ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Perrigo Company and Paddock Laboratories, Inc.

File No.* 111-0083 *C-4329

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Perrigo Company ("Perrigo") and Paddock Laboratories, Inc. ("Paddock") that is designed to remedy the anticompetitive effects resulting from Perrigo's acquisition of Paddock. Under the terms of the proposed Consent Agreement, the companies would be required to divest to Watson Pharmaceuticals, Inc. ("Watson") Paddock's rights and assets necessary to manufacture and market generic: (1) ammonium lactate external cream 12 percent ("ammonium lactate cream"); (2) ammonium lactate topical lotion 12 percent ("ammonium lactate lotion"); (3) ciclopirox shampoo 1 percent ("ciclopirox shampoo"); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg ("promethazine suppository"). The proposed Consent Agreement also requires the companies to divest to Watson all of Perrigo's rights and assets necessary to manufacture and market generic clobetasol proprionate spray 0.05 percent ("clobetasol spray") and diclofenac sodium topical solution 1.5 percent ("diclofenac solution"). Further, the proposed Consent Agreement prohibits the companies from accepting certain payments under a backup supply agreement between Paddock and Abbott Laboratories ("Abbott") for Androgel, the branded version of testosterone gel 1 percent ("testosterone gel"), and entering into any "pay-for-delay" arrangements with Abbott.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to a Purchase Agreement dated January 20, 2011, Perrigo plans to acquire substantially all of Paddock's assets for $540 million. The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceuticals: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the "Products"); and (7) testosterone gel. The proposed Consent Agreement will remedy the alleged violations in each of these markets.

II. The Products and Structure of the Markets

The proposed acquisition would reduce the number of generic suppliers in six generic drug markets. The number of generic suppliers has a direct and substantial impact on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here and the branded products are substantially more expensive than the generic versions, the branded versions no longer significantly constrain the generics' pricing.

The proposed acquisition would reduce the number of competitors from three to two in four markets: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; and (4) promethazine suppository. The structure of each of these markets is as follows:

- The ammonium lactate cream and lotion products are both prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. In 2010, annual sales of ammonium lactate cream were approximately $9.7 million, while sales of the ammonium lactate lotion totaled $19 million. The same firms compete in both markets – Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. ("Taro"), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo leads the market for ammonium lactate cream with a 70 percent share in the United States. Paddock has 17 percent of the market and Taro has 12 percent. In the market for ammonium lactate cream, the combined firm would account for 87 percent after the proposed acquisition. Perrigo and Paddock are the leading U.S. suppliers of ammonium lactate lotion, with 43 percent and 50 percent of the market, respectively. Taro has only captured a 5 percent market share to date. Post-acquisition, Perrigo's share would increase to 93 percent of the market.

- Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Paddock is the leading supplier in the $14.5 million market for ciclopirox shampoo, with a share of approximately 83 percent. Perrigo, with a share of 16 percent, and E. Fougera & Co., with a 1 percent share, are the only other U.S. suppliers of the product. The proposed acquisition, therefore, would result in a combined market share of 99 percent.

- Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. Sales of the 12.5 mg and 25 mg strengths were approximately $7.9 million and $36.1 million in 2010, respectively. Perrigo, Paddock, and G&W Laboratories, Inc. ("G&W") are the only U.S. suppliers of both strengths. For the 12.5 mg strength, Perrigo has 15 percent of the market, Paddock has 19 percent, and G&W has 66 percent. For the 25 mg strength, Perrigo has 15 percent of the market, Paddock has 20 percent, and G&W has 65 percent. A combined Perrigo and Paddock would possess 34 percent of the 12.5 mg market and 35 percent of the 25 mg market.

Both Perrigo and Paddock also are developing products for two future generic drug markets: (1) clobetasol spray and (2) diclofenac solution. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are among a limited number of suppliers that are capable of, and interested in, entering these markets in a timely manner. Accordingly, the proposed acquisition would eliminate important future competition in these markets.

Finally, the proposed acquisition also could inhibit important future competition in the testosterone gel market. Testosterone gel, marketed by Abbott under the brand name Androgel, is a prescription gel used to treat adult males with a testosterone deficiency. Perrigo is one of a limited number of suppliers capable of entering this future generic market in a timely manner. Pursuant to an agreement between Par Pharmaceutical Companies, Inc. ("Par"), Paddock, and Solvay Pharmaceuticals, the former owner of Androgel, Par agreed to delay introducing a generic version of Androgel in exchange for, among other things, payments under a backup supply agreement. That agreement has since been transferred to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product.

III. Entry

Entry into the markets for the manufacture and sale of the products would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and U.S. Food and Drug Administration ("FDA") drug approval requirements take a minimum of two years. Furthermore, entry would not be likely because many of the relevant markets are small, so the limited sales opportunities available to a new entrant would likely be insufficient to warrant the time and investment necessary to enter.

IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. The evidence shows that with the entry of each additional competitor, the prices of the generic products at issue have decreased. Customers consistently state that the price of a generic drug decreases with the entry of the second, third, and even fourth competitor. In these markets, the proposed acquisition would eliminate one of only three competitors. The evidence indicates that anticompetitive effects – both unilateral and coordinated – are likely to result from a decrease in the number of independent competitors in these markets, thereby increasing the likelihood that customers will pay higher prices.

The proposed acquisition also eliminates or delays important future competition between Perrigo and Paddock in the U.S. markets for clobetasol spray and diclofenac solution. Perrigo's and Paddock's independent entry into these markets likely would have resulted in lower prices for customers. The proposed acquisition would deprive customers of the expected price decrease that would occur upon the parties' entry into these markets.

Similarly, the proposed acquisition increases the likelihood and degree of coordinated interaction between Perrigo and Abbott in the U.S. testosterone gel market. Perrigo would become a party to the Par/Paddock backup supply agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product. Perrigo's independent entry into the market likely would result in lower prices for customers. The proposed acquisition could therefore deprive customers of the expected price decrease that would ensue upon Perrigo's timely entry into the market.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant product markets by requiring a divestiture of the Products to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

The Consent Agreement requires that the parties divest rights and assets related to the Products to Watson. Watson is the third largest generic drug manufacturer in the United States, and well-situated to manufacture and market the acquired products. Watson has extensive experience in the development, manufacturing, and distribution of generic pharmaceuticals, as well as experience transferring assets from other pharmaceutical companies. Watson has approximately 325 active products and an active product development pipeline. Moreover, Watson's acquisition of the divested assets does not in itself present competitive concerns because Watson does not compete, nor does it have plans to independently enter, any of the markets affected by the proposed transaction. With its resources, capabilities, strong reputation, and experience manufacturing and marketing generic products, Watson is well-positioned to replicate the competition that would be lost with the acquisition.

If the Commission ultimately determines that Watson is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Watson is not acceptable, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Perrigo and Paddock to provide transitional services to enable Watson to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same

manner and quality employed or achieved by Perrigo and Paddock. In addition, the parties must supply Watson with the Products pursuant to a supply agreement while they transfer the manufacturing technology to a third-party manufacturer of Watson's choice.

The Consent Agreement also preserves competition in the market for testosterone gel by prohibiting the parties from: (1) receiving any payments that accrue after the initial term of the backup supply agreement aside from those for manufacturing the product; and (2) entering into any anticompetitive pay-for-delay arrangements with Abbott regarding the testosterone gel product.

The Commission has appointed F. William Rahe of Quantic Regulatory Services, LLC ("Quantic") as the Interim Monitor to oversee the asset transfer and to ensure Perrigo and Paddock's compliance with the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.