IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

TEVA PHARMACEUTICALS USA, INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant, Teva Pharmaceuticals USA, Inc. ("Teva USA"), responds to the numbered paragraphs of the Complaint filed by Plaintiffs, Takeda Pharmaceutical Company Ltd. and TAP Pharmaceutical Products Inc., (collectively "Plaintiffs") as follows:

ANSWER

THE PARTIES

1. Teva USA 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 USA denies the allegations of Paragraph 1.

2. Teva USA 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 USA denies the allegations of Paragraph 2.

3. Teva USA admits the allegations of Paragraph 3.

JURISDICTION AND VENUE

4. Teva USA 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 USA denies any and all remaining allegations in Paragraph 4 of the Complaint including denying that it has infringed any valid and enforceable claim of any of Plaintiffs' patents-in-suit.

5. Teva USA admits the allegations of Paragraph 5.

6. Teva USA admits the allegations of Paragraph 6.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

7. In response to the allegations of Paragraph 7 of the Complaint, Teva USA states that the referenced patent, which appears to be attached to the Complaint, speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 and therefore denies them.

8. Upon information and belief, Teva USA admits that the term of the '098 Patent without adjustment has expired. Except to the extent expressly admitted, Teva USA denies the allegations of Paragraph 8.

9. In response to the allegations of Paragraph 9 of the Complaint, Teva USA states that the certificate extending patent term of the '098 patent speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 and therefore denies them.

10. In response to the allegations of Paragraph 10 of the Complaint, Teva USA states that the referenced patent, which appears to be attached to the Complaint, speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 and therefore denies them.

11. In response to the allegations of Paragraph 11 of the Complaint, Teva USA states that the referenced patent, which appears to be attached to the Complaint, speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 11 and therefore denies them.

12. In response to the allegations of Paragraph 12 of the Complaint, Teva USA states that the referenced patent, a complete copy of which is not attached to the Complaint, speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 12 and therefore denies them.

13. In response to the allegations of Paragraph 13 of the Complaint, Teva USA states that the referenced patent, which appears to be attached to the Complaint, speaks for itself and Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 13 and therefore denies them.

14. Upon information and belief, Teva USA admits that the FDA approved NDA No. 20-406 for lansoprazole delayed release capsules, 15 and 30 mg, on May 10, 1995. Except to the extent expressly admitted, Teva USA is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 14 and therefore denies them.

15. Teva USA admits the allegations of Paragraph 15.

16. Teva USA admits that it has submitted to the FDA an amendment to ANDA No. 77-255 having a Paragraph IV certification. Except as expressly admitted, Teva USA denies the allegations of Paragraph 16.

17. Upon information and belief, Teva USA admits the allegations of Paragraph 17.

18. Upon information and belief, Teva USA admits the allegations of Paragraph 18.

FIRST CLAIM FOR RELIEF
(Purported infringement of the '098 Patent)

19. Teva USA incorporates by reference as if stated fully herein its responses to paragraphs 1 through 18 of the Complaint.

20. Teva USA denies the allegations of Paragraph 20.

21. Teva USA denies the allegations of Paragraph 21.

22. Teva USA denies the allegations of Paragraph 22.

23. Teva USA admits that its Paragraph IV certification does not claim that claims 1, 2, 5, 6, 8 and 10 of the '098 Patent are not infringed. Teva USA admits that its Paragraph IV certification claims that these claims are invalid. Except as expressly admitted, Teva USA denies the allegations of Paragraph 23.

24. Teva USA denies the allegations of Paragraph 24.

25. Teva USA denies the allegations of Paragraph 25.

SECOND CLAIM FOR RELIEF
(Purported infringement of the '560 Patent)

26. Teva USA incorporates by reference as if stated fully herein its responses to paragraphs 1 through 18 of the Complaint.

27. Teva USA denies the allegations of Paragraph 27.

28. Teva USA denies the allegations of Paragraph 28.

29. Teva USA denies the allegations of Paragraph 29.

30. Teva USA denies the allegations of Paragraph 30.

31. Teva USA denies the allegations of Paragraph 31.

THIRD CLAIM FOR RELIEF
(Purported infringement of the '321 Patent)

32. Teva USA incorporates by reference as if stated fully herein its responses to paragraphs 1 through 18 of the Complaint.

33. Teva USA denies the allegations of Paragraph 33.

34. Teva USA denies the allegations of Paragraph 34.

35. Teva USA denies the allegations of Paragraph 35.

36. Teva USA denies the allegations of Paragraph 36.

37. Teva USA denies the allegations of Paragraph 37.

FOURTH CLAIM FOR RELIEF
(Purported infringement of the '132 Patent)

38. Teva USA incorporates by reference as if stated fully herein its responses to paragraphs 1 through 18 of the Complaint.

39. Teva USA denies the allegations of Paragraph 39.

40. Teva USA denies the allegations of Paragraph 40.

41. Teva USA denies the allegations of Paragraph 41.

42. Teva USA denies the allegations of Paragraph 42.

43. Teva USA denies the allegations of Paragraph 43.

FIFTH CLAIM FOR RELIEF
(Purported infringement of the '959 Patent)

44. Teva USA incorporates by reference as if stated fully herein its responses to paragraphs 1 through 18 of the Complaint.

45. Teva USA denies the allegations of Paragraph 45.

46. Teva USA denies the allegations of Paragraph 46.

47. Teva USA denies the allegations of Paragraph 47.

48. Teva USA denies the allegations of Paragraph 48.

49. Teva USA denies the allegations of Paragraph 49.

50. Teva USA denies each and every request for relief stated in the *ad damnum* clause of the Complaint or otherwise.

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

DEFENSES

FIRST DEFENSE

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 4,628,098 ("the '098 Patent").

SECOND DEFENSE

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 5,026,560 ("the '560 Patent").

THIRD DEFENSE

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 5,045,321 ("the '321 Patent").

FOURTH DEFENSE

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 5,093,132 ("the '132 Patent").

FIFTH DEFENSE

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent 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.

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 '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.

COUNTERCLAIMS

Defendant Teva USA hereby counterclaims against Plaintiffs, and in support thereof, alleges as follows:

1. The Plaintiffs have filed this Complaint against Teva USA seeking, *inter alia*, a judgment that Teva USA has infringed the claims of the '098 Patent, the '560 Patent, the '321 Patent, the '132 Patent, and the '959 Patent by Teva USA filing ANDA No. 77-255 and a Paragraph IV certification. An immediate and justiciable controversy exists between the Plaintiffs and Teva USA 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, 1338.

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

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

6. Teva USA incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

7. Teva USA has not infringed, is not infringing, and will not infringe any valid claims of the '098 Patent, literally or under the Doctrine of Equivalents.

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

8. Teva USA incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

9. Teva USA has not infringed, is not infringing, and will not infringe any valid claims of the '560 Patent, literally or under the Doctrine of Equivalents.

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

10. Teva USA incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

11. Teva USA has not infringed, is not infringing, and will not infringe any valid claims of the '321 Patent, literally or under the Doctrine of Equivalents.

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

12. Teva USA incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

13. Teva USA has not infringed, is not infringing, and will not infringe any valid claims of the '132 Patent, literally or under the Doctrine of Equivalents.

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

14. Teva USA incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

15. Teva USA has not infringed, is not infringing, and will not infringe any valid claims of the '959 Patent, literally or under the Doctrine of Equivalents.

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

16. Teva USA incorporates by reference the allegations contained in paragraphs 1-5 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 USA incorporates by reference the allegations contained in paragraphs 1-5 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 USA incorporates by reference the allegations contained in paragraphs 1-5 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 USA incorporates by reference the allegations contained in paragraphs 1-5 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 USA incorporates by reference the allegations contained in paragraphs 1-5 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.

PRAYER FOR RELIEF

WHEREFORE, Teva USA 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 that Teva USA has not infringed any valid claims of the '098 Patent;

(c) declaring that Teva USA has not infringed any valid claims of the '560 Patent;

(d) declaring that Teva USA has not infringed any valid claims of the '321 Patent;

(e) declaring that Teva USA has not infringed any valid claims of the '132 Patent;

(f) declaring that Teva USA has not infringed any valid claims of the '959 Patent;

(g) declaring that all claims of the '098 Patent are invalid;

(h) declaring that all claims of the '560 Patent are invalid;

(i) declaring that all claims of the '321 Patent are invalid;

(j) declaring that all claims of the '132 Patent are invalid;

(k) declaring that all claims of the '959 Patent are invalid;

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

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

February 6, 2006

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on February 6, 2006, 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 February 6, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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