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

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	)	
Plaintiffs,	)	
	)	**Civil Action No. 3:11-cv-1714**
v.	)	
	)	**JURY TRIAL DEMAND**
TOLMAR, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Galderma Laboratories, L.P. and Galderma S.A. (collectively "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 552, CH-10018 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. On information and belief, Defendant Tolmar 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, manufacture, marketing, and sale of generic

pharmaceutical products, including a generic 1% metronidazole topical gel (the "Accused Product").

JURISDICTION AND VENUE

4. This is a patent infringement action arising under the patent laws of the United States of America, 35 U.S.C. § 101, *et seq*.

5. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1332, 1338, and 1367.

6. This district has personal jurisdiction over Tolmar. Tolmar manufactures products with knowledge that these products are shipped into this jurisdiction and sold to consumers located in this district. On information and belief, upon receiving FDA approval, Tolmar intends to sell the Accused Product in or for distribution to this district.

7. On information and belief, Tolmar is registered to conduct business in the State of Texas. Tolmar may properly 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.

8. On information and belief, Tolmar is doing business in this state because Tolmar transacts business over the internet 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, prices, 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.

9. 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.

10. In addition, Tolmar filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") for the Accused Product, and issued a certification notice under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification Notice") with knowledge that Galderma Laboratories, L.P. would be injured by such actions in this district. Moreover, Tolmar delivered the Paragraph IV Certification Notice to Galderma Laboratories, L.P. in this district.

11. Tolmar also purposefully availed itself to the jurisdiction of this Court in another patent infringement litigation brought, in part, by Galderma Laboratories, L.P. and Galderma S.A., Civil Action No. 3:09-CV-0400-N, which is currently pending in this district.

12. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

13. Galderma Laboratories, L.P. is located in this district, and Galderma's witnesses and documents will be material to this litigation.

14. The claims asserted herein arise out of acts of patent infringement purposefully targeting a resident of this district (Galderma Laboratories, L.P.).

STATEMENT OF FACTS

The Asserted Patent

15. On July 19, 2011, the United States Patent and Trademark Office ("USPTO") duly and legally issued U.S. Patent No. 7,981,916 (the "'916 Patent") entitled, "Solubilizing of Metronidazole."

16. Galderma S.A. owns all right, title, and interest in and to the '916 Patent.

17. Galderma Laboratories, L.P. is the exclusive licensee of the '916 Patent.

18. The '916 Patent is valid, enforceable and has not expired.

19. The application leading to the ’916 Patent was published as U.S. Publication No. 2008-0161375 on July 3, 2008, and was thereafter publicly available.

20. On information and belief, Tolmar was aware of the application leading to the ’916 Patent when it filed ANDA No. 090-903.

MetroGel 1% and the Accused Product

21. 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.

22. Galderma Laboratories, L.P. is the current holder of NDA No. 21-789 for 1% metronidazole gel, which it sells under the trade name, MetroGel®.

23. Tolmar submitted an ANDA (“Tolmar’s ANDA”) to the FDA on or about October 21, 2008 seeking approval to engage in the commercial manufacture, use, and sale of a generic equivalent to MetroGel® prior to the expiration of U.S. Patent Nos. 6,881,726 and 7,348,317 (collectively, the “MetroGel® Patents”), which are listed in the Food and Drug Administration’s publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as covering MetroGel®.

24. Under the Hatch-Waxman Act, Tolmar’s ANDA may be approved only if the Accused Product contains the same active pharmaceutical ingredient (“API”) as MetroGel®, the same route of administration as MetroGel®, the same dosage form as MetroGel®, the same strength of the API in MetroGel®, and the same product label as MetroGel®. Moreover, the Accused Product must be bioequivalent to MetroGel®, within certain statistical parameters.

25. Consequently, the Accused Product described in Tolmar’s ANDA is a 1% metronidazole topical gel indicated for use in treating rosacea.

26. On information and belief, there are no uses for which the Accused Product is indicated or approved except for the treatment of rosacea.

27. On information and belief, the package insert of the Accused Product instructs patients to apply a thin film of the Accused Product once daily to the affected areas. A true and correct copy of the most recently approved MetroGel® package insert is attached hereto as Exhibit A.

The MetroGel® Suit

28. On information and belief, the FDA accepted Tolmar's ANDA submission in January of 2009, and assigned it Serial No. 090-903.

29. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Tolmar's ANDA contained a Paragraph IV Certification that the Accused Product does not infringe any claim of the MetroGel® Patents.

30. On or about January 19, 2009, Tolmar sent Galderma Laboratories, L.P. notice that ANDA No. 090-903 contains a Paragraph IV Certification.

31. Galderma Laboratories, L.P. received Tolmar's notice on or about January 22, 2009.

32. Tolmar's notice included the specific chemical composition and formulation of the Accused Product.

33. Within forty-five (45) days of receiving Tolmar's notice letter, Galderma Laboratories, L.P. and Galderma S.A., in addition to Dow Pharmaceutical Sciences, Inc., which owns the MetroGel® Patents, sued Tolmar for patent infringement under 35 U.S.C. § 271(e)(2) (the "MetroGel® Suit"), thereby triggering a 30-month stay during which the FDA is prohibited

from granting final approval to Tolmar's ANDA. The MetroGel® Suit is currently pending in this jurisdiction as Civil Action No. 3:09-CV-0400-N.

34. Due to the 30-month stay, Tolmar has been prohibited by law from selling the Accused Product.

35. Tolmar's ANDA received tentative FDA approval on or about December 22, 2010.

36. Tolmar's 30-month stay is scheduled to expire on or about July 22, 2011.

37. After July 22, 2011, the FDA may grant final approval to Tolmar's ANDA, upon which Tolmar, barring an injunction entered in connection with the MetroGel® Suit, may market and distribute the Accused Product.

Tolmar's Infringing Activities

38. During pre-trial scheduling negotiations in the MetroGel® Suit, Tolmar refused to refrain from marketing the Accused Product until a decision in that case has been issued.

39. Moreover, Tolmar refused to provide Galderma Laboratories, L.P. and Galderma S.A. with notice prior to marketing the Accused Product.

40. On information and belief, Tolmar intends to market and sell the Accused Product immediately upon the FDA's final approval of Tolmar's ANDA.

41. On information and belief, Tolmar is making or is having made the Accused Product in preparation of marketing and distributing the Accused Product immediately upon final FDA approval.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,981,916

42. Plaintiffs repeat and re-allege each and every allegation contained in paragraphs 1 through 41 above as though fully stated herein.

43. Under 35 U.S.C. § 282, the ’916 Patent enjoys a statutory presumption of validity.

44. Through the conduct alleged above, Tolmar has infringed, and continues to infringe, one or more claims of the ’916 Patent, either literally or under the doctrine of equivalents.

45. 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 MetroGel® Patents, Tolmar has committed an act of infringement under 35 U.S.C. § 271(e)(2).

46. By making or having another make the Accused Product, Tolmar has committed an act of infringement under 35 U.S.C. § 271(a).

47. On information and belief, upon final FDA approval of Tolmar’s ANDA and marketing of the Accused Product, Tolmar knows that physicians will prescribe, and patients will use, the Accused Product to treat rosacea.

48. By marketing and distributing the Accused Product, which instructs patients using the Accused Product on how to treat rosacea, Tolmar will induce infringement of one or more claims of the ’916 Patent under 35 U.S.C. § 271(b).

49. By making or having made the Accused Product, which instructs patients using the Accused Product on how to treat rosacea, Tolmar is liable for contributory infringement of one or more claims of the ’916 Patent under 35 U.S.C. § 271(c).

50. Plaintiffs have not consented to any of Tolmar's acts of infringement of the '916 Patent.

51. Tolmar will continue to infringe the '916 Patent, and Plaintiffs will be irreparably harmed unless Tolmar is enjoined by this Court. Galderma has no adequate remedy at law.

PRAYER FOR RELIEF

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

1. An order adjudicating and decreeing that Tolmar has infringed the '916 Patent;
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 '916 Patent, 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 the '916 Patent;
4. An order directing Tolmar to deliver all infringing products 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 sells the Accused Product during the pendency of this litigation, Plaintiffs will incur damages and, therefore, will demand damages and trial by jury on all issues and claims alleged herein.

Dated: July 18, 2011

Respectfully submitted,

BY: /S/ *Jamil N. Alibhai*

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