

IN THE UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF TEXAS – SAN ANTONIO DIVISION

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CLERK, US DISTRICT COURT  
WESTERN DISTRICT OF TEXAS

BY [Signature]  
DEPUTY

MEDICIS PHARMACEUTICAL  
CORPORATION,

Plaintiff,

v.

STIEFEL LABORATORIES, INC.,

Defendant.

**SA10CA0621 OG**

Civil Action No. \_\_\_\_\_

*Jury Trial Requested*

**COMPLAINT FOR DECLARATORY RELIEF (PATENT INFRINGEMENT)**

Plaintiff Medicis Pharmaceutical Corporation (“Medicis”) alleges as follows:

**The Parties**

1. Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. Medicis is a leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and podiatric conditions and aesthetics medicine. Medicis has developed and commercialized leading branded prescription products in a number of therapeutic categories. Because of their clinical effectiveness and high quality, Medicis’s products have earned wide acceptance by both physicians and patients.

2. On information and belief, Defendant Stiefel Laboratories, Inc. (“Stiefel”) is incorporated in Delaware, has its principal place of business in Coral Gables, Florida, and has its headquarters in Research Triangle Park, North Carolina.

3. On information and belief, Stiefel conducts business operations in the United States, including in the State of Texas.

**Jurisdiction and Venue**

4. This action arises under the Declaratory Judgment Act and the Patent Statute of the United States of America, Titles 28 and 35 of United States Code, and jurisdiction is founded on Title 28, United States Code §§ 2201, 2202, 1331, and 1338(a).

5. On information and belief, this Court has personal jurisdiction over Stiefel because Stiefel has maintained continuous and systematic contacts with the State of Texas.

6. On information and belief, drug products are being manufactured for Stiefel in the State of Texas.

7. On information and belief, Stiefel has entered into agreements with manufacturers in this district for the manufacture of its accused infringing product. Exhibit 1 (Stiefel's product insert.)

8. On information and belief, drug products developed and manufactured by Stiefel and approved by the FDA are for sale and are sold in the State of Texas.

9. For all the reasons set forth above, this Court has personal jurisdiction over Stiefel.

10. Venue is proper in this Court for this action under at least Title 28, United States Code § 1391(b) and (c).

**Background**

11. On February 16, 2010, United States Letters Patent No. US RE41,134 (the '134 patent), entitled SLOW RELEASE VEHICLES FOR MINIMIZING SKIN IRRITANCY OF TOPICAL COMPOSITIONS, duly and legally issued to Dr. Gail S. Bazzano. The '134 patent is currently scheduled to expire on February 24, 2015. The '134 patent discloses and claims novel

pharmaceutical compositions of tretinoin for application to the skin, as well as novel methods for treating a skin condition with tretinoin. Exhibit 2 (Copy of the '134 patent.)

12. Alyzan, Inc. is the owner through assignment of the '134 patent.

13. Medicis is the exclusive licensee of the '134 patent, and Medicis is the owner of an approved New Drug Application ("NDA") for clindamycin phosphate 1.2% and tretinoin 0.025% gel (NDA No. 050802) that is sold under the trademark Ziana.<sup>®</sup>

14. Medicis's Ziana<sup>®</sup> gel is extremely successful and is widely used in the State of Texas, the United States, and throughout the world to treat diseases of the skin, including acne vulgaris.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the United States Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act (FFDCA). Medicis has listed the '134 patent in the Orange Book as covering its Ziana<sup>®</sup> gel.

16. On information and belief, Stiefel filed an NDA with the FDA for an antibiotic/retinoid gel branded by Stiefel as "Veltin." In its 2009 Annual Report, Stiefel's parent company stated that the NDA for Veltin was submitted by Stiefel in October 2009. Exhibit 3 (An excerpt from the Annual Report.)

17. On information and belief, Stiefel filed its NDA for Veltin because Stiefel seeks to enter the lucrative tretinoin composition market that Ziana<sup>®</sup> gel has created with its beneficial and advantageous treatments for diseases of the skin, including acne vulgaris.

18. On information and belief, Stiefel's NDA was approved by the FDA on July 16, 2010. Exhibit 4 (Copy of Stiefel's press releases.)

19. On information and belief, the manufacture of Veltin in this district by or on behalf of Stiefel for sale is imminent or is already occurring. Exhibit 1 (Stiefel's product insert.)

20. On information and belief, the manufacture, sale, and offer to sell Veltin would directly infringe and induce the infringement of the '134 patent's claims.

**Count I – Declaratory Judgment of Infringement**

21. Each of the preceding paragraphs 1 – 20 is incorporated as if fully set forth herein.

22. On information and belief, Stiefel actively and knowingly filed its NDA to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the '134 patent, before the expiration of the '134 patent. On information and belief, Stiefel will commit an act of patent infringement under 35 U.S.C. § 271.

23. On information and belief, Stiefel's infringement of the '134 patent is imminent, and thus creates a real and actual controversy between Medicis and Stiefel. Stiefel's imminent infringement is demonstrated by, at least, its recent planned production of a print advertisement for Veltin, the product that is the subject of Stiefel's NDA. Exhibit 5 (The casting call for actors for the Veltin advertisement.) Imminent infringement is also demonstrated by Stiefel's parent company's Annual Report (Exh. 3), Stiefel's announcement that the FDA has approved Stiefel's NDA for Veltin (Exh. 4), and the statements of several online pharmaceutical vendors that Veltin is "coming soon." Exhibit 6 (Product order forms for Veltin.) Finally, Stiefel's parent company posted a job opening on July 9, 2010 that explains that the hire will, among other things, "[l]ead near-term launch for Veltin." Exhibit 7 (Job posting for Director position.)

24. On information and belief, when Stiefel drafted or filed its NDA, Stiefel was aware of at least the original issue of the '134 patent (U.S. Patent No. 5,721,275). Exhibit 8 (Copy of the '275 patent.)

25. On information and belief, Stiefel acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '134 patent. As a result, Stiefel's imminent infringement will be willful and deliberate, making this an exceptional case under the United States patent laws.

**Requested Relief**

Plaintiff respectfully seeks the following relief:

- a. That a declaratory judgment be entered that Stiefel's manufacture, causing to be made, using, offering for sale, sale, or importing of Veltin will infringe the '134 patent;
- b. That a preliminary and permanent injunction restraining or enjoining Stiefel, its officers, agents or attorneys or employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any therapeutic composition or method of use covered by the '134 patent for the full term thereof, and from inducing or contributing to such activities;
- c. That this is an exceptional case under 35 U.S.C. § 285 and that judgment be entered for costs and reasonable attorney fees to be awarded to Medicis; and
- d. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Medicis requests a trial by jury for any issues so triable.

Dated: July 28, 2010

Respectfully submitted,

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