IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LTD., TAP PHARMACEUTICAL PRODUCTS INC., and ETHYPHARM, S.A. Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD. Defendants.	)	C.A. No. 07-331-SLR

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

Defendants, Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively "Teva"), respond to the numbered paragraphs of the Complaint filed by Plaintiffs, Takeda Pharmaceutical Company Ltd., TAP Pharmaceutical Products Inc., and Ethypharm, S.A. (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 Complaint, and therefore, Teva denies the allegations in 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 Complaint, and therefore, Teva denies the allegations in Paragraph 2.

3. Teva states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and therefore, Teva denies the allegations in Paragraph 3.

4. Teva admits the allegations in Paragraph 4 of the Complaint.

5. 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 5 of the Complaint.

6. Teva admits the allegations in Paragraph 6 of the Complaint.

7. Teva denies the allegations in Paragraph 7 of the Complaint.

8. Teva admits only that Teva USA conducts business in the United States of America. Except as expressly admitted above, Teva denies the allegations in Paragraph 8 of the Complaint.

JURISDICTION AND VENUE

9. 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 9 of the Complaint including denying that it has infringed any valid and enforceable claim of any of Plaintiffs' patents-in-suit.

10. 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 10 of the Complaint.

11. Teva admits only that Teva USA conducts business within the District of Delaware. Except as expressly admitted above, Teva denies the allegations in Paragraph 11 of the Complaint.

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

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

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

15. Teva denies the allegations in Paragraph 15 of the Complaint.

16. 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 16 of the Complaint.

17. Teva admits the allegations in Paragraph 17 of the Complaint.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

18. In response to the allegations in Paragraph 18 of the 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 18 and therefore denies them.

19. Upon information and belief, Teva admits the allegations in Paragraph 19 of the Complaint.

20. Upon information and belief, Teva admits the allegations in Paragraph 20 of the Complaint.

21. In response to the allegations in Paragraph 21 of the 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 in Paragraph 22 of the 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 in Paragraph 23 of the 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. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, on August 30, 2002. 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 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 Complaint.

27. Teva denies the allegations of Paragraph 27 of the Complaint as stated.

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

29. Teva admits only that Teva filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, Teva was aware of the patents-in-suit when

Teva filed ANDA No. 78-730, and Teva was aware of commercial information relating to Prevacid SoluTab Orally Disintegrating Tablets when Teva filed ANDA No. 78-730. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 29 of the Complaint.

30. Teva admits only that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 30 of the Complaint.

31. Teva admits only that Teva USA submitted to the FDA ANDA No. 78-730 that included a Paragraph IV certification. Except as expressly admitted above, Teva denies the allegations in Paragraph 31 of the Complaint.

32. In response to the allegations in Paragraph 32 of the Complaint, Teva admits sending a letter to Plaintiffs dated April 12, 2007 and states that the referenced letter speaks for itself. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 34.

33. Teva admits only that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 33 of the Complaint.

34. Teva admits only that Teva Ltd. was aware of the patents-in-suit when Teva USA filed ANDA No. 78-730 and the Paragraph IV certification with the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 34 of the Complaint.

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

36. Teva admits only that Teva USA continues to seek approval of ANDA No. 78-730 from the FDA. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 36 of the Complaint.

FIRST CLAIM FOR RELIEF

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

38. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '098 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 38 of the Complaint.

39. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '098 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 39 of the Complaint.

40. Teva admits only that Teva USA was aware of the existence of the '098 patent prior to submitting ANDA No. 78-730. Except as expressly admitted above, Teva denies the allegations in Paragraph 40 of the Complaint.

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

42. Teva admits that its Paragraph IV certification does not address whether claims 1, 2, 5, 6, 8 and 10 of the '098 patent are not infringed. Teva admits that its Paragraph IV certification asserts that these claims are invalid or unenforceable. Except as expressly admitted above, Teva denies the allegations in Paragraph 42 of the Complaint.

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

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

SECOND CLAIM FOR RELIEF

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

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

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

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

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

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

THIRD CLAIM FOR RELIEF

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

52. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '321 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 52 of the Complaint.

53. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '321 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 53 of the Complaint.

54. Teva admits only that Teva USA was aware of the existence of the '321 patent prior to submitting ANDA No. 78-730. Except as expressly admitted above, Teva denies the allegations in Paragraph 54 of the Complaint.

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

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

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

FOURTH CLAIM FOR RELIEF

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

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

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

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

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

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

FIFTH CLAIM FOR RELIEF

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

65. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '632 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 65 of the Complaint.

66. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '632 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 66 of the Complaint.

67. Teva admits only that Teva USA was aware of the existence of the '632 patent prior to submitting ANDA No. 78-730. Except as expressly admitted above, Teva denies the allegations in Paragraph 67 of the Complaint.

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

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

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

SIXTH CLAIM FOR RELIEF

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

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

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

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

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

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

SEVENTH CLAIM FOR RELIEF

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

78. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that the '994 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 78 of the Complaint.

79. Teva admits that Teva USA filed ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets with the FDA, and its Paragraph IV certification asserts that

the '994 patent is invalid, unenforceable or not infringed. Except as expressly admitted above, Teva denies the allegations set forth in Paragraph 79 of the Complaint.

80. Teva admits only that Teva USA was aware of the existence of the '994 patent prior to submitting ANDA No. 78-730. Except as expressly admitted above, Teva denies the allegations in Paragraph 80 of the Complaint.

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

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

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

EIGHTH CLAIM FOR RELIEF

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

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

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

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

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

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

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

91. Teva denies that Plaintiffs, or any one of them, are entitled to the relief sought in the Complaint, or to any relief.

DEFENSES

FIRST DEFENSE

Teva has not infringed, is not infringing and will not infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 4,628,098 ("the '098 Patent"). Furthermore, Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '098 patent.

SECOND DEFENSE

Teva has not infringed, is not infringing and will not infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 5,045,321 ("the '321 Patent"). Furthermore, Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '321 patent.

THIRD DEFENSE

Teva has not infringed, is not infringing and will not infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 5,464,632 ("the '632 Patent"). Furthermore, Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '632 patent.

FOURTH DEFENSE

Teva has not infringed, is not infringing and will not infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 6,328,994 ("the '994 Patent"). Furthermore, Teva Ltd. has not induced, is not inducing and will not induce

infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '994 patent.

FIFTH 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.

SIXTH DEFENSE

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 and failed to disclose material information to the PTO during prosecution of patent application no. 06/760,568, the application that led to the issuance of the '098 patent. 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.

SEVENTH DEFENSE

The patent term extension for the '098 patent is unenforceable as procured through inequitable conduct before the PTO. On July 6, 1995, Takeda filed for a patent term extension for the '098 patent pursuant to 35 U.S.C. §§ 155-156. On January 6, 1997, the PTO awarded Takeda a patent term extension of 1381 days extending the term of the patent to May 10, 2009. Without that patent term extension, the '098 patent would be expired and would not be part of this action. At the time the patent term extension was sought, Takeda knew that the '098 patent was invalid as obvious and unenforceable due to its inequitable conduct before the PTO during prosecution. The patent term extension granted for the '098 patent therefore is unenforceable.

EIGHTH 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 '632 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 '994 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 35-42 of the Counterclaims below, which paragraphs are incorporated herein by reference, the claims of the '632 patent are unenforceable as procured through inequitable conduct before the PTO. In violation of the duty of candor to the PTO under 37 C.F.R. § 1.555, Laboratoires Prographarm ("Prographarm"), predecessor-in-interest to Plaintiff Ethypharm as assignee of the '632 patent, failed to disclose to the PTO the revocation of European Patent No. EP 0548356 ("the EP '356 patent") and/or the basis for that revocation during the reexamination of the '632 patent by the PTO. In light of all of the relevant facts, the evidence indicates that Prographarm, through its representatives, withheld disclosure of the revocation with the intent to deceive the PTO concerning the patentability of the application

that resulted in the '632 patent as amended pursuant to the reexamination. Prographarm therefore is guilty of inequitable conduct rendering the '632 patent unenforceable.

TWELFTH DEFENSE

As set forth in greater detail in paragraphs 43-50 of the Counterclaims below, which paragraphs are incorporated herein by reference, the claims of the '994 patent are unenforceable as procured through inequitable conduct before the PTO. Before the '994 patent was granted, a continuation patent application was filed. Certain material prior art that was disclosed to the PTO during prosecution of that continuation application from the '994 patent was not disclosed to the PTO during prosecution of the '994 patent. In light of all of the relevant facts, the evidence indicates that Takeda, through its representatives, withheld disclosure of the material prior art with the intent to deceive the PTO concerning the patentability of the application that resulted in the '994 patent. Takeda therefore is guilty of inequitable conduct rendering the '994 patent unenforceable.

COUNTERCLAIMS

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

1. The Plaintiffs filed this Complaint against Teva seeking, *inter alia*, a judgment that Teva infringed the claims of the '098 patent, the '321 patent, the '632 patent, and the '994 patent (collectively "the patents-in-suit") by Teva USA filing ANDA No. 78-730 and a Paragraph IV certification. As a result of the filing of the 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' 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, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '098 Patent.

8. Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '098 patent.

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

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

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

11. Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '321 patent.

COUNT THREE
(Non-infringement of the '632 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, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '632 patent.

14. Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '632 patent.

COUNT FOUR
(Non-infringement of the '994 Patent)

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

16. Teva has not infringed, is not infringing and will not infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '994 patent.

17. Teva Ltd. has not induced, is not inducing and will not induce infringement, either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '994 patent.

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

18. Teva incorporates by reference all allegations contained in Paragraphs 1 through 17 of its Counterclaims.

19. 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 SIX
(Declaration of Unenforceability of the '098 Patent Due to Inequitable Conduct)

20. Teva incorporates by reference all allegations contained in Paragraphs 1 through 19 of its Counterclaims.

21. In violation of Takeda's duty of candor to the PTO under 37 C.F.R. § 1.56, Takeda failed to disclose material information and made material misrepresentations to the PTO during prosecution of patent application no. 06/760,568, the application that led to the issuance of the '098 patent.

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

COUNT SEVEN
(Declaration of Unenforceability of the Patent Term Extension for the '098 Patent)

23. Teva incorporates by reference all allegations contained in Paragraphs 1 through 22 of its Counterclaims.

24. The '098 patent issued on December 9, 1986. On July 6, 1995, Takeda applied for a Patent Term Extension pursuant to 35 U.S.C. §§ 155-156. On January 6, 1997, the PTO awarded Takeda a Patent Term Extension of 1381 days extending the term of the patent to May 10, 2009.

25. At the time it sought the patent term extension, Takeda knew that the '098 patent was invalid and unenforceable due to its inequitable conduct before the PTO during prosecution. Takeda knew that the '098 patent was invalid and unenforceable, yet Takeda continued to pursue the patent term extension through the PTO.

26. For at least the foregoing reasons, the patent term extension granted for the '098 patent is unenforceable.

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

27. Teva incorporates by reference all allegations contained in Paragraphs 1 through 26 of its Counterclaims.

28. 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 '632 Patent)

29. Teva incorporates by reference all allegations contained in Paragraphs 1 through 28 of its Counterclaims.

30. Upon information and belief, the claims of the '632 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 '994 Patent)

31. Teva incorporates by reference all allegations contained in Paragraphs 1 through 30 of its Counterclaims.

32. Upon information and belief, the claims of the '994 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)

33. Teva incorporates by reference all allegations contained in Paragraphs 1 through 32 of its Counterclaims.

34. 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 '632 Patent Due to Inequitable Conduct)

35. Teva incorporates by reference all allegations contained in Paragraphs 1 through 34 of its Counterclaims.

36. The claims of the '632 patent are unenforceable as procured through inequitable conduct before the PTO. In violation of the duty of candor to the PTO under 37 C.F.R. § 1.555, Laboratoires Prographarm ("Prographarm"), predecessor-in-interest to Plaintiff Ethypharm as assignee of the '632 patent, failed to disclose to the PTO the revocation of European Patent No. EP 0548356 ("the EP '356 patent") and/or the basis for that revocation during the reexamination of the '632 patent by the PTO.

37. The EP '356 patent is the European counterpart to the '632 patent. Both patents claim priority to the same French patent application. Both patents' written descriptions contain the same examples and other features in common. The claims of both patents as originally granted contain many of the same elements. Furthermore, in both the PTO reexamination proceeding and in the European Patent Office ("EPO") opposition proceeding, Prographarm proposed similar amendments to the granted claims in order to overcome invalidating prior art and other defects in the patent, including without limitation amendment of Claim 1 to limit its scope to cover a tablet disintegrating in less than 60 seconds in the mouth with saliva to provide a suspension easy to swallow.

38. The Division of Opposition of the EPO issued a decision on January 22, 2001 revoking the EP '356 patent as granted and as amended for failure to provide a sufficient disclosure of the technical information needed to reproduce the claimed tablets. Among the numerous bases for the revocation was an opposition declaration submitted on October 28, 1997, establishing that the alleged invention could not be duplicated.

39. At the time of the revocation, the '632 patent was undergoing reexamination in the PTO. During the reexamination, Prographarm was subject to the duty of disclosure under 37 C.F.R. § 1.555 until the '632 patent reissued on February 20, 2001 – a month after the revocation of the EP '356 patent. Even in light of the claim amendments that resulted from the PTO examination, the grounds for EPO revocation were material to, at the very least, the enablement requirement of 35 U.S.C. § 112.

40. Prographarm thus had a duty to disclose the EP '356 patent revocation and/or the basis therefor to the PTO. The revocation and/or the basis therefor were material because a reasonable patent examiner would have considered one or both pieces of information important to the determination of patentability of the '632 patent. Despite this materiality, Prographarm chose not to disclose the revocation or the basis therefor.

41. In particular, a representative of Prographarm, Gustave Koch of the Cabinet Plasseraud firm in Paris, France, was aware of the EPO opposition proceedings in detail, and was in communication and participation with Prographarm's PTO counsel, Alan H. Bernstein and Robert S. Silver of Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., during the PTO reexamination proceedings. Mr. Bernstein and Mr. Silver served as Prographarm's attorneys for reexamination of the '632 patent. Mr. Koch served as an attorney for Prographarm in the reexamination of the '632 patent and in the EP '356 patent opposition, and was the named

recipient of the January 22, 2001 notice of revocation of the EP '356 patent. In the United States, Mr. Koch and Mr. Bernstein attended Examiner Interviews on behalf of Prographarm during the reexamination of the '632 patent. Although an attorney for Prographarm with actual knowledge of the opposition proceedings and the revocation was in communication with Prographarm's PTO attorney, neither Prographarm nor any of its attorneys notified the PTO of the revocation or the basis therefor.

42. In light of all of the relevant facts, the evidence indicates that Prographarm, through its representatives Mr. Bernstein, Mr. Silver, Mr. Koch, or others, withheld disclosure of the revocation with the intent to deceive the PTO concerning the patentability of the application as amended pursuant to the reexamination, and Prographarm therefore is guilty of inequitable conduct rendering the '632 patent unenforceable.

COUNT THIRTEEN
(Declaration of Unenforceability of the '994 Patent Due to Inequitable Conduct)

43. Teva incorporates by reference all allegations contained in Paragraphs 1 through 42 of its Counterclaims.

44. The claims of the '994 patent are unenforceable as procured through inequitable conduct committed before the PTO. In violation of Takeda's duty of candor to the PTO under 37 C.F.R. § 1.56, Takeda intentionally failed to disclose material prior art references to the PTO during the prosecution of the application that led to the '994 patent.

45. The '994 patent was filed as a PCT application on May 17, 1999, and was granted by the PTO on December 11, 2001. On or about October 30, 2001, a U.S. Patent Application No. 10/017,755 ("the '755 application") was filed as a continuation of the '994 patent application. The '755 application has the same named inventors and written description as the '994 patent, and, like the '994 patent, the '755 application is assigned to Takeda. Elements of

the claims of the '994 patent also are elements of the proposed claims of the '755 application. Attorneys Mark Chao and Elaine M. Ramesh handled the prosecution of both the '994 patent and the '755 application.

46. During the prosecution of the '755 application, numerous prior art references were disclosed to the PTO by Takeda. Several of those prior art references were not disclosed to the PTO during prosecution of the '994 patent even though they are material to the patentability of the '994 patent. These undisclosed material prior art references include one or more of the following documents: U.S. Patent No. 5,026,560, U.S. Patent No. 5,464,632, U.S. Patent No. 5,549,911, U.S. Patent No. 5,798,120, European Patent No. EP 0452862, PCT Publication No. WO 97/25979, PCT Publication No. WO 95/10264, PCT Publication No. WO 97/04278, PCT Publication No. WO 97/25065, Japanese Patent No. JP 9-71523, Japanese Patent No. JP 9-48726, Japanese Patent No. JP 8-27033, Japanese Patent No. JP 5-92918, Japanese Patent No. JP 1-268628, and an article entitled Watanabe, Y. et al., "New Compressed Tablet Rapidly Disintegrating in Saliva in the Mouth using Crystalline Cellulose and a Disintegrant", Bio. Pharm. Bull., Vol. 18, No. 9, pp. 1308-1310 (1995).

47. Those prior art references were material to the patentability of the '994 patent because a reasonable patent examiner would have considered them important in making the patentability decision. This is demonstrated by the fact that Takeda disclosed the references to the PTO during the prosecution of the '755 application, which is a continuation of the '994 patent and has the same named inventors and written description as the '994 patent. The elements of the claims of the '994 patent also are elements of the proposed claims of the '755 application. Thus, references that Takeda believed were material enough to disclose to the PTO

during prosecution of the '755 application also should have been disclosed during prosecution of the application for the '994 patent.

48. The materiality of European Patent No. 0452862 and the Watanabe article in particular are further evidenced by the fact that the examiner of the '755 application cited those references on multiple occasions in rejecting the proposed claims of the '755 application as obvious under 35 U.S.C. § 103.

49. Upon information and belief, Takeda had knowledge of one or more of the references identified above during the prosecution of the '994 patent but chose not to disclose such references to the PTO. For instance, prior art U.S. Patent No. 5,026,560 is assigned to Takeda on its face. In addition, the attorneys that disclosed those references on behalf of Takeda during the prosecution of the '755 application, Mark Chao and Elaine M. Ramesh, also were the prosecuting attorneys for the '994 patent.

50. In light of all of the relevant facts, the evidence indicates that Takeda, through its representatives Mr. Chao, Mrs. Ramesh, and others, withheld disclosure of material prior art references with the intent to deceive the PTO concerning the patentability of the application, and Takeda therefore is guilty of inequitable conduct rendering the '994 patent unenforceable.

PRAYER FOR RELIEF

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

(a) dismissing the 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 '321 patent;

(d) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '632 patent;

(e) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '994 patent;

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

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

(h) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '632 patent;

(i) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '994 patent;

(j) declaring Teva Ltd. has not induced and is not inducing infringement of any valid and enforceable claim of the '098 patent;

(k) declaring Teva Ltd. has not induced and is not inducing infringement of any valid and enforceable claim of the '321 patent;

(l) declaring Teva Ltd. has not induced and is not inducing infringement of any valid and enforceable claim of the '632 patent;

(m) declaring Teva Ltd. has not induced and is not inducing infringement of any valid and enforceable claim of the '994 patent;

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

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

(p) declaring all claims of the '632 patent invalid;

(q) declaring all claims of the '994 patent invalid;

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

(s) declaring the patent term extension of the '098 patent unenforceable;

(t) declaring all claims of the '632 patent unenforceable;

(u) declaring all claims of the '994 patent unenforceable;

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

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

March 17, 2008

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