

For Release: August 12, 2004

Related Documents:

Generic Drug Marketers Settle FTC Charges

[Perrigo Company and
Alpharma Inc., F.T.C. v.](#) (D.C.
D.C.), File No. 021 0197

Complaint Charges Unlawful Agreement Not to Compete Drove Up Prices for Over-the-Counter Children's Ibuprofen; Companies to Give-Up Illegal Profits

Generic drug manufacturers Alpharma, Inc. and Perrigo Company will give up \$6.25 million in illegal profits to settle Federal Trade Commission charges that their agreement to limit competition for over-the-counter (OTC) store-brand children's liquid ibuprofen drove up prices and violated federal law. According to the FTC's complaint, Perrigo paid Alpharma – the only other manufacturer of OTC store-brand children's liquid ibuprofen approved by the U. S. Food and Drug Administration (FDA) – to eliminate Alpharma as a competing supplier. The settlements call for Perrigo to pay \$3.75 million and Alpharma to pay \$2.5 million to the FTC. In addition, the companies will pay the state attorneys general an additional \$1.5 million to resolve their claim challenging the same agreement. The FTC's settlements will bar the companies from entering into agreements not to compete when either party is the first filer of an abbreviated new drug application (ANDA) with the FDA. The settlements also require the companies to notify the FTC of agreements that fall within four narrow exceptions to the general prohibition.



"This case involves a clear antitrust violation," said Timothy J. Muris, Chairman of the FTC. "The only two competitors for a generic version of OTC Children's Motrin agreed to stop competing and share the resulting profits. This settlement demonstrates that companies can not expect to profit from violating the law." Chairman Muris added, "This case is the first Commission implementation of the disgorgement policy statement issued by the FTC in July 2003."

According to the FTC complaint, in 1996, Perrigo and Alpharma each filed ANDAs with the FDA for approval to sell a generic version of Children's liquid Motrin, a drug used to relieve pain and reduce inflammation. Such generics are commonly known in the industry as a "store-brand" product.

Both parties expected to receive final approval for their products in June 1998, and, in expectation of those approvals, both companies tried to secure customer commitments. Customers used the competition between Perrigo and Alpharma to obtain substantially lower prices for store-brand OTC children's liquid ibuprofen.

An April 1998 change in the FDA's regulations gave Alpharma a significant competitive advantage. The FDA determined that Alpharma was eligible for 180 days of market exclusivity, which meant that the FDA would not approve Perrigo's product until 180 days after Alpharma began marketing its product.

The FTC alleges that Perrigo then approached Alpharma and sought to negotiate an agreement that would allow Perrigo to sell its product during the exclusivity period. Both parties, however, calculated that an agreement eliminating competition between them would allow Perrigo to raise prices. The companies projected the size of the higher profits by avoiding competition and then bargained over how to share those profits.

In June 1998, Perrigo and Alpharma signed an agreement allocating to Perrigo the sale of OTC children's liquid ibuprofen for seven years. In exchange for agreeing not to compete, Alpharma received an up-front payment and a royalty on Perrigo's sales of children's liquid ibuprofen.

Perrigo launched its children's liquid ibuprofen product in January 1999. Within six months of launching its product, Perrigo raised prices to those customers who had obtained lower prices when Perrigo and Alpharma were competing for customers.

According to the FTC, Perrigo and Alpharma still are the only two companies to obtain FDA approval for a generic OTC version of liquid ibuprofen that is bio-equivalent to Children's liquid Motrin. Alpharma has not marketed its product, despite having received regulatory approval in April 1999.

The FTC alleges that the agreement between Perrigo and Alparma unlawfully drove up prices for wholesale customers – including supermarkets, drug chains and mass merchandisers – and violated the FTC Act.

Under the proposed final orders, the companies pay a total of \$6.25 million to settle charges that they earned illegal profits from the agreement. The FTC will use those funds to compensate customers harmed by the companies' conduct. The proposed orders also bar each company from repeating the alleged unlawful conduct by entering into similar agreements not to compete where one party to the agreement is a first ANDA-filer, subject to certain exceptions identified in the orders. Perrigo and Alparma must provide notice to the FTC of any agreement falling within one of these exceptions. The settlements also contain certain record-keeping provisions to allow the FTC to monitor compliance.

Michigan-based Perrigo manufactures OTC analgesics, cough and cold remedies, and gastrointestinal products sold by retail stores under store brand or "value brand" labels. According to its annual report, Perrigo currently markets approximately 1,200 store brand products to approximately 300 customers. Its net sales for 2003 were \$826 million. Alparma, the largest manufacturer of generic liquid and topical pharmaceuticals in the United States, is based in Maryland. It produces both over-the-counter and prescription products. Its net sales for 2003 were \$1.3 billion.

The FTC conducted its investigation jointly with the States of Maryland, Florida, Colorado, and Ohio. Fifty states and territories are filing a complaint challenging the same agreement and reached a settlement prohibiting the same conduct that the FTC's settlements with the companies prohibit. In addition, the companies will pay a total of \$1.5 million in lieu of civil fines or forfeitures to those states and territories.

The Commission vote to authorize staff to file the complaint and stipulated permanent injunction was 5-0. A copy of the complaint will be available on the FTC Web site at www.ftc.gov after it is filed with the district court. The final orders are available with this press release.

NOTE: This consent decree is for settlement purposes only and does not constitute an admission by the defendant of a law violation. Consent decrees have the force of law when signed by the judge.

Copies of the final orders are available from the FTC's Web site at <http://www.ftc.gov> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC's Bureau of Competition seeks to prevent business practices that restrain competition. The Bureau carries out its mission by investigating alleged law violations and, when appropriate, recommending that the Commission take formal enforcement action. To notify the Bureau concerning particular business practices, call or write the Office of Policy and Evaluation, Room 394, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580, Electronic Mail: antitrust@ftc.gov; Telephone (202) 326-3300. For more information on the laws that the Bureau enforces, the Commission has published Promoting Competition, Protecting Consumers: A Plain English Guide to Antitrust Laws, which can be accessed at <http://www.ftc.gov/bc/compguide/index.htm>.

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(<http://www.ftc.gov/opa/2004/08/perrigoalparma.htm>)