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Civil Action 1:05-cv-02182-CKK

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and

STATE OF VERMONT

by Attorney General William H. Sorrell  
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PLAINTIFFS,

v.

WARNER CHILCOTT HOLDINGS  
COMPANY III, LTD.  
100 Enterprise Drive  
Rockaway, New Jersey 07866

WARNER CHILCOTT CORPORATION  
100 Enterprise Drive  
Rockaway, New Jersey 07866

WARNER CHILCOTT (US) INC.  
100 Enterprise Drive  
Rockaway, New Jersey 07866

WARNER CHILCOTT COMPANY, INC.  
Union Street, Km. 1.1  
Fajardo, Puerto Rico 00738

and

BARR PHARMACEUTICALS, INC.  
2 Quaker Road  
Box 2900  
Pomona, New York 10970

DEFENDANTS.

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**SECOND AMENDED COMPLAINT**

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The states of Colorado, Maryland, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Vermont, the commonwealths of Kentucky,

Massachusetts and Virginia, and the District of Columbia, by their Attorneys General (“Plaintiff States” or “States”), bring this action against Defendants Warner Chilcott Holdings Company III, Limited, Warner Chilcott Corporation, Warner Chilcott (US), Inc., Warner Chilcott Company, Inc., (collectively “Warner Chilcott”) and Barr Pharmaceuticals, Inc. (“Barr”) and make the following allegations:

### **SUMMARY OF COMPLAINT**

1. Warner Chilcott and Barr entered into an anticompetitive agreement not to compete, in violation of the antitrust laws.

2. Warner Chilcott is a pharmaceutical company that develops, manufactures, and markets proprietary women’s healthcare and dermatology prescription pharmaceutical products.

3. Barr is a pharmaceutical company that develops, manufactures, and markets generic and proprietary prescription pharmaceutical products.

4. Warner Chilcott markets Ovcon, a proprietary prescription pharmaceutical product that contains norethindrone and ethinyl estradiol as its active pharmaceutical ingredients. Ovcon is an oral contraceptive product prescribed to women for the prevention of pregnancy.

5. Warner Chilcott is the exclusive marketer of Ovcon, pursuant to an agreement with Bristol-Myers Squibb.

6. Barr developed a generic version of Ovcon and submitted an abbreviated new drug application (“ANDA”) for generic versions of Ovcon with the U.S. Food and Drug Administration (“FDA”).

7. On or about March 24, 2004, Warner Chilcott and Barr entered into an Option and License Agreement (the “Agreement”) not to compete. Warner Chilcott exercised that option on May 6, 2004.

8. Prior to May 6, 2004, Barr planned on competing with Warner Chilcott by marketing its lower-priced generic version of Ovcon after obtaining FDA approval.

9. The Agreement prevented persons in the Plaintiff States from purchasing a less-expensive generic version of Ovcon.

10. The States request a finding that Warner Chilcott and Barr violated state and federal antitrust and related laws, a permanent injunction barring Warner Chilcott and Barr from engaging in similar conduct in the future, other equitable relief, civil penalties, and/or other relief for injuries caused by the illegal Agreement.

### **JURISDICTION AND VENUE**

11. This Court has jurisdiction pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1 and Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331 and 1337. In addition to pleading violations of federal antitrust law, the States also allege violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws. The States seek civil penalties and/or equitable relief under those state laws.

12. All claims under federal and state law are based upon a common nucleus of operative fact, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding.

13. This Court has jurisdiction of state law claims under 28 U.S.C. §1367(a), as well as under the principles of supplemental jurisdiction. Supplemental jurisdiction will avoid unnecessary duplication and multiplicity of actions and should be exercised in the interests of judicial economy, convenience, and fairness.

14. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and under 28 U.S.C. §§ 1391(b) and (c), because: (1) Warner Chilcott and Barr transact business and

are found within this district; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this district.

### **PARTIES**

15. Defendant Warner Chilcott Holdings Company III, Limited, is a privately-owned for-profit enterprise organized under the laws of Bermuda, with its principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey, 07866-2129.

16. Defendant Warner Chilcott Corporation is a for-profit Delaware corporation with its principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey, 07866-2129. Defendant Warner Chilcott Corporation is an indirect wholly-owned subsidiary of Defendant Warner Chilcott Holdings Company III, Limited.

17. Defendant Warner Chilcott (US), Inc., is a for-profit Delaware corporation with its principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey, 07866-2129. Defendant Warner Chilcott (US), Inc., is a direct wholly-owned subsidiary of Defendant Warner Chilcott Corporation.

18. Warner Chilcott develops, manufactures, and markets proprietary women's healthcare and dermatology prescription pharmaceutical products. For the fiscal quarter ending March 31, 2005, Warner Chilcott Holdings Company III, Limited reported net revenue of approximately \$133.7 million. During that period, sales of Ovcon increased 30.8% to approximately \$22,900,000 for the quarter.

19. Defendant Warner Chilcott Company, Inc., a wholly-owned subsidiary of Warner Chilcott Holdings Company III, Ltd., is organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico.



20. Defendant Barr Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business at 400 Chestnut Ridge Rd., Woodcliff Lake, New Jersey 07677-7668. Barr Laboratories, Inc., is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. Barr develops, manufactures, and markets generic and proprietary prescription pharmaceutical products.

21. The Plaintiff States bring this action in their sovereign and/or quasi-sovereign capacities by their Attorneys General as the Plaintiff States' chief civil law enforcement officials seeking relief 1) pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, as *parens patriae*, and 2) pursuant to state law as a civil law enforcement action.

### **FACTUAL BACKGROUND**

#### **A. New Drug Applications**

22. A drug manufacturer must obtain approval from the U.S. Food and Drug Administration ("FDA") before the manufacturer may lawfully introduce a new drug in the United States.

23. To have one of its new drugs considered for approval, a manufacturer must file a New Drug Application ("NDA") with the FDA. The NDA must contain information demonstrating that the drug is safe and effective for its intended use.

24. A drug that is approved through the NDA process may be listed by the FDA as a "Reference Listed Drug" in the FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book."

#### **B. Generic Drugs**

25. Generic drugs are similar to, but not necessarily identical to, Reference Listed Drugs. A generic drug contains the same active pharmaceutical ingredient(s) (or contains the same therapeutic moiety, but may be a different salt, ester, or complex of that moiety) as the

corresponding Reference Listed Drug, but may contain other ingredients (such as colors and flavors) that are different. A generic drug is comparable to a Reference Listed Drug in dosage form, strength, route of administration, quality, performance characteristics and intended use. A generic drug must be bioequivalent to the corresponding Reference Listed Drug.

26. The Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355, (the “Hatch-Waxman Act”) established a procedure that has often allowed generic drugs to enter the market earlier than had been possible in the past. The Hatch-Waxman Act allows a company to seek FDA approval to market a generic version of a Reference Listed Drug by filing an Abbreviated New Drug Application (“ANDA”). An ANDA is generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.

27. Because the FDA has already determined that a Reference Listed Drug is safe and effective for use, an ANDA filer may rely on the safety and efficacy data previously provided for a specific Reference Listed Drug, so long as the ANDA filer sufficiently demonstrates to the FDA that its generic drug is bioequivalent to the Reference Listed Drug.

28. Generic versions of Reference Listed Drugs are usually sold at prices substantially below the prices charged for the Reference Listed Drugs. Persons in the Plaintiff States save significant amounts of money by purchasing generic drugs.

**C. Warner Chilcott’s Ovcon Products**

29. Ovcon has been available to the general public as a prescription pharmaceutical product since approximately 1976.

30. Prior to January 26, 2000, Bristol-Myers Squibb Company (“BMS”) manufactured, distributed, and marketed Ovcon in the United States.

31. On January 26, 2000, Warner Chilcott purchased from BMS certain rights, title, and interest in Ovcon products.

32. On January 26, 2000, Warner Chilcott entered into a supply agreement with Bristol Myers-Squibb Laboratories Company (“BMSLC”), a wholly owned subsidiary of BMS. The supply agreement states the terms and conditions associated with the supply of Ovcon product by BMSLC to Warner Chilcott.

33. Warner Chilcott then began marketing Ovcon manufactured by BMSLC, and continues to be the exclusive marketer of Ovcon at the present time.

34. Warner Chilcott’s sales of Ovcon have continued to increase, and Warner Chilcott has continued to increase the price charged for Ovcon.

**D. Competition by Barr Laboratories’ Generic Ovcon**

35. In September 2001, Barr filed ANDAs with the FDA for approval to market generic versions of Ovcon.

36. In January 2003, Barr publicly communicated its intent to launch a generic version of Ovcon by the end of 2003.

37. Barr intended to offer its generic version of Ovcon for sale at a price approximately 30% less than the price charged by Warner Chilcott.

**E. Warner Chilcott and Barr’s Illegal Agreement not to Compete**

38. At all times since executing its agreement to purchase rights to Ovcon from BMS, Warner Chilcott has remained the only marketer of Ovcon; no generic version of Ovcon has ever been released to the public.

39. Warner Chilcott was aware that its revenues could be substantially decreased if a generic version of Ovcon became available to consumers.

40. Warner Chilcott's first attempt to eliminate the threat posed by the entry of a generic version of Ovcon was the development of a line extension to Ovcon.

41. Warner Chilcott's strategy was to introduce its line extension (a chewable version of Ovcon) prior to the entry of a generic version of non-chewable Ovcon.

42. Warner Chilcott planned to engage in various practices that would ultimately result in the replacement of prescriptions for (and supply of) non-chewable Ovcon with chewable Ovcon.

43. In 2003, Warner Chilcott became aware that its position as the exclusive marketer of Ovcon was facing an imminent threat from the generic version of Ovcon being developed by Barr.

44. By mid-2003, Warner Chilcott learned that it would likely be unable to begin marketing a chewable version of Ovcon prior to Barr's launch of a generic version of Ovcon.

45. Warner Chilcott's inability to begin marketing its line extension prior to the availability of Barr's generic version of Ovcon would substantially reduce Warner Chilcott's revenues.

46. In August 2003, Warner Chilcott responded to Barr's impending launch of a generic version of Ovcon by engaging in discussions with Barr regarding an anticompetitive agreement not to compete.

47. On September 10, 2003, Warner Chilcott and Barr signed a letter of intent to enter into an agreement that gave Warner Chilcott the exclusive option to market all products produced pursuant to Barr's ANDAs for generic versions of Ovcon.

48. On March 24, 2004, the Defendants signed the Agreement, as contemplated by their letter of intent.

49. Through the Agreement, Barr agreed to stay off the market and give Warner Chilcott the exclusive right to market, distribute, and sell Barr's generic version of Ovcon.

50. Warner Chilcott paid Barr \$1,000,000 in exchange for the option contained in the Agreement.

51. On April 22, 2004, the FDA granted final approval of Barr's ANDAs for the generic versions of Ovcon.

52. On April 23, 2004, Barr publicly communicated its intent to begin marketing its generic version of Ovcon in the event that Warner Chilcott chose not to exercise its option under the Agreement.

53. On May 6, 2004, Warner Chilcott exercised its option under the Agreement. Pursuant to the terms of the Agreement, Warner Chilcott paid Barr \$19,000,000 in exchange for Barr's promise not to compete with Warner Chilcott by introducing a generic version of Ovcon and for giving Warner Chilcott the exclusive right to market, distribute, and sell Barr's generic version of Ovcon.

54. Warner Chilcott and Barr also entered into a Finished Product Supply Agreement ("Supply Agreement") on March 24, 2004. The Supply Agreement became effective when Warner Chilcott exercised its option under the Agreement.

55. The Supply Agreement allowed Warner Chilcott to purchase generic Ovcon from Barr at a premium price of 200% of Barr's actual fully loaded manufacturing cost.

56. As a consequence of the anticompetitive Agreement, no generic version of Ovcon was ever launched, and Barr has agreed not to launch a generic version of Ovcon until at least May 2009.

57. In the absence of the anticompetitive Agreement, Barr would have begun marketing its product shortly after obtaining FDA approval.

58. In the absence of the competitive threat that Barr would have provided in a free marketplace, Ovcon consumers were required to continue purchasing the brand-name Ovcon product when a less expensive generic version would have otherwise been available.

59. If Barr had introduced its generic product into the market, the average price paid for Ovcon products would have decreased rapidly and substantially.

60. No company, other than Barr, has received FDA approval for a generic version of Ovcon.

61. The Agreement between Warner Chilcott and Barr destroyed the competition that is intrinsic to our market-based economy.

#### **TRADE AND COMMERCE**

62. During the relevant period, Ovcon was sold throughout the United States. Ovcon was transported across state lines and sold in each of the Plaintiff States. The Defendants' unlawful activities alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce.

#### **ANTICOMPETITIVE EFFECTS OF DEFENDANTS' ILLEGAL CONDUCT**

63. Warner Chilcott and Barr's Agreement not to compete was a naked restraint of trade with the purpose of stifling competition, and is anticompetitive.

64. The Agreement is anticompetitive pursuant to every relevant legal analysis.

65. Warner Chilcott and Barr's conduct had the purpose and effect of unreasonably and illegally restraining trade and preventing competition.

66. Warner Chilcott and Barr's Agreement to eliminate competition is not reasonably necessary to accomplish any procompetitive objective. The Agreement was not subsidiary to any procompetitive objective. Eliminating competition from Barr was the primary purpose of Warner Chilcott's unlawful Agreement with Barr.

67. The Defendants could have accomplished any of the purported competitive benefits of the Agreement by other less-restrictive means that would not have destroyed competition.

68. As a direct and proximate result of the illegal conduct alleged in this complaint, persons in the Plaintiff States have not been and are not able to purchase generic versions of Ovcon, which would have been available at prices lower than those paid for Ovcon.

69. Warner Chilcott and Barr deprived persons in the Plaintiff States of the benefits of competition that the federal and state antitrust laws, consumer protection laws and/or unfair competition statutes and related state laws are designed to promote, preserve, and protect.

70. As a direct and proximate result of the unlawful conduct alleged above, Warner Chilcott has unjustly profited from the Agreement with Barr.

71. As a direct and proximate result of the unlawful conduct alleged above, Barr has unjustly profited from the Agreement with Warner Chilcott.

72. As a direct and proximate result of the unlawful conduct alleged above, injury has been sustained by the general economies of the Plaintiff States.

#### **CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT**

73. The Agreement between Warner Chilcott and Barr constitutes a restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 .

#### **SUPPLEMENTAL STATE LAW CLAIMS**

74. Plaintiff State of Alaska repeats and realleges each and every allegation contained in paragraphs 1 through 73.

75. Defendants' acts violate, and Plaintiff State of Alaska is entitled to relief under, AS 45.50.471 and AS 45.50.562 - .596.

76. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 73.

77. Defendants' acts violate, and Plaintiff State of Arizona is entitled to relief under, Arizona Uniform State Antitrust Act, Arizona Revised Statutes section 44-1401 et seq.

78. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 73.

79. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief under, the Arkansas Deceptive Trade Practices Act, A.C.A. § 4-88-101, et seq. and the Arkansas Unfair Practices Act, A.C.A. § 4-75-301 et seq.

80. Plaintiff State of California repeats and realleges each and every allegation contained in paragraphs 1 through 73.

81. Defendants' acts violate, and Plaintiff State of California is entitled to relief under, the Cartwright Act, Business & Professions Code § 16700, et seq., and the California Unfair Competition Act, Bus. & Prof. Code § 17200, et seq.

82. Plaintiff State of Colorado repeats and realleges each and every allegation contained in paragraphs 1 through 73.

83. Defendants' acts violate, and Plaintiff State of Colorado is entitled to relief under, the Colorado Antitrust Act of 1992, § 6-4-101, et seq., Colo. Rev. Stat.



84. Plaintiff State of Delaware repeats and realleges each and every allegation contained in paragraphs 1 through 73.

85. Defendants' acts violate, and Plaintiff State of Delaware is entitled to relief under, the Delaware Antitrust Act, 6 Del.C. § 2101, et seq.

86. Plaintiff District of Columbia repeats and realleges each and every allegation contained in paragraphs 1 through 73.

87. Defendants' acts violate, and Plaintiff District of Columbia is entitled to relief under, D.C. Official Code § 28-4502, et seq. (2001).

88. Plaintiff State of Florida repeats and realleges each and every allegation contained in paragraphs 1 through 73.

89. Defendants' acts violate, and Plaintiff State of Florida is entitled to relief under, the Florida Antitrust Act of 1980, § 542.15 Florida Statutes, et seq., and the Florida Deceptive and Unfair Trade Practices Act, § 501.201 Florida Statutes, et seq.

90. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 73.

91. Defendants' acts violate, and Plaintiff State of Idaho is entitled to relief under, the Idaho Competition Act, Idaho Code § 48-101 et seq.

92. Plaintiff State of Illinois repeats and realleges each and every allegation contained in paragraphs 1 through 73.

93. Defendants' acts violate, and Plaintiff State of Illinois is entitled to relief under, the Illinois Antitrust Act, 740 ILCS 10/1, et seq.

94. Plaintiff State of Iowa repeats and realleges each and every allegation contained in paragraphs 1 through 73.

95. Defendants' acts violate, and Plaintiff State of Iowa is entitled to relief under, the laws of the State of Iowa, alleging violations of the Iowa Competition Act, Iowa Code sections 553 et seq., and the Iowa Consumer Fraud Act, Iowa Code section 714.16.

96. Plaintiff State of Kansas repeats and realleges each and every allegation contained in paragraphs 1 through 73.

97. Defendants' acts violate, and Plaintiff State of Kansas is entitled to relief under, Kan. Stat. Ann. §50-101, et seq.

98. Plaintiff Commonwealth of Kentucky repeats and realleges each and every allegation contained in paragraphs 1 through 73.

99. Defendant's acts violate, and Plaintiff Commonwealth of Kentucky is entitled to relief under, the Kentucky Antitrust Law, KRS 367.175.

100. Plaintiff State of Louisiana repeats and realleges each and every allegation contained in paragraphs 1 through 73.

101. Defendants' acts violate, and Plaintiff State of Louisiana is entitled to relief under, the Louisiana Antitrust Act, La. R.S. 51: 122, et seq., and La. R.S. 51:1401, et seq.

102. Plaintiff State of Maine repeats and realleges each and every allegation contained in paragraphs 1 through 73.

103. Defendants' acts violate, and Plaintiff State of Maine is entitled to relief under, Maine's Monopolies and Profiteering law, Title 10, Maine Revised Statutes, §§ 1101 and 1104.

104. Plaintiff State of Maryland repeats and realleges each and every allegation contained in paragraphs 1 through 73.

105. Defendants' acts violate, and Plaintiff State of Maryland is entitled to relief under, the Maryland Antitrust Act, Md. Com. Law Code Ann. § 11-201, et seq.

106. Plaintiff Commonwealth of Massachusetts repeats and realleges each and every allegation contained in paragraphs 1 through 73.

107. Defendants' acts violate, and Plaintiff Commonwealth of Massachusetts is entitled to relief under, the Consumer Protection and Antitrust Acts, G.L. c.93A § 2, et seq., and G.L. c.93 § 4, et seq., respectively.

108. Plaintiff State of Michigan repeats and realleges each and every allegation contained in paragraphs 1 through 73.

109. Defendants' acts violate, and Plaintiff State of Michigan is entitled to relief under, the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.771, et seq., the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq., and the common law of Michigan.

110. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 73.

111. Defendants' acts violate, and Plaintiff State of Minnesota is entitled to relief under, the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66 (2004), and Minn. Stat. § 8.31 (2004).

112. Plaintiff State of Mississippi repeats and realleges each and every allegation contained in paragraphs 1 through 73.

113. Defendants' acts violate, and Plaintiff State of Mississippi is entitled to relief under, its Consumer Protection Act found at Miss. Code Ann. § 75-24-1, et seq. (1972, as amended) and its Antitrust Act found at Miss. Code Ann. § 75-21-1, et seq. (1972, as amended).

114. Plaintiff State of Missouri repeats and realleges each and every allegation contained in paragraphs 1 through 73.

115. Defendants' acts violate, and Plaintiff State of Missouri is entitled to relief under, the Missouri Merchandising Practices Act, Revised Statutes of Missouri § 407.010 et seq., and the Missouri Antitrust Act, Revised Statutes of Missouri § 416.011 et seq.

116. Plaintiff State of Nevada repeats and realleges each and every allegation contained in paragraphs 1 through 73.

117. Defendants' acts violate, and Plaintiff State of Nevada is entitled to relief under the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. § 598A.010 et seq.

118. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 73.

119. Defendants' acts violate, and Plaintiff State of New York is entitled to relief under, N.Y. Gen. Bus. Law §§ 340, 342, and 342-a.

120. Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 73.

121. Defendants' acts violate, and Plaintiff State of North Carolina is entitled to relief under, N.C. Gen. Stat. §§ 75-1, 75-1.1, 75-2, 75-2.1.

122. Plaintiff State of North Dakota repeats and realleges each and every allegation contained in paragraphs 1 through 73.

123. Defendants' acts violate, and Plaintiff State of North Dakota is entitled to relief under, the Uniform State Antitrust Act, N.D. Cent. Code § 51-08.1-01, et seq.

124. Plaintiff State of Ohio repeats and realleges each and every allegation contained in paragraphs 1 through 73.

125. Defendants' acts violate, and Plaintiff State of Ohio is entitled to relief under, Ohio's Antitrust Law, Ohio Revised Code, § 109.81 and 1331.01, et seq.

126. Plaintiff State of Oklahoma repeats and realleges each and every allegation contained in paragraphs 1 through 73.

127. Defendants' acts violate, and Plaintiff State of Oklahoma is entitled to relief under, The Oklahoma Antitrust Reform Act, 79 O.S. 2001 §201, et seq., and the Oklahoma Consumer Protection Act 15 O.S.2001, § 751 et seq.

128. Plaintiff State of Oregon repeats and realleges each and every allegation contained in paragraphs 1 through 73.

129. Defendants' acts violate, and Plaintiff State of Oregon is entitled to relief under, the Oregon Antitrust Act, ORS 646.705, et seq.

130. Plaintiff State of Rhode Island repeats and realleges each and every allegation contained in paragraphs 1 through 73.

131. Defendants' acts violate, and Plaintiff State of Rhode Island is entitled to relief under, Rhode Island General Laws Chapter 6-36, entitled the "Rhode Island Antitrust Act."

132. Plaintiff State of South Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 73.

133. Defendants' acts violate, and Plaintiff State of South Carolina is entitled to relief under, the South Carolina Unfair Trade Practices Act, §§ 39-5-10, et seq.

134. Plaintiff State of Tennessee repeats and realleges each and every allegation contained in paragraphs 1 through 73.

135. Defendants' acts violate, and Plaintiff State of Tennessee is entitled to relief under, the Tennessee Antitrust Act, Tenn. Code Ann. §§ 47-25-101, et seq.

136. Plaintiff State of Texas repeats and realleges each and every allegation contained in paragraphs 1 through 73.

137. Defendants' acts violate, and Plaintiff State of Texas is entitled to relief under, the Texas Free Enterprise and Antitrust Act of 1983, Tex. Bus. & Com. Code § 15.01, et seq.

138. Plaintiff State of Utah repeats and realleges each and every allegation contained in paragraphs 1 through 73.

139. Defendants' acts violate, and Plaintiff State of Utah is entitled to relief under, the Utah Antitrust Act, Sections 76-10-911 through 76-10-926, Utah Code Annotated, as amended.

140. Plaintiff State of Vermont repeats and realleges each and every allegation contained in paragraphs 1 through 73.

141. Defendants' acts violate, and Plaintiff State of Vermont is entitled to relief under, the Vermont Consumer Fraud Act, 9 V.S.A. Section 2451, et seq.

142. Plaintiff Commonwealth of Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 73.

143. Defendants' acts violate, and Plaintiff Commonwealth of Virginia is entitled to relief under, the Virginia Antitrust Act, Va. Code Ann. Section 59.1-9.5

### **REQUEST FOR RELIEF**

Accordingly, the Plaintiff States request that this Court:

1. Adjudge and decree that Defendants engaged in conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1;

2. Adjudge and decree that Defendants engaged in conduct in violation of each of the state statutes and common law enumerated in this Complaint;

3. Enjoin and restrain, pursuant to federal and state law, Defendants, their affiliates, assignees, subsidiaries, successors and transferees, and their officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with

them, from continuing to engage in any anticompetitive conduct (including the anticompetitive terms of the Agreement) and from adopting in the future any practice, plan, program or device having a similar purpose or effect to the anticompetitive actions set forth above.;

4. Award to Plaintiff States any other equitable relief as the Court finds appropriate to redress Defendants' violations of state law;

5. Award to each Plaintiff State the maximum civil penalties allowed by law;

6. Award to each Plaintiff State its costs, including reasonable attorneys' fees; and

7. Order any other relief that this Court deems proper.

DATED: July 14, 2006

Respectfully submitted,

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Civil Action No. 1:05-cv-02182-CKK-AK

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PLAINTIFFS,

v.

BARR PHARMACEUTICALS, INC.  
2 Quaker Road  
Box 2900  
Pomona, New York 10970

DEFENDANT.

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**STIPULATED FINAL ORDER AND PERMANENT INJUNCTION**

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**WHEREAS** Plaintiffs, the states of Colorado, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Vermont, the commonwealths of Kentucky, Massachusetts and Virginia, and the District of Columbia, by their Attorneys General, (“Plaintiff States” or “States”), filed their Second Amended Complaint, on October 3, 2006, pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and state antitrust, consumer protection and/or unfair competition statutes and related state laws, seeking civil penalties; injunctive and other equitable relief;

**AND WHEREAS**, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction (“Final Order”), Plaintiff States and Barr Pharmaceuticals, Inc. (“Barr”), by their

respective attorneys, have stipulated and agreed to entry by the Court of this Final Order without trial or adjudication of any issue of fact or law;

**AND WHEREAS**, this Final Order is entered for settlement purposes only and does not constitute any evidence against, or an admission of liability, wrongdoing, or of any issue of fact or law, by Defendant Barr;

**AND WHEREAS**, the parties agree to be bound by the provisions of this Final Order pending its approval by the Court;

**AND WHEREAS**, Defendant Barr has launched the generic product at issue in the Complaint and this Final Order, as described herein, requires Defendant Barr to refrain from entering into certain identified types of agreements in the future;

**AND WHEREAS**, Barr agrees to make a monetary payment to the Plaintiff States in the amount of \$5.9 million, subject to the terms and conditions provided herein;

**AND WHEREAS**, Defendant Barr has represented to the Plaintiff States that the relief required below can and will be made and that Defendant Barr will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the terms of the relief contained below;

**AND WHEREAS**, Barr retains the right to seek to modify this Final Order, either unilaterally or jointly with the Plaintiff States (at the Plaintiff States' discretion), pursuant to Fed. R. Civ. P. 60(b)(6);

**AND WHEREAS**, Defendant Barr, without admitting that it has violated any provision of federal or state law, agrees to the entry of this Final Order;

**NOW THEREFORE**, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is

**ORDERED, ADJUDGED AND DECREED THAT:**

**I. Jurisdiction and Venue**

- A. Solely for purposes of entry of this Final Order and enforcement thereof, this Court has jurisdiction over the parties and the subject matter of this action.
- B. Solely for purposes of entry of this Final Order and enforcement thereof, venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).
- C. The parties waive all rights to appeal or otherwise challenge or contest the validity of this Final Order.
- D. Entry of this order is in the public interest.

## II. Definitions

As used in this Final Order:

- A. “Agreement” means anything that would constitute a contract, combination, or conspiracy within the meaning of Section 1 of the Sherman Act, 15 U.S.C. § 1, regardless of whether such contract, combination, or conspiracy is in restraint of trade.
- B. “ANDA” means an Abbreviated New Drug Application filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j).
- C. “ANDA Filer” means the party to a Branded/Generic Supply Agreement or a Branded/Generic Agreement who controls an ANDA for the Subject Drug Product or has the exclusive right to distribute the Generic Product.
- D. “Barr” means Barr Pharmaceuticals, Inc., and its officers, directors, employees, agents and representatives, successors, and assigns; United States subsidiaries, divisions, groups, and affiliates controlled by Barr; and the officers, directors, employees, agents and representatives, successors, and assigns of each.
- E. “Branded/Generic Agreement” means any Agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product.
- F. “Branded/Generic Supply Agreement” means any supply agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product, and the ANDA Filer agrees to supply Generic Product to the NDA Holder.
- G. “Commerce” has the same definition as it has in the Clayton Act, 15 U.S.C. § 12.



- H. “Drug Product” means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- I. “Enter Into” and “Entering Into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- J. “FDA” means the United States Food and Drug Administration.
- K. “Generic Product” means a Drug Product manufactured under an ANDA.
- L. “Plaintiff States’ Liaison Counsel” or “Liaison Counsel” means counsel for the States of Colorado and New York, unless the Plaintiff States appoint other counsel to serve as Liaison Counsel and so advise Barr in writing; in no event shall there be more than two Liaison Counsel at a time.
- M. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), et seq.
- N. “NDA Holder” means the party to a Branded/Generic Agreement or a Branded/Generic Supply Agreement that controls the NDA for the Subject Drug Product, or has the exclusive right to distribute branded Subject Drug Product.
- O. “Patent Infringement Claim” means any written allegation of patent infringement, whether or not included in a complaint filed with a court of law, including, but not limited to, where the alleged infringer challenges only patent validity.
- P. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- Q. “Qualifying Pharmaceutical Company” means a pharmaceutical company, other than the NDA Holder or Barr, that (i) has annual gross sales of generic pharmaceutical products in

the United States of at least \$250 million; and (ii) neither controls an ANDA for a Subject Generic Equivalent nor has the exclusive right to distribute a Subject Generic Equivalent.

- R. “Subject Drug Product” means a Drug Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.
- S. “Subject Generic Equivalent” means a Generic Product that is bioequivalent to the branded Subject Drug Product.
- T. “Subject Generic Product” means a Generic Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.

### **III. Prohibited Agreements**

Until the expiration of this Final Order as provided in Paragraph VII, Barr is enjoined from Entering Into, or attempting to Enter Into, directly or indirectly, or through any corporate or other device:

- A. Any Branded/Generic Supply Agreement where:
  - 1) Barr is the ANDA Filer; and
  - 2) Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution or sale of the Subject Generic Product.
- B. Any Branded/Generic Agreement where:
  - 1) Barr is the ANDA Filer;
  - 2) Barr receives monetary or other valuable consideration;
  - 3) Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution, or sale of the Subject Generic Product; and

- 4) Such Branded/Generic Agreement unreasonably restrains competition.

***Provided, however,*** that nothing in Paragraph III.A. shall prohibit Barr from entering into such Branded/Generic Supply Agreement, if, prior to or contemporaneously with entering into such Branded/Generic Supply Agreement,

- 1) Barr has, in good faith, assigned, transferred, or otherwise given, to a Qualifying Pharmaceutical Company, the rights as Barr may possess them necessary to manufacture, market, distribute, and sell the Subject Generic Product (“Transfer Agreement”);
- 2) the Qualifying Pharmaceutical Company has agreed, in good faith and as part of the Transfer Agreement, to use commercially reasonable efforts to exploit such rights as soon as practicable;
- 3) Barr has agreed in good faith to supply (which includes, if applicable, acting in good faith to obtain the regulatory and other approvals necessary to supply) the Subject Generic Product to such Qualifying Pharmaceutical Company on such terms and conditions that will allow the Qualifying Pharmaceutical Company to compete effectively for sales of the Subject Generic Equivalent until such time as the Qualifying Pharmaceutical Company can manufacture commercial quantities of the Subject Generic Product on its own or obtain commercial quantities of the Subject Generic Equivalent from another source;
- 4) Barr has provided a copy of this Final Order and Stipulated Permanent Injunction to the persons responsible for assisting with the Transfer Agreement, of the Qualifying Pharmaceutical Company;

- 5) the Qualifying Pharmaceutical Company has agreed to cooperate with any inquiry made by a Plaintiff State relating to the activities covered by the provision; and
- 6) Barr has provided notice to the Plaintiff States of any such Transfer Agreement with a Qualifying Pharmaceutical Company, in the form specified in Paragraph IV.C.

***Provided, further,*** that nothing in this Paragraph III shall prohibit Barr from entering into a Branded/Generic Agreement, including a Branded/Generic Supply Agreement, that resolves a Patent Infringement Claim involving the Subject Drug Product, where such Branded/Generic Agreement does not unreasonably restrain competition.

#### **IV. Agreements Subject to Notification**

- A. Commencing with the date of entry of this Final Order and for a period of ten years, Barr shall provide notice to the Plaintiff States' Liaison Counsel of:
  - 1) any Branded/Generic Supply Agreement entered into after the date of entry of this Final Order, and
  - 2) any Branded/Generic Agreement entered into after the date of entry of this Final Order in which Barr is the ANDA Filer and agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution, or sale of the Subject Drug Product, except those that resolve a Patent Infringement Claim (except as otherwise provided by this Final Order).("Agreements Subject to Notification").
- B. The notification required by Paragraph IV.A. shall be made within the later of:
  - 1) Thirty days after the entry of this Final Order, or
  - 2) within ten business days after the Agreement Subject to Notification is executed.

- C. The notification required by Paragraph IV.A. of this Final Order shall be in the form of a letter (“Notification Letter”) submitted to the Plaintiff States’ Liaison Counsel containing the following information:
- 1) A statement that the purpose of the Notification Letter is to give the Plaintiff States notification of an Agreement Subject to Notification as required by Paragraph IV of this Final Order;
  - 2) Identification of all Persons involved in the Agreement Subject to Notification; and
  - 3) A copy of the Agreement Subject to Notification, and in the event that any Agreement Subject to Notification has not been reduced to text, written descriptions of such Agreement Subject to Notification that are sufficient to disclose all the terms and conditions of the Agreement Subject to Notification.
- D. In addition to the Notification required by Paragraphs A-C. above, and until the expiration of this Final Order, Barr shall provide to the Plaintiff States’ Liaison Counsel copies of all materials required to be submitted to the Federal Trade Commission pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (including any subsequent modifications of the notification provisions created by such Act) (“MMA Materials”). The MMA Materials shall be provided to the Liaison Counsel within the time frame and in the form applicable to submissions to the Federal Trade Commission under the Medicare Prescription Drug Improvement and Modernization Act of 2003.
- E. All Notification Letters and MMA Materials shall be submitted to the Plaintiff States’ Liaison Counsel at the addresses listed in Paragraph V.D.

**V. Notice and Reporting Requirements**

- A. Barr shall file a verified, written report with the Plaintiff States' Liaison Counsel setting forth in detail the manner and form in which it has complied and is complying with this Final Order:
- 1) within ninety days from the date this Final Order is entered;
  - 2) annually thereafter for three years on the anniversary of the date this Final Order is entered; and
  - 3) at any such other times as the Plaintiff States' Liaison Counsel may request by written notice.
- B. For a period of three years from the date this Final Order is entered, Barr shall maintain and make available to Plaintiff States for inspection and copying upon reasonable notice, records sufficient to describe in detail any action taken in connection with the activities covered by this Final Order.
- C. Until expiration of this Final Order, as provided in Paragraph VII, Barr shall notify the Plaintiff States' Liaison Counsel at least thirty days prior to any
- 1) proposed dissolution of Barr
  - 2) acquisition, merger or consolidation of Barr, or
  - 3) any other change in Barr that may affect compliance obligations arising out of this Final Order.
- D. Barr shall address each notice and report required by Paragraph IV of the Final Order to Plaintiff States' Liaison Counsel at the below addresses unless otherwise directed in writing by such Liaison Counsel:

Office of the Colorado Attorney General  
Antitrust Enforcement  
1525 Sherman Street, Seventh Floor  
Denver, Colorado 80203

Office of the New York Attorney General  
Chief, Antitrust Bureau  
120 Broadway, 26<sup>th</sup> Floor  
New York, New York 10271

## **VI. Monetary Relief**

Not later than ten business days after receiving the Payment Information (defined below), Barr shall pay the sum of \$5.9 million to the Plaintiff States (the “Payment”) under the following terms and conditions:

A. The Payment must be made by wire transfer or ACH transfer made payable and delivered as directed by the Plaintiff States. The Plaintiff States shall advise undersigned counsel for Barr in writing of the information necessary for Barr to effectuate the wire transfer or ACH transfer within five business days after entry of this Final Order (“Payment Information”). Barr shall have no dominion, control or title to the Payment. The Payment shall be used by the Attorney General of each Plaintiff State at his/her sole discretion according to the terms of this Final Order. The Attorney General of each Plaintiff State shall use these funds consistently with his/her state laws for any of the following purposes:

- 1) payment of attorneys’ fees and costs;
- 2) antitrust or consumer protection law enforcement;
- 3) deposit into a state antitrust or consumer protection revolving fund; or
- 4) as otherwise provided by state law.<sup>1</sup>

All funds paid to the Plaintiff States pursuant to this Final Order shall be deposited into accounts administered by the Plaintiff States or their agent(s).

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<sup>1</sup> With respect to the State of Colorado, its apportionment shall be used first for reimbursement of Colorado’s actual costs and attorneys fees and second, to be held along with any interest thereon, in trust

B. Barr shall have no right to challenge the Plaintiff States' distribution of the Payment. Barr shall have no right to contest the manner in which the funds are utilized.

**VII. Termination of Final Order**

This Final Order shall take effect on, and expire ten years from, the date this Final Order is entered.


**VIII. Retention of Jurisdiction**

The Court retains jurisdiction of this matter for purposes of construction, modification and enforcement of this Final Order.

**IX. Dismissal and Costs**

This action shall be dismissed with prejudice. Unless specifically set forth in this agreement, each party shall bear its own costs of this action.

Entered this 25<sup>th</sup> day of February, 2008.

  
Colleen Kollar-Kotelly  
U.S. District Judge

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by the Attorney General for future consumer education, consumer fraud or antitrust enforcement efforts.