IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STIEFEL RESEARCH AUSTRALIA PTY. LTD. Plaintiff	)	
v.	)	Civil Action No. _____
PERRIGO COMPANY and PERRIGO ISRAEL PHARMACEUTICALS LTD. Defendants	)	

COMPLAINT

Plaintiff Stiefel Research Australia Pty. Ltd. ("Stiefel"), for its Complaint against Defendants Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (collectively, "Perrigo"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 6,946,120 B2 (the "'120 patent"). This action relates to an Abbreviated New Drug Application ("ANDA") filed by Perrigo seeking approval from the United States Food and Drug Administration ("FDA") to market a generic version of Men's Rogaine® (minoxidil) topical aerosol foam 5%. This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*

PARTIES

2. Plaintiff Stiefel is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court,

Rowville, Victoria 3168, Australia. Stiefel is a wholly-owned subsidiary of Stiefel Laboratories, Inc.

3. Upon information and belief, Perrigo Company is a global healthcare supplier that develops, manufactures and distributes over-the-counter and generic prescription pharmaceuticals, nutritional products, active pharmaceutical ingredients and pharmaceutical and medical diagnostic products.

4. Upon information and belief, Perrigo Company is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

5. Upon information and belief, Perrigo Israel Pharmaceuticals Ltd. is an Israeli corporation with its headquarters and corporate offices at 29 Lehi Street, Bnei Brak 51200, Israel.

6. Upon information and belief, Perrigo Israel Pharmaceuticals Ltd. is a wholly owned subsidiary of Perrigo Company.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

9. This Court also has personal jurisdiction over Perrigo. On information and belief, Perrigo manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceuticals and nutritional products. Perrigo's products are sold by mass merchandisers, food stores and drug stores throughout the United States, including within this judicial district.

10. On information and belief, Perrigo derives substantial revenue from the sales of those products in this district. Perrigo has been sued for patent infringement in this judicial district (C.A. Nos. 99-813, 04-107 and 09-167), and has admitted that it is subject to personal jurisdiction in this Court.

11. Perrigo has engaged in substantial and/or continuous and systematic contacts with the State of Delaware, which satisfy due process and confer personal jurisdiction over Perrigo. Personal jurisdiction over Perrigo is authorized under the laws of Delaware.

FACTUAL BACKGROUND

The Drug Approval Process

12. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to the FDA, and the FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

13. A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on and take advantage of the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug.

Stiefel's Men's Rogaine® Product and '120 Patent

14. Men's Rogaine® (minoxidil) is a topical aerosol foam, 5% commercial formulation of minoxidil manufactured and sold by McNEIL-PPC, Inc. On March 23, 2005, Pharmacia and Upjohn filed an NDA seeking FDA approval to market Minoxidil Topical Aerosol Foam, 5% (NDA 21-812).

15. On January 20, 2006, the FDA approved NDA 21-812, which provides for the use of Men's Rogaine (5% minoxidil) Topical Aerosol for the nonprescription treatment of androgenic alopecia of the vertex of the scalp.

16. Johnson and Johnson is the current holder of NDA 21-812.

17. On September 20, 2005, the '120 patent titled "PHARMACEUTICAL COMPOSITION," was duly and legally issued to Tony Wai-Chiu So, Peter Paul Deo, and Russell John Tait, and assigned on its face to Connetics Australia Pty. Ltd. On or about March 26, 2007, Connetics Australia Pty. Ltd. changed its name to Stiefel Research Australia Pty. Ltd. Since that time, Stiefel has been and is the assignee and owner of the '120 patent. A true and correct copy of the '120 patent is attached hereto as Exhibit A.

18. Stiefel's '120 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Men's Rogaine® (minoxidil) in a topical aerosol foam 5%.

Perrigo's ANDA Filing and Notice Letter

19. On August 26, 2009, Perrigo sent Johnson and Johnson and Stiefel a paragraph IV notice, stating that Perrigo had filed with the FDA ANDA No. 91-344 for Minoxidil Topical Aerosol Foam, 5% pursuant to 21 U.S.C. §§ 35(j)(1) and (j)(2)(A), with a

paragraph IV certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Minoxidil Topical Aerosol Foam, 5%, before the expiration of the ’120 patent.

20. Through its paragraph IV certification to the FDA, Perrigo alleged that the ’120 patent is invalid, unenforceable, and/or will not be infringed by its commercial manufacture, use, sale or importation of the drug product described in Perrigo’s ANDA.

21. This suit is being filed within 45 days of Stiefel’s receipt of the paragraph IV notice.

COUNT I: INFRINGEMENT OF THE ’120 PATENT

22. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

23. Perrigo’s submission of ANDA No. 91-344 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Minoxidil Topical Aerosol Foam, 5% prior to the expiration of the ’120 patent and any additional periods of exclusivity, constitutes infringement of one or more of the valid claims of the ’120 patent under 35 U.S.C. § 271(e)(2)(A).

24. Perrigo’s commercial manufacture, use, offer to sell, sale, or importation of Minoxidil Topical Aerosol Foam, 5% described in ANDA No. 91-344 prior to the expiration of the ’120 patent and any additional periods of exclusivity, or their inducement of or contribution to such conduct, would further infringe the ’120 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

25. Perrigo’s filing of its ANDA and their intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Minoxidil Topical Aerosol

Foam, 5% upon receiving FDA approval, create an actual case or controversy with respect to infringement of the ’120 patent.

26. Upon FDA approval of Perrigo’s ANDA, Defendants will infringe the ’120 patent by making, using, offering to sell, selling, or importing Minoxidil Topical Aerosol Foam, 5% in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

27. Stiefel will be irreparably harmed if Defendants’ infringement is not enjoined. Stiefel does not have an adequate remedy at law.

28. Stiefel is entitled to the relief provided by 35 U.S.C. § 271(e)(4).

PRAYER FOR RELIEF

WHEREFORE, Stiefel respectfully requests that judgment be entered that:

(a) Perrigo has infringed one or more claims of the ’120 patent.

(b) The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Minoxidil Topical Aerosol Foam, 5% described in ANDA No. 91-344 would infringe one or more claims of the ’120 patent;

(c) The effective date of any approval of ANDA No. 91-344 for Minoxidil Topical Aerosol Foam, 5% be not earlier than the expiration date of the ’120 patent and any additional periods of exclusivity;

(d) Preliminarily and permanently enjoining Perrigo, its officers, agents, servants and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Minoxidil Topical Aerosol Foam, 5%;

(e) This is an exceptional case entitling Stiefel to an award of its reasonable attorneys’ fees, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285; and

(f) Granting such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

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