence of paragraph 6 states a legal conclusion to which no response is required. To the extent that a response is required, Besins denies the remaining allegations in paragraph 6.

7. The allegations in paragraph 7 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 7.

8. Besins does not have sufficient knowledge and information to admit or deny the first sentence of paragraph 8. Besins admits that Teva purported to allege a counterclaim for

sham litigation. Besins also admits that Perrigo's application to the FDA contained a Paragraph IV certification that stated that, in the opinion of the applicant and to the best of the applicant's knowledge, the '894 Patent was invalid and/or unenforceable and/or would not be infringed by the proposed drug. Besins denies the remaining allegations in paragraph 8.

9. The allegations in paragraph 9 are not directed to Besins and, accordingly, no response is required. To the extent a response is required, Besins denies the allegations in paragraph 9.

10. The allegations in paragraph 10 are not directed to Besins and, accordingly, no response is required. To the extent a response is required, Besins denies the allegations in paragraph 10.

II. Jurisdiction and Venue

11. Paragraph 11 asserts legal conclusions to which no answer is required. Besins denies any remaining factual allegations in paragraph 11.

12. Besins admits that it is subject to the Court's personal jurisdiction relating to this suit. The remaining allegations of paragraph 12 assert legal conclusions to which no answer is required. To the extent that a response is required, Besins denies the remaining allegations in paragraph 12.

13. Besins admits that venue is proper in this District. Besins denies that it committed an illegal or tortious act, in this district or elsewhere, as alleged in the complaint. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 13 regarding Defendants other than Besins and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the remaining allegations in paragraph 13.

14. Paragraph 14 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 14.

15. Paragraph 15 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 15.

III. The Parties

16. Paragraph 16 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 16.

17. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 17 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 17.

18. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 18 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 18.

19. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 19 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 19.

20. Besins admits the first and third sentences in paragraph 20. Besins denies that allegations in the second and fourth sentences of paragraph 20.

21. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 21 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 21.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States provides several potential pathways for marketing a generic version of a brand-name drug.

22. Paragraph 22 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 22.

23. Paragraph 23 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 23.

24. Paragraph 24 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 24.

25. Paragraph 25 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 25.

26. Paragraph 26 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 26.

27. Paragraph 27 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 27.

28. Paragraph 28 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 28.

B. Consumers benefit from generic drugs.

29. Paragraph 29 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 29.

30. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 30 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 30.

31. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 31 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 31.

32. Besins admits that, according to the FDA, Perrigo's 1% testosterone gel has been assigned a therapeutic equivalence rating of AB. Besins further responds that it lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 32 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 32.

33. Paragraph 33 asserts legal conclusions to which no answer is required. To the extent that a further response is required, Besins denies the allegations in paragraph 33.

34. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 34 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 34.

35. Besins admits that as a general matter, generic drugs are priced lower than their brand-name competition. Besins further responds that it lacks knowledge or information sufficient to form a belief concerning the remaining statements or allegations in paragraph 35 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 35.

C. AndroGel is a highly successful, highly profitable brand-name drug.

36. Besins admits the allegations and statements in the first sentence of paragraph 36. Besins further responds that some of the allegations in paragraph 36 purport to summarize and characterize the FDA-approved label for AndroGel, to which Besins refers for a true and complete statement of its contents. Besins denies the remaining allegations in paragraph 36.

37. Besins admits that Unimed and Besins entered into a License Agreement and a Supply Agreement in August 1995. Besins refers to those agreements for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 37.

38. Besins admits the allegations and statements in paragraph 38.

39. Besins is generally aware that: Solvay acquired Unimed; Abbott later acquired at least parts of Solvay's businesses; Abbott subsequently divided itself into different entities, with AbbVie being one such entity; and AbbVie ultimately holds Unimed's rights under the AndroGel license agreement. Besins further responds that it lacks knowledge or information sufficient to form a belief concerning the remaining statements or allegations in paragraph 39 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 39.

40. Besins admits that AndroGel 1.62% was launched in or around April 2011 and that the formulation of AndroGel 1.62% differs from that of AndroGel 1%. Besins further responds that it lacks knowledge or information sufficient to form a belief concerning the remaining statements or allegations in paragraph 40 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 40.

41. Besins generally acknowledges that AndroGel sales in the United States have grown over time and represent millions of dollars. Besins further responds that it lacks knowledge or information sufficient to form a belief concerning the remaining statements or allegations in paragraph 41 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 41.

42. Besins lacks knowledge or information sufficient to form a belief concerning the statements or allegations in paragraph 42 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 42.

43. Besins lacks knowledge or information sufficient to form a belief concerning the statements or allegations in paragraph 43 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 43.

V. The Narrow '894 Patent

44. Besins admits that testosterone itself is not patented and that testosterone was first artificially synthesized in 1935. Besins lacks knowledge or information sufficient to form a belief concerning the remaining statements or allegations in paragraph 44 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 44.

45. Besins admits that United States Patent Application Serial No. 09/651,777 was filed with the U.S. Patent and Trademark Office (the "PTO") in August 2000. The allegations in paragraph 45 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 45.

46. The allegations in paragraph 46 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 46.

A. Unimed and Besins initially sought to include all penetration enhancers in their patent claims.

47. The allegations in paragraph 47 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 47.

48. The allegations in paragraph 48 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 48.

49. The allegations in paragraph 49 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 49.

50. The allegations in paragraph 50 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 50.

B. Unimed and Besins next attempted to include a group of 24 penetration enhancers in their patent claims.

51. The allegations in paragraph 51 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 51.

52. The allegations in paragraph 52 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 52.

53. The allegations in paragraph 53 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 53.

54. The allegations in paragraph 54 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 54.

C. Unimed and Besins finally obtain a patent by limiting their claims to a single penetration enhancer, IPM.

55. The allegations in paragraph 55 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 55.

56. The allegations in paragraph 56 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 56.

57. The allegations in paragraph 57 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 57.

58. Besins admits the PTO issued the '894 Patent on January 7, 2003, and that Unimed and Besins co-own the '894 Patent. The remaining allegations in paragraph 58 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 58.

59. Besins admits that the FDA's "Orange Book" lists the '894 Patent as applicable to Androgel and that the '894 Patent will expire in August 2020.

60. Besins admits that it and Unimed are the co-owners of the '894 Patent. Besins denies the remaining allegations in paragraph 60.

61. Besins denies the allegations in paragraph 61.

VI. Perrigo's and Teva's Products

62. Besins admits that, according to Perrigo, Perrigo developed a testosterone gel formulation containing isostearic acid. The remaining allegations in paragraph 62 purport to summarize and characterize selected portions of one or more documents. Besins refer to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 62.

63. Besins admits that, according to Teva, Teva developed a testosterone gel formulation containing isopropyl palmitate. The remaining allegations in paragraph 63 purport to summarize and characterize selected portions of one or more documents. Besins refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 63.

A. In 2009, Solvay and Besins decided not to file an infringement suit against Perrigo.

64. Besins admits that it received a notice purporting to state that Perrigo had filed an ANDA containing a Paragraph IV certification asserting that, in the opinion of the applicant and to the best of the applicant's knowledge, the '894 Patent was invalid and/or unenforceable and/or would not be infringed by the proposed generic drug, and purporting to contain an offer of confidential access to Perrigo's ANDA with certain limitations. Besins denies the remaining allegations in paragraph 64.

65. Besins admits that it consulted with patent counsel regarding Perrigo's 2009 paragraph IV letter. Besins specifically asserts and does not waive any attorney client privilege, work product protections, or any other relevant privileges regarding that representation. Besins admits that it was aware that Solvay was represented by counsel in or around 2009. As to the scope and terms of that representation Besins lacks sufficient knowledge and information to

admit or deny the allegation in paragraph 65. If a further response is required, Besins denies the remaining allegations in paragraph 65.

66. Besins admits that Solvay (Unimed's parent company) and Besins did not sue Perrigo for patent infringement in 2009. The remaining allegations in paragraph 66 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 66.

67. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 67 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 67.

B. Abbott filed a citizen petition with the FDA, causing Perrigo and Teva to seek approval of their products through NDA filings.

68. Besins lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 68 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the allegations in paragraph 68.

69. Besins admits that it is generally aware that, at some point in time Abbott submitted a citizens petition to the FDA regarding the need for additional safety studies. Besins lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 69 and, therefore, can neither admit nor deny them. To the extent that a further response is required, Besins denies the remaining allegations in paragraph 69.

70. The allegations in paragraph 70 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 70.

71. Besins admits that, according to the FDA, Teva and Perrigo each filed an application with the FDA for approval to market a 1% testosterone gel in January 2011 and July 2011, respectively. Besins also admits that, according to Perrigo and Teva, they filed applications to the FDA to market testosterone gels that do not contain isopropyl myristate. Besins denies the remaining allegations in paragraph 71.

72. The phrase “multiple venues” is vague and ambiguous such that Besins is not able to admit or deny the allegations incorporating that phrase. To the extent a further response is required, Besins denies the allegations in paragraph 72.

C. AbbVie and Defendants repeatedly claimed that different penetration enhancers are not equivalent.

73. Besins admits, according to the FDA, Watson Pharmaceuticals, Inc. (“Watson”) and Paddock Laboratories, Inc. (“Paddock”) each filed an ANDA for approval to market a generic 1% testosterone gel. Besins also admits that, in 2003, Unimed and Besins sued Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. for infringement of the ‘894 Patent in the U.S. District Court for the Northern District of Georgia. Some of the remaining allegations in paragraph 73 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 73.

74. Besins admits that Unimed and Besins have asserted and continue to assert that every claim of the ‘894 Patent is nonobvious. Some of the remaining allegations in paragraph 74 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 74.

75. The allegations in paragraph 75 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 75.

76. The allegations in paragraph 76 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 76.

77. Besins admits that Abbot submitted a citizens petition to the FDA on or about August 18, 2011. Some of the remaining allegations in paragraph 77 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 77.

VII. Exclusionary Conduct Through Sham Litigations

78. Besins denies the allegations in paragraph 78.

A. AbbVie and Defendants sued Teva even though Teva's product does not contain IPM.

79. Besins admits that it received a letter dated March 16, 2011, stating that Teva had submitted NDA No. 202763 to the FDA for a testosterone gel product and that such NDA contained a Paragraph IV certification asserting that, in the opinion of the applicant and to the best of the applicant's knowledge, the '894 Patent was invalid and/or unenforceable and/or would not be infringed by the proposed drug. Besins further admits that the aforementioned letter purported to contain an offer of confidential access to Teva's NDA. Besins denies the remaining allegations in paragraph 79.

80. Besins admits that it or its representatives received documents that, according to Teva, constituted portions of Teva's NDA. Some of the remaining allegations in paragraph 80 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 80.

81. Besins admits that, on April 29, 2011, Unimed and Besins sued Teva for patent infringement in the U.S. District Court for the District of Delaware. The remaining allegations in paragraph 81 assert legal conclusions to which no answer is required. To the extent a further response is required, Besins denies the remaining allegations in paragraph 81.

82. Besins admits it contended that Teva infringed the '894 Patent under the doctrine of equivalents. Some of the remaining allegations in paragraph 82 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 82.

83. Besins admits that Teva purported to allege a counterclaim arising under the antitrust laws. Some of the remaining allegations in paragraph 83 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 83.

84. Besins admits that on August 1, 2011, Teva filed a motion for summary judgment on the issue of prosecution history estoppel; that on October 25, 2011, the district court denied that motion as moot; and that the district court set a limited bench trial to begin on May 21, 2012. Besins denies the remaining allegations in paragraph 84.

85. Besins admits the allegations in paragraph 85.

B. AbbVie and Besins sued Perrigo even though Perrigo's product does not contain IPM.

86. Besins admits that it received a letter dated September 20, 2011, stating that Perrigo had submitted NDA No. 203098 to the FDA for a testosterone gel product and that such NDA contained a Paragraph IV certification asserting that, in the opinion of the applicant and to the best of the applicant's knowledge, the '894 Patent was invalid and/or unenforceable and/or would not be infringed by the proposed drug. Besins further admits that the aforementioned letter purported to contain an offer of confidential access to Perrigo's NDA. Some of the remaining allegations in paragraph 86 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 86.

87. Besins admits that it or its representatives received documents that, according to Perrigo, constituted portions of Perrigo's NDA. Some of the remaining allegations in paragraph 87 purport to summarize, characterize, and quote from selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise denies any remaining allegations in paragraph 87.

88. Besins admits that on October 31, 2011, Unimed and Besins sued Teva for patent infringement in the U.S. District Court for the District of New Jersey. The remaining allegations in paragraph 88 assert legal conclusions to which no answer is required. To the extent a further response is required, Besins denies the remaining allegations in paragraph 88.

89. Besins admits that it contended that Perrigo infringed the '894 Patent under the doctrine of equivalents. Some of the remaining allegations in paragraph 89 purport to summarize and characterize selected portions of one or more documents. Besins refers to those

documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 89.

90. Besins admits that the FDA approved Perrigo's NDA on January 31, 2013, and assigned Perrigo's product an AB rating on July 23, 2014. Besins denies the remaining allegations in paragraph 90.

C. AbbVie Defendants and Besins's lawsuits were sham.

91. Besins denies the allegations in paragraph 91.

92. Besins admits that it contended that Teva and Perrigo each infringed the '894 Patent under the doctrine of equivalents. Some of the remaining allegations in paragraph 92 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 92.

93. The allegations in paragraph 93 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 93.

94. The allegations in paragraph 94 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 94.

95. The allegations in paragraph 95 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 95.

96. The allegations in paragraph 96 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 96.

97. Besins denies the allegations in paragraph 97.

98. Besins denies the allegations in paragraph 98.

99. Besins deny the allegation in paragraph 99.

100. Paragraph 100 asserts a legal conclusion to which no answer is required. Besins denies any remaining factual allegations in paragraph 100.

VIII. Exclusionary Conduct and Restraint of Trade Through An Anticompetitive Agreement

101. The allegations in paragraph 101 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 101.

102. The allegations in paragraph 102 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, the allegations in paragraph 102 purport to summarize and characterize selected portions of one or more documents. Besins refers to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 102.

103. The allegations in paragraph 103 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 103.

104. The allegations in paragraph 104 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 104.

105. The allegations in paragraph 105 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 105.

A. The sham lawsuits did not eliminate the threat of Teva's and Perrigo's products to AbbVie Defendants and Besins's monopoly.

106. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that Paragraph 106 asserts legal conclusion to which no answer is required. Besins denies any remaining factual allegations in paragraph 106.

107. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that Paragraph 107 asserts legal conclusion to which no answer is required. Besins denies any remaining factual allegations in paragraph 107.

108. The allegations in paragraph 108 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this

paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 108.

109. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 109 and, therefore, denies them.

110. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 110 and, therefore, denies them.

111. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 111.

B. AbbVie Defendants paid Teva in the form of the TriCor authorized generic deal to drop its patent challenge and refrain from competing until December 2014.

112. The allegations in paragraph 112 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 112.

113. The allegations in paragraph 113 are not directed to Besins and, accordingly, no response is required. Besins further responds that because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this

paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 113.

114. The allegations in paragraph 114 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 114 and, therefore, denies them.

115. The allegations in paragraph 115 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 115 and, therefore, denies them.

116. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent that a response is required, Besins admits that Abbott Products, Inc., Unimed, Besins, and Teva entered into a written settlement agreement of the patent litigation on December 20, 2011, to which Besins refers for a true and complete statement of its contents. Besins denies remaining allegations in paragraph 116.

117. The allegations in paragraph 117 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 117 and, therefore, denies them.

118. The allegations in paragraph 118 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 118 and, therefore, denies them.

C. The TriCor authorized generic deal was a large payment to Teva.

119. The allegations in paragraph 119 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 119 and, therefore, denies them.

120. The allegations in paragraph 120 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 120 and, therefore, denies them.

121. The allegations in paragraph 121 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 121 and, therefore, denies them.

122. The allegations in paragraph 122 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the

extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 122 and, therefore, denies them.

123. The allegations in paragraph 123 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 123 and, therefore, denies them.

124. The allegations in paragraph 124 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 124 and, therefore, denies them.

D. The TriCor authorized generic deal is unjustified.

125. The allegations in paragraph 125 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 125 and, therefore, denies them.

126. The allegations in paragraph 126 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 126 and, therefore, denies them.

127. The allegations in paragraph 127 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 127 and, therefore, denies them.

128. The allegations in paragraph 128 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 128 and, therefore, denies them.

129. The allegations in paragraph 129 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 129 and, therefore, denies them.

130. The allegations in paragraph 130 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 130 and, therefore, denies them.

131. The allegations in paragraph 131 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the

extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 131 and, therefore, denies them.

132. The allegations in paragraph 132 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 132 and, therefore, denies them.

E. AbbVie Defendants agreement with Teva effectively blocked Perrigo's generic AndroGel entry

133. The allegations in paragraph 133 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 133 and, therefore, denies them.

134. The allegations in paragraph 134 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 134 and, therefore, denies them.

135. The allegations in paragraph 135 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 135 and, therefore, denies them.

136. The allegations in paragraph 136 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins admits admit that that Abbott Products, Inc., Unimed, Besins, and Perrigo entered into a written settlement agreement of the patent litigation on December 8, 2011, to which Besins refers for a true and complete statement of its contents. Besins denies the remaining allegations in paragraph 136.

137. The allegations in paragraph 137 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 137 and, therefore, denies them.

IX. AbbVie Defendants and Besins's Market and Monopoly Power

138. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 138.

139. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 139 and, therefore, denies them.

140. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 140 and, therefore, denies them.

141. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 141.

142. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins admits that Teva and Perrigo received FDA approval for their respective testosterone gels in February 2012 and January 2013, respectively. Besins denies the remaining allegations in paragraph 142.

143. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins denies the allegations in paragraph 143.

144. The allegations in paragraph 144 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 144 and, therefore, denies them.

145. The allegations in paragraph 145 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 145 and, therefore, denies them.

146. The allegations in paragraph 146 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue

in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 146 and, therefore, denies them.

147. The allegations in paragraph 147 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 147 and, therefore, denies them.

148. The allegations in paragraph 148 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 148 and, therefore, denies them.

149. The allegations in paragraph 149 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 149 and, therefore, denies them.

150. The allegations in paragraph 150 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 150 and, therefore, denies them.

151. The allegations in paragraph 151 are not directed to Besins and, accordingly, no response is required. Because Count II, and Count I to the extent based on the conduct at issue in Count II, has been dismissed by the Court, no answer to this paragraph is required. To the extent a response is required, Besins admits that AndroGel 1.62% has been marketed since 2012. To the extent a further response is required, Besins responds that it lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 151 and, therefore, denies them.

Count I
Monopolization—Against AbbVie, Abbott, Unimed, and Besins

152. Besins repeats and reasserts all the responses set forth above as if fully set forth herein.

153. Besins denies the allegations in paragraph 153.

Count II
Monopolization—Against AbbVie, Abbott, Unimed, and Teva

154. The allegations in Count II are not directed to Besins and, accordingly, no response is required. Count II has been dismissed by the Court and therefore no response to paragraph 154 is required. To the extent a response is required, Besins repeats and reasserts all the responses set forth above as if fully set forth herein.

155. The allegations in Count II are not directed to Besins and, accordingly, no response is required. Count II has been dismissed by the Court and therefore no response to paragraph 155 is required. To the extent a response is required, Besins denies the allegations in paragraph 155.

Prayer for Relief

Besins denies that Plaintiff is entitled to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without assuming any burden of proof that they would not otherwise bear, Besins asserts the following separate and additional affirmative defenses, all of which are pleaded in the alternative:

First Defense

The Complaint fails to state a claim against Besins upon which relief can be granted.

Second Defense

Plaintiff's claims are barred, in whole or in part, because U.S. Patent No. 6,503,894 is valid, enforceable, and infringed by Teva's and Perrigo's respective New Drug Applications for testosterone gels.

Third Defense

Plaintiff's claims are barred, in whole or in part, because Besins had a good faith basis to initiate and maintain its patent infringement litigations against Teva and Perrigo.

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations.

Fifth Defense

Plaintiff's claims are barred because Besins's actions were taken in good faith to advance legitimate business interests and had the effect of promoting, encouraging, and increasing competition.

Sixth Defense

Count II (and Count I to the extent based on the conduct at issue in Count II) has been dismissed by the Court such that any affirmative defenses thereto need not be stated. To the extent such defenses need to be stated, Plaintiff's claims are barred, in whole or in part, because even assuming arguendo that the antitrust laws applied and further assuming arguendo that the

alleged conduct had any potential anticompetitive effect, the relevant settlement agreement(s) is governed by the rule of reason and is lawful, as the procompetitive benefits outweigh any alleged anticompetitive effect.

Seventh Defense

Plaintiff's claims are barred, in whole or in part, because Besins's conduct is protected under the *Noerr-Pennington* doctrine and under the Constitution of the United States.

Eighth Defense

Plaintiff's claims are barred, in whole or in part, for failure to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

Ninth Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff has not properly alleged either a relevant product market or a relevant geographic market.

Tenth Defense

Plaintiff's claims are barred, in whole or in part, because the acts or omissions of Besins did not substantially lessen or harm competition in any properly defined market.

Eleventh Defense

Plaintiff's claims are barred, in whole or in part, because Besins did not and do not maintain monopoly power in the relevant market.

Twelfth Defense

Plaintiff's claims are barred, in whole or in part, because Besins's conduct was lawful under all applicable laws, status, ordinances, and decrees, including the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984, and related legislation.

Thirteenth Defense

Plaintiff's claims are barred, in whole or in part, under the *Trinko* doctrine and its progeny because any harm to competition complained of stems from the intricate, multi-tiered regulatory regime which governs the production, sale, and manufacture of pharmaceutical products, including the Hatch-Waxman Act.

RESERVATION OF DEFENSES AND AFFIRMATIVE DEFENSES

Besins reserves the right to assert and rely on any additional defenses and affirmative defenses that may come available or apparent, and to amend their answer and/or defenses.

Dated: May 20, 2015

Respectfully submitted,

/s/ Paul H. Saint-Antoine
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CERTIFICATE OF SERVICE

The undersigned certifies that on the 20th day of May 2015 the foregoing Besins Healthcare, Inc.'s Answer to the Complaint was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. This document is available for reviewing and download.

/s/ Todd N. Hutchison

Todd N. Hutchison