IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LTD. and TAP PHARMACEUTICAL PRODUCTS INC.,	)	
Plaintiffs and Counterclaim-Defendants,	)	
v.	)	C.A. No. 06-33-SLR
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants and Counterclaim-Plaintiffs.	)	

TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS TO AMENDED COMPLAINT

Defendants and Counterclaim-Plaintiffs, Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively "Teva"), respond to the numbered paragraphs of the Amended Complaint filed by Plaintiffs and Counterclaim-Defendants, Takeda Pharmaceutical Company Ltd. and TAP Pharmaceutical Products Inc., (collectively "Plaintiffs") as follows:

ANSWER

THE PARTIES

1. Teva states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Amended Complaint, and therefore, Teva denies the allegations of Paragraph 1.

2. Teva states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Amended Complaint, and therefore, Teva denies the allegations of Paragraph 2.

3. Teva admits the allegations in Paragraph 3 of the Amended Complaint.

4. Teva admits Teva Ltd. is an Israeli corporation having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. Teva further admits Teva Ltd. manufactures pharmaceutical products. Except as expressly admitted above, Teva denies the allegations in Paragraph 4 of the Amended Complaint.

5. Teva admits the allegations in Paragraph 5 of the Amended Complaint.

6. Teva denies the allegations in Paragraph 6 of the Amended Complaint.

7. Teva admits only that Teva USA conducts business in North America. Except as expressly admitted above, Teva denies the allegations in Paragraph 7 of the Amended Complaint.

JURISDICTION AND VENUE

8. Teva admits only that this action purports to arise under the patent laws of the United States and that this Court has subject matter jurisdiction. Teva denies any and all remaining allegations in Paragraph 8 of the Amended Complaint including denying that it has infringed any valid and enforceable claim of any of Plaintiffs' patents-in-suit.

9. Teva admits only that Teva USA is subject to personal jurisdiction in this District, Teva USA is incorporated in Delaware, and Teva USA conducts business within the District of Delaware. Except as expressly admitted above, Teva denies the allegations in Paragraph 9 of the Amended Complaint.

10. Teva admits only that Teva USA conducts business within the District of Delaware. Except as expressly admitted above, Teva denies the allegations in Paragraph 10 of the Amended Complaint.

11. Teva denies the allegations in Paragraph 11 of the Amended Complaint.

12. Teva denies the allegations in Paragraph 12 of the Amended Complaint.

13. Teva denies the allegations in Paragraph 13 of the Amended Complaint.

14. Teva denies the allegations in Paragraph 14 of the Amended Complaint.

15. Teva admits only that Teva Ltd. is subject to personal jurisdiction in this District for purposes of this action, Teva USA is incorporated in Delaware, and Teva USA conducts business in the District of Delaware. Except as expressly admitted above, Teva denies the allegations in Paragraph 15 of the Amended Complaint.

16. Teva admits the allegations in Paragraph 16 of the Amended Complaint.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

17. In response to the allegations of Paragraph 17 of the Amended Complaint, Teva states that the referenced patent speaks for itself and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17 and therefore denies them.

18. Upon information and belief, Teva admits the term of the '098 patent without adjustment has expired. Except as expressly admitted above, Teva denies the allegations in Paragraph 18 of the Amended Complaint.

19. In response to the allegations of Paragraph 19 of the Amended Complaint, Teva states that the certificate extending the patent term of the '098 patent speaks for itself and Teva is

without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19 and therefore denies them.

20. In response to the allegations of Paragraph 20 of the Amended Complaint, Teva states that the referenced patent speaks for itself and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20 and therefore denies them.

21. In response to the allegations of Paragraph 21 of the Amended Complaint, Teva states that the referenced patent speaks for itself and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21 and therefore denies them.

22. In response to the allegations of Paragraph 22 of the Amended Complaint, Teva states that the referenced patent speaks for itself and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22 and therefore denies them.

23. In response to the allegations of Paragraph 23 of the Amended Complaint, Teva states that the referenced patent speaks for itself and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 23 and therefore denies them.

24. Upon information and belief, Teva admits that the FDA approved NDA No. 20-406 for lansoprazole delayed release capsules, 15 and 30 mg, on May 10, 1995. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 24 and therefore denies them.

25. Teva admits the allegations in Paragraph 25 of the Amended Complaint.

26. Teva admits only that Teva Ltd. offers a broad range of generic pharmaceutical products. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 26 of the Amended Complaint.

27. Teva admits only that Teva USA manufactures, markets, and sells pharmaceutical products within the United States generally and the State of Delaware specifically. Except as expressly admitted above, Teva denies the allegations of Paragraph 27 of the Amended Complaint.

28. Teva denies the allegations in Paragraph 28 of the Amended Complaint as stated.

29. Teva admits only that Teva USA filed ANDA No. 77-255 for lansoprazole delayed release capsules with the FDA, Teva Ltd. was aware of the patents-in-suit when Teva USA filed ANDA No. 77-255, and Teva Ltd. was aware of commercial information relating to lansoprazole when Teva USA filed ANDA No. 77-255. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 29 of the Amended Complaint.

30. Teva admits only that Teva USA filed ANDA No. 77-255 for lansoprazole delayed release capsules with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 30 of the Amended Complaint.

31. Teva admits only that Teva USA submitted to the FDA an amendment to ANDA No. 77-255 that included a Paragraph IV certification. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 31 of the Amended Complaint.

32. Upon information and belief, Teva admits the allegations of Paragraph 32 of the Amended Complaint.

33. Teva admits only that Teva USA filed ANDA No. 77-255 for lansoprazole delayed release capsules with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 33 of the Amended Complaint.

34. Teva admits only that Teva Ltd. was aware of the patents-in-suit when Teva USA filed ANDA No. 77-255 and the Paragraph IV certification with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 34 of the Amended Complaint.

35. Upon information and belief, Teva admits the allegations of Paragraph 35 of the Amended Complaint.

36. Teva admits only that Teva USA continues to seek approval of ANDA No. 77-255 from the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 36 of the Amended Complaint.

FIRST CLAIM FOR RELIEF

37. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1 through 36 of the Amended Complaint.

38. Teva denies the allegations in Paragraph 38 of the Amended Complaint.

39. Teva denies the allegations in Paragraph 39 of the Amended Complaint.

40. Teva admits only that Teva USA was aware of the existence of the '098 patent prior to amending ANDA No. 77-255. Except as expressly admitted above, Teva denies the allegations of Paragraph 40 of the Amended Complaint.

41. Teva denies the allegations in Paragraph 41 of the Amended Complaint.

42. Teva admits that its Paragraph IV certification does not assert that claims 1, 2, 5, 6, 8, and 10 of the '098 patent are not infringed. Teva further admits that its Paragraph IV

certification asserts that these claims are invalid. Except as expressly admitted, Teva denies the allegations set forth in Paragraph 42 of the Amended Complaint.

43. Teva denies the allegations in Paragraph 43 of the Amended Complaint.

44. Teva denies the allegations in Paragraph 44 of the Amended Complaint.

SECOND CLAIM FOR RELIEF

45. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1 through 44 of the Amended Complaint.

46. Teva denies the allegations in Paragraph 46 of the Amended Complaint.

47. Teva denies the allegations in Paragraph 47 of the Amended Complaint.

48. Teva denies the allegations in Paragraph 48 of the Amended Complaint.

49. Teva denies the allegations in Paragraph 49 of the Amended Complaint.

50. Teva denies the allegations in Paragraph 50 of the Amended Complaint.

THIRD CLAIM FOR RELIEF

51. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 50 of the Amended Complaint.

52. Teva denies the allegations in Paragraph 52 of the Amended Complaint.

53. Teva denies the allegations in Paragraph 53 of the Amended Complaint.

54. Teva denies the allegations in Paragraph 54 of the Amended Complaint.

55. Teva denies the allegations in Paragraph 55 of the Amended Complaint.

56. Teva denies the allegations in Paragraph 56 of the Amended Complaint.

57. Teva denies the allegations in Paragraph 57 of the Amended Complaint.

FOURTH CLAIM FOR RELIEF

58. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 57 of the Amended Complaint.

59. Teva denies the allegations in Paragraph 59 of the Amended Complaint.

60. Teva denies the allegations in Paragraph 60 of the Amended Complaint.

61. Teva denies the allegations in Paragraph 61 of the Amended Complaint.

62. Teva denies the allegations in Paragraph 62 of the Amended Complaint.

63. Teva denies the allegations in Paragraph 63 of the Amended Complaint.

FIFTH CLAIM FOR RELIEF

64. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 63 of the Amended Complaint.

65. Teva denies the allegations in Paragraph 65 of the Amended Complaint.

66. Teva denies the allegations in Paragraph 66 of the Amended Complaint.

67. Teva denies the allegations in Paragraph 67 of the Amended Complaint.

68. Teva denies the allegations in Paragraph 68 of the Amended Complaint.

69. Teva denies the allegations in Paragraph 69 of the Amended Complaint.

70. Teva denies the allegations in Paragraph 70 of the Amended Complaint.

SIXTH CLAIM FOR RELIEF

71. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 70 of the Amended Complaint.

72. Teva denies the allegations in Paragraph 72 of the Amended Complaint.

73. Teva denies the allegations in Paragraph 73 of the Amended Complaint.

74. Teva denies the allegations in Paragraph 74 of the Amended Complaint.

75. Teva denies the allegations in Paragraph 75 of the Amended Complaint.

76. Teva denies the allegations in Paragraph 76 of the Amended Complaint.

SEVENTH CLAIM FOR RELIEF

77. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 76 of the Amended Complaint.

78. Teva denies the allegations in Paragraph 78 of the Amended Complaint.

79. Teva denies the allegations in Paragraph 79 of the Amended Complaint.

80. Teva denies the allegations in Paragraph 80 of the Amended Complaint.

81. Teva denies the allegations in Paragraph 81 of the Amended Complaint.

82. Teva denies the allegations in Paragraph 82 of the Amended Complaint.

83. Teva denies the allegations in Paragraph 83 of the Amended Complaint.

EIGHTH CLAIM FOR RELIEF

84. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1 through 83 of the Amended Complaint.

85. Teva denies the allegations in Paragraph 85 of the Amended Complaint.

86. Teva denies the allegations in Paragraph 86 of the Amended Complaint.

87. Teva denies the allegations in Paragraph 87 of the Amended Complaint.

88. Teva denies the allegations in Paragraph 88 of the Amended Complaint.

89. Teva denies the allegations in Paragraph 89 of the Amended Complaint.

NINTH CLAIM FOR RELIEF

90. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 89 of the Amended Complaint.

91. Teva denies the allegations in Paragraph 91 of the Amended Complaint.

92. Teva denies the allegations in Paragraph 92 of the Amended Complaint.

93. Teva denies the allegations in Paragraph 93 of the Amended Complaint.

94. Teva denies the allegations in Paragraph 94 of the Amended Complaint.

95. Teva denies the allegations in Paragraph 95 of the Amended Complaint.

96. Teva denies the allegations in Paragraph 96 of the Amended Complaint.

TENTH CLAIM FOR RELIEF

97. Teva incorporates by reference as if fully stated herein its responses to Paragraphs 1 through 96 of the Amended Complaint.

98. Teva denies the allegations in Paragraph 98 of the Amended Complaint.

99. Teva denies the allegations in Paragraph 99 of the Amended Complaint.

100. Teva denies the allegations in Paragraph 100 of the Amended Complaint.

101. Teva denies the allegations in Paragraph 101 of the Amended Complaint.

102. Teva denies the allegations in Paragraph 102 of the Amended Complaint.

103. To the extent any allegation in any paragraph of Plaintiffs' Amended Complaint is not specifically admitted or otherwise responded to, it is hereby denied.

DEFENSES

FIRST DEFENSE

Teva has not infringed, is not infringing and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 4,628,098 ("the '098 patent").

SECOND DEFENSE

Teva has not infringed, is not infringing and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 5,026,560 ("the '560 patent").

THIRD DEFENSE

Teva has not infringed, is not infringing and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 5,045,321 ("the '321 patent").

FOURTH DEFENSE

Teva has not infringed, is not infringing and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 5,093,132 ("the '132 patent").

FIFTH DEFENSE

Teva has not infringed, is not infringing and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 5,433,959 ("the '959 patent").

SIXTH DEFENSE

Upon information and belief, the claims of the '098 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTH DEFENSE

Upon information and belief, the claims of the '560 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

EIGTH DEFENSE

Upon information and belief, the claims of the '321 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

NINTH DEFENSE

Upon information and belief, the claims of the '132 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

TENTH DEFENSE

Upon information and belief, the claims of the '959 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

ELEVENTH DEFENSE

As set forth in greater detail in paragraphs 28-34 of the Counterclaim below, which paragraphs are incorporated herein by reference, the claims of the '098 patent are unenforceable as procured through inequitable conduct before the United States Patent and Trademark Office ("PTO").

In violation of Takeda's duty of candor to the PTO under 37 C.F.R. § 1.56, Takeda intentionally misled the PTO concerning the effectiveness of the alleged invention during

prosecution of patent application no. 06/760,568 ("the '568 application"), the application that led to the issuance of the '098 patent. More particularly, to support patentability of the '568 application, Takeda asserted that the alleged invention exhibited superior anti-ulcer activity, up to 20 times more effective, over "known" prior art compounds. (See, e.g., '098 patent, col. 6, ll. 5-36.)

Having chosen to assert efficacy data as a basis for patentability, any efficacy data that was not cumulative of and that refuted or was inconsistent with the submitted data became material to patentability and would have been considered important by a reasonable examiner in deciding whether or not to allow the application to issue as a patent. Takeda had a duty under 37 C.F.R. § 1.56 to disclose all such data in its possession to the PTO during the prosecution of the of the application that led to the '098 patent. Takeda, however, chose not to disclose the material test data or reports thereof or to correct the misrepresentations in its patent application. Takeda did so with the intent to deceive the PTO concerning the patentability of the application, and therefore is guilty of inequitable conduct rendering the '098 patent unenforceable.

COUNTERCLAIMS

Defendants Teva hereby counterclaim against Plaintiffs, and in support thereof, allege as follows:

1. The Plaintiffs have filed an Amended Complaint against Teva seeking, *inter alia*, a judgment that Teva infringed the claims of the '098 patent, the '560 patent, the '321 patent, the '132 patent, and the '959 patent (collectively "the patents-in-suit") by Teva USA filing ANDA No. 77-255 and a Paragraph IV certification. As a result of the filing of the Amended Complaint, an immediate and justiciable controversy exists between the Plaintiffs and Teva regarding the alleged infringement and validity of the patents-in-suit.

2. The following counterclaims 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.

3. This Court has personal jurisdiction over the Plaintiffs because, *inter alia*, the Plaintiffs have submitted to the jurisdiction of this Court by filing Plaintiffs' Amended Complaint.

4. Subject matter jurisdiction in this Court is proper under, *inter alia*, 28 U.S.C. §§ 1331 and 1338.

5. Venue is proper in this Court because, *inter alia*, the Plaintiffs have submitted to the jurisdiction of this Court and selected this venue by filing their Complaint with this Court.

COUNT ONE
(Non-infringement of the '098 Patent)

6. Teva incorporates by reference all allegations contained in Paragraphs 1 through 5 of its Counterclaims.

7. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '098 patent.

COUNT TWO
(Non-infringement of the '560 Patent)

8. Teva incorporates by reference all allegations contained in Paragraphs 1 through 7 of its Counterclaims.

9. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '560 patent.

COUNT THREE
(Non-infringement of the '321 Patent)

10. Teva incorporates by reference all allegations contained in Paragraphs 1 through 9 of its Counterclaims.

11. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '321 patent.

COUNT FOUR
(Non-infringement of the '132 Patent)

12. Teva incorporates by reference all allegations contained in Paragraphs 1 through 11 of its Counterclaims.

13. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '132 patent.

COUNT FIVE
(Non-infringement of the '959 Patent)

14. Teva incorporates by reference all allegations contained in Paragraphs 1 through 13 of its Counterclaims.

15. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '959 patent.

COUNT SIX
(Declaration of Invalidity of the '098 Patent)

16. Teva incorporates by reference the allegations contained in paragraphs 1-15 of its Counterclaims.

17. The claims of the '098 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT SEVEN
(Declaration of Invalidity of the '560 Patent)

18. Teva incorporates by reference the allegations contained in paragraphs 1-17 of its Counterclaims.

19. The claims of the '560 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT EIGHT
(Declaration of Invalidity of the '321 Patent)

20. Teva incorporates by reference the allegations contained in paragraphs 1-19 of its Counterclaims.

21. The claims of the '321 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT NINE
(Declaration of Invalidity of the '132 Patent)

22. Teva incorporates by reference the allegations contained in paragraphs 1-21 of its Counterclaims.

23. The claims of the '132 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT TEN
(Declaration of Invalidity of the '959 Patent)

24. Teva incorporates by reference the allegations contained in paragraphs 1-23 of its Counterclaims.

25. The claims of the '959 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT ELEVEN
(Declaration of Award of Attorneys' Fees, Costs, and Expenses)

26. Teva incorporates by reference the allegations contained in paragraphs 1-25 of its Counterclaims.

27. This action is an exceptional case under 35 U.S.C. § 285, and Teva is entitled to reimbursement of attorneys' fees, costs, and expenses from Plaintiffs.

COUNT TWELVE
(Declaration of Unenforceability of the '098 Patent Due to Inequitable Conduct)

28. Teva incorporates by reference the allegations contained in paragraphs 1-27 of its Counterclaims.

29. In violation of Takeda's duty of candor to the PTO under 37 C.F.R. § 1.56, Takeda intentionally misled the PTO concerning the effectiveness of the alleged invention during prosecution of patent application no. 06/760,568 ("the '568 application"), the application that led to the issuance of the '098 patent. More particularly, to support patentability of the '568 application, Takeda represented to the PTO in the application that led to the '098 patent that prior art compounds' "gastric mucous membrane protecting action is insufficient, thus being hardly considered satisfactory as anti-ulcer agents." (*See* '098 patent, Col. 1, ln. 14-16.)

30. Takeda further asserted that the alleged invention exhibited superior anti-ulcer activity, up to 20 times more effective, over "known" prior art compounds and summarized results of unidentified test data in the table located in Column 6 of the '098 patent. (See, e.g., '098 patent, col. 6, ll. 5-36.)

31. Takeda's internal documents and test results, including monthly status reports and test data reports, dated prior to issuance of the '098 patent show that Takeda knew that the

claimed invention was not superior to certain prior art compounds and certainly not 20 times superior to competitive anti-ulcer prior art compounds.

32. Having chosen to assert efficacy data as a basis for patentability, any efficacy data that was not cumulative of and that refuted or was inconsistent with the submitted data became material to patentability and would have been considered important by a reasonable examiner in deciding whether or not to allow the application to issue as a patent. Takeda had a duty under 37 C.F.R. § 1.56 to disclose all such data in its possession to the PTO during the prosecution of the of the application that led to the '098 patent. Takeda, however, chose not to disclose the material test data or reports thereof or to correct the misrepresentations in its patent application. Takeda did so with the intent to deceive the PTO concerning the patentability of the application, and therefore is guilty of inequitable conduct rendering the '098 patent unenforceable.

33. The efficacy of the claimed invention relative to prior art compounds is material to patentability. Takeda had a duty to disclose the test data or results thereof demonstrating efficacy data contrary to the representations made during prosecution to the PTO pursuant to 37 C.F.R. § 1.56 but failed to disclose any test data or reports thereof.

34. Takeda intentionally misrepresented the efficacy of the claimed invention to the PTO during prosecution to support patentability and intentionally did not disclose to the PTO contemporaneous test results material to patentability with the intent to deceive the PTO.

35. For at least the foregoing reasons, the '098 patent is unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

(a) dismissing the Amended Complaint, and each and every claim for relief contained therein, with prejudice;

(b) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '098 patent;

(c) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '560 patent;

(d) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '321 patent;

(e) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '132 patent;

(f) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '959 patent;

(g) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '098 patent;

(h) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '560 patent;

(i) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '321 patent;

(j) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '132 patent;

(k) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '959 patent;

(l) declaring all claims of the '098 patent invalid;

(m) declaring all claims of the '560 patent invalid;

(n) declaring all claims of the '321 patent invalid;

(o) declaring all claims of the '132 patent invalid;

(p) declaring all claims of the '959 patent invalid;

(q) declaring all claims of the '098 patent unenforceable;

(r) declaring this an exceptional case under 35 U.S.C. § 285 and awarding Teva its attorneys' fees, costs, and expenses; and

(s) granting Teva such other and further relief as this Court deems just and proper.

July 10, 2007

YOUNG CONAWAY STARGATT & TAYLOR LLP

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on July 10, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on July 10, 2007, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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