IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

FIRST AMENDED AND CONSOLIDATED
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff LEO Pharma A/S ("LEO Pharma") for its First Amended and Consolidated Complaint herein against defendants Tolmar, Inc. ("Tolmar"), and Teva Pharmaceutical Industries Ltd. ("Teva"), by and through its Teva Active Pharmaceutical Ingredients Division ("TAPI") and/or by and through the Teva Group Active Pharmaceutical Ingredients Division, hereby alleges as follows:

Nature of Action

1. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code.

The Parties

2. Plaintiff LEO Pharma is a corporation organized and existing under the laws of Denmark with its corporate headquarters at Industriparken 55, DK-2750 Ballerup, Denmark.

3. Upon information and belief, defendant Tolmar is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 701 Centre Ave, Fort Collins, CO 80526.

4. Upon information and belief, defendant Teva is a corporation organized and existing under the laws of the Israel with its corporate headquarters at 5 Basel St., P.O. Box 3190, Petach Tikva 49131, Israel.

Jurisdiction and Venue

5. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, this Court has personal jurisdiction over Tolmar, a Delaware Corporation.

7. Upon information and belief, Tolmar derives substantial revenue from selling various products and doing business throughout the United States, including in Delaware and this District.

8. Upon information and belief, Tolmar manufactures bulk pharmaceuticals and pharmaceutical products that are sold throughout the United States, including within this District.

9. Upon information and belief, Teva is subject to personal jurisdiction in Delaware because it manufactures pharmaceuticals and pharmaceutical products that are sold, and used, throughout the United States, including Delaware and this District.

10. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c) and 28 U.S.C. § 1400(b).

Background

11. LEO Pharma is the holder of New Drug Application ("NDA") No. 20-554, which relates to creams containing 0.005% calcipotriene monohydrate. On July 22, 1996, the United States Food and Drug Administration ("FDA") approved the use of the creams described in NDA No. 20-554 for the treatment of plaque psoriasis. These creams are prescribed and sold in the United States under the trademark Dovonex®.

12. LEO Pharma is the holder of New Drug Application ("NDA") No. 21-852, which relates to ointments containing 0.064% betamethasone dipropionate and 0.005% calcipotriene monohydrate. On January 9, 2006, the United States Food and Drug Administration ("FDA") approved the use of the creams described in NDA No. 21-852 for the treatment of psoriasis vulgaris. These ointments are prescribed and sold in the United States under the trade name Taclonex®.

13. United States Patent No. 5,763,426 (the "'426 Patent," copy attached as Exhibit A), "Crystalline Form of a Vitamin D Analogue," was duly and legally issued by the United States Patent and Trademark Office on June 9, 1998. The '426 Patent was reissued as RE 39,706 on June 26, 2007 (the "Reissued '706 Patent," copy attached as Exhibit B). The Reissued '706 Patent claims, *inter alia*, calcipotriene monohydrate, which is the active ingredient in Dovonex® cream. The Reissued '706 Patent is currently listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "FDA Orange Book") for both Dovonex® cream and Taclonex® ointment

14. The named inventors on the Reissued '706 Patent are Erik Torngaard Hansen, Niels Smidt Rastrup Andersen, and Lene Hoffmeyer Ringborg, who assigned their rights in the '426 Patent to LEO Pharmaceutical Products, Ltd. LEO Pharmaceutical Products,

Ltd. subsequently changed its name to LEO Pharma A/S. The Reissued '706 Patent is assigned to LEO Pharma.

15. United States Patent No. 6,753,013 (the "'013 Patent," copy attached as Exhibit C), "Pharmaceutical Composition," was duly and legally issued by the United States Patent and Trademark Office on June 22, 2004. The '013 Patent claims, *inter alia*, vitamin D or a vitamin D analogue in combination with a corticosteroid, which are the active ingredients in Taclonex® ointment. The '013 Patent is currently listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "FDA Orange Book") for Taclonex® ointment.

16. The named inventors on the '013 Patent are Erik Didriksen and Gert Høy, who assigned their right in the '013 Patent to LEO Pharmaceutical Products, Ltd. A/S. LEO Pharmaceutical Products, Ltd. A/S subsequently changed its name to LEO Pharma A/S.

CLAIMS FOR RELIEF

Count I

Infringement of Reissued Patent No. 39,706 (ANDA No. 20-935) Against Tolmar

17. Plaintiff repeats and realleges paragraphs 1 - 16 above as if set forth herein.

18. Upon information and belief, Tolmar submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-935, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of creams containing 0.005% calcipotriene monohydrate ("Tolmar Proposed ANDA Cream Product").

19. Upon information and belief, ANDA No. 20-935 seeks approval to manufacture, use, sell and/or import calcipotriene monohydrate for the purpose of treating plaque psoriasis in humans.

20. By letter dated February 23, 2010 (the "February 23, 2010 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Tolmar notified LEO Pharma that it had submitted ANDA No. 20-935 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of creams containing, upon information and belief, 0.005% calcipotriene monohydrate, prior to the expiration of the Reissued '706 Patent.

21. In its February 23, 2010 Notice Letter, Tolmar notified LEO Pharma that, as a part of ANDA No. 20-935, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to the Reissued '706 Patent. On information and belief, Tolmar certified that, in its opinion and to the best of its knowledge, the Reissued '706 Patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which ANDA No. 20-935 was submitted.

22. By filing ANDA No. 20-935 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of creams containing, upon information and belief, 0.005% calcipotriene monohydrate, prior to the expiration of the Reissued '706 Patent, Tolmar has committed an act of infringement of the Reissued '706 Patent under 35 U.S.C. § 271(e)(2).

23. Upon information and belief, Tolmar lacked a good faith basis for alleging non-infringement when ANDA No. 20-935 was filed and when the Paragraph IV certification was made. Tolmar's ANDA and Paragraph IV certification is a wholly unjustified infringement of the Reissued '706 Patent.

24. Upon information and belief, the commercial manufacture, use, sale and/or importation of creams containing 0.005% calcipotriene monohydrate for the use for which

Tolmar seeks approval in ANDA No. 20-935 will infringe, induce infringement and/or contributorily infringe one or more claims of the Reissued '706 Patent.

Count II
Infringement of Reissued Patent No. 39,706 (ANDA No. 20-1615) Against Tolmar

25. Plaintiff repeats and realleges paragraphs 1-24 above as if fully set forth herein.

26. Upon information and belief, Tolmar submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-1615, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing 0.005% calcipotriene monohydrate.

27. Upon information and belief, ANDA No. 20-1615 seeks approval to manufacture, use, sell and/or import calcipotriene monohydrate for the purpose of treating psoriasis vulgaris in humans.

28. By letter dated July 12, 2010 (the "July 12, 2010 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Tolmar notified LEO Pharma that it had submitted ANDA No. 20-1615 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate, prior to the expiration of the Reissued '706 Patent.

29. In its July 12, 2010 Notice Letter, Tolmar notified LEO Pharma that, as a part of ANDA No. 20-1615, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to the Reissued '706 Patent. On information and belief, Tolmar certified that, in its opinion and to the best of its knowledge, the Reissued '706 Patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which ANDA No. 20-1615 was submitted.

30. By filing ANDA No. 20-1615 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate, prior to the expiration of the Reissued '706 Patent, Tolmar has committed an act of infringement of the Reissued '706 Patent under 35 U.S.C. § 271(e)(2).

31. Upon information and belief, Tolmar lacked a good faith basis for alleging non-infringement when ANDA No. 20-1615 was filed and when the Paragraph IV certification was made. Tolmar's ANDA and Paragraph IV certification is a wholly unjustified infringement of the Reissued '706 Patent.

32. Upon information and belief, the commercial manufacture, use, sale and/or importation of ointments containing 0.005% calcipotriene monohydrate for the use for which Tolmar seeks approval in ANDA No. 20-1615 will infringe, induce infringement and/or contributorily infringe one or more claims of the Reissued '706 Patent.

Count III
Infringement of Patent No. 6,753,013 (ANDA No. 20-1615) Against Tolmar

33. Plaintiff repeats and realleges paragraphs 1-32 above as if fully set forth herein.

34. Upon information and belief, Tolmar submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-1615, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate ("Tolmar Proposed ANDA Ointment Product").

35. Upon information and belief, ANDA No. 20-1615 seeks approval to manufacture, use, sell and/or import ointment containing calcipotriene monohydrate and betamethasone dipropionate for the purpose of treating psoriasis vulgaris in humans.

36. By letter dated July 12, 2010 (the "July 12, 2010 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Tolmar notified LEO Pharma that it had submitted ANDA No. 20-1615 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate, prior to the expiration of the '013 Patent.

37. In its July 12, 2010 Notice Letter, Tolmar notified LEO Pharma that, as a part of ANDA No. 20-1615, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to the '013 Patent. Upon information and belief, Tolmar certified that, in its opinion and to the best of its knowledge, the '013 Patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which ANDA No. 20-1615 was submitted.

38. By filing ANDA No. 20-1615 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate, prior to the expiration of the '013 Patent, Tolmar committed an act of infringement of the '013 Patent under 35 U.S.C. § 271(e)(2).

39. Upon information and belief, Tolmar lacked a good faith basis for alleging invalidity when ANDA No. 20-1615 was filed and when the Paragraph IV certification was

made. Tolmar's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '013 Patent.

40. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of ointments containing 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate for the use for which Tolmar seeks approval in ANDA No. 20-1615 will infringe, induce infringement and/or contributorily infringe one or more claims of the '013 Patent.

Count IV
Infringement of Reissued Patent No. 39,706 Against Teva

41. Plaintiff repeats and realleges paragraphs 1-40 above as if fully set forth herein.

42. Teva manufactures the active pharmaceutical ingredient ("API") for use in Tolmar's Proposed ANDA Ointment Product and Tolmar's Proposed ANDA Cream Product, as described in ANDA Nos. 20-1615 and 20-935, respectively.

43. Upon information and belief, Teva submitted Drug Master File ("DMF") No. 16958 on November 13, 2003 to the FDA for the purpose of manufacturing calcipotriene for use in the United States.

44. Upon information and belief, Teva will manufacture the calcipotriene API in Beer Sheva, Israel and, without authority, import the calcipotriene API into the United States and/or sell it to Tolmar within the United States for subsequent commercial sale by Tolmar under ANDA Nos. 20-935 and 20-1615.

45. If Teva commercially manufactures, uses, offers for sale or sells the calcipotriene API within the Unites States, it would further infringe the Reissued '706 patent under 35 U.S.C. § 271(a) and/or (g).

46. Moreover, if Teva imports the calcipotriene API into the United States, or, it would further infringe the '706 patent under 35 U.S.C. § 271(a) and/or (g).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Tolmar's ANDA No. 20-935 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration of the Reissued '706 Patent or any later date of exclusivity to which Plaintiff and/or this patent is or becomes entitled;

(b) A judgment declaring that the effective date of any approval of Tolmar's ANDA No. 20-1615 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration of the Reissued '706 Patent or any later date of exclusivity to which Plaintiff and/or this patent is or becomes entitled;

(c) A judgment declaring that the effective date of any approval of Tolmar's ANDA No. 20-1615 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration of the '013 Patent or any later date of exclusivity to which Plaintiff and/or this patent is or becomes entitled;

(d) A permanent injunction restraining and enjoining Teva and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic calcipotriene products as claimed in the '706 patent;

(e) A judgment declaring that Teva will infringe the Reissued '706 Patent under 35 U.S.C. § 271(a) by offering for sale, selling and/or importing of the API in Tolmar's Proposed ANDA Cream Product prior to patent expiry;

(f) A judgment declaring that Teva will infringe the '706 Patent under 35 U.S.C. § 271(a)by offering for sale, selling and/or importing the API used in Tolmar's Proposed ANDA Ointment Product prior to patent expiry, which will constitute an act of infringement of the '706 Patent;

(g) A judgment declaring that the Reissued '706 Patent remains valid and enforceable and has been infringed by Tolmar;

(h) A judgment declaring that the '013 Patent remains valid, enforceable and has been infringed by Tolmar;

(i) A permanent injunction against any infringement of the Reissued '706 Patent by Tolmar, its officers, agents, attorneys and employees, and those acting in privity or contract with them;

(j) A permanent injunction against any infringement of the '013 Patent by Tolmar, its officers, agents, attorneys and employees, and those acting in privity or contract with them;

(k) A permanent injunction against any infringement of the Reissued '706 Patent by Teva, its officers, agents, attorneys and employees, and those acting in privity or contract with them;

(l) A judgment that this is an exceptional case, and that Plaintiff is entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(m) Costs and expenses in this action; and

(n) Such other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff LEO Pharma A/S

OF COUNSEL:

Dominick Conde
William E. Solander
Steven S. Kim
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
(212) 218-2100

November 3, 2010

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 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:

Adam Poff, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

I further certify that I caused copies of the foregoing document to be served on November 3, 2011, upon the following in the manner indicated:

Adam Poff, Esquire — *VIA ELECTRONIC MAIL*
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street
17th Floor
Wilmington, DE 19801

Jeffrey R. Gargano, Esquire — *VIA ELECTRONIC MAIL*
Brent A. Hawkins, Esquire
Krista Vink Venegas, Esquire
Wan-Shon Lo, Esquire
MCDERMOTT WILL & EMERY LLP
227 West Monroe Street
Suite 4400
Chicago, IL 60606

Maryellen Noreika (#3208)