IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff/Counterclaim-Defendant, v. PAR PHARMACEUTICAL, INC., Defendant/Counterclaimant.	C.A. No. 12-419-SLR

DEFENDANT PAR'S ANSWER TO TAKEDA'S AMENDED COMPLAINT FOR PATENT INFRINGEMENT, SEPARATE DEFENSES, AND COUNTERCLAIMS

Defendant Par Pharmaceutical, Inc. ("Par"), by and through its attorneys, for its Answer to the Amended Complaint of Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda" or "Plaintiff"), hereby declares as follows:

NATURE OF THE ACTION

1. Par admits that the Complaint purports to be a civil action for infringement of U.S. Patent Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,093,297 ("the '297 patent"); 8,097,655 ("the '655 patent"), 8,415,395 ("the '395 patent") and 8,415,396 ("the '396 patent") (collectively, the "patents-in-suit" or the "Patents"). Par denies the remaining allegations of Paragraph 1.

THE PARTIES

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Takeda. Par is also without knowledge and information sufficient to form a belief as to whether Takeda owns the entire right, title, and interest in the patents-in-suit. Par thus denies all allegations of Paragraph 2.

3. Par admits that it is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977, and admits that it is in the business of selling pharmaceuticals throughout the United States. Par denies the remaining allegations of Paragraph 3.

JURISDICTION AND VENUE

4. Paragraph 4 states a legal conclusion to which no response is required. To the extent a response is required, Par does not dispute that this Court has jurisdiction over the subject matter of this action.

5. Paragraph 5 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it is a Delaware corporation, has previously consented to personal jurisdiction in this District, and has asserted counterclaims in other actions initiated in this District. Par denies the remaining allegations of Paragraph 5.

6. Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, for the limited purpose of this action only, Par admits that venue is proper.

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

7. Par admits that COLCRYS® is indicated for treating "gout flares" and avers that that COLCRYS® is indicated for treating "Familial Mediterranean fever (FMF) in adults and children 4 years or older." Par denies the remaining allegations of Paragraph 7.

8. On information and belief, Par admits that the Food and Drug Administration ("FDA") approved COLCRYS® in 2009. Par denies the remaining allegations of Paragraph 8.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 9, and thus denies the allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par is without knowledge and information sufficient to form a belief as to whether Takeda is the lawful owner of all right, title, and interest in the patents-in-suit, including the right to sue and to recover for infringement of patents containing one or more claims covering methods of use of COLCRYS®. Par thus denies all allegations of Paragraph 10.

A. Par admits that the '004 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," states the date of issue as November 17, 2009, and lists Matthew Davis as the inventor. Par denies that the '004 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(A).

B. Par admits that the '758 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares," states the date of issue as October 13, 2009, and lists Matthew Davis as the inventor. Par denies that the '758 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(B).

C. Par admits that the '681 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," states the date of issue as October 26, 2010, and lists Matthew Davis as the inventor. Par denies that the '681 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(C).

D. Par admits that the '269 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," states the date of issue as March 29, 2011, and lists Matthew Davis as the inventor. Par denies that the '269 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(D).

E. Par admits that the '647 patent, on its face, is titled "Colchicine Compositions and Methods," states the date of issue as June 21, 2011, and lists Matthew Davis as the inventor. Par denies that the '647 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(E).

F. Par admits that the '648 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," states the date of issue as June 21, 2011, and lists Matthew Davis as the inventor. Par denies that the '648 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(F).

G. Par admits that the '938 patent, on its face, is titled "Colchicine Compositions and Methods," states the date of issue as July 19, 2011, and lists Matthew Davis as the inventor. Par denies that the '938 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(G).

H. Par admits that the '296 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," states the date of issue as

January 10, 2012, and lists Matthew Davis as the inventor. Par denies that the '296 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(H).

I. Par admits that the '297 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," states the date of issue as January 10, 2012, and lists Matthew Davis as the inventor. Par denies that the '297 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(I).

J. Par admits that the '655 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," states the date of issue as January 17, 2012, and lists Matthew Davis as the inventor. Par denies that the '655 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 10(J).

K. Par admits that the '395 patent, on its face, is titled "Colchicine Compositions and Methods," states the date of issue as April 9, 2013, and names Matthew Davis and Hengsheng Feng as the inventors. Par denies that the '395 patent was duly and legally issued. Par denies any remaining allegations in Paragraph 10(K) of the Complaint.

L. Par admits that the '396 patent, on its face, is titled "Colchicine Compositions and Methods," states the date of issue as April 9, 2013, and names Matthew Davis and Hengsheng Feng as the inventors. Par denies that the '396 patent was duly and legally issued. Par denies any remaining allegations in Paragraph 10(L) of the Complaint.

11. No response is required to the defined term of Paragraph 11. To the extent a response is required, Par admits that the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, and '396 patents may be defined as the "Patents."

12. Par admits that patent information relating to New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-352 is included in the FDA's "Approved Drug Products with

Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). Par is without knowledge or information sufficient to form a belief as to whether Takeda submitted such patent information, and thus denies the remaining allegations of Paragraph 12.

13. Par admits that it submitted Abbreviated New Drug Application ("ANDA") No. 20-3976 to the FDA, seeking to market a 0.6 mg oral tablet generic version of COLCRYS® prior to the stated term of the patents-in-suit. Par denies that Takeda has any enforceable patent rights in the patents-in-suit and denies all remaining allegations of Paragraph 13.

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that COLCRYS® is indicated for treatment of "gout flares" and "Familial Mediterranean fever (FMF) in adults and children 4 years or older." Par denies the remaining allegations of Paragraph 14.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 15.

16. Par is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 16, and thus denies the allegations of Paragraph 16.

17. Par is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 17, and thus denies the allegations of Paragraph 17.

18. Par is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 18, and thus denies the allegations of Paragraph 18.

19. Par denies the allegations of Paragraph 19.

20. Par denies the allegations of Paragraph 20.

21. Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it sent AR Holding Company, Inc. a signed notice

letter, dated February 21, 2012, informing AR Holding Company, Inc. that Par had filed ANDA No. 20-3976. Par avers that the letter also notified AR Holding Company, Inc. that Par had filed an amended certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (an amended "Paragraph IV Certification") that the '004, '758, '681, '269, '647, '648, '938, '296, '297, and '655 patents are invalid and/or would not be infringed. Par is without information or belief as to the remaining allegations of Paragraph 21, and thus denies the remaining allegations of Paragraph 21.

22. Paragraph 22 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that it sent AR Holding Company, Inc. a signed second notice letter, dated March 15, 2012, informing AR Holding Company, Inc. that Par had filed ANDA No. 20-3976. Par avers that the notice letter indicated that Par had made an amended Paragraph IV Certification that the '004, '758, '681, '269, '647, '648, '938, '296, '297, and '655 patents are invalid or would not be infringed. Par is without information or belief as to the remaining allegations of Paragraph 22, and thus denies the remaining allegations of Paragraph 22.

23. Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it sent Takeda a signed second notice letter, informing Takeda that Par had filed ANDA No. 20-3976 and made a Paragraph IV Certification that the '395 and '396 patents are invalid or would not be infringed. Par is without information or belief as to the remaining allegations in paragraph 23, and thus denies the remaining allegations of Paragraph 23.

24. Paragraph 24 states a legal conclusion to which no response is required. To the extent a response is required, Par admits the accuracy of the quoted statute and regulation of Paragraph 24.

25. Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 25.

26. Paragraph 26 states a legal conclusion to which no response is required. To the extent a response is required, Par does not dispute that notice of a Paragraph IV letter under 21 U.S.C. § 355(j)(B)(iii) triggers a forty-five day period in which the patentee may file an action for patent infringement. Par denies the remaining allegations of Paragraph 26.

27. Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 27.

28. Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is required, Par does not dispute that 21 U.S.C. § 355(j)(5)(B)(iii) provides for a thirty-month stay. Par denies the remaining allegations of Paragraph 28.

29. Par avers that it sent its letter of February 21, 2012, prior to receiving the letter from the Secretary concerning ANDA No. 20-3976. Par denies the remainder of allegations of Paragraph 28.

30. Par admits the allegations of Paragraph 29.

31. Paragraph 30 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 30.

32. Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 31.

COUNT I
(Infringement of the '004 Patent Under 35 U.S.C. § 271 against Par)[1]

33. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 32.

34. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '004 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 34.

35. Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 35.

36. Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 36.

37. Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 37.

38. Paragraph 38 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 38.

39. Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 39.

[1] Headings are reprinted here with the same language as used in Plaintiff's Complaint, simply for ease of reference, and do not constitute an admission.

COUNT II
(Infringement of the '758 Patent Under 35 U.S.C. § 271 against Par)

40. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 39.

41. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '758 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 41.

42. Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 42.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 43.

44. Paragraph 44 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 44.

45. Paragraph 45 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 45.

46. Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 46.

COUNT III
(Infringement of the '681 Patent Under 35 U.S.C. § 271 against Par)

47. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 46.

48. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '681 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 48.

49. Paragraph 49 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 49.

50. Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 50.

51. Paragraph 51 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 51.

52. Paragraph 52 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 52.

COUNT IV
(Infringement of the '269 Patent Under 35 U.S.C. § 271 against Par)

53. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 52.

54. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '269 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 54.

55. Paragraph 55 states a legal conclusion to which no response is required. To the

extent a response is required, Par denies the allegations of Paragraph 55.

56. Paragraph 56 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 56.

57. Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 57.

58. Paragraph 58 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 58.

59. Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 59.

COUNT V
(Infringement of the '647 Patent Under 35 U.S.C. § 271 against Par)

60. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 59.

61. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '647 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 61.

62. Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 62.

63. Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 63.

64. Paragraph 64 states a legal conclusion to which no response is required. To the

extent a response is required, Par denies the allegations of Paragraph 64.

65. Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 65.

COUNT VI
(Infringement of the '648 Patent Under 35 U.S.C. § 271 against Par)

66. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 65.

67. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '648 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 67.

68. Paragraph 68 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 68.

69. Paragraph 69 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 69.

70. Paragraph 70 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 70.

71. Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 71.

COUNT VII
(Infringement of the '938 Patent Under 35 U.S.C. § 271 against Par)

72. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby

incorporates by reference its responses to Paragraphs 1 through 71.

73. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '938 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 73.

74. Paragraph 74 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 74.

75. Paragraph 75 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 75.

76. Paragraph 76 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 76.

77. Paragraph 77 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 77.

COUNT VIII
(Infringement of the '296 Patent Under 35 U.S.C. § 271 against Par)

78. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 77.

79. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '296 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 79.

80. Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 80.

81. Paragraph 81 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 81.

82. Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 82.

83. Paragraph 83 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 83.

84. Paragraph 84 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 84.

COUNT IX
(Infringement of the '297 Patent Under 35 U.S.C. § 271 against Par)

85. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 84.

86. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '297 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 86.

87. Paragraph 87 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 87.

88. Paragraph 88 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 88.

89. Paragraph 89 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 89.

90. Paragraph 90 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 90.

91. Paragraph 91 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 91.

COUNT X
(Infringement of the '655 Patent Under 35 U.S.C. § 271 against Par)

92. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 91.

93. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '655 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 93.

94. Paragraph 94 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 94.

95. Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 95.

96. Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 96.

97. Paragraph 97 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 97.

COUNT XI
(Infringement of the '395 Patent Under 35 U.S.C. § 271 against Par)

98. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 97.

99. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the stated expiration of the '395 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 99.

100. Paragraph 100 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 100.

101. Paragraph 101 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 101.

102. Paragraph 102 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 102.

103. Paragraph 103 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 103.

COUNT XII
(Infringement of the '396 Patent Under 35 U.S.C. § 271 against Par)

104. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 103.

105. Par admits that it submitted to the FDA ANDA No. 20-3976 with a Paragraph IV Certification, seeking to obtain approval to market a generic colchicine product prior to the

stated expiration of the '396 patent. Par denies that by submitting ANDA No. 20-3976, Par committed an act of infringement under 35 U.S.C. §271(e)(2), and Par denies the remaining allegations of Paragraph 105.

106. Paragraph 106 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 106.

107. Paragraph 107 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 107.

108. Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 108.

109. Paragraph 109 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 109.

EXCEPTIONAL CASE

110. Par denies the allegations of Paragraph 110. Par avers that it was not aware of the '655 patent, '395 patent, or '396 patent before submitting ANDA No. 20-3976.

111. Par denies the allegations of Paragraph 111.

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF

Par denies that Takeda is entitled to the relief it seeks in Paragraphs (A)–(F) or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Takeda's allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are

appropriate.

FIRST SEPARATE DEFENSE
(Invalidity of the Patents-in-Suit)

112. The claims of the '004 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

113. The claims of the '758 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

114. The claims of the '681 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

115. The claims of the '269 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

116. The claims of the '647 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

117. The claims of the '648 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

118. The claims of the '938 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

119. The claims of the '296 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

120. The claims of the '297 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

121. The claims of the '655 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

122. The claims of the '395 patent are invalid for failing to meet one or more

requirements for patentability under Title 35 of the United States Code.

123. The claims of the '396 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SECOND SEPARATE DEFENSE
(Noninfringement of the Patents-in-Suit)

124. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '004 patent.

125. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '004 patent under the doctrine of equivalents.

126. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '758 patent.

127. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '758 patent under the doctrine of equivalents.

128. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '681 patent.

129. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the

infringement of any valid or enforceable claim of the '681 patent under the doctrine of equivalents.

130. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '269 patent.

131. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '269 patent under the doctrine of equivalents.

132. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '647 patent.

133. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '647 patent under the doctrine of equivalents.

134. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '648 patent.

135. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '648 patent under the doctrine of equivalents.

136. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '938 patent.

137. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '938 patent under the doctrine of equivalents.

138. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '296 patent.

139. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '296 patent under the doctrine of equivalents.

140. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '297 patent.

141. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '297 patent under the doctrine of equivalents.

142. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '655 patent.

143. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '655 patent under the doctrine of equivalents.

144. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '395 patent.

145. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '395 patent under the doctrine of equivalents.

146. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '396 patent.

147. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '396 patent under the doctrine of equivalents.

THIRD SEPARATE DEFENSE
(Prosecution History Estoppel)

148. Takeda is estopped from asserting any scope of the '004 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '004 patent.

149. Takeda is estopped from asserting any scope of the '758 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '758 patent.

150. Takeda is estopped from asserting any scope of the '681 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '681 patent.

151. Takeda is estopped from asserting any scope of the '269 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '269 patent.

152. Takeda is estopped from asserting any scope of the '647 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '647 patent.

153. Takeda is estopped from asserting any scope of the '648 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '648 patent.

154. Takeda is estopped from asserting any scope of the '938 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '938 patent.

155. Takeda is estopped from asserting any scope of the '296 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '296 patent.

156. Takeda is estopped from asserting any scope of the '297 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '297 patent.

157. Takeda is estopped from asserting any scope of the '655 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '655 patent.

158. Takeda is estopped from asserting any scope of the '395 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '395 patent.

159. Takeda is estopped from asserting any scope of the '396 patent that would cover Par's Product because of statements made during the prosecution of the applications leading to the issuance of the '396 patent.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Counterclaimant, Par Pharmaceutical, Inc. ("Par"), asserts the following counterclaims against Plaintiff/Counterclaim-defendant Takeda Pharmaceuticals, U.S.A., Inc. ("Takeda") for declaratory judgment that U.S. Patent Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647

patent"); 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,093,297 ("the '297 patent"); 8,097,655 ("the '655 patent"), 8,415,395 ("the '395 patent"); and 8,415,396 ("the '396 patent") (collectively, "the patents-in-suit") are not infringed by the colchicine product described in Par's ANDA No. 203976, and/or are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

THE PARTIES

1. Counterclaimant Par is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. On information and belief, and based on Plaintiff's allegations, Counterclaim-Defendant/Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

NATURE OF THE ACTION

3. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief: a declaration that the patents-in-suit are not infringed by the colchicine product described in Par Abbreviated New Drug Application ("ANDA") No. 203976 and/or are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Par and Takeda, arising under the patent laws of

the United States, 35 U.S.C. §1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

5. This Court has personal jurisdiction over Takeda based on, *inter alia*, Takeda's filing of this lawsuit in this jurisdiction.

6. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

7. The '004 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as November 17, 2009.

8. The '758 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares" and states its date of issue as October 13, 2009.

9. The '681 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as October 26, 2010.

10. The '269 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as March 29, 2011.

11. The '647 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as June 21, 2011.

12. The '648 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as June 21, 2011.

13. The '938 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as July 19, 2011.

14. The '296 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as January 10, 2012.

15. The '297 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as January 10, 2012.

16. The '655 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as January 17, 2012.

17. The '395 patent, on its face, is titled "Colchicine Compositions and Methods," and states its date of issue as April 9, 2013.

18. The '396 patent, on its face, is titled "Colchicine Compositions and Methods," and states its date of issue as April 9, 2013.

19. On information and belief, and based on Takeda's allegations, the patents-in-suit are owned by Takeda.

20. On information and belief, and based on Takeda's allegations, Takeda is the holder of New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353 for colchicine, sold in the United States as COLCRYS®.

21. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 22-351 on July 30, 2009.

22. On information and belief, the FDA approved NDA No. 22-352 on July 29, 2009.

23. On information and belief, the FDA approved NDA No. 22-353 on October 16, 2009.

24. Par submitted ANDA No. 20-3976 to the FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of a 0.6 mg colchicine product before the stated expiration of the '758, '004, '681, '269, '647, '648,

'938, '296, and '297 patents. Par made a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the '758, '004, '681, '269, '647, '648, '938, '296, and '297 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the Par product that is the subject of ANDA No. 20-3976 ("Par's Product").

25. On February 21, 2012, Par amended its Paragraph IV Certification, adding that no valid or enforceable claim of the newly-issued '655 patent would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the Par Product.

26. On February 21, 2012, and in response to its February 21, 2012, amendment of its Paragraph IV Certification to include the newly-issued '655 patent, Par sent a letter to AR Holding stating that Par's ANDA No. 20-3976 contained a Paragraph IV certification regarding all the patents-in-suit.

27. On April 4, 2012, AR Holding filed a Complaint alleging infringement by Par of the '758, '004, '681, '269, '647, '648, '938, '296, '297, and '655 patents.

28. On May 17, 2013, Par amended its Paragraph IV Certification, adding that no valid or enforceable claim of the newly-issued '395 and '396 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the Par Product.

29. On June 13, 2013, Takeda amended its Complaint to allege infringement of the '395 and '396 patents.

COUNT I
(Declaration of Invalidity of the Patents-in-Suit)

30. Par incorporates by reference Paragraphs 1 through 29 of its Counterclaims as if fully set forth herein.

31. The claims of the '004 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

32. The claims of the '758 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

33. The claims of the '681 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

34. The claims of the '269 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

35. The claims of the '647 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

36. The claims of the '648 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

37. The claims of the '938 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

38. The claims of the '296 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

39. The claims of the '297 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

40. The claims of the '655 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

41. The claims of the '395 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

42. The claims of the '396 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

43. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the patents-in-suit, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

44. Par is entitled to a judicial declaration that each of the patents-in-suit is invalid.

COUNT II
(Declaration of Noninfringement of the Patents-in-Suit)

45. Par incorporates by reference Paragraphs 1 through 44 of its Counterclaims as if fully set forth herein.

46. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '004 patent.

47. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '004 patent under the doctrine of equivalents.

48. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '758 patent.

49. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '758 patent under the doctrine of equivalents.

50. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '681 patent.

51. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '681 patent under the doctrine of equivalents.

52. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '269 patent.

53. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '269 patent under the doctrine of equivalents.

54. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '647 patent.

55. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '647 patent under the doctrine of equivalents.

56. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '648 patent.

57. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '648 patent under the doctrine of equivalents.

58. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '938 patent.

59. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '938 patent under the doctrine of equivalents.

60. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '296 patent.

61. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '296 patent under the doctrine of equivalents.

62. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '297 patent.

63. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '297 patent under the doctrine of equivalents.

64. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '655 patent.

65. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '655 patent under the doctrine of equivalents.

66. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '395 patent.

67. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '395 patent under the doctrine of equivalents.

68. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '396 patent.

69. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '396 patent under the doctrine of equivalents.

70. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's Product of the patents-in-

suit, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

71. Par is entitled to a judicial declaration that each of the patents-in-suit is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par requests the following relief:

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

b) Declaring all claims of the patents-in-suit invalid;

c) Declaring all claims of the patents-in-suit not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's Product;

d) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par its attorneys' fees, costs, and expenses in this action; and

e) Awarding Par such other and further relief as the Court deems just and proper.

/s/ Steven J. Fineman
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