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Nycomed US Inc.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

NYCOMED US INC.

Plaintiff,

v.

GRACEWAY PHARMACEUTICALS,  
LLC AND 3M INNOVATIVE  
PROPERTIES COMPANY

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY  
JUDGMENT**

Plaintiff Nycomed US Inc. (“Nycomed”), by its attorneys, alleges as follows:

**NATURE OF THE CASE**

1. This is an action for a declaratory judgment that U.S. Patent Nos. 7,902,209, 7,902,210, 7,902,211, 7,902,212, 7,902,213, 7,902,214, 7,902,215, 7,902,216, 7,902,242, 7,902,243, 7,902,244, 7,902,245, 7,902,246, and 7,696,159 (“the patents-in-suit”) are invalid and not infringed by Nycomed.

**THE PARTIES**

2. Nycomed is a company organized and existing under the laws of the State of New York, having a place of business at 60 Baylis Road, Melville, New York 11747.

3. On information and belief, Graceway Pharmaceuticals, LLC (“Graceway”) is a Delaware limited liability company with a principal place of business at 340 Martin Luther King Junior Boulevard, Suite 500, Bristol, Tennessee 37620.

4. On information and belief, 3M Innovative Properties Company (“3M IPC”) is a Delaware corporation with a principal place of business at 3M Center, St. Paul, Minnesota 55144.

### **JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338, 2201, and 2202.

6. This Court has personal jurisdiction over Graceway and 3M IPC (collectively, “Defendants”). On information and belief, Defendants have systematic and continuous contacts in this judicial District, regularly transact business within this judicial District, and regularly avail themselves of the benefits of this judicial District. In addition, Defendants have filed an action for patent infringement against Nycomed in this District. *See* Graceway Pharmaceuticals, LLC and 3M Innovative Properties Company v. Nycomed US Inc., Civil Action No. 2:10cv937 (WJM)(MF). That action is related to the instant action and is currently pending.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

### **FACTUAL ALLEGATIONS**

8. On or about March 8, 2011, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 7,902,209 (“the ‘209 patent”), entitled “Method of Preparing a Pharmaceutical Cream and Minimizing Imiquimod Impurity Formation,” to Alexis S. Statham and Robert J. Nelson.

9. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,210 (“the ‘210 patent”), entitled “Reduction of Imiquimod Impurities at Two Months Using Refined Oleic Acid,” to Alexis S. Statham and Robert J. Nelson.

10. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,211 (“the ‘211 patent”), entitled “Method of Inducing Interferon Biosynthesis,” to Alexis S. Statham and Robert J. Nelson.

11. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,212 (“the ‘212 patent”), entitled “X-Fold Less Imiquimod Impurities at Six Months Between Refined and Compendial,” to Alexis S. Statham and Robert J. Nelson.

12. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,213 (“the ‘213 patent”), entitled “Pharmaceutical Cream with Reduced Imiquimod Impurities at Four Months Using Refined Oleic Acid,” to Alexis S. Statham and Robert J. Nelson.

13. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,214 (“the ‘214 patent”), entitled “Method of Treating a Mucosal and/or Dermal Associated Condition,” to Alexis S. Statham and Robert J. Nelson.

14. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,215 (“the ‘215 patent”), entitled “Pharmaceutical Creams with Reduced Imiquimod Impurities,” to Alexis S. Statham and Robert J. Nelson.

15. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,216 (“the ‘216 patent”), entitled “Pharmaceutical Creams with Refined Oleic Acid,” to Alexis S. Statham and Robert J. Nelson.

16. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,242 (“the ‘242 patent”), entitled “Method of Stabilizing Imiquimod,” to Alexis S. Statham and Robert J. Nelson.

17. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,243 (“the ‘243 patent”), entitled “Methods for Improving Imiquimod Availability at Two Months, Four Months and Six Months Between Refined and Compendial,” to Alexis S. Statham and Robert J. Nelson.

18. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,244 (“the ‘244 patent”), entitled “Method of Preparing a Pharmaceutical Cream and Minimizing Imiquimod Impurity Formation (At Least Four Months Storage),” to Alexis S. Statham and Robert J. Nelson.

19. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,245 (“the ‘245 patent”), entitled “Methods for Reducing Imiquimod Impurities for Two Months, Four Months, and Six Months,” to Alexis S. Statham and Robert J. Nelson.

20. On or about March 8, 2011, the PTO issued U.S. Patent No. 7,902,246 (“the ‘246 patent”), entitled “Methods for Controlling Formation of Imiquimod Impurities for Two Months, Four Months, and Six Months,” to Alexis S. Statham and Robert J. Nelson.

21. On or about April 13, 2010, the PTO issued U.S. Patent No. 7,696,159 (“the ‘159 patent”), entitled “Treatment for Basal Cell Carcinoma,” to Mary L. Owens, Terrance L. Fox, and Angela M. Ginkel.

22. On information and belief, 3M IPC is the owner of the ‘209, ‘210, ‘211, ‘212, ‘213, ‘214, ‘215, ‘216, ‘242, ‘243, ‘244, ‘245, and ‘246 patents (collectively, “the 3M Patents”).

23. On information and belief, Graceway is a licensee of the 3M Patents and has the right to enforce the 3M Patents.

24. On information and belief, Graceway is the owner of the ‘159 patent and has the right to enforce the ‘159 patent.

25. Defendants have exhibited an intent to bring infringement claims under their patents against Nycomed. For example, on or about February 23, 2010, Defendants sued Nycomed in this District, accusing Nycomed's Imiquimod Cream 5% product of infringing U.S. Patent No. 7,655,672 ("the '672 patent"). *See* Graceway Pharmaceuticals, LLC and 3M Innovative Properties Company v. Nycomed US Inc., Civil Action No. 2:10cv937 (WJM)(MF). That action is currently pending.

26. The '672 patent issued on or around February 2, 2010.

27. On information and belief, between January 29 and February 1, 2010, Defendants filed or caused to be filed 27 applications with the PTO. Thirteen of these applications issued as the 3M Patents on March 8, 2011.

28. The 27 applications, including the applications that issued as the 3M Patents, are all continuations of the application that issued as the '672 patent. The 27 applications, including the applications that issued as the 3M Patents, all share the same specification as the '672 patent.

29. During prosecution of each of the 27 applications, including the applications that issued as the 3M Patents, Defendants submitted or caused to be submitted a Petition to Make Special with a request for accelerated examination. On information and belief, Defendants requested an accelerated examination to bring infringement claims against Nycomed on patents issuing from these applications as soon as possible.

30. In addition, on or around April 23, 2010, Nycomed received a demand letter from Graceway accusing Nycomed's Imiquimod Cream 5% product of infringing the '159 patent. To date, Graceway has not withdrawn its accusations of infringement.

**FIRST CLAIM FOR RELIEF**

(Declaratory Judgment of Non-Infringement of the '209 Patent)

31. Nycomed repeats and realleges the allegations contained in paragraphs 1-30 above as if fully set forth herein.

32. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '209 patent.

33. Nycomed has not infringed, and is not infringing, any valid claim of the '209 patent.

34. Nycomed is entitled to a declaratory judgment that it does not infringe the '209 patent.

**SECOND CLAIM FOR RELIEF**

(Declaratory Judgment of Invalidity of the '209 Patent)

35. Nycomed repeats and realleges the allegations contained in paragraphs 1-34 above as if fully set forth herein.

36. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '209 patent.

37. Each and every claim of the '209 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

38. Nycomed is entitled to a declaratory judgment that the '209 patent is invalid.

**THIRD CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '210 Patent)**

39. Nycomed repeats and realleges the allegations contained in paragraphs 1-38 above as if fully set forth herein.

40. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '210 patent.

41. Nycomed has not infringed, and is not infringing, any valid claim of the '210 patent.

42. Nycomed is entitled to a declaratory judgment that it does not infringe the '210 patent.

**FOURTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '210 Patent)**

43. Nycomed repeats and realleges the allegations contained in paragraphs 1-42 above as if fully set forth herein.

44. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '210 patent.

45. Each and every claim of the '210 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

46. Nycomed is entitled to a declaratory judgment that the '210 patent is invalid.

**FIFTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '211 Patent)**

47. Nycomed repeats and realleges the allegations contained in paragraphs 1-46 above as if fully set forth herein.

48. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '211 patent.

49. Nycomed has not infringed, and is not infringing, any valid claim of the '211 patent.

50. Nycomed is entitled to a declaratory judgment that it does not infringe the '211 patent.

**SIXTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '211 Patent)**

51. Nycomed repeats and realleges the allegations contained in paragraphs 1-50 above as if fully set forth herein.

52. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '211 patent.

53. Each and every claim of the '211 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

54. Nycomed is entitled to a declaratory judgment that the '211 patent is invalid.



**SEVENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '212 Patent)**

55. Nycomed repeats and realleges the allegations contained in paragraphs 1-54 above as if fully set forth herein.

56. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '212 patent.

57. Nycomed has not infringed, and is not infringing, any valid claim of the '212 patent.

58. Nycomed is entitled to a declaratory judgment that it does not infringe the '212 patent.

**EIGHTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '212 Patent)**

59. Nycomed repeats and realleges the allegations contained in paragraphs 1-58 above as if fully set forth herein.

60. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '212 patent.

61. Each and every claim of the '212 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

62. Nycomed is entitled to a declaratory judgment that the '212 patent is invalid.

**NINTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '213 Patent)**

63. Nycomed repeats and realleges the allegations contained in paragraphs 1-62 above as if fully set forth herein.

64. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '213 patent.

65. Nycomed has not infringed, and is not infringing, any valid claim of the '213 patent.

66. Nycomed is entitled to a declaratory judgment that it does not infringe the '213 patent.

**TENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '213 Patent)**

67. Nycomed repeats and realleges the allegations contained in paragraphs 1-66 above as if fully set forth herein.

68. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '213 patent.

69. Each and every claim of the '213 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

70. Nycomed is entitled to a declaratory judgment that the '213 patent is invalid.

**ELEVENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '214 Patent)**

71. Nycomed repeats and realleges the allegations contained in paragraphs 1-70 above as if fully set forth herein.

72. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '214 patent.

73. Nycomed has not infringed, and is not infringing, any valid claim of the '214 patent.

74. Nycomed is entitled to a declaratory judgment that it does not infringe the '214 patent.

**TWELFTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '214 Patent)**

75. Nycomed repeats and realleges the allegations contained in paragraphs 1-74 above as if fully set forth herein.

76. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '214 patent.

77. Each and every claim of the '214 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

78. Nycomed is entitled to a declaratory judgment that the '214 patent is invalid.

**THIRTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '215 Patent)**

79. Nycomed repeats and realleges the allegations contained in paragraphs 1-78 above as if fully set forth herein.

80. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '215 patent.

81. Nycomed has not infringed, and is not infringing, any valid claim of the '215 patent.

82. Nycomed is entitled to a declaratory judgment that it does not infringe the '215 patent.

**FOURTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '215 Patent)**

83. Nycomed repeats and realleges the allegations contained in paragraphs 1-82 above as if fully set forth herein.

84. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '215 patent.

85. Each and every claim of the '215 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

86. Nycomed is entitled to a declaratory judgment that the '215 patent is invalid.

**FIFTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '216 Patent)**

87. Nycomed repeats and realleges the allegations contained in paragraphs 1-86 above as if fully set forth herein.

88. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '216 patent.

89. Nycomed has not infringed, and is not infringing, any valid claim of the '216 patent.

90. Nycomed is entitled to a declaratory judgment that it does not infringe the '216 patent.

**SIXTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '216 Patent)**

91. Nycomed repeats and realleges the allegations contained in paragraphs 1-90 above as if fully set forth herein.

92. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '216 patent.

93. Each and every claim of the '216 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

94. Nycomed is entitled to a declaratory judgment that the '216 patent is invalid.

**SEVENTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '242 Patent)**

95. Nycomed repeats and realleges the allegations contained in paragraphs 1-94 above as if fully set forth herein.

96. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '242 patent.

97. Nycomed has not infringed, and is not infringing, any valid claim of the '242 patent.

98. Nycomed is entitled to a declaratory judgment that it does not infringe the '242 patent.

**EIGHTEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '242 Patent)**

99. Nycomed repeats and realleges the allegations contained in paragraphs 1-98 above as if fully set forth herein.

100. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '242 patent.

101. Each and every claim of the '242 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

102. Nycomed is entitled to a declaratory judgment that the '242 patent is invalid.

**NINETEENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '243 Patent)**

103. Nycomed repeats and realleges the allegations contained in paragraphs 1-102 above as if fully set forth herein.

104. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '243 patent.

105. Nycomed has not infringed, and is not infringing, any valid claim of the '243 patent.

106. Nycomed is entitled to a declaratory judgment that it does not infringe the '243 patent.

**TWENTIETH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '243 Patent)**

107. Nycomed repeats and realleges the allegations contained in paragraphs 1-106 above as if fully set forth herein.

108. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '243 patent.

109. Each and every claim of the '243 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

110. Nycomed is entitled to a declaratory judgment that the '243 patent is invalid.

**TWENTY-FIRST CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '244 Patent)**

111. Nycomed repeats and realleges the allegations contained in paragraphs 1-110 above as if fully set forth herein.

112. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '244 patent.

113. Nycomed has not infringed, and is not infringing, any valid claim of the '244 patent.

114. Nycomed is entitled to a declaratory judgment that it does not infringe the '244 patent.

**TWENTY-SECOND CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '244 Patent)**

115. Nycomed repeats and realleges the allegations contained in paragraphs 1-114 above as if fully set forth herein.

116. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '244 patent.

117. Each and every claim of the '244 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

118. Nycomed is entitled to a declaratory judgment that the '244 patent is invalid.



**TWENTY-THIRD CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '245 Patent)**

119. Nycomed repeats and realleges the allegations contained in paragraphs 1-118 above as if fully set forth herein.

120. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '245 patent.

121. Nycomed has not infringed, and is not infringing, any valid claim of the '245 patent.

122. Nycomed is entitled to a declaratory judgment that it does not infringe the '245 patent.

**TWENTY-FOURTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '245 Patent)**

123. Nycomed repeats and realleges the allegations contained in paragraphs 1-122 above as if fully set forth herein.

124. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '245 patent.

125. Each and every claim of the '245 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

126. Nycomed is entitled to a declaratory judgment that the '245 patent is invalid.

**TWENTY-FIFTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '246 Patent)**

127. Nycomed repeats and realleges the allegations contained in paragraphs 1-126 above as if fully set forth herein.

128. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '246 patent.

129. Nycomed has not infringed, and is not infringing, any valid claim of the '246 patent.

130. Nycomed is entitled to a declaratory judgment that it does not infringe the '246 patent.

**TWENTY-SIXTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '246 Patent)**

131. Nycomed repeats and realleges the allegations contained in paragraphs 1-130 above as if fully set forth herein.

132. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '246 patent.

133. Each and every claim of the '246 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

134. Nycomed is entitled to a declaratory judgment that the '246 patent is invalid.

**TWENTY-SEVENTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '159 Patent)**

135. Nycomed repeats and realleges the allegations contained in paragraphs 1-134 above as if fully set forth herein.

136. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding non-infringement of the '159 patent.

137. Nycomed has not infringed, and is not infringing, any valid claim of the '159 patent.

138. Nycomed is entitled to a declaratory judgment that it does not infringe the '159 patent.

**TWENTY-EIGHTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '159 Patent)**

139. Nycomed repeats and realleges the allegations contained in paragraphs 1-138 above as if fully set forth herein.

140. There is an actual, substantial, and continuing justiciable case or controversy between Nycomed and Defendants regarding the validity of the '159 patent.

141. Each and every claim of the '159 patent is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

142. Nycomed is entitled to a declaratory judgment that the '159 patent is invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Nycomed respectfully requests that the Court enter judgment in its favor and against Defendants as follows:

- (a) Declare that no valid claim of the patents-in-suit is infringed by Nycomed or Nycomed's Imiquimod Cream 5% product;
- (b) Declare that the claims of the patents-in-suit are invalid;
- (c) Award Nycomed costs (including expert fees), disbursements, and reasonable attorneys' fees incurred in this action, pursuant to 35 U.S.C. § 285; and
- (d) Grant Nycomed such other and further relief as the Court may deem just and proper.

Dated: March 8, 2011

Respectfully submitted,

s/ Leda Dunn Wettre

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