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 Alpharma Inc. ("Alpharma") 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 Alpharma 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 Alpharma is a corporation organized, existing and doing business under and by virtue of the laws of Delaware. Alpharma's office and principal place of business is located at One Executive Drive, Fort Lee, New Jersey 07024. Alpharma is engaged in the business, among other things, of developing, manufacturing, marketing, and distributing liquid and topical prescription and OTC generic pharmaceutical products. In the twelve months ending December 31, 2003, Alpharma had net revenues of $1.3 billion and net income of $17 million.

Statutory and Regulatory Background

11. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate the entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. A company seeking approval from the Food and Drug Administration (FDA) to market a new drug (i.e., a branded drug or brand) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b).

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 certain circumstances, the first company to file an ANDA with a paragraph IV certification relating to a particular branded drug is granted the exclusive right to market a generic version of that branded drug for 180 days (the 180-day exclusivity). 21 U.S.C. § 355

(j)(5)(B)(iv)). Until the exclusivity expires, the FDA may not approve any additional ANDAs for the same product.

16. Other regulatory provisions may also prevent the FDA from approving any ANDA for a certain period of time. For example, the branded drug company may receive a three-year market exclusivity for performing certain additional clinical testing, (21 U.S.C. § 355(j)(5)(D)(iii)), or a six-month pediatric exclusivity for demonstrating that a drug is safely used by children. 21 U.S.C. § 355a(b).

Perrigo and Alpharma Aggressively Competed for Customers

17. McNeil Consumer & Specialty Pharmaceuticals (McNeil) makes and sells Children's liquid Motrin, a popular OTC medication used by children to reduce fever and relieve pain. Pursuant to FDA regulations, McNeil was entitled to a three-year marketing exclusivity for Children's Motrin, which expired on June 18, 1998. McNeil's sales of Children's liquid Motrin exceeded $55 million in 1998, the last year before generic entry.

18. In 1996, Perrigo and Alpharma each filed ANDAs with the FDA for approval to sell a generic, or, as commonly known in the OTC industry, a "store brand" version of Children's Motrin. A store brand is an OTC generic drug that is sold under the retailer's label, not the manufacturer's. A store brand product typically sells at retail at a 25-30% discount from the branded product's price, and provides the retailer a greater per unit profit relative to the corresponding branded product.

19. Perrigo and Alpharma each submitted with its ANDA a paragraph IV certification stating that its store brand product did not infringe any of the patents listed with the FDA for

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. Alpharma submitted the first substantially complete ANDA for store brand Children's liquid Motrin, along with a paragraph IV certification. Prior to April 1998, however, Alpharma had not been eligible for the 180-day exclusivity period, because McNeil did not sue Alpharma for patent infringement. Under the pre-April 1998 FDA regulations, the first ANDA filer would receive the 180-day exclusivity for its generic product only if it successfully defended a patent lawsuit filed against it.

21. By early 1998, Perrigo and Alpharma both had received tentative regulatory approval for their store brand versions of Children's liquid Motrin. At that time, branded Children's Motrin's three-year marketing exclusivity (set to expire in June 1998) was the only exclusivity period blocking FDA from granting final approval of the Perrigo and Alpharma ANDAs. Defendants began actively competing to secure customers in anticipation of their expected store brand Children's liquid Motrin product launches when that exclusivity expired.

22. Perrigo approached customers first, gaining many customer commitments to purchase Perrigo's product once it received FDA approval to go to market. By March 1998, Alpharma recognized that Perrigo was handily winning this pre-launch competition and that it needed to lower its prices to secure remaining uncommitted accounts. Alpharma responded by offering new, discounted prices – nearly 20% off its initial bids – to certain major accounts.

23. Faced with Alpharma's aggressive new pricing strategy, Perrigo reacted by cutting its own price to win or retain customer commitments. Some large purchasers successfully leveraged the Alpharma-Perrigo rivalry to obtain significantly lower prices. For example, one

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. Alpharma, 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 Alpharma. Alpharma'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 Alpharma's U.S. Pharmaceutical Division to propose an arrangement that would allow Perrigo to enter the market during Alpharma's 180-day exclusivity period. In response, Alpharma 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 Alpharma 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 Alpharma. 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 to confront such competition from any company other than Alpharma for at least 18 months. Accordingly, Perrigo predicted – by eliminating competition from Alpharma – it could charge a price that was 35% higher, and earn millions of dollars in additional revenues. Perrigo concluded it was willing to agree to a long-term transaction and pay the amount Alpharma demanded, but only if the agreement precluded Alpharma from competing.

29. Alpharma also calculated the value to Perrigo if Alpharma did not compete. Based on its own financial models, entitled – "If we exit our business value to Perrigo" –

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 and Alpharma Allocate the Market

30. On June 16, 1998, Alpharma and Perrigo signed an agreement that eliminated the companies' vigorous competition to secure customers of store brand Children's liquid ibuprofen. Under the agreement, Alpharma promised to refrain from marketing, distributing, or selling its store brand Children's liquid Motrin product for seven years and Perrigo obtained the exclusive right to do so during that period.

31. Alpharma also gave up the right to decide unilaterally whether to compete with any other store brand Children's liquid ibuprofen product. Alpharma agreed not to market, distribute, or sell any other store brand Children's liquid ibuprofen product (such as a store brand liquid ibuprofen that is bioequivalent to the branded product Advil) unless it offered the product to Perrigo and Perrigo refused to exercise its right to market, distribute, or sell the product on its own.

32. In exchange for Alpharma's promises not to compete, Perrigo agreed to pay Alpharma a lump sum fee of $3.5 million plus a royalty equal to 20% of Perrigo's net sales of store brand Children's liquid Motrin during the first three years of the agreement, and 15% royalty thereafter.

33. Defendants understood that Perrigo was paying these funds as consideration for Alpharma's promise not to compete with any store brand Children's liquid ibuprofen product.

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 granted final approval to Alpharma's ANDA; and (3) Perrigo could unilaterally terminate the agreement without penalty if Alpharma did not obtain FDA approval and waive exclusivity in favor of Perrigo by August 3, 1998.

36. Shortly after signing their agreement, defendants encountered two complications that delayed each party's ability to obtain the negotiated benefits of their anticompetitive transaction. First, the FDA granted McNeil's request for a six-month pediatric exclusivity period

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, Alpharma 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 Alpharma obtained final approval of its ANDA. Accordingly, until it obtained FDA approval, Alpharma'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, Alpharma 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 Alpharma 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 Alpharma to obtain a price savings. For example, one national chain had successfully leveraged the pre-agreement competition between Perrigo and Alpharma to obtain a 40%

discount for its initial purchases. In July 1999, however, following Alpharma's promise not to compete, Perrigo raised that chain's price by 64%.

39. In April 1999, four months after Perrigo entered with its store brand Children's liquid Motrin product, Alpharma received final FDA approval for its competing store brand Children's liquid Motrin product. Consistent with its promise not to compete against Perrigo, however, Alpharma has never sold this product in the market.

40. At all times since executing their June 1998 agreement, Perrigo and Alpharma have been the only two companies to obtain FDA approval for a generic version of liquid ibuprofen that is bioequivalent to Children's Motrin.

41. As of the date of this complaint, Perrigo remains the only company selling store brand Children's liquid Motrin, or any other store brand Children's liquid ibuprofen product, to customers.

42. In May 2004, defendants rescinded their non-compete agreement in the face of an FTC investigation.

The Agreement is Anticompetitive

43. Perrigo and Alpharma's seven-year agreement to stop competing is a naked restraint on competition, i.e., an agreement without any redeeming value. The agreement to stop competing is not ancillary to any efficiency enhancing purpose. Any purported post-agreement benefits to consumers are speculative, and in any event, were not contemplated by Perrigo and Alpharma when they agreed to eliminate competition between them. Moreover, Perrigo and Alpharma could have achieved any such purported benefits without agreeing to stop competing for seven years. The agreement therefore is per se unlawful.

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.

RESPECTFULLY SUBMITTED,

William E. Kovacic
General Counsel

Susan A. Creighton
Director

Bernard A. Nigro, Jr.
Deputy Director
D.C. Bar No. 412357

Jeffrey W. Brennan
Assistant Director
D.C. Bar No. 447438

Bradley S. Albert
Ellen Connelly
Garth W. Huston

Attorneys
Bureau of Competition

Attorneys for Plaintiff

By:

_____

Michael Kades
Attorney for Plaintiff
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-3681

Dated: August _____, 2004