

**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

**ABBVIE DEFENDANTS' ANSWER TO THE COMPLAINT**

Defendants AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC (the “AbbVie Defendants”) hereby submit their 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 the AbbVie Defendants refer for a true and complete statement of its contents. The AbbVie Defendants deny the remaining allegations in paragraph 1.

2. The AbbVie Defendants admit that Unimed Pharmaceuticals LLC (“Unimed”) is a wholly owned, indirect subsidiary of AbbVie Inc., that Unimed co-owns U.S. Patent No. 6,503,894 (the “’894 Patent”), that the ’894 Patent relates to AndroGel, and that the term “penetration enhancer” can be used to refer to a chemical moiety used to enhance the transport or 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. The AbbVie Defendants refer to those documents

for a true and complete statement of their contents and otherwise deny the allegations in paragraph 2.

3. The AbbVie Defendants admit that, according to Perrigo and Teva, they filed applications with the FDA to market testosterone gels containing isostearic acid and isopropyl palmitate, respectively. The AbbVie Defendants deny the remaining allegations in paragraph 3.

4. The AbbVie Defendants admit that Perrigo was not sued for infringement of the '894 Patent in 2009. Some of the further allegations in paragraph 4 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 4.

5. The AbbVie Defendants admit that, in 2011, Unimed and Besins sued Teva and Perrigo for infringement of the '894 Patent. The AbbVie Defendants deny the remaining allegations in paragraph 5.

6. The AbbVie Defendants admit that Unimed did not contend in the above-referenced lawsuits that Teva and Perrigo had literally infringed the '894 Patent. To the extent paragraph 6 asserts legal conclusions, no answer is required. The AbbVie Defendants deny the remaining factual allegations in paragraph 6.

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

8. The AbbVie Defendants admit that Teva purported to allege a counterclaim for sham litigation. The AbbVie Defendants also admit 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. The AbbVie Defendants deny the remaining allegations in paragraph 8.

9. The AbbVie Defendants admit that Abbott Products, Inc., Unimed, Besins, and Teva entered into a written settlement agreement, and that Abbott Laboratories and Teva entered into a written supply option agreement, to which the AbbVie Defendants refer for true and complete statements of their contents. The AbbVie Defendants deny the remaining allegations in paragraph 9.

10. The AbbVie Defendants deny the allegations in paragraph 10.

## **“II. Jurisdiction and Venue”**

11. Paragraph 11 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 11.

12. The AbbVie Defendants admit that they are subject to the Court's personal jurisdiction. The remaining allegations of paragraph 12 assert legal conclusions to which no answer is required.

13. The AbbVie Defendants admit that venue is proper in this District. The AbbVie Defendants deny that they committed an illegal or tortious act, in this district or elsewhere, as alleged in the complaint. The AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 13 regarding Defendants other than the AbbVie Defendants, and, therefore, deny them. Otherwise, paragraph 13 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 13.

14. Paragraph 14 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 14.

15. Paragraph 15 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 15.

**“III. The Parties”**

16. Paragraph 16 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 16.

17. The AbbVie Defendants admit that Abbott Laboratories (“Abbott”) is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. The AbbVie Defendants also admit that Abbott has engaged in the sale and distribution of medical devices, medical diagnostic products, nutritional products, and branded pharmaceutical products, including AndroGel. The AbbVie Defendants also admit that Abbott’s stock is publicly traded and that the separation of AbbVie Inc. (“AbbVie”) from Abbott occurred on or around January 1, 2013. The AbbVie Defendants deny the remaining allegations in paragraph 17.

18. The AbbVie Defendants admit that AbbVie is a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. The AbbVie Defendants also admit that AbbVie has been engaged in the sale and distribution of branded pharmaceutical products, including AndroGel, since January 1, 2013. The AbbVie Defendants admit that AbbVie Products LLC f/k/a Abbott Products Inc. f/k/a Solvay Pharmaceuticals, Inc. is currently a wholly owned subsidiary of AbbVie and was previously acquired by Abbott in 2010. The AbbVie Defendants also admit that AbbVie’s stock has been publicly traded since approximately January 1, 2013. The AbbVie Defendants also admit that, in the twelve months ending December 31, 2013, AbbVie’s sales were approximately \$18.8 billion, and that its U.S.

sales for AndroGel exceeded \$1 billion. The AbbVie Defendants deny the remaining allegations in paragraph 18.

19. The AbbVie Defendants admit that Unimed is a Delaware limited liability company with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. The AbbVie Defendants also admit that Unimed is a wholly owned indirect subsidiary of AbbVie. The AbbVie Defendants deny the remaining allegations in paragraph 19.

20. The AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 20 and, therefore, deny them.

21. The AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 21 and, therefore, deny them.

#### **“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. The AbbVie Defendants deny any remaining factual allegations in paragraph 22.

23. Paragraph 23 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 23.

24. Paragraph 24 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 24.

25. Paragraph 25 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 25.

26. Paragraph 26 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 26.

27. Paragraph 27 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 27.

28. The AbbVie Defendants deny the allegations in paragraph 28.

**“B. Consumers benefit from generic drugs.”**

29. Paragraph 29 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 29.

30. Paragraph 30 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 30.

31. The AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 31 and, therefore, deny them.

32. The AbbVie Defendants admit that, according to the FDA, Perrigo’s 1% testosterone gel has been assigned a therapeutic equivalence rating of AB. The AbbVie Defendants deny the remaining allegations in paragraph 32.

33. Paragraph 33 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 33.

34. The allegations in paragraph 34 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 34.

35. The allegations in paragraph 35 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 35.

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

36. The AbbVie Defendants admit that AbbVie markets AndroGel. Some of the allegations in paragraph 36 purport to summarize and characterize the FDA-approved label for

AndroGel, to which the AbbVie Defendants refer for a true and complete statement of its contents. The AbbVie Defendants deny the remaining allegations in paragraph 36.

37. The AbbVie Defendants admit that Unimed and Besins entered into a License Agreement and a Supply Agreement in August 1995. The AbbVie Defendants refer to those agreements for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 37.

38. The AbbVie Defendants admit the allegations in paragraph 38.

39. The AbbVie Defendants admit that Solvay Pharmaceuticals, Inc. (“Solvay”) acquired Unimed in 1999, that Abbott acquired Solvay in February 2010, that the separation of AbbVie from Abbott occurred on or about January 1, 2013, and that AbbVie was established in January 2013 as an independent, publicly traded company from the research-based pharmaceutical business of Abbott Laboratories. The AbbVie Defendants deny any remaining allegations in paragraph 39.

40. The AbbVie Defendants admit 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%. The AbbVie Defendants deny any remaining allegations in paragraph 40.

41. The AbbVie Defendants admit the allegations in paragraph 41.

42. The AbbVie Defendants deny the allegations in paragraph 42.

43. The AbbVie Defendants admit that AndroGel is profitable and deny the remaining allegations in paragraph 43.

#### **“V. The Narrow ’894 Patent”**

44. Paragraph 44 asserts legal conclusions to which no answer is required. The AbbVie Defendants admit that testosterone was first artificially synthesized in 1935, but lack knowledge or information sufficient to form a belief concerning the allegations that testosterone

“has been available in various drug products since the 1950s” and that pharmaceutical gel products have “been available for decades” and, therefore, deny them. The AbbVie Defendants deny the remaining allegations in paragraph 44.

45. The AbbVie Defendants admit 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 45.

46. The allegations in paragraph 46 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 47.

48. The allegations in paragraph 48 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 48.

49. The allegations in paragraph 49 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those

documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 49.

50. The allegations in paragraph 50 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 51.

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

53. The allegations in paragraph 53 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 53.

54. The allegations in paragraph 54 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 55.

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

57. The allegations in paragraph 57 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 57.

58. The AbbVie Defendants admit that 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 58.

59. The AbbVie Defendants admit that the Orange Book lists the '894 Patent as applicable to AndroGel and that the '894 Patent will expire in August 2020. The AbbVie Defendants deny the remaining allegations in paragraph 59.

60. The AbbVie Defendants admit that Unimed and Besins co-own the '894 Patent. The AbbVie Defendants deny the remaining allegations in paragraph 60.

61. The AbbVie Defendants deny the allegations in paragraph 61.

**“VI. Perrigo’s and Teva’s Products”**

62. The AbbVie Defendants admit 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 62.

63. The AbbVie Defendants admit 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. The AbbVie Defendants 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. The AbbVie Defendants admit that Solvay and Unimed 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. The AbbVie Defendants deny the remaining allegations in paragraph 64.

65. The AbbVie Defendants admit that Solvay was represented by counsel in or around 2009. The AbbVie Defendants assert and do not waive the attorney-client privilege and work-product protection with respect to the details of Solvay’s representation by counsel. The

AbbVie Defendants therefore are not in a position to admit or deny the remaining allegations in paragraph 65 and, on that basis, deny them.

66. The AbbVie Defendants admit that Solvay, Unimed, 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 66.

67. The allegations in paragraph 67 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining 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. The allegations in paragraph 68 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 68.

69. The AbbVie Defendants admit that Abbott submitted a citizen petition to the FDA on or about April 9, 2010. Some of the remaining allegations in paragraph 69 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any 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. The AbbVie Defendants refer to those

documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 70.

71. The AbbVie Defendants admit 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. The AbbVie Defendants also admit that, according to Perrigo and Teva, they filed applications to the FDA to market testosterone gels that do not contain isopropyl myristate. The AbbVie Defendants deny the remaining allegations in paragraph 71.

72. The allegations in paragraph 72 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 72.

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

73. The AbbVie Defendants admit that, 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. The AbbVie Defendants also admit 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 73.

74. The AbbVie Defendants admit 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 74.

75. The allegations in paragraph 75 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 76.

77. The AbbVie Defendants admit that Abbott submitted a citizen 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 77.

**“VII. Exclusionary Conduct Through Sham Litigations”**

78. The AbbVie Defendants deny the allegations in paragraph 78.

**“A. AbbVie and Defendants sued Teva even though Teva’s product does not contain IPM.”**

79. The AbbVie Defendants admit that they 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. The AbbVie Defendants also admit that the aforementioned letter purported to contain an offer of confidential access to Teva's NDA. The AbbVie Defendants deny the remaining allegations in paragraph 79.

80. The AbbVie Defendants admit that they received documents that, according to Teva, constituted portions of Teva's NDA. Some of the remaining allegations in paragraph 80 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 80.

81. The AbbVie Defendants admit 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.

82. The AbbVie Defendants admit that they contended that Teva infringed the '894 Patent under the doctrine of equivalents. Some of the remaining allegations in paragraph 82 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 82.

83. The AbbVie Defendants admit that Teva purported to allege a counterclaim arising under the antitrust laws. Some of the remaining allegations in paragraph 83 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 83.

84. The allegations in paragraph 84 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 84.

85. The AbbVie Defendants admit the allegations in paragraph 85.

**“B. AbbVie and Besins sued Perrigo even though Perrigo’s product does not contain IPM.”**

86. The AbbVie Defendants admit that they 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. The AbbVie Defendants also admit 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 86.

87. The AbbVie Defendants admit that they received documents that, according to Perrigo, constituted portions of Perrigo’s NDA. Some of the remaining allegations in paragraph 87 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 87.

88. The AbbVie Defendants admit 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.

89. The AbbVie Defendants admit that they 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 89.

90. The AbbVie Defendants admit that the FDA approved Perrigo's NDA on January 31, 2013, and assigned Perrigo's product an AB rating on July 23, 2014. The AbbVie Defendants deny the remaining allegations in paragraph 90.

**“C. AbbVie Defendants and Besins's lawsuits were sham.”**

91. The AbbVie Defendants deny the allegations in paragraph 91.

92. The AbbVie Defendants admit that they 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. The AbbVie Defendants refer 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. The AbbVie Defendants refer 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. The AbbVie Defendants refer 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. The AbbVie Defendants refer 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. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 96.

97. The AbbVie Defendants deny the allegations in paragraph 97.

98. The AbbVie Defendants deny the allegations in paragraph 98.

99. The AbbVie Defendants deny the allegations in paragraph 99.

100. Paragraph 100 asserts legal conclusion to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 100.

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

101. 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 AbbVie Defendants deny the allegations in paragraph 101.

102. 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. The AbbVie Defendants refer to those documents

for a true and complete statement of their contents and otherwise deny any remaining allegations in paragraph 102.

103. 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 AbbVie Defendants deny the allegations in paragraph 103.

104. 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 AbbVie Defendants deny the allegations in paragraph 104.

105. 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 AbbVie Defendants deny 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, the AbbVie Defendants state that Paragraph 106 asserts legal conclusion to which no answer is required. The AbbVie Defendants deny 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, the AbbVie Defendants state that Paragraph 107 asserts legal conclusion to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 107.

108. 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 AbbVie Defendants state that the allegations in paragraph 108 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny any remaining 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, the AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 109 and, therefore, deny 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, the AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 110 and, therefore, deny 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, the AbbVie Defendants deny 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. 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 AbbVie Defendants deny the allegations in paragraph 112.

113. 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 AbbVie Defendants deny the allegations in paragraph 113.

114. 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 AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 114 and, therefore, deny them.

115. 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 AbbVie Defendants admit that the litigation in which Unimed and Besins asserted that Teva infringed the '894 Patent has been settled. The AbbVie Defendants deny the remaining allegations in paragraph 115.

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 a response is required, the AbbVie Defendants admit that Abbott Products, Inc., Unimed, Besins, and Teva entered into a written settlement agreement of the patent litigation on December 20, 2011, to which the AbbVie Defendants refer for a true and complete statement of its contents. The AbbVie Defendants deny the remaining allegations in paragraph 116.

117. 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 AbbVie Defendants admit that Abbott and Teva entered into a written supply agreement on December 20, 2011, to which the to which the AbbVie Defendants refer for

a true and complete statement of its contents. The AbbVie Defendants deny the remaining allegations in paragraph 117.

118. 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 AbbVie Defendants lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of paragraph 118 and, therefore, deny them. Some of the further allegations in paragraph 118 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 118.

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

119. 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 AbbVie Defendants deny the allegations in paragraph 119.

120. 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 AbbVie Defendants deny the allegations in paragraph 120.

121. 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 121 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 121.

122. 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 AbbVie Defendants deny the allegations in paragraph 122.

123. 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 AbbVie Defendants deny the allegations in paragraph 123.

124. 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 AbbVie Defendants state that Paragraph 124 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 124.

**“D. The TriCor authorized generic deal is unjustified.”**

125. 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 AbbVie Defendants deny the allegations in paragraph 125.

126. 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 126 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 126.

127. 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 127 purport to summarize and characterize

selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 127.

128. 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 128 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 128.

129. 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 AbbVie Defendants admit that Teva began marketing generic versions of TriCor in 145 mg and 48 mg strengths on or about November 16, 2012. Some of the remaining allegations in paragraph 129 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 129.

130. 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 AbbVie Defendants deny the allegations in paragraph 130.

131. 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 AbbVie Defendants deny the allegations in paragraph 131.

132. 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 132 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 132.

**“E. AbbVie Defendants agreement with Teva effectively blocked Perrigo’s generic AndroGel entry”**

133. 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 AbbVie Defendants deny the allegations in paragraph 133.

134. 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 first sentence of paragraph 134 asserts legal conclusions to which no answer is required. The AbbVie Defendants deny any remaining factual allegations in paragraph 134.

135. 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 AbbVie Defendants admit that the patent-infringement lawsuits against Teva and Perrigo were filed in different courts. The AbbVie Defendants deny the remaining allegations in paragraph 135.

136. 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 AbbVie Defendants 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 the AbbVie Defendants refer for a true and complete statement of its contents. The AbbVie Defendants deny the remaining allegations in paragraph 136.

137. 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 137 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 137.

**“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, the AbbVie Defendants deny 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, the AbbVie Defendants deny the allegations in paragraph 139.

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, the AbbVie Defendants deny the allegations in paragraph 140.

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, the AbbVie Defendants deny 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, the AbbVie Defendants admit that Teva and Perrigo received FDA approval for their respective testosterone gels in February 2012 and January 2013, respectively. The AbbVie Defendants deny 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, the AbbVie Defendants deny the allegations in paragraph 143.

144. 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 AbbVie Defendants deny the allegations in paragraph 144.

145. 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 AbbVie Defendants deny the allegations in paragraph 145.

146. 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 AbbVie Defendants deny the allegations in paragraph 146.

147. 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 AbbVie Defendants deny the allegations in paragraph 147.

148. 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 148 purport to summarize and characterize selected portions of one or more documents. The AbbVie Defendants refer to those documents

for a true and complete statement of their contents and otherwise deny the allegations in paragraph 148.

149. 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 AbbVie Defendants admit that the FDA assigned an AB rating to Perrigo's product. The AbbVie Defendants deny the remaining allegations in paragraph 149.

150. 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 150 purport to summarize, characterize, and quote from selected portions of one or more documents. The AbbVie Defendants refer to those documents for a true and complete statement of their contents and otherwise deny the allegations in paragraph 150.

151. 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 AbbVie Defendants admit that AndroGel 1.62% has been marketed since 2012. The AbbVie Defendants deny the remaining allegations in paragraph 151.

### **Count I**

#### **“Monopolization—Against AbbVie, Abbott, Unimed, and Besins”**

152. The AbbVie Defendants repeat and reassert all of the responses set forth above as if fully set forth herein.

153. The AbbVie Defendants deny the allegations in paragraph 153.

## **Count II**

### **“Monopolization—Against AbbVie, Abbott, Unimed, and Teva”**

154. Count II has been dismissed by the Court and therefore no response to paragraph 154 is required. To the extent that a response is required, the AbbVie Defendants repeat and reassert all of the responses set forth above as if fully set forth herein.

155. Count II has been dismissed by the Court and therefore no response to paragraph 155 is required. To the extent that a response is required, the AbbVie Defendants deny the allegations in paragraph 153.

### **“Prayer for Relief”**

The AbbVie Defendants deny that Plaintiff is entitled to any relief whatsoever.

## **AFFIRMATIVE DEFENSES**

Without assuming any burden of proof that they would not otherwise bear, the AbbVie Defendants assert 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 the AbbVie Defendants 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 Unimed and 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 the AbbVie Defendants' 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 AbbVie Defendants' settlement agreements are governed by the rule of reason and are lawful, as their procompetitive benefits outweigh any alleged anticompetitive effect.

**Seventh Defense**

Plaintiff's claims are barred, in whole or in part, because the AbbVie Defendants' 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 the AbbVie Defendants 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 the AbbVie Defendants 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 the AbbVie Defendants' 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**

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 the supply and manufacturing agreement Abbott entered with Teva did not involve any large and unjustified payment.

**Fourteenth 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**

The AbbVie Defendants reserve 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/ Stuart N. Senator  
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**CERTIFICATE OF SERVICE**

I certify that, on May 20, 2015, the foregoing document was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. The document is available for viewing and downloading.

Dated: May 20, 2015

s/ Adam R. Lawton