

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GALDERMA LABORATORIES, L.P.,)
GALDERMA S.A. and GALDERMA)
RESEARCH AND DEVELOPMENT, S.N.C.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
TOLMAR, INC.,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research & Development, S.N.C. (collectively, “Galderma”) file this Complaint for patent infringement against Tolmar, Inc. and allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. Galderma Laboratories, L.P. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

2. Plaintiff Galderma S.A. is a Swiss company having a principal place of business at World Trade Center, Avenue de Gratta-Paille 1, Case Postale 552, 1000 Lausanne 30 Grey. Galderma S.A. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

3. Plaintiff Galderma Research & Development, S.N.C. is a French company having a principal place of business at 2400 Route Des Colles, Les Templiers, 06410 Biot, France. Galderma Research & Development, S.N.C. is engaged in the business of research

and development of dermatological and pharmaceutical products. Galderma Research & Development, S.N.C. is the current owner of United States Patent No. 7,579,377.

4. On information and belief, Tolmar, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526. Tolmar, Inc. is engaged in the research, development, marketing, and sale of pharmaceutical products. On information and belief, Tolmar, Inc.'s products are marketed and sold for distribution in Delaware and throughout the United States.

5. The Court has personal jurisdiction over Tolmar, Inc. because Tolmar, Inc. is a Delaware corporation and has a registered agent in Delaware.

6. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

7. Galderma realleges and incorporates by reference paragraphs 1-6.

8. United States Patent No. 7,579,377 (“the ‘377 patent”), entitled “Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]- 2-naphthoic acid for the treatment of dermatological disorders,” was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the United States Patent and Trademark Office (“PTO”) on August 25, 2009. The ‘377 patent is currently owned by Galderma Research & Development, S.N.C. and expires on February 23, 2025. This expiration date includes a 714 day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the ‘377 patent is attached

as Exhibit A. A true and correct copy of the Issue Notification reflecting the patent term adjustment is attached as Exhibit B.

9. Galderma Laboratories, L.P. is the holder of New Drug Application (“NDA”) No. 21-753 for the use of Differin[®] 0.3% gel in the topical treatment of *acne vulgaris*. The FDA approved NDA No. 21-753 on June 19, 2007. The ’377 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-753.

10. Galderma manufactures and sells various dosage strengths of topical gels and cream containing the active ingredient 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid (also known as “adapalene”) in the United States under the brand name Differin[®].

11. On information and belief, Tolmar, Inc. submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Adapalene gel 0.3% (“Defendant’s Adapalene Gel”) in the United States before the expiration of the ’377 patent.

12. On information and belief, ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the ’377 patent would not be infringed by Defendant’s Adapalene Gel.

13. Tolmar, Inc. sent or caused to be sent to Galderma a letter dated December 10, 2009 (“the Notice Letter”) notifying Galderma that Tolmar, Inc. had submitted ANDA No. 200-298, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges noninfringement of claims 1-3 of the ’377 patent.

14. Under 35 U.S.C. § 271(e)(2)(A), Tolmar, Inc. infringed one or more claims of the ’377 patent, in violation of Galderma’s patent rights, by submitting to the FDA an

ANDA that seeks approval to commercially market--before the expiration date of the '377 patent--Defendant's Adapalene Gel, the use of which would directly infringe one or more claims of the '377 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the '377 patent by users of Defendant's Adapalene Gel.

15. Upon information and belief, Tolmar, Inc. has also induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '377 patent--in violation of Galderma's patent rights--if the FDA approves the sale of Defendant's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '377 patent by users of Defendant's Adapalene Gel.

16. On information and belief, Tolmar, Inc. seeks approval of at least one indication for Defendant's Adapalene Gel that is claimed in the '377 patent.

17. On information and belief, Tolmar, Inc. knows that physicians will prescribe, and patients will use, Defendant's Adapalene Gel in accordance with the indications sought by Tolmar, Inc. and will therefore infringe one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c).

18. Galderma will be substantially and irreparably harmed by Tolmar, Inc.'s infringing activities unless those activities are enjoined by this Court. Galderma has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

19. Galderma realleges and incorporates by reference paragraphs 1-18.

20. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

21. The manufacture, sale, offer for sale, and/or importation of Defendant's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

22. On information and belief, if the FDA approves ANDA No. 200-298, Tolmar, Inc. or its agents plan to begin marketing, selling, and offering to sell Defendant's Adapalene Gel in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 200-298.

23. Tolmar, Inc.'s actions in actively aiding, abetting, encouraging, and inducing sales of Defendant's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '377 patent in violation of Galderma's patent rights.

24. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar, Inc. as to liability for the infringement of the '377 patent claims. Tolmar, Inc.'s actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar, Inc.'s threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Galderma respectfully requests that this Court enter judgment in its favor as follows:

a) declare that, under 35 U.S.C. § 271(e)(2)(A), Tolmar, Inc. infringed United States Patent No. 7,579,377 by submitting ANDA No. 200-298 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Defendant's Adapalene Gel prior to the expiration of said patent;

b) declare that Tolmar, Inc.'s commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Defendant's Adapalene Gel prior to the expiration of United States Patent No. 7,579,377 would constitute infringement of said patent in violation of Galderma's patent rights;

c) order that the effective date of any FDA approval of Defendant's Adapalene Gel shall be no earlier than the expiration date of United States Patent No. 7,579,377 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

d) enjoin Tolmar, Inc., and all persons acting in concert with Tolmar, Inc., from seeking, obtaining, or maintaining final approval of ANDA No. 200-298 until the expiration of United States Patent No. 7,579,377;

e) enjoin Tolmar, Inc., and all persons acting in concert with Tolmar, Inc., from commercially manufacturing, using, offering for sale, or selling Defendant's Adapalene Gel within the United States, or importing Defendant's Adapalene Gel into the United States, until the expiration of United States Patent No. 7,579,377, in accordance with 35 U.S.C. § 271(e)(4)(B); and

f) grant Galderma such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP

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