

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

FEDERAL TRADE COMMISSION,

Plaintiff,

V.

**WATSON PHARMACEUTICALS,
INC., ET AL.,**

Defendants.

CASE NO. 1:09-CV-00955-TWT

**DEFENDANT’S ANSWER TO PLAINTIFF’S SECOND AMENDED
COMPLAINT**

Defendant Watson Pharmaceuticals, Inc., now known as Actavis, Inc. (“Actavis”), by and through its undersigned attorneys, hereby responds to the Second Amended Complaint for Injunctive and Other Equitable Relief (“SAC”) in the above-referenced action. Actavis avers generally that the answers contained herein are with respect to the allegations directed to Actavis only, as Actavis is not required to respond to allegations put forth against any other Defendant. Actavis generally denies each and every allegation that Actavis does not expressly admit. Actavis also specifically denies some allegations without affecting its general denial of other allegations. In addition to the above general answers, Actavis now

offers the following answers to the specific allegations set forth in each numbered paragraph of the SAC:

1. Paragraph 1 states legal conclusions or arguments to which no answer is required. To the extent an answer may be required, Actavis denies the allegations in paragraph 1.

2. Actavis admits that Watson Laboratories, Inc. filed an application with the U.S. Food and Drug Administration (“FDA”) to market a generic version of AndroGel, and that Watson Laboratories, Inc. received final approval from the FDA to market its AB-rated generic version of AndroGel. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 2.

3. Paragraph 3 contains legal conclusions or arguments to which no answer is required. Actavis admits that Unimed and Besins filed a patent infringement suit against it relating to its generic version of AndroGel. To the extent the allegations in paragraph 3 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 3 do not accurately reflect those documents, Actavis denies the allegations in paragraph 3. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 3.

4. Actavis denies the allegations in the first sentence of paragraph 4.

Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 4.

5. Actavis denies the allegations in paragraph 5.

6. Actavis denies the allegations in paragraph 6.

7. Paragraph 7 states legal conclusions or arguments to which no answer is required.

8. Paragraph 8 states legal conclusions or arguments to which no answer is required. To the extent that an answer may be required, Actavis admits that the Court has personal jurisdiction over Actavis.

9. Paragraph 9 states legal conclusions or arguments to which no answer is required. To the extent any response is required, Actavis admits that venue is proper in the Northern District of Georgia and that Actavis manufactures products that are sold and/or distributed in the District. Actavis denies the remaining allegations in paragraph 9.

10. Paragraph 10 states legal conclusions or arguments to which no answer is required.

11. Paragraph 11 states legal conclusions or arguments to which no answer is required.

12. Actavis admits the allegations in paragraph 12.

13. Actavis admits that it is a Nevada corporation, and that the Actavis group of companies develops, manufactures, markets and distributes generic drug products. Actavis also admits that Watson Pharmaceuticals, Inc. had net revenues of approximately \$2.5 billion in 2007, a portion of which were related to the sale of generic drugs. Actavis denies the remaining allegations in paragraph 13.

14. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 14.

15. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 15.

16. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 16.

17. Paragraph 17 describes legal conclusions to which no answer is required.

18. Paragraph 18 describes legal conclusions to which no answer is required.

19. Paragraph 19 describes legal conclusions to which no answer is required.

20. Paragraph 20 describes legal conclusions to which no answer is required.

21. Paragraph 21 describes legal conclusions to which no answer is required.

22. Paragraph 22 describes legal conclusions to which no answer is required.

23. Paragraph 23 describes legal conclusions to which no answer is required.

24. Actavis admits that generic drugs are generally less costly than the brand name drugs to which they are AB-rated. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 24.

25. Paragraph 25 describes legal conclusions to which no answer is required. To the extent an answer may be required, Actavis admits that generally AB-rated generic versions of drugs can be substituted for their corresponding reference listed drug. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 25.

26. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 26.

27. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 27.

28. To the extent the allegations in paragraph 28 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 28 do not accurately reflect those documents, Actavis denies the allegations in paragraph 28. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 28.

29. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 29.

30. To the extent the allegations in paragraph 30 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 30 do not accurately reflect those documents, Actavis denies the allegations in paragraph 30. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 30.

31. Actavis admits that Solvay has marketed a branded prescription drug called AndroGel, a pharmaceutical gel containing synthetic testosterone. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 31.

32. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 32.

33. Actavis admits the allegations in the second and third sentences of paragraph 33. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 33.

34. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 34.

35. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 35.

36. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 36.

37. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 37.

38. Paragraph 38 describes legal conclusions to which no answer is required.

39. Paragraph 39 contains legal conclusions or arguments to which no answer is required. Actavis admits that the inventors applied for a U.S. patent relating to AndroGel in August 2000. To the extent the allegations in paragraph 39 rely on publicly available documents, those documents speak for themselves. To

the extent that the allegations in paragraph 39 do not accurately reflect those documents, Actavis denies the allegations in paragraph 39.

40. To the extent that Plaintiff's allegations rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 40 do not accurately reflect those documents, Actavis denies the allegations in paragraph 40. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 40.

41. To the extent that Plaintiff's allegations rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 41 do not accurately reflect those documents, Actavis denies the allegations in paragraph 41. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 41.

42. Actavis admits that U.S. Patent Office (PTO) issued Patent No. 6,503,894 on January 7, 2003. To the extent Plaintiff's allegations rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 42 do not accurately reflect those documents, Actavis denies the allegations in paragraph 42. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 42.

43. To the extent Plaintiff's allegations rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 43 do not accurately reflect those documents, Actavis denies the allegations in paragraph 43. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 43.

44. Actavis admits that it filed an application with the FDA for approval to market a generic version of AndroGel in May 2003, and as part of that application Actavis certified that in its opinion the patent was invalid and not infringed. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 44.

45. Actavis admits the allegations in paragraph 45.

46. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 46.

47. Actavis admits that Unimed and Besins filed a patent infringement suit against it in August 2003. The second and third sentences of paragraph 47 state legal conclusions or arguments to which no answer is required. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 47.

48. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 48.

49. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 49.

50. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 50.

51. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 51.

52. Actavis admits that Watson Laboratories, Inc. received final approval from the FDA to market its AB-rated generic version of AndroGel. The remaining allegations in paragraph 52 state legal conclusions or arguments to which no answer is required.

53. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 53.

54. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 54.

55. Actavis admits that it ordered selected equipment that may have been required for manufacturing generic AndroGel. Actavis denies the remaining allegations in paragraph 55.

56. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 56.

57. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 57.

58. To the extent the allegations in paragraph 58 relate to Actavis, Actavis denies the allegations in paragraph 58. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 58.

59. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 59.

60. Actavis denies the allegations in the first sentence of paragraph 60. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 60.

61. Actavis denies the allegations in the first, second, third and fourth sentences of paragraph 61. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 61.

62. Actavis denies the allegations in the first sentence of paragraph 62. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 62.

63. Actavis admits that Solvay planned to develop and market a low-volume testosterone gel. Actavis denies the remaining allegations in paragraph 63.

64. Actavis denies the allegations in paragraph 64.

65. Actavis admits the allegations in the first sentence of paragraph 65.

Actavis admits that it obtained a license to market generic AndroGel on August 31, 2015, or earlier if another generic company launches a generic version of AndroGel before that date.

66. Actavis admits that Watson Pharma, Inc. entered into a co-promotion deal with Solvay Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc. under which Watson Pharma, Inc. would be compensated for promoting AndroGel to urologists. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 66.

67. Actavis denies the allegations in paragraph 67.

68. Actavis admits the allegations in paragraph 68.

69. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 69.

70. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 70.

71. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 71.

72. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 72.

73. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 73.

74. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 74.

75. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 75.

76. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 76.

77. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 77.

78. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 78.

79. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 79.

80. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 80.

81. Actavis denies the allegations in paragraph 81.

82. Actavis denies the allegations in the first sentence of paragraph 82 and the allegations in subparts 2 and 3. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 82 and its subparts.

83. To the extent that the allegations in paragraph 83 relate to Actavis, Actavis denies the allegations in paragraph 83. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 83.

84. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 84.

85. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 85.

86. Paragraph 86 states legal conclusions or arguments to which no answer is required. To the extent that the allegations in paragraph 86 rely on publicly available documents, those documents speak for themselves. To the

extent that the allegations in paragraph 86 do not accurately reflect those documents, Actavis denies the allegations in paragraph 86.

87. To the extent that the allegations in paragraph 87 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 87 do not accurately reflect those documents, Actavis denies the allegations in paragraph 87.

88. To the extent that the allegations in paragraph 88 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 88 do not accurately reflect those documents, Actavis denies the allegations in paragraph 88.

89. To the extent that the allegations in paragraph 89 rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 89 do not accurately reflect those documents, Actavis denies the allegations in paragraph 89.

90. Actavis admits the allegations in paragraph 90.

91. Paragraph 91 states legal conclusions or arguments to which no answer is required. To the extent an answer may be required, Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 91.

92. Paragraph 92 states legal conclusions or arguments to which no answer is required. To the extent an answer may be required, Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 92.

93. Paragraph 93 states legal conclusions or arguments to which no answer is required. To the extent an answer may be required, Actavis denies the allegations in paragraph 93.

94. Paragraph 94 states legal conclusions or arguments to which no answer is required. To the extent an answer may be required, Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 94.

95. Actavis lacks knowledge or information sufficient to form a belief concerning the allegations in paragraph 95.

96. Actavis denies the allegations in paragraph 96.

97. Paragraph 97 contains legal conclusions or arguments to which no answer is required. Actavis denies the remaining allegations in paragraph 97.

98. Actavis admits that generic drugs are generally less costly than the brand name drugs to which they are AB-rated. Actavis denies the allegations in

the last sentence of paragraph 98. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 98.

99. Paragraph 99 contains legal conclusions or arguments to which no answer is required. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 99.

100. Paragraph 100 contains legal conclusions or arguments to which no answer is required. Actavis denies the remaining allegations in paragraph 100.

101. Paragraph 101 contains legal conclusions or arguments to which no answer is required. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 101.

102. Actavis denies the allegations in paragraph 102.

103. Paragraph 103 contains legal conclusions or arguments to which no answer is required. Actavis lacks knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 103.

104. Paragraph 104 states legal conclusions or arguments to which no answer is required. To the extent that an answer may be required, Actavis denies the allegations in paragraph 104.

105. Paragraph 105 states legal conclusions or arguments to which no answer is required. To the extent that an answer may be required, Actavis denies the allegations in paragraph 105.

FIRST COUNT

106. Actavis denies the allegations in paragraph 106.

SECOND COUNT

107. This count makes no allegations against Actavis.

108. This count makes no allegations against Actavis.

THIRD COUNT

109. This count makes no allegations against Actavis.

110. This count makes no allegations against Actavis.

111. Actavis denies the allegations in paragraph 111 to the extent they relate to Actavis. This count otherwise makes no allegations against Actavis.

112. This count makes no allegations against Actavis.

REQUEST FOR RELIEF

Actavis disputes that Plaintiff is entitled to any relief whatsoever.

AFFIRMATIVE DEFENSES

Actavis asserts the following affirmative defenses without assuming any burden that it would not otherwise bear:

FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the acts or omissions of Actavis did not result in significant anticompetitive effects in any properly defined market.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Actavis's alleged conduct was reasonable and procompetitive and based on independent, legitimate business and economic justifications.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Watson Pharma, Inc.'s co-promotion deal with Solvay and Unimed did not constitute a large and unjustified payment, but rather value for services that was fair and/or justified under the circumstances.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff has failed to properly allege either a relevant product market or a relevant geographic market.

FIFTH AFFIRMATIVE 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.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Actavis's actions were legal under the law of the Eleventh Circuit at the time they were taken.

Actavis reserves the right to amend this Answer or to assert other defenses as this action proceeds.

PRAYER FOR RELIEF

WHEREFORE, Actavis demands judgment against the Plaintiff as follows:

- (1) Deny any and all relief requested under Plaintiff's SAC;
- (2) For costs of suit incurred and for reasonable attorneys' fees; and
- (3) Awarding Defendants such other and further relief as the Court

deems just and proper.

Respectfully submitted this 15th day of January, 2014.

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* Practicing pursuant to this Court's
Initial Case Management Order.

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CERTIFICATE OF SERVICE

I hereby certify that I have this day electronically filed the foregoing **DEFENDANT'S ANSWER TO PLAINTIFF'S SECOND AMENDED COMPLAINT** with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to the attorneys of record.

This 15th day of January, 2014.

s/ Brian J. Levy

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