IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| TAKEDA PHARMACEUTICALS U.S.A., INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | C. A. No.: 14-268-SLR |
| v. | ) | |
| | ) | |
| WATSON LABORATORIES, INC. | ) | |
| | ) | |
| Defendant. | ) | |

**WATSON LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO AMENDED COMPLAINT**

Defendant Watson Laboratories, Inc. ("Watson") hereby answers and counterclaims to the Complaint of Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda" or "Plaintiff") as follows, wherein each paragraph 1-154 in the following Answer responds to the same-numbered paragraph in the Complaint:

## ANSWER

## PARTIES

1. Watson is without knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Amended Complaint, and, therefore, denies them.

2. Watson admits that it is a Nevada corporation having a place of business at 311 Bonnie Circle, Corona, CA 92878.

## JURISDICTION AND VENUE

3. Paragraph 3 of the Complaint asserts a legal conclusion to which Watson believes no response is required. To the extent a response is required, Watson admits that this action purports to arise under 35 U.S.C. § 271.

4. Paragraph 4 of the Complaint asserts a legal conclusion to which Watson believes no response is required. To the extent a response is required, Watson denies that the Court has subject matter jurisdiction over the declaratory judgment counts of the Amended Complaint. Watson denies the remaining allegations in paragraph 4 of the Amended Complaint.

5. Paragraph 5 of the Complaint asserts a legal conclusion to which Watson believes no response is required. To the extent a response is required, Watson does not contest personal jurisdiction in this judicial district for purposes of this action only.

6. Paragraph 6 of the Complaint asserts legal conclusions to which Watson believes no response is required. To the extent a response is required, Watson admits that it asserted counterclaims in *Merck & Co. Inc. v. Watson Labs., Inc.*, C.A. No. 05-658 (D. Del.), but otherwise denies the allegations of paragraph 6 of the Amended Complaint.

7. Watson admits that venue is proper in the District for purposes of this action only, but otherwise denies the allegations of paragraph 7 of the Amended Complaint.

## STATEMENT OF FACTS RELEVANT TO ALL COUNTS

8. Watson admits that gout is a type of severe arthritis characterized by "flares" resulting from a build-up of uric acid and that Colcrys® is approved by the FDA to treat and prevent gout flares. Watson lacks knowledge and information sufficient to form a belief as to the truth of the other allegations in paragraph 8 of the Amended Complaint, and, therefore, denies them.

9. Watson admits that Familial Mediterranean Fever ("FMF") is a disease characterized by recurrent and/or chronic inflammation and that Colcrys® is approved by the FDA to treat FMF. Watson lacks knowledge and information sufficient to form a belief as to the truth of the other allegations in paragraph 9 of the Amended Complaint, and, therefore, denies them.

10. Watson admits that the FDA approved Colcrys® under New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353. Watson is without knowledge and information sufficient to form a belief as to the truth of the other allegations in paragraph 10 of the Complaint, and, therefore, denies them.

11. Watson admits that the FDA granted Orphan Drug exclusivity to COLCRYS® and that this exclusivity expires on July 29, 2016.

12. Watson admits that the FDA approved COLCRYS® in 2009, but otherwise denies the allegations of paragraph 12 of the Amended Complaint.

13. Watson is without knowledge and information sufficient to form a belief as to the truth of the allegations of paragraph 13, and, therefore, denies them.

A. Watson admits that on March 15, 2011, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,906,519 ("the '519 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '519 patent is attached as Exhibit A to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(A) of the Amended Complaint.

B. Watson admits that on May 3, 2011, the PTO issued U.S. Patent No. 7,935,731 ("the '731 patent"), entitled on its face "METHODS FOR CONCOMITANT

ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '731 patent is attached as Exhibit B to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(B) of the Amended Complaint.

C. Watson admits that on January 10, 2012, the PTO issued U.S. Patent No. 8,093,298 ("the '298 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '298 patent is attached as Exhibit C to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(C) of the Amended Complaint.

D. Watson admits that on June 21, 2011, the PTO issued U.S. Patent No. 7,964,648 ("the '648 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '648 patent is attached as Exhibit D to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(D) of the Amended Complaint.

E. Watson admits that on January 10, 2012, the PTO issued U.S. Patent No. 8,093,297 ("the '297 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '297 patent is attached as Exhibit E to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(E) of the Amended Complaint.

F. Watson admits that on November 17, 2009, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,619,004 ("the '004 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '004 patent is attached as Exhibit F to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(F) of the Amended Complaint.

G. Watson admits that on October 13, 2009, the PTO issued U.S. Patent No. 7,601,758 ("the '758 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS IN THE TREATMENT OF GOUT FLARES," naming Matthew Davis as the inventor. Watson further admits that a copy of the '758 patent is attached as Exhibit G to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(G) of the Amended Complaint.

H. Watson admits that on October 26, 2010, the PTO issued U.S. Patent No. 7,820,681 ("the '681 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '681 patent is attached as Exhibit H to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(H) of the Amended Complaint.

I. Watson admits that on March 29, 2011, the PTO issued U.S. Patent No. 7,915,269 ("the '269 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '269 patent is attached

as Exhibit I to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(I) of the Amended Complaint.

J. Watson admits that on June 21, 2011, the PTO issued U.S. Patent No. 7,964,647 ("the '647 patent"), entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '647 patent is attached as Exhibit J to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(J) of the Amended Complaint.

K. Watson admits that on July 19, 2011, the PTO issued U.S. Patent No. 7,981,938 ("the '938 patent"), entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '938 patent is attached as Exhibit K to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(K) of the Amended Complaint.

L. Watson admits that on January 10, 2012, the PTO issued U.S. Patent No. 8,093,296 ("the '296 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '296 patent is attached as Exhibit L to Plaintiff's Amended Complaint. Watson otherwise denies all allegation in paragraph 13(L) of the Amended Complaint.

M. Watson admits that on January 17, 2012, the PTO issued U.S. Patent No. 8,097,655 ("the '655 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," naming Matthew Davis as the inventor. Watson further admits that a copy of the '655 patent is attached

as Exhibit M to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(M) of the Amended Complaint.

N. Watson admits that on April 9, 2013, the PTO issued U.S. Patent No. 8,415,395 ("the '395 patent"), entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," naming Matthew Davis and Hengsheng Feng as the inventors. Watson further admits that a copy of the '395 patent is attached as Exhibit N to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(N) of the Amended Complaint.

O. Watson admits that on April 9, 2013, the PTO issued U.S. Patent No. 8,415,396 ("the '396 patent"), entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," naming Matthew Davis and Hengsheng Feng as the inventors. Watson further admits that a copy of the '396 patent is attached as Exhibit O to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(O) of the Amended Complaint.

P. Watson admits that on May 14, 2013, the PTO issued U.S. Patent No. 8,440,721 ("the '721 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '721 patent is attached as Exhibit P to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(P) of the Amended Complaint.

Q. Watson admits that on May 14, 2013, the PTO issued U.S. Patent No. 8,440,722 ("the '722 patent"), entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," naming Matthew Davis as the inventor. Watson further admits that a copy of the '722 patent is attached

as Exhibit Q to Plaintiff's Amended Complaint. Watson otherwise denies all allegations in paragraph 13(Q) of the Amended Complaint.

14. Watson acknowledges Takeda's definition of "FMF Patents" in paragraph 14 of the Amended Complaint and uses this term consistently in this Answer.

15. Watson acknowledges Takeda's definition of "Gout Patents" in paragraph 15 of the Amended Complaint and uses this term consistently in this Answer.

16. Watson acknowledges Takeda's definition of "COLCRYS® Patents" in paragraph 16 of the Amended Complaint and uses this term consistently in this Answer.

17. Watson admits patent information has been submitted to the FDA in connection with Colcrys®, and that the FDA has published the same in the Orange Book. Watson is without knowledge and information sufficient to admit or deny the remaining allegations of paragraph 17 of the Amended Complaint, and, therefore, denies them.

**THE GOUT AND FMF MARKETS IN THE UNITED STATES**

18. Watson admits that the National Institute of Health Office of Rare Diseases classifies FMF as a "rare disease" affecting fewer than 200,000 individuals in the United States. Watson is without knowledge and information sufficient to admit or deny the remaining allegations of paragraph 18 of the Amended Complaint, and, therefore, denies them.

19. Watson is without knowledge and information sufficient to admit or deny the allegations of paragraph 19 of the Amended Complaint, and, therefore, denies them.

20. Watson denies the allegations of paragraph 20 of the Amended Complaint.

**PHYSICIAN AND PHARMACY PRESCRIBING PRACTICES**

21. Watson admits that physicians may make prescribing decisions for medication based on, *inter alia*, their knowledge, experience, review of the medical literature, and review of

the PDR or package insert for a given drug. Watson denies the remaining allegations of paragraph 21 of the Amended Complaint.

22. Watson admits that pharmacists sometimes substitute a generic version for a brand drug when filling prescriptions. Watson further admits that a copy of the 2014 National Association of Boards of Pharmacy (NABP) *Survey of Pharmacy Law* is attached to the Amended Complaint as Exhibit S and that it states that 14 states mandatorily require a pharmacist to substitute a generic version of the prescribed drug if all prescription requirements are met. Watson is without knowledge and information sufficient to admit or deny the remaining allegations of paragraph 22 of the Amended Complaint, and, therefore, denies them.

23. Watson admits that, prior to 2009, colchicine was prescribed in the United States. Watson is without knowledge and information sufficient to admit or deny the remaining allegations of paragraph 23 of the Amended Complaint, and, therefore, denies them.

**WATSON'S ACTIONS GIVING RISE TO THIS SUIT**

24. Watson admits that it submitted Abbreviated New Drug Application ("ANDA") No. 204461 to the FDA seeking approval for a 0.6 mg oral colchicine tablet. Watson otherwise denies the allegations in paragraph 24 of the Amended Complaint.

25. Watson admits that it sent its Notice Letter to Plaintiff on January 30, 2014 ("Watson's First PIV Notice Letter"); that Plaintiff received Watson's First PIV Notice Letter on January 31, 2014; that Watson's First PIV Notice Letter was signed by a representative of Watson; and that Watson's Notice Letter stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721, and '722 patents. Watson otherwise denies all allegations in paragraph 25 of the Amended Complaint.

26. Watson admits that Takeda filed a lawsuit against Watson in this District within 45 days of receipt of Watson's January 30, 2014 First PIV Notice Letter, alleging infringement under 35 U.S.C. § 271 of the Gout Patents. Watson denies the remaining allegations of Paragraph 26 of the Amended Complaint.

27. Watson admits that it amended its ANDA No. 204461 to withdraw its request for approval for the treatment of gout after the initiation of this lawsuit by Takeda. Watson denies the remaining allegations of paragraph 27 of the Amended Complaint.

28. Watson admits that it sent a Notice Letter to Plaintiff on May 9, 2014 ("Watson's Second PIV Notice Letter"); that Watson's Second PIV Notice Letter was signed by a representative of Watson; and that Watson's Second PIV Notice Letter stated that its ANDA included Paragraph IV Certifications to the '519, '298, '731, '648, and '297 patents. Watson otherwise denies all allegations in paragraph 28 of the Amended Complaint.

29. Watson admits that Watson's Second PIV Notice Letter stated that it had carved out of its proposed label (i.e., draft package insert and medication guide) all applicable sections pertaining to an indication for the prophylaxis and treatment of gout flares. Watson otherwise denies all allegations in paragraph 29 of the Amended Complaint.

30. Watson admits that it submitted to the FDA an amendment to its ANDA No. 204461 to request approval from the FDA to market colchicine for the treatment of FMF and to carve out of its proposed label all applicable sections to the indication for prophylaxis and treatment of gout flares. Watson otherwise denies the remaining allegations of paragraph 30 of the Amended Complaint.

31. Watson admits that the FDA approved product label for COLCRYS® contains methods of using COLCRYS® for gout, but denies the remaining allegations in paragraph 31 as requiring legal conclusions as to the meaning of the claims of the Gout Patents.

32. Watson admits that the FDA approved product label for COLCRYS® contains methods of using COLCRYS® for FMF, but denies the remaining allegations in paragraph 32 as requiring legal conclusions as to the meaning of the claims of the FMF Patents.

33. Paragraph 33 asserts legal conclusions to which Watson believes no response is required. To the extent a response is required, Watson denies all allegations in paragraph 33 of the Amended Complaint.

34. Watson denies the allegations of Paragraph 34 of the Amended Complaint.

35. Watson denies the allegations of Paragraph 35 of the Amended Complaint.

36. Watson denies the allegations of Paragraph 36 of the Amended Complaint.

37. Watson denies the allegations of Paragraph 37 of the Amended Complaint.

38. Watson admits that it is seeking approval of ANDA No. 204461 from the FDA to market colchicine for the treatment of FMF. Watson otherwise denies all allegations in paragraph 38 of the Amended Complaint.

39. Watson denies the allegations of paragraph 39 of the Amended Complaint.

40. Watson denies the allegations of Paragraph 40 of the Amended Complaint.

41. Watson denies the allegations of Paragraph 41 of the Amended Complaint, but admits that Takeda amended its complaint within 45 days of receiving Watson's Second PIV Notice Letter

**COUNT I**

**(Infringement of the '519 patent)**

42. Watson incorporates herein paragraphs 1-41, above, in response to paragraph 42 of the Amended Complaint.

43. Watson denies the allegations in paragraph 43 of the Amended Complaint.

44. Watson denies the allegations in paragraph 44 of the Amended Complaint.

45. Watson denies the allegations in paragraph 45 of the Amended Complaint.

46. Watson denies the allegations in paragraph 46 of the Amended Complaint.

47. Watson denies the allegations in paragraph 47 of the Amended Complaint.

48. Watson denies the allegations in paragraph 48 of the Amended Complaint.

**COUNT II**

**(Infringement of the '731 patent)**

49. Watson incorporates herein paragraphs 1-48, above, in response to paragraph 49 of the Amended Complaint.

50. Watson denies the allegations in paragraph 50 of the Amended Complaint.

51. Watson denies the allegations in paragraph 51 of the Amended Complaint.

52. Watson denies the allegations in paragraph 52 of the Amended Complaint.

53. Watson denies the allegations in paragraph 53 of the Amended Complaint.

54. Watson denies the allegations in paragraph 54 of the Amended Complaint.

55. Watson denies the allegations in paragraph 55 of the Amended Complaint.

**COUNT III**

**(Infringement of the '298 patent)**

56. Watson incorporates herein paragraphs 1-55, above, in response to paragraph 56 of the Amended Complaint.

57. Watson denies the allegations in paragraph 57 of the Amended Complaint.

58. Watson denies the allegations in paragraph 58 of the Amended Complaint.

59. Watson denies the allegations in paragraph 59 of the Amended Complaint.

60. Watson denies the allegations in paragraph 60 of the Amended Complaint.

61. Watson denies the allegations in paragraph 61 of the Amended Complaint.

62. Watson denies the allegations in paragraph 62 of the Amended Complaint.

**COUNT IV**

**(Infringement of the '648 patent)**

63. Watson incorporates herein paragraphs 1-62, above, in response to paragraph 63 of the Amended Complaint.

64. Watson denies the allegations in paragraph 64 of the Amended Complaint.

65. Watson denies the allegations in paragraph 65 of the Amended Complaint.

66. Watson denies the allegations in paragraph 66 of the Amended Complaint.

67. Watson admits that it has knowledge of the '648 patent, but otherwise denies the allegations in paragraph 67 of the Amended Complaint.

68. Watson denies the allegations in paragraph 68 of the Amended Complaint.

69. Watson denies the allegations in paragraph 69 of the Amended Complaint.

70. Watson denies the allegations in paragraph 70 of the Amended Complaint.

71. Watson denies the allegations in paragraph 71 of the Amended Complaint.

**COUNT V**

**(Infringement of the '297 patent)**

72. Watson incorporates herein paragraphs 1-71, above, in response to paragraph 72 of the Amended Complaint.

73. Watson denies the allegations in paragraph 73 of the Amended Complaint.

74. Watson denies the allegations in paragraph 74 of the Amended Complaint.

75. Watson denies the allegations in paragraph 75 of the Amended Complaint.

76. Watson admits that it has knowledge of the '297 patent, but otherwise denies the allegations in paragraph 76 of the Amended Complaint.

77. Watson denies the allegations in paragraph 77 of the Amended Complaint.

78. Watson denies the allegations in paragraph 78 of the Amended Complaint.

79. Watson denies the allegations in paragraph 79 of the Amended Complaint.

80. Watson denies the allegations in paragraph 80 of the Amended Complaint.

**COUNT VI**

**(Infringement of the '004 patent)**

81. Watson incorporates herein paragraphs 1-80, above, in response to paragraph 81 of the Amended Complaint.

82. Watson admits that it has knowledge of the '004 patent, but otherwise denies the allegations in paragraph 82 of the Amended Complaint.

83. Watson denies the allegations in paragraph 83 of the Amended Complaint.

84. Watson denies the allegations in paragraph 84 of the Amended Complaint.

85. Watson denies the allegations in paragraph 85 of the Amended Complaint.

86. Watson denies the allegations in paragraph 86 of the Amended Complaint.

**COUNT VII**

**(Infringement of the '758 patent)**

87. Watson incorporates herein paragraphs 1-86, above, in response to paragraph 87 of the Amended Complaint.

88. Watson admits that it has knowledge of the '758 patent, but otherwise denies the allegations in paragraph 88 of the Amended Complaint.

89. Watson denies the allegations in paragraph 89 of the Amended Complaint.

90. Watson denies the allegations in paragraph 90 of the Amended Complaint.

91. Watson denies the allegations in paragraph 91 of the Amended Complaint.

92. Watson denies the allegations in paragraph 92 of the Amended Complaint.

**COUNT VIII**

**(Infringement of the '681 patent)**

93. Watson incorporates herein paragraphs 1-92, above, in response to paragraph 93 of the Amended Complaint.

94. Watson admits that it has knowledge of the '681 patent, but otherwise denies the allegations in paragraph 94 of the Amended Complaint.

95. Watson denies the allegations in paragraph 95 of the Amended Complaint.

96. Watson denies the allegations in paragraph 96 of the Amended Complaint.

97. Watson denies the allegations in paragraph 97 of the Amended Complaint.

98. Watson denies the allegations in paragraph 98 of the Amended Complaint.

**COUNT IX**

**(Infringement of the '269 patent)**

99. Watson incorporates herein paragraphs 1-98, above, in response to paragraph 99 of the Amended Complaint.

100. Watson admits that it has knowledge of the '269 patent, but otherwise denies the allegations in paragraph 100 of the Amended Complaint.

101. Watson denies the allegations in paragraph 101 of the Amended Complaint.

102. Watson denies the allegations in paragraph 102 of the Amended Complaint.

103. Watson denies the allegations in paragraph 103 of the Amended Complaint.

104. Watson denies the allegations in paragraph 104 of the Amended Complaint.

**COUNT X**

**(Infringement of the '647 patent)**

105. Watson incorporates herein paragraphs 1-104, above, in response to paragraph 105 of the Amended Complaint.

106. Watson admits that it has knowledge of the '647 patent, but otherwise denies the allegations in paragraph 106 of the Amended Complaint.

107. Watson denies the allegations in paragraph 107 of the Amended Complaint.

108. Watson denies the allegations in paragraph 108 of the Amended Complaint.

109. Watson denies the allegations in paragraph 109 of the Amended Complaint.

110. Watson denies the allegations in paragraph 110 of the Amended Complaint.

**COUNT XI**

**(Infringement of the '938 patent)**

111. Watson incorporates herein paragraphs 1-110, above, in response to paragraph 111 of the Amended Complaint.

112. Watson admits that it has knowledge of the '938 patent, but otherwise denies the allegations in paragraph 112 of the Amended Complaint.

113. Watson denies the allegations in paragraph 113 of the Amended Complaint.

114. Watson denies the allegations in paragraph 114 of the Amended Complaint.

115. Watson denies the allegations in paragraph 115 of the Amended Complaint.

116. Watson denies the allegations in paragraph 116 of the Amended Complaint.

## COUNT XII

**(Infringement of the '296 patent)**

117. Watson incorporates herein paragraphs 1-116, above, in response to paragraph 117 of the Amended Complaint.

118. Watson admits that it has knowledge of the '296 patent, but otherwise denies the allegations in paragraph 118 of the Amended Complaint.

119. Watson denies the allegations in paragraph 119 of the Amended Complaint.

120. Watson denies the allegations in paragraph 120 of the Amended Complaint.

121. Watson denies the allegations in paragraph 121 of the Amended Complaint.

122. Watson denies the allegations in paragraph 122 of the Amended Complaint.

## COUNT XIII

**(Infringement of the '655 patent)**

123. Watson incorporates herein paragraphs 1-122, above, in response to paragraph 123 of the Amended Complaint.

124. Watson admits that it has knowledge of the '655 patent, but otherwise denies the allegations in paragraph 124 of the Amended Complaint.

125. Watson denies the allegations in paragraph 125 of the Amended Complaint.

126. Watson denies the allegations in paragraph 126 of the Amended Complaint.

127. Watson denies the allegations in paragraph 127 of the Amended Complaint.

128. Watson denies the allegations in paragraph 128 of the Amended Complaint.

## COUNT XIV

**(Infringement of the '395 patent)**

129. Watson incorporates herein paragraphs 1-128, above, in response to paragraph 129 of the Amended Complaint.

130. Watson admits that it has knowledge of the '395 patent, but otherwise denies the allegations in paragraph 130 of the Amended Complaint.

131. Watson denies the allegations in paragraph 131 of the Amended Complaint.

132. Watson denies the allegations in paragraph 132 of the Amended Complaint.

133. Watson denies the allegations in paragraph 133 of the Amended Complaint.

134. Watson denies the allegations in paragraph 134 of the Amended Complaint.

**COUNT XV**

**(Infringement of the '396 patent)**

135. Watson incorporates herein paragraphs 1-134, above, in response to paragraph 135 of the Amended Complaint.

136. Watson admits that it has knowledge of the '396 patent, but otherwise denies the allegations in paragraph 136 of the Amended Complaint.

137. Watson denies the allegations in paragraph 137 of the Amended Complaint.

138. Watson denies the allegations in paragraph 138 of the Amended Complaint.

139. Watson denies the allegations in paragraph 139 of the Amended Complaint.

140. Watson denies the allegations in paragraph 140 of the Amended Complaint.

**COUNT XVI**

**(Infringement of the '721 patent)**

141. Watson incorporates herein paragraphs 1-140, above, in response to paragraph 141 of the Amended Complaint.

142. Watson admits that it has knowledge of the '721 patent, but otherwise denies the allegations in paragraph 142 of the Amended Complaint.

143. Watson denies the allegations in paragraph 143 of the Amended Complaint.

144. Watson denies the allegations in paragraph 144 of the Amended Complaint.

145. Watson denies the allegations in paragraph 145 of the Amended Complaint.

146. Watson denies the allegations in paragraph 146 of the Amended Complaint.

**COUNT XVII**

**(Infringement of the '722 patent)**

147. Watson incorporates herein paragraphs 1-146 above, in response to paragraph 147 of the Amended Complaint.

148. Watson admits that it has knowledge of the '722 patent, but otherwise denies the allegations in paragraph 148 of the Amended Complaint.

149. Watson denies the allegations in paragraph 149 of the Amended Complaint.

150. Watson denies the allegations in paragraph 150 of the Amended Complaint.

151. Watson denies the allegations in paragraph 151 of the Amended Complaint.

152. Watson denies the allegations in paragraph 152 of the Amended Complaint.

**EXCEPTIONAL CASE**

153. In response to paragraph 153, Watson admits that is was aware of the COLCRYS® Patents before submitting ANDA No. 204461 and its label amendment to the FDA.

154. Watson denies the allegations in paragraph 154 of the Complaint.

**ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF**

Watson denies that Takeda is entitled to the relief demanded in paragraphs (A) through (H) of the prayer for relief on pages 30-32 of the Amended Complaint, or any relief for the allegations set forth in the Amended Complaint.

## AFFIRMATIVE DEFENSES

In further answer to the complaint, Watson alleges the following, separate affirmative defenses, while expressly reserving its right to assert any additional defenses that discovery may reveal:

### First Affirmative Defense: Noninfringement

1. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '519 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

2. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '731 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

3. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '298 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

4. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will

not infringe any valid and enforceable claim of the '648 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

5. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '297 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

6. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '004 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

7. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '758 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

8. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '681 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

9. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '269 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

10. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '647 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

11. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '938 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

12. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '296 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

13. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '655 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

14. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204661 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '395 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

15. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204661 has not infringed, does not infringe, and will

not infringe any valid and enforceable claim of the '396 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

16. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204661 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '721 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

17. The manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204661 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '722 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

**Second Affirmative Defense: Patent Invalidity**

18. Each and every claim of the '519 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

19. Each and every claim of the '731 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

20. Each and every claim of the '298 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

21. Each and every claim of the '648 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

22. Each and every claim of the '297 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

23. Each and every claim of the '004 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

24. Each and every claim of the '758 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

25. Each and every claim of the '681 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

26. Each and every claim of the '269 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

27. Each and every claim of the '647 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

28. Each and every claim of the '938 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

29. Each and every claim of the '296 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

30. Each and every claim of the '655 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

31. Each and every claim of the '395 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

32. Each and every claim of the '396 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

33. Each and every claim of the '721 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

34. Each and every claim of the '722 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

## COUNTERCLAIMS

For its counterclaims against Takeda, Counterclaimant Watson Laboratories, Inc. ("Watson") alleges: first, that the 0.6 mg colchicine tablets described in Watson's ANDA No. 204461 do not infringe any valid and enforceable claim of U.S. Patent No. 7,906,519 ("the '519 Patent"), U.S. Patent No. 7,935,731 ("the '731 patent"), U.S. Patent No. 8,093,298 ("the '298 patent"), U.S. Patent 7,964,648 ("the '648 Patent"), U.S. Patent No. 8,093,297 ("the '297 Patent"), 7,619,004 ("the '004 Patent"), US. Patent No. 7,601,758 ("the '758 Patent"), U.S. Patent No. 7,820,681 ("the '681 Patent"), U.S. Patent No. 7,915,269 ("the '269 Patent"), U.S. Patent No. 7,964,647 ("the '647 Patent"), U.S. Patent No. 7,981,938 ("the '938 Patent"), U.S. Patent No. 8,093,296 ("the '296 Patent"), U.S. Patent No. 8,097,655 ("the '655 Patent"), U.S. Patent No. 8,415,395 ("the '395 Patent"), U.S. Patent No. 8,415,396 ("the '396 Patent"), U.S. Patent No. 8,440,721 ("the '721 Patent"), and U.S. Patent 8,440,722 ("the '722 Patent); and second, that each and every claim of the patents are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.:

## THE PARTIES

1. Watson is a Nevada corporation with a place of business at 311 Bonnie Circle, Corona, CA 92878.

2. Upon information and belief, Takeda is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

## JURISDICTION AND VENUE

3. This Court has jurisdiction over these counterclaims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 1, 21 U.S.C. § 355(c)(3)(D) and 21 U.S.C. § 355(j)(5)(c)(ii)(I).

4. Takeda has submitted to the personal jurisdiction of this Court by bringing suit against Watson in this Court.

5. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400.

6. There is an actual justiciable controversy between the parties concerning non-infringement and invalidity of the '519 patent, the '731 patent, the '298 patent, the '648 patent, the '297 patent, the '004 Patent, the '758 patent, the '681 Patent, the '269 Patent, the '647 Patent, the '938 Patent, the '296 Patent, the '655 Patent, the '395 Patent, the '396 Patent, the '721 Patent, and the '722 Patent.

## FACTUAL BACKGROUND

7. According to the FDA Orange Book, Takeda holds approved New Drug Application ("NDA") No. 22-352 for Colcrys®, which contains the active ingredient colchicine. Takeda has also stated in its Complaint that it holds NDA Nos. 22-351 and 22-353 for Colcrys®. The FDA database lists NDA Nos. 22-351 and 22-353 for Colcrys® under the company name AR Holding Co. Inc.

8. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the FDA publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations" (the "Orange Book").

9. The '519 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued March 15, 2011.

10. The '731 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and was issued May 3, 2011.

11. The '298 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and was issued on January 10, 2012.

12. The '648 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued June 21, 2011.

13. The '297 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued January 10, 2012.

14. The '004 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and was issued November 17, 2009.

15. The '758 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS IN THE TREATMENT OF GOUT FLARES," and was issued October 13, 2009.

16. The '681 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued October 26, 2010.

17. The '269 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued March 29, 2011.

18. The '647 patent is entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," and was issued June 21, 2011.

19. The '938 patent is entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," and was issued July 19, 2011.

20. The '296 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and was issued January 10, 2012.

21. The '655 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and was issued January 17, 2012.

22. The '395 patent is entitled on its face "COLCHICINE COMPOSITIONS AND METHODS," and was issued April 9, 2013.

23. The '396 patent is titled on its face "COLCHICINE COMPOSITIONS AND METHODS" and was issued April 9, 2013.

24. The '721 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued May 14, 2013.

25. The '722 patent is entitled on its face "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," and was issued May 14, 2013.

26. Upon information and belief, Takeda owns the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, and '722 patents.

27. Upon information and belief, Takeda caused the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, and '722 patents to be listed in the Orange Book as patents that claim COLCRYS® and/or claim a method of using COLCRYS®.

28. Watson's ANDA No. 204461 seeks FDA approval to engage in the commercial manufacture, use, and sale of colchicine 0.6 mg tablets prior to the expiration of the '519, '731, '298, '648, and '297 patents.

29. Watson's ANDA No. 204461 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '519, '731, '298, '648, and '297 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product.

30. On February 27, 2014, Takeda filed this lawsuit alleging infringement of the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721, and '722 patents.

31. On September 4, 2014, Takeda filed an Amended Complaint, additionally alleging infringement of the '519, '731, '298 patents.

**FIRST COUNTERCLAIM**

**Declaratory Judgment of Non-Infringement of the Patents-In-Suit**

32. Watson re-alleges and incorporates by reference the allegations in paragraphs 1-31 of its Counterclaims.

33. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Watson's ANDA No. 204461 and/or manufacture, use,

offer to sell, sale, and/or importation into the United States of Watson's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, and '722 patent ("the Patents-in-Suit").

34. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '519 patent and is not liable for such infringement.

35. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '731 patent and is not liable for such infringement.

36. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '298 patent and is not liable for such infringement.

37. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '648 patent and is not liable for such infringement.

38. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '297 patent and is not liable for such infringement.

39. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '004 patent and is not liable for such infringement.

40. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '758 patent and is not liable for such infringement.

41. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '681 patent and is not liable for such infringement.

42. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '269 patent and is not liable for such infringement.

43. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '647 patent and is not liable for such infringement.

44. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '938 patent and is not liable for such infringement.

45. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '296 patent and is not liable for such infringement.

46. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '655 patent and is not liable for such infringement.

47. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '395 patent and is not liable for such infringement.

48. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '396 patent and is not liable for such infringement.

49. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '721 patent and is not liable for such infringement.

50. Watson has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '722 patent and is not liable for such infringement.

51. Watson is entitled to a judicial declaration that: Watson has not infringed, contributed to the infringement of, or induced the infringement of any of the Patents-in-Suit; and that the manufacture, use, sale, offer for sale, or importation of the colchicine product that is the subject of Watson's ANDA No. 204461 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of any of the Patents-in-Suit.

## SECOND COUNTERCLAIM

### Invalidity of the Patents-in-Suit

52. Watson re-alleges and incorporates by reference the allegations in paragraphs 1-51 of its Counterclaims.

53. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647,

'938, '296, '655, '395, '396, '721, and '722 patents ("the Patents-in-Suit"), based on Takeda's allegation in its Complaint that Watson has infringed or will infringe the Patents-in-Suit.

54. Each and every claim of the '519 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

55. Each and every claim of the '731 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

56. Each and every claim of the '298 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

57. Each and every claim of the '648 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

58. Each and every claim of the '297 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

59. Each and every claim of the '004 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

60. Each and every claim of the '758 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

61. Each and every claim of the '681 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

62. Each and every claim of the '269 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

63. Each and every claim of the '647 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

64. Each and every claim of the '938 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

65. Each and every claim of the '296 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

66. Each and every claim of the '655 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

67. Each and every claim of the '395 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

68. Each and every claim of the '396 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

69. Each and every claim of the '721 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

70. Each and every claim of the '722 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

71. Watson is entitled to a judicial declaration that all claims of each of the Patents-in-Suit are invalid.

**WATSON'S PRAYER FOR RELIEF**

WHEREFORE, Watson prays for judgment in its favor and against Takeda as follows:

(a) Dismissing the Complaint with prejudice and denying each request for relief made by Takeda;

(b) Declaring all claims of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, and '722 patents invalid;

(c) Declaring that the filing of Watson's ANDA No. 204461 has not infringed and does not infringe any valid and enforceable claim of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, or '722 patents;

(d) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Watson's ANDA Product does not, and would not, if marketed,

directly or indirectly infringe any valid and enforceable claim of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '647, '938, '296, '655, '395, '396, '721, and '722 patents;

(e) Declaring this an exceptional case in favor of Watson and awarding its attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Awarding Watson its costs and fees; and

(g) Awarding Watson such other and further relief as the Court deems just and equitable.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

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Dated: September 22, 2014

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