IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 10-269-SLR
	)	
TOLMAR, INC. AND	)	
TEVA PHARMACEUTICAL INDUSTRIES	)	
LTD.,	)	
	)	
Defendants.	)	

LEO PHARMA'S ANSWER TO TOLMAR'S AMENDED COUNTERCLAIMS

Plaintiff/Counterclaim Defendant LEO Pharma A/S ("LEO Pharma" or "Plaintiff") answers the Amended Counterclaims of Defendant/Counterclaim Plaintiff Tolmar, Inc. ("Tolmar") as follows:

The Parties

1. Plaintiff admits the allegations of Paragraph 1, upon information and belief.

2. Plaintiff admits the allegations of Paragraph 2.

Jurisdiction and Venue

3. Plaintiff denies the allegations of Paragraph 3, except admits that Tolmar alleges counterclaims that arise under the Patent Laws of the United States.

4. Plaintiff denies the allegations of Paragraph 4, except admits that subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

5. Plaintiff denies the allegations of Paragraph 5, except admits that this Court has personal jurisdiction over it for purposes of these Counterclaims.

6. Plaintiff denies the allegations of Paragraph 6, except admits that venue is proper in this District under 28 U.S.C. § 1391(b) and (c).

Factual Background

7. Plaintiff admits the allegations of Paragraph 7.

8. Plaintiff denies the allegations of Paragraph 8, except admits that it is the owner of the '706 Patent.

9. Plaintiff admits the allegations of Paragraph 9.

10. Plaintiff denies the allegations of Paragraph 10, except admits that it is the owner of the '013 Patent.

11. Plaintiff admits the allegations of Paragraph 11.

12. Plaintiff admits the allegations of Paragraph 12.

13. Plaintiff denies the allegations of Paragraph 13, except admits that Tolmar filed ANDA No. 200935 with the FDA under 21 U.S.C. § 355(j) for the approval of Tolmar's cream product containing 0.005% calcipotriene before the expiration date of the '706 patent and that Tolmar filed a Paragraph IV Certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV"), alleging that the claims of the '426 and '706 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale offer for sale or import of the Tolmar Cream Product that is the subject of ANDA No. 200935.

14. Plaintiff denies the allegations of Paragraph 14, except admits that LEO Pharma filed a suit alleging that Tolmar has infringed the '706 Patent based on, *inter alia*, Tolmar's filing of ANDA No. 20-0935 and that Tolmar is seeking approval to engage in the commercial manufacture, use, sale, and/or importation of creams containing or using calcipotriene monohydrate.

15. Plaintiff denies the allegations of Paragraph 15, except admits that Tolmar filed ANDA No. 201615 with the FDA under 21 U.S.C. §355(j) for the approval of Tolmar's topical ointment product ("the Tolmar Product") before the expiration date of the '706 patent and before the expiration date of the '013 patent.

16. Plaintiff admits the allegations of Paragraph 16.

17. Plaintiff denies the allegations of Paragraph 17, except admits that on August 25, 2010, LEO Pharma filed a suit alleging that Tolmar has infringed the '706 Patent based on, *inter alia*, Tolmar's filing of ANDA No. 20-1615 and that Tolmar is seeking approval to engage in the commercial manufacture, use, sale, and/or importation of ointments containing or using calcipotriene monohydrate.

18. Plaintiff denies the allegations of Paragraph 18, except admits that LEO Pharma filed an amended complaint alleging that Tolmar has infringed the '706 Patent and '013 Patent based on, *inter alia*, the filing of Tolmar's ANDA Nos. 20-0935 and 20-1615 and that Tolmar is seeking approval to engage in the commercial manufacture, use, sale, and/or importation of creams containing calcipotriene monohydrate and ointments containing calcipotriene monohydrate and betamethasone dipropionate.

19. Plaintiff denies the allegations of Paragraph 19, except admits that an actual, substantial, and continuing justiciable case or controversy between the parties exists regarding validity and infringement of the '706 and '013 Patents.

Count I
(Declaratory Judgment of Invalidity of the '706 Patent)

20. Plaintiff repeats its responses to Paragraphs 1-19 as if stated fully herein.

21. Plaintiff denies the allegations of Paragraph 21.

22. Plaintiff denies the allegations of Paragraph 22.

Count II
(Declaratory Judgment of Non-Infringement of the '706 Patent)

23. Plaintiff repeats its responses to Paragraphs 1-22 as if stated fully herein.

24. Plaintiff admits the allegations of Paragraph 24.

25. Plaintiff denies the allegations of Paragraph 25.

26. Plaintiff denies the allegations of Paragraph 26.

27. Plaintiff denies the allegations of Paragraph 27.

28. Plaintiff denies the allegations of Paragraph 28.

29. Plaintiff denies the allegations of Paragraph 29.

30. Plaintiff denies the allegations of Paragraph 30.

31. Plaintiff denies the allegations of Paragraph 31.

32. Plaintiff denies the allegations of Paragraph 32.

Count III
(Declaratory Judgment of Non-Infringement of the '013 Patent)

33. Plaintiff repeats its responses to Paragraphs 1-32 as if stated fully herein.

34. Plaintiff denies the allegations of Paragraph 34.

35. Plaintiff denies the allegations of Paragraph 35.

36. Plaintiff denies the allegations of Paragraph 36.

37. Plaintiff denies the allegations of Paragraph 37.

38. Plaintiff denies the allegations of Paragraph 38.

39. Plaintiff denies the allegations of Paragraph 39.

Count IV
(Declaratory Judgment of Invalidity of the '013 Patent)

40. Plaintiff repeats its responses to Paragraphs 1-39 as if stated fully herein.

41. Plaintiff denies the allegations of Paragraph 41.

42. Plaintiff denies the allegations of Paragraph 42.

General Denials

Except as otherwise expressly admitted in paragraphs 1 through 42 above, Plaintiff/Counterclaim Defendant LEO Pharma denies each and every allegation of Defendant/Counterclaim Plaintiff Tolmar's Answer, Defenses, and Counterclaims, including, without limitations, the headings and subheadings contained in the Answer, Defenses, and Counterclaims. Pursuant to Rule 8(b) of the Federal Rules of Civil Procedure, allegations contained in the Answer, Defenses, and Counterclaims to which no responsive pleading is required shall be deemed denied. LEO Pharma expressly reserves the right to amend and/or supplement its answer.

With respect to the paragraphs in Tolmar's Answer, Defenses and Counterclaims in which Tolmar prays for relief, LEO Pharma denies that Tolmar is so entitled to any relief.

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December 8, 2011

CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 8, 2011, upon the following in the manner indicated:

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