IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

TAKEDA PHARMACEUTICAL COMPANY, LTD.'S, TAP PHARMACEUTICAL PRODUCTS INC.'S AND ETHYPHARM, S.A.'s REPLY TO TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S AMENDED COUNTERCLAIMS TO AMENDED COMPLAINT

Plaintiffs-Counterclaim Defendants Takeda Pharmaceutical Company Limited ("Takeda"), TAP Pharmaceutical Products Inc. ("TAP"), and Ethypharm, S.A. ("Ethypharm"), by their undersigned attorneys, herein reply to the Amended Counterclaims ("Counterclaims") of Defendants-Counterclaimants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva") to the Complaint as follows:

1. Plaintiffs admit that they have filed a Complaint and hereby repeat and reallege each and every allegation contained in the Complaint, admit that a justiciable controversy exists between the parties hereto with respect to infringement and validity of certain claims of U.S. Patent Nos. 4,628,098, 5,045,321, 5,464,632, and 6,328,994, and deny the remaining allegations set forth in paragraph 1 of Teva's Counterclaims.

2. Plaintiffs admit that Teva's Counterclaims purport to arise pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 2201 and 2202 and deny the remaining allegations set forth in paragraph 2 of Teva's Counterclaims.

3. Plaintiffs admit that the Court has personal jurisdiction over Plaintiffs.

4. Plaintiffs admit that Teva purports to invoke the jurisdiction of the Court pursuant to 28 U.S.C. §§ 1331, 1338 and deny the remaining allegations set forth in paragraph 4 of Teva's Counterclaims.

5. Plaintiffs admit that venue is proper in this Court.

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

6. Plaintiffs repeat and re-allege their responses to paragraphs 1-5 of Teva's Counterclaims as if fully set forth herein.

7. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 7 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of Teva's Counterclaims.

8. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 8 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of Teva's Counterclaims.

COUNT TWO
(Alleged Non-Infringement of the '321 Patent)

9. Plaintiffs repeat and re-allege their responses to paragraphs 1-8 of Teva's Counterclaims as if fully set forth herein.

10. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 10 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of Teva's Counterclaims.

11. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 11 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of Teva's Counterclaims.

COUNT THREE
(Alleged Non-Infringement of the '632 Patent)

12. Plaintiffs repeat and re-allege their responses to paragraphs 1-11 of Teva's Counterclaims as if fully set forth herein.

13. Plaintiffs deny each and every allegation contained in paragraph 13 of Teva's Counterclaims.

14. Plaintiffs deny each and every allegation contained in paragraph 14 of Teva's Counterclaims.

COUNT FOUR
(Alleged Non-Infringement of the '994 Patent)

15. Plaintiffs repeat and re-allege their responses to paragraphs 1-14 of Teva's Counterclaims as if fully set forth herein.

16. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 16 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of Teva's Counterclaims.

17. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 17 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of Teva's Counterclaims.

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

18. Plaintiffs repeat and re-allege their responses to paragraphs 1-17 of Teva's Counterclaims as if fully set forth herein.

19. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 19 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of Teva's Counterclaims.

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

20. Plaintiffs repeat and re-allege their responses to paragraphs 1-19 of Teva's Counterclaims as if fully set forth herein.

21. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 21 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of Teva's Counterclaims.

22. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 22 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of Teva's Counterclaims.

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

23. Plaintiffs repeat and re-allege their responses to paragraphs 1-22 of Teva's Counterclaims as if fully set forth herein.

24. Plaintiffs Takeda and TAP admit that the '098 patent issued on December 9, 1986, admit that on July 6, 1995, Takeda applied for a Patent Term Extension pursuant to 35 U.S.C. §§ 155-156, and admit that on July 6, 1997, the PTO awarded Takeda a Patent Term Extension of 1381 days extending the term of the patent to May 10, 2009. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of Teva's Counterclaims.

25. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 25 of Teva's Counterclaims and aver that this Court has already rejected this claim by order entered on July 3, 2007 (D.I. 120) in the pending litigation, C.A. No. 06-33-SLR. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of Teva's Counterclaims.

26. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 25 of Teva's Counterclaims and aver that this Court has already rejected this claim by order entered on July 3, 2007 (D.I. 120) in the pending litigation, C.A. No. 06-33-SLR. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of Teva's Counterclaims.

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

27. Plaintiffs repeat and re-allege their responses to paragraphs 1-26 of Teva's Counterclaims as if fully set forth herein.

28. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 28 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of Teva's Counterclaims.

COUNT NINE
(Declaration of Alleged Invalidity of the '632 Patent)

29. Plaintiffs repeat and re-allege their responses to paragraphs 1-28 of Teva's Counterclaims as if fully set forth herein.

30. Plaintiffs deny each and every allegation contained in paragraph 30 of Teva's Counterclaims.

COUNT TEN
(Declaration of Alleged Invalidity of the '994 Patent)

31. Plaintiffs repeat and re-allege their responses to paragraphs 1-30 of Teva's Counterclaims as if fully set forth herein.

32. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 32 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 32 of Teva's Counterclaims.

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

33. Plaintiffs repeat and re-allege their responses to paragraphs 1-32 of Teva's Counterclaims as if fully set forth herein.

34. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 34 of Teva's Counterclaims. Plaintiff Ethypharm denies each and every allegation contained in paragraph 34 with respect to Counts Three and Nine of Teva's Counterclaims, and

denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 34 of Teva's Counterclaims with respect to all other Counts.

COUNT TWELVE
(Declaration of Alleged Unenforceability of the '632 Patent Due to Inequitable Conduct)

35. Plaintiffs repeat and re-allege their responses to paragraphs 1-34 of Teva's Counterclaims as if fully set forth herein.

36. Plaintiffs deny each and every allegation contained in paragraph 36 of Teva's Counterclaims.

37. Plaintiffs state that the EP '356 patent, the EPO opposition proceedings, the '632 patent, and the PTO reexamination proceedings speak for themselves and deny the remaining allegations contained in paragraph 37 of Teva's Counterclaims.

38. Plaintiffs state that the EPO opposition proceedings speak for themselves and deny the remaining allegations contained in paragraph 38 of Teva's Counterclaims.

39. Plaintiffs state that the EP '356 patent, the EPO opposition proceedings, the '632 patent, and the PTO reexamination proceedings speak for themselves and deny the remaining allegations contained in paragraph 39 of Teva's Counterclaims.

40. Plaintiffs deny each and every allegation contained in paragraph 40 of Teva's Counterclaims.

41. Plaintiffs state that the EP '356 patent, the EPO opposition proceedings, the '632 patent, and the PTO reexamination proceedings speak for themselves and deny the remaining allegations contained in paragraph 41 of Teva's Counterclaims.

42. Plaintiffs deny each and every allegation contained in paragraph 42 of Teva's Counterclaims.

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

43. Plaintiffs repeat and re-allege their responses to paragraphs 1-42 of Teva's Counterclaims as if fully set forth herein.

44. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 44 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 44 of Teva's Counterclaims.

45. Plaintiffs Takeda and TAP state that the '994 patent and the '755 application speak for themselves and deny the remaining allegations contained in paragraph 45 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 45 of Teva's Counterclaims.

46. Plaintiffs Takeda and TAP state that the '994 patent and the '755 application speak for themselves and deny the remaining allegations contained in paragraph 46 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 46 of Teva's Counterclaims.

47. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 47 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 47 of Teva's Counterclaims.

48. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 48 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or

information sufficient to form a belief as to the truth of the allegations contained in paragraph 48 of Teva's Counterclaims.

49. Plaintiffs Takeda and TAP state that the '994 patent, the '755 application, and U.S. Patent No. 5,026,560 speak for themselves and deny the remaining allegations contained in paragraph 49 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 49 of Teva's Counterclaims.

50. Plaintiffs Takeda and TAP deny each and every allegation contained in paragraph 50 of Teva's Counterclaims. Plaintiff Ethypharm denies having knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 50 of Teva's Counterclaims.

51. Plaintiffs deny each and every other allegation in Teva's Counterclaims not heretofore expressly admitted herein.

FIRST AFFIRMATIVE DEFENSE TO COUNTERCLAIMS
(Failure to State a Claim)

52. Count Twelve of Teva's Counterclaims fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE TO COUNTERCLAIMS
(Unclean Hands)

53. Count Twelve of Teva's Counterclaims is barred by the doctrine of unclean hands.

THIRD AFFIRMATIVE DEFENSE TO COUNTERCLAIMS
(Res Judicata and Collateral Estoppel)

53. Counts Five, Six, Seven, and Eight of Teva's Counterclaims are barred by the doctrines of res judicata and collateral estoppel.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek the following relief:

A. An order dismissing Teva's Counterclaims with prejudice and denying each and every Prayer for Relief sought by Teva;

B. An order granting each and every Prayer for Relief sought by Plaintiffs in the Complaint;

C. A declaration that this is an exceptional case, and an award of attorneys' fees from Teva in this action pursuant to 35 U.S.C. § 285;

D. An award of costs and expenses of Plaintiffs in defending these Counterclaims;

E. Such further and other relief as this Court determines to be just and proper.

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Dated April 14, 2008

CERTIFICATE OF SERVICE

I hereby certify that on April 14, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Karen L. Pascale, Esquire
Karen E. Keller, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on April 14, 2008 upon the following individuals in the manner indicated:

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