

ORIGINAL

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

U.S. DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

FILED

MAR - 3 2009

CLERK, U.S. DISTRICT COURT

By _____ Deputy

VN

GALDERMA LABORATORIES, L.P.,)
GALDERMA S.A.,)
and)
DOW PHARMACEUTICAL SCIENCES,)
INC.,)

Plaintiffs,)

v.)

TOLMAR, INC.,)

Defendant.)

3-09CV0400-N

Civil Action No. _____

JURY TRIAL DEMANDED

29310

COMPLAINT

Plaintiffs, Galderma Laboratories, L.P. and Galderma S.A. (collectively "Galderma") and Dow Pharmaceutical Sciences, Inc. ("Dow" and collectively with Galderma, "Plaintiffs"), for their Complaint against Defendant, Tolmar, Inc. ("Tolmar"), allege as follows:

THE 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. As part of its business, Galderma Laboratories, L.P. is involved in the research, development, marketing, and sale of pharmaceutical products.

2. Plaintiff Galderma S.A. is a Swiss corporation, having a principal place of business at World Trade Center, Avenue de Gratta-Paille 2, Case Postale 453, CH-1000 Lausanne 30 Grey, Switzerland. As part of its business, Galderma S.A. is involved in the research, development, marketing, and sale of pharmaceutical products.

3. Plaintiff Dow Pharmaceutical Sciences, Inc. is a Delaware corporation, having a principal place of business at 1330 Redwood Way, Petaluma, California 94954. As part of its business, Dow is involved in the research and development of pharmaceutical products.

4. On information and belief, Defendant Tolmar, Inc. is a Delaware corporation, having a principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526. Tolmar is engaged in the research, development, marketing, and sale of pharmaceutical products. Tolmar may be served with process by and through its Texas registered agent, Corporation Service Company d/b/a CSC – Lawyers Incorporating Service Company, 701 Brazos, Suite 1050, Austin, Texas 78701.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 101, *et seq.* This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1332, 1338, and 1367.

6. This Court has personal jurisdiction over Tolmar in that Tolmar sells products for distribution throughout the United States including in this district and, on information and belief, is registered to conduct business in the State of Texas. Further, on information and belief, Tolmar is doing business in this state because Tolmar transacts business over the internet, such as entering into contracts and knowing and repeated transmission of files of information, throughout the United States including in this district. Through Tolmar's fully interactive website, residents in the State of Texas, including those in this district, can search for products; view product descriptions, price, and pictures; and enter into agreements to purchase products directly through Tolmar's website by providing credit card and shipping information for delivery in Texas. As a result, Tolmar purposefully avails itself of the privilege of doing business in the State of Texas. Further, by doing business in Texas, Tolmar avails itself of the

protections of Texas, and in turn, consents to jurisdiction in the State of Texas, including jurisdiction in this district. In addition, Tolmar filed an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the “Paragraph IV Certification”) – the acts which give rise to the instant litigation – with knowledge that Galderma Laboratories, L.P. would be injured by such actions in this district. Moreover, Tolmar delivered the Paragraph IV Certification to Galderma Laboratories, L.P. in this district. Further, on information and belief, upon receiving FDA approval, Tolmar intends to sell the infringing product in or for distribution to this district.

7. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b). For example, Plaintiff Galderma Laboratories, L.P. is located in this district, and Galderma’s witnesses and documents will be material to this litigation. As another example, venue is appropriate in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, Tolmar’s filing of the ANDA) purposefully targeting a resident of this district (Galderma Laboratories, L.P.). As a further example, 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this district as the only proper venue in which Tolmar could file suit seeking a declaration of non-infringement in connection with its ANDA.

STATEMENT OF FACTS

8. On April 19, 2005, the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 6,881,726 (the “’726 Patent”) entitled, “Aqueous Compositions Containing Metronidazole,” to Dow, the assignee of the named inventors, Yunik Chang and Gordon Dow. Dow is the current assignee of the ’726 Patent. A copy of the ’726 Patent is attached hereto as Exhibit A.

9. On March 25, 2008, the USPTO issued U.S. Patent No. 7,348,317 (the “’317 Patent”) entitled, “Aqueous Compositions Containing Metronidazole,” to Dow, the assignee of the named inventors, Yunik Chang and Gordon Dow. Dow is the current assignee of the ’317 Patent. A copy of the ’317 Patent is attached hereto as Exhibit B.

10. Dow granted Galderma S.A. an exclusive license under the ’726 Patent and the ’317 Patent (collectively, the “Patents-in-Suit”) to make, distribute, market, sell, and use the inventions disclosed in the Patents-in-Suit. Galderma’s exclusive license includes the right to grant sublicenses, and the right to enforce to the Patents-in-Suit.

11. The Patents-in-Suit are valid, enforceable, and have not expired.

12. On June 30, 2005, the FDA approved New Drug Application (“NDA”) No. 21-789 for a 1% metronidazole topical gel for use in the treatment of rosacea. Galderma Laboratories, L.P. is the current holder of NDA No. 21-789 for 1% metronidazole gel, which Galderma sells under the trade name, MetroGel®.

13. The Patents-in-Suit are listed in the FDA publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book,” as covering MetroGel®.

14. On information and belief, Tolmar submitted ANDA No. 090-903 (“Tolmar’s ANDA” or “ANDA No. 090-903”) to the FDA on or about October 21, 2008 to seek approval to engage in the commercial manufacture, use, and sale of a generic equivalent to MetroGel® prior to the expiration of the Patents-in Suit.

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), on or about January 19, 2009, Tolmar sent Plaintiffs a Paragraph IV Certification providing that, in Tolmar’s opinion, the 1% metronidazole gel disclosed in ANDA No. 090-903 does not infringe the Patents-in-Suit.

16. The FDA accepted Tolmar's ANDA filing on or about January 2009, and assigned the filing serial number 090-903.

17. On information and belief, Tolmar was aware of the Patents-in-Suit when it filed ANDA No. 090-903 and the Paragraph IV Certification.

18. Plaintiffs filed this action within 45 days of the date that they received notice of Tolmar's ANDA and the Paragraph IV Certification. Therefore, Plaintiffs are entitled to the benefits of 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314 *et seq.*

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,881,726

19. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 18 above as though fully stated herein.

20. The '726 Patent is enforceable and, pursuant to 35 U.S.C. § 282, enjoys a statutory presumption of validity.

21. Through the conduct alleged above, Tolmar has infringed, and continues to infringe, one or more claims of the '726 Patent, either literally or by the doctrine of equivalents.

22. By filing ANDA No. 090-903 with a Paragraph IV Certification seeking approval to engage in the commercial manufacture, use, and sale of the 1% metronidazole gel prior to the expiration of the '726 Patent, Tolmar has infringed the '726 Patent under 35 U.S.C. § 271(e).

23. The 1% metronidazole gel disclosed in Tolmar's ANDA will induce infringement of one or more claims of the '726 Patent.

24. Plaintiffs have not consented to any of Tolmar's acts of infringement of the '726 Patent.

25. Tolmar will continue to infringe the '726 Patent, and Plaintiffs will be irreparably harmed unless Tolmar is enjoined by this Court.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 7,348,317

26. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 25 above as though fully stated herein.

27. The '317 Patent is enforceable and, pursuant to 35 U.S.C. § 282, enjoys a statutory presumption of validity.

28. Through the conduct alleged above, Tolmar has infringed, and continues to infringe, one or more claims of the '317 Patent, either literally or by the doctrine of equivalents.

29. By filing ANDA No. 090-903 with a Paragraph IV Certification seeking approval to engage in the commercial manufacture, use, and sale of the 1% metronidazole gel prior to the expiration of the '317 Patent, Tolmar has infringed the '317 Patent under 35 U.S.C. § 271(e).

30. The 1% metronidazole gel disclosed in Tolmar's ANDA will induce infringement of one or more claims of the '317 Patent.

31. Plaintiffs have not consented to any of Tolmar's acts of infringement of the '317 Patent.

32. Tolmar will continue to infringe the '317 Patent, and Plaintiffs will be irreparably harmed unless Tolmar is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor, including:

1. An order adjudicating and decreeing that Tolmar has infringed the Patents-in-Suit;
2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that Tolmar's ANDA may not be approved by the FDA until after expiration of the '726 and '317 Patents, respectively, including any extensions;
3. An order for preliminary and permanent injunctive relief prohibiting Tolmar, its officers, agents, servants, employees, successors, assigns, or all other persons or entities in active concern, participation or privity with any of the foregoing, from any further acts of infringement, contributory infringement or inducement of infringement of United States Patent Nos. 6,881,726 and 7,348,317;
4. An order directing Tolmar to deliver all infringing products, if any, for destruction;
5. An award of Plaintiffs' actual damages proximately caused by Tolmar's unlawful acts;
6. An assessment of interest on the damages so computed;
7. An award of Plaintiffs' attorneys' fees and costs in this action; and
8. Such other and further relief as the Court deems just and proper.

JURY DEMAND

If Tolmar should launch a product during the pendency of this litigation, and Plaintiffs incur damages, Plaintiffs will demand damages and trial by jury of all issues and claims alleged herein.

Dated: March 3, 2009

Respectfully submitted,

BY: 

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