IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TOLMAR, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff LEO Pharma A/S ("LEO Pharma") for its Complaint against Tolmar, Inc. ("Tolmar"), 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.

Jurisdiction and Venue

4. 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).

5. Upon information and belief, this Court has personal jurisdiction over Tolmar, a Delaware corporation.

6. 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.

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

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

Claim For Relief – Patent Infringement

9. 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 ointments described in NDA No. 21-852 for the treatment of psoriasis vulgaris. These ointments are prescribed and sold in the United States under the trademark Taclonex®.

10. 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 one of the active ingredients in Taclonex® ointment. The Reissued '706 Patent is currently listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "FDA Orange Book") for Taclonex® ointment.

11. 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.

12. 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 0.064% betamethasone dipropionate and 0.005% calcipotriene monohydrate.

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

Infringement of Reissued U.S. Patent No. 39,706 (ANDA No. 20-1615)

14. Plaintiff repeats and realleges paragraphs 1–13 above as if fully set forth herein.

15. 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.

16. 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.

17. 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).

18. 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.

19. 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.

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. 20-1615 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 date of the Reissued '706 Patent and any later date of exclusivity to which Plaintiff and/or the Reissued '706 patent are or become entitled;

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

(c) 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;

(d) 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;

(e) Costs and expenses in this action; and

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

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