

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580,

Plaintiff,

v.

PERRIGO COMPANY  
515 Eastern Avenue  
Allegan, MI 49010,

and

ALPHARMA INC.  
One Executive Drive  
Fort Lee, NJ 07024,

Defendants.

Civil Action No. 1: 04CV01397 (RMC)

**COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), by its designated attorneys, petitions the Court, pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), for a permanent injunction, and other equitable relief against Defendants Perrigo Company (“Perrigo”) and Alparma Inc. (“Alparma”) for their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

## Nature of the Case

1. This case involves a horizontal market allocation between Perrigo and Alpharma. Perrigo and Alpharma are the only two approved manufacturers of a generic over-the-counter product that is bioequivalent to Children's liquid Motrin (store brand Children's liquid Motrin), a drug product to relieve pain and inflammation in children. Prior to entering their anticompetitive agreement, Perrigo and Alpharma aggressively competed to secure customers for their respective product launches in June 1998. Until defendants terminated this competition, it had driven prices down, by as much as 40% in some cases, for store brand Children's liquid Motrin sold to supermarkets, retail drug chains, and mass merchandisers.

2. In June 1998, defendants conspired to stop competing. Alpharma agreed to withhold its store brand Children's liquid Motrin from the market for seven years, in exchange for which Perrigo paid Alpharma a flat fee of \$3.5 million plus 15-20% of its future revenues on the product. Defendants expected Perrigo's future revenues to grow substantially because, absent rivalry from Alpharma, Perrigo could charge a significantly higher price. They projected the magnitude of the resulting higher profits, and then bargained over how to share them. After Alpharma abandoned its competition, Perrigo – as defendants predicted – promptly raised its price to customers. As a consequence, many purchasers – including supermarkets, drug chains and mass merchandisers – have paid substantially higher prices for store brand Children's liquid Motrin. Perrigo and Alpharma each obtained ill-gotten profits by virtue of this unlawful conduct.

### **Jurisdiction and Venue**

3. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

4. This Court has personal jurisdiction over each of the defendants pursuant to 15 U.S.C. § 53(b), and because each of the defendants has the requisite constitutional contacts with the United States of America and with the District of Columbia.

5. Venue in this district is proper under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), and 28 U.S.C. § 1391(c)).

6. The defendants' unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

7. Defendants Perrigo and Alparma are, and at all relevant times herein have been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

### **The Parties**

8. Plaintiff Commission is an administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices at 600 Pennsylvania Avenue, NW, Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of the FTC Act.

9. Defendant Perrigo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Michigan. Perrigo's office and principal place of business is located at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo is engaged in the

business of developing, manufacturing, marketing, and distributing a broad range of over-the-counter (OTC) generic pharmaceutical and nutritional products that are sold by supermarket, drug and mass merchandise chains under their own labels. Among other pharmaceuticals, Perrigo manufactures and distributes Children's strength store brand liquid Motrin. In the twelve months ending June 2003, Perrigo had net sales of \$826 million and net income of \$54 million. During that same period, Perrigo's net sales of store brand Children's liquid Motrin totaled \$17.4 million.

10. Defendant Alharma is a corporation organized, existing and doing business

12. Once an NDA has been approved, another company seeking to market a generic version of the branded drug may file an Abbreviated New Drug Application (ANDA). A generic drug is one that the FDA has found to be “bioequivalent” to a branded drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the formulation, quality, and effectiveness of the products. *See* 21 U.S.C. § 355(j)(8)(B).

13. Under the Hatch-Waxman Act, the FDA may not approve the marketing of a generic drug prior to the expiration of a patent listed in the FDA’s so-called “Orange Book” relating to the branded drug, unless the applicant makes a “paragraph IV certification” with its ANDA, stating that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii).

14. If the holder of a patent claiming the branded drug then files a patent infringement suit within 45 days after receiving notification of such a certification, then the FDA’s approval of the ANDA is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time (30-month stay). 21 U.S.C. 355(j)(5)(B)(iii). If, however, the patent holder does not file a patent infringement suit against the generic drug applicant within the 45-day period, then the FDA approval process for the ANDA may proceed. Upon receiving final FDA approval, the ANDA filer may market its generic drug.

15. ~~Under~~ ~~in~~ certain circumstances, the first c



Children's Motrin. McNeil did not sue either for patent infringement. Neither applicant's store brand product approval, therefore, was subject to the Hatch-Waxman 30-month stay.

20. Alparma submitted the first substantially complete ANDA for store brand Children's liquid Motrin, along with a paragraph IV certification. Prior to April 1998, however, Alparma had not been eligible for the 180-day exclusivity period, because McNeil did not sue Alparma for patent infringement. Under

large pharmacy chain used a competing offer from Alpharma to secure from Perrigo a 40% discount for its initial purchase of store brand Children's liquid Motrin. Other retailers also achieved substantial savings by virtue of the price competition between Alpharma and Perrigo.

**Perrigo and Alpharma Recognize the Profits to be Gained by  
Eliminating Competition Between Them**

24. In April 1998, the United States Court of Appeals for the District of Columbia Circuit struck down portions of the FDA's regulations that required the first ANDA filer to be sued and to successfully defend that lawsuit to be eligible for the 180-day Exclusivity Period. *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). In response to the *Mova* decision, the FDA determined that Alpharma was automatically eligible for 180-day market exclusivity for its store brand Children's liquid Motrin product, even though Alpharma had not been sued for patent infringement by the branded drug manufacturer.

25. Alpharma's newly determined exclusivity rights blocked the FDA from granting final approval to Perrigo's ANDA. This posed a problem for Perrigo, because it had committed to supplying its retail customers immediately upon expiration of the brand's exclusivity in June. Perrigo believed that any delay in launching its product would disappoint its customers and could adversely affect its reputation. Moreover, if it had to wait until Alpharma's exclusivity period expired before launching its store brand Children's liquid Motrin product, Perrigo expected to lose the business for which it had competed successfully earlier that year, costing the company millions of dollars in lost sales. In addition, to win back those customers, Perrigo projected that it would have to lower its price even further.



26. Alparma, virtually overnight, obtained a valuable competitive advantage. Any purchaser seeking to buy store brand Children's liquid Motrin when the branded product's exclusivity expired would have no choice but to purchase from Alparma. Alparma's exclusivity rights offered the company – in terms used by its sales and marketing personnel – a “home run opportunity” to secure customers and supply the entire market.

27. On or about May 20, 1998, a Perrigo senior executive contacted the president of Alparma's U.S. Pharmaceutical Division to propose an arrangement that would allow Perrigo to enter the market during Alparma's 180-day exclusivity period. In response, Alparma made clear that it desired a deal that would govern the defendants' actions not just for 180 days, but for many years, and would include a large up-front payment to Alparma plus a share of Perrigo's profits.

28. Perrigo recognized that a long-term arrangement would be lucrative for Perrigo so long as it eliminated competition from Alparma. Perrigo understood that the price of store brand Children's liquid Motrin would fall with the entry of competing store brand Children's liquid Motrin products. But its market research showed that it was unlikely

Alpharma estimated (i) a 30% higher price for store brand Children's liquid Motrin if Alpharma did not compete; (ii) that the higher price alone would generate an additional \$4 to \$5.5 million profit for Perrigo over 7 years; and (iii) that the total value to Perrigo of buying off competition from Alpharma would be \$9 to \$11 million.

Perrigo's stated view is that it would have been "oxymoronic" to make such sizable payments if it still had to compete with Alpharma over the course of the agreement's seven-year term.

34. The agreement set a minimum amount for the royalty payment – \$.20 per four ounce bottle – until such time as the FDA approves an ANDA from a third party for a generic product that is bioequivalent to Children's Motrin. At that time, the minimum royalty would be eliminated. Perrigo viewed this provision as necessary to enable it to respond effectively to competitive threats from alternate store brand Children's liquid Motrin suppliers. Entry of other children's pain relief products, such as store brand Children's liquid acetaminophen, however, had no impact on Perrigo's contractual obligation to pay the minimum royalty.

35. At the time defendants executed their agreement in June 1998, both expected Alpharma to receive final FDA approval of its ANDA for store brand Children's liquid Motrin by August 1998, if not sooner. This mutual expectation is manifested in the June 1998 agreement which provides that (1) Perrigo could not obtain final FDA approval and enter until after Alpharma first obtained final approval of its ANDA and waived its exclusivity rights to Perrigo; (2) Alpharma would not receive any payments from Perrigo pursuant to the agreement until after FDA g

for OTC Children's Motrin. This new exclusivity prevented FDA from granting final approval of any store brand Children's liquid Motrin equivalent until December 1998.

37. Second, Alparma did not receive final FDA approval of its ANDA for store brand Children's liquid Motrin as quickly as the defendants expected. Under FDA's regulations, a generic drug manufacturer may selectively waive its 180-day exclusivity period (i.e., waive in favor of another specific generic drug company) only after such exclusivity period actually begins – which, in this case, could not occur until after Alparma obtained final approval of its ANDA. Accordingly, until it obtained FDA approval, Alparma's choices were to either relinquish its exclusivity entirely (i.e., allowing FDA to approve any store brand Children's liquid Motrin ANDA), or continue to block Perrigo's approval. Based on Perrigo's assessment that there was little chance of competition for at least a year, Alparma relinquished its exclusivity in December 1998.

#### **Perrigo Sold its Store Brand Children's Liquid Motrin Product Without Competition**

38. Shortly thereafter, on December 22, 1998, Perrigo received final FDA approval of its ANDA for store brand Children's liquid Motrin and launched its product. As required by the agreement, Perrigo paid Alparma the lump sum fee of \$3.5 million at that time. As the only supplier of store brand Children's liquid Motrin, Perrigo was now unconstrained in raising its price to those customers that, prior to the agreement, had leveraged the rivalry between Perrigo and Alparma to obtain a price savings. For example, one national chain had successfully leveraged the pre-agreement competition between Perrigo and Alparma to obtain a 40%



44. Even under a broader inquiry, the agreement is anticompetitive. The purpose and effect of defendants' actions was to raise prices for store brand Children's liquid ibuprofen. As a result of defendants' unlawful conduct, many purchasers – including supermarkets, drug chains and mass merchandisers – have paid higher prices for store brand Children's liquid Motrin than would have prevailed had Alpharma competed.

45. Perrigo and Alpharma each has obtained ill-gotten profits from this unlawful conduct.

### **Agreement in Restraint of Trade**

46. The Commission realleges and incorporates by reference paragraphs 1 through 45.

47. Defendants' agreement to allocate between them sales of store brand Children's liquid ibuprofen to Perrigo for seven years and to share the resulting supracompetitive profits unreasonably restricts competition. The purpose and effect of this agreement was to eliminate competition from the only other known supplier of store brand Children's liquid ibuprofen during the term of the agreement. By eliminating such competition, the agreement raised prices for store brand liquid ibuprofen.

48. Defendants' agreement to eliminate competition from Alpharma is not reasonably necessary to accomplish any procompetitive objective; nor is it subsidiary to any procompetitive objective. Rather, eliminating competition from Alpharma was a primary purpose of defendants' unlawful agreement.

49. By entering into this unlawful market allocation agreement, defendants Perrigo and Alpharma have engaged in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act.

### **The Court's Power to Grant Relief**

50. Section 13(b) of the FTC Act empowers this Court to issue injunctive relief against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order other ancillary equitable relief, including disgorgement, to remedy the injury caused by defendants' violations.

### **Prayer For Relief**

WHEREFORE, the Commission requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26, and pursuant to its own equitable powers, enter final judgment against Defendants declaring, ordering, and adjudging:

1. That Defendants Perrigo and Alpharma violated Section 5(a) of the FTC Act;
2. That Defendants Perrigo and Alpharma be permanently enjoined from engaging in conduct violating Section 5(a) of the FTC Act; and

3. That the Court grant such other equitable relief, including disgorgement, as the Court finds necessary to redress and prevent recurrence of defendants' violation of Section 5(a) of the FTC Act as herein alleged.

William E. Kovacic  
General Counsel

RESPECTFULLY SUBMITTED,

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