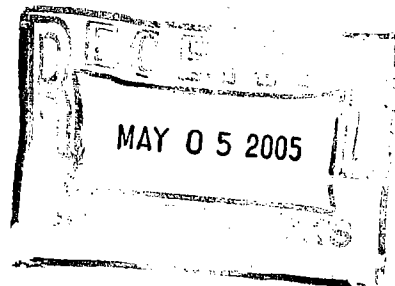


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Pharmaceuticals Co.*



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MC NEIL-PPC, INC., MERCK & CO., INC., and)
JOHNSON & JOHNSON • MERCK CONSUMER)
PHARMACEUTICALS CO.)

Plaintiffs,)

v.)

PERRIGO COMPANY, L. PERRIGO)
COMPANY, and PERRIGO RESEARCH &)
DEVELOPMENT COMPANY)

Defendants.)
_____)

C. A. No. 05 CV 1321 (WHP) (DFE)

Electronically Filed

**FIRST AMENDED COMPLAINT OF MC NEIL-PPC, INC., MERCK & CO., INC. AND
JOHNSON & JOHNSON • MERCK CONSUMER PHARMACEUTICALS CO.
FOR PATENT INFRINGEMENT**

Plaintiffs, McNeil-PPC, Inc. (“McNeil-PPC”), Merck & Co., Inc. (“Merck”), and
Johnson & Johnson • Merck Consumer Pharmaceuticals Co. (“JJMCP”), by their undersigned
attorneys, bring this action against defendants, Perrigo Company, L. Perrigo Company, and
Perrigo Research & Development Company, for patent infringement and allege as follows:

1. Plaintiff McNeil-PPC is a New Jersey corporation with its principal place
of business at 199 Grandview Road, Skillman, New Jersey 08558-9418. McNeil-PPC is an

operating company and its subsidiaries are engaged in the business of marketing prescription and non-prescription pharmaceutical products in the United States.

2. Plaintiff Merck is a New Jersey corporation with a principal place of business at 1 Merck Drive, Whitehouse Station, New Jersey 08889-0100.

3. Plaintiff JIMCP is a New Jersey partnership with its principal place of business at 7050 Camp Hill Rd., Fort Washington, Pennsylvania 19034.

4. Upon information and belief, defendant Perrigo Company is a company incorporated and existing under the laws of the State of Michigan, having a principal place of business at 515 Eastern Ave., Allegan, Michigan 49010.

5. Upon information and belief, defendant L. Perrigo Company is a company incorporated and existing under the laws of the State of Michigan, having its principal place of business at 900 Brooks Ave, Holland, Michigan 49423.

6. Upon information and belief, defendant Perrigo Research & Development Company is a company incorporated and existing under the laws of the State of Michigan, having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

7. Upon information and belief, defendants L. Perrigo Company and Perrigo Research & Development Company are subsidiary companies of defendant Perrigo Company.

8. Upon information and belief, the acts complained of herein were done by, at the direction of, with the authorization, cooperation, participation, or assistance of, or at least in part for the benefit of Perrigo Company, L. Perrigo Company, and Perrigo Research & Development Company. In addition, the ANDA notice letter described below in paragraph 18 was sent by "Perrigo," which the letter states refers to Perrigo Company and its subsidiaries L. Perrigo Company and Perrigo Research & Development Company.

9. Defendants Perrigo Company, L. Perrigo Company, and Perrigo Research & Development Company are referred to hereinafter collectively as “Perrigo.”

JURISDICTION AND VENUE

10. Upon information and belief, Perrigo sells a substantial amount of products and otherwise transacts business throughout the United States and within this District.

11. This action for patent infringement arises under the patent laws of the United States, Title 35, United States Code, Section 271(e)(2) and Title 21, United States Code, Section 355. Jurisdiction is based on Title 28, United States Code, Sections 1331 and 1338(a).

12. Venue is proper in this Court pursuant to Title 28, United States Code, Sections 1391(c) and 1400(b).

CLAIM FOR RELIEF

13. Merck is the holder of approved New Drug Application (“NDA”) No. 20-958, for a tablet containing 10 mg famotidine, 165 mg magnesium hydroxide, and 800 mg calcium carbonate as active ingredients, marketable as an over the counter pharmaceutical. The tablets described in the NDA are for use in the relief of heartburn associated with acid indigestion and sour stomach. The tablets are marketed as an over the counter pharmaceutical under the trade name Pepcid Complete®.

14. McNeil-PPC is the owner of United States Patent No. 5,817,340 (“the ’340 patent”), which discloses and claims oral dosage forms, and methods for making the same, comprising as active ingredients impermeably coated famotidine granules and either aluminum hydroxide or magnesium hydroxide. On October 6, 1998, the ’340 patent duly and legally issued. The ’340 patent was filed on November 25, 1996, with priority claimed to a patent

application filed on December 1, 1992. The '340 patent expires on December 1, 2012, with pediatric exclusivity until June 1, 2013. A copy of the '340 patent is attached as Exhibit A.

15. JJMCP markets and sells Pepcid Complete[®] in the United States. JJMCP's Pepcid Complete[®] tablets contain 10 mg famotidine, 165 mg magnesium hydroxide, and 800 mg calcium carbonate as active ingredients. The Pepcid Complete[®] tablets are covered by Merck's NDA No. 20-958. JJMCP sells Pepcid Complete[®] tablets under license from McNeil-PPC and Merck.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '340 patent is identified in the Food and Drug Administration publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), as covering Pepcid Complete[®] products.

17. Perrigo has filed Abbreviated New Drug Application ("ANDA") No. 77-355 with the United States Food and Drug Administration. ANDA No. 77-355 is directed to tablets containing 10 mg famotidine, 165 mg magnesium hydroxide, and 800 mg calcium carbonate (the "ANDA product"). In connection with that ANDA, Perrigo has filed a certification under § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell the ANDA product prior to the expiration of the '340 patent. Perrigo has alleged that its ANDA product will not infringe any claim of the '340 patent and that all claims of the '340 patent are invalid.

18. On or about December 23, 2004, Perrigo sent a notice letter to McNeil Consumer & Specialty Pharmaceuticals in which Perrigo represented that it had filed ANDA No. 77-355 with a § 505(j)(2)(B)(ii) certification with respect to the '340 patent, and that it sought approval of its ANDA prior to the expiration of the '340 patent. Perrigo's notice alleged that its

ANDA product will not infringe any claim of the '340 patent and that all claims of the '340 patent are invalid. Perrigo also sent a notice letter to Merck.

19. Because Perrigo seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a compound claimed in the '340 patent before its expiration, Perrigo has infringed the '340 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

20. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Perrigo's ANDA be a date that is not earlier than December 1, 2012, the expiration date of the '340 patent, or any later expiration of exclusivity to which the '340 patent is or becomes entitled.

21. Upon information and belief, Perrigo was aware of the existence of the '340 patent and was aware that the filing of its ANDA and certification with respect to the '340 patent constituted an act of infringement of that patent.

22. Perrigo's statement of the factual and legal bases for its opinion regarding the invalidity or noninfringement of the '340 patent is devoid of an objective good faith basis in either the facts or the law.

23. Perrigo's infringement of the '340 patent was and is willful.

24. Plaintiffs will be irreparably harmed if Perrigo is not enjoined from infringing or actively inducing or contributing to infringement of the '340 patent. Plaintiffs do not have an adequate remedy at law.

25. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

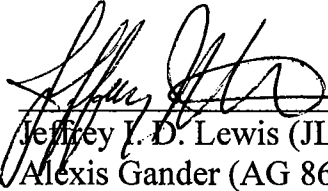
PRAYER FOR RELIEF

WHEREFORE, plaintiffs McNeil-PPC, Merck, and JJMCP request that:

- a. Judgment be entered that Defendants have infringed the '340 patent by submitting ANDA No. 77-355;
- b. Judgment be entered that Defendants' infringement of the '340 patent was and is willful, and Plaintiffs are entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285;
- c. To the extent Defendants have committed any acts with respect to what is claimed in the '340 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiffs be awarded damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;
- d. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys 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 drug compounds as claimed in the '340 patent;
- e. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 77-355 be a date which is not earlier than December 1, 2012, the expiration date for the '340 patent, or any later expiration of exclusivity to which the '340 patent is or becomes entitled; and

f. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: May 4, 2005



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