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Office of the Secretary

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

June 21, 2012

Richard A. Samp Chief Counsel Washington Legal Foundation 2009 Massachusetts Ave., NW Washington, DC 20036

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

File No. 111 0083, Docket No. C-4329

Dear Mr. Samp:

This letter responds to your comments on behalf of the Washington Legal Foundation ("WLF") regarding the consent order accepted for public comment involving the acquisition by Perrigo Co. of Paddock Laboratories, Inc. WLF objects to provisions contained in the proposed order that were designed to preserve potential competition as to testosterone gel products, on the grounds that there is no competitive issue with regard to these products and that the proposed relief is inappropriate. But, as discussed below, your objections are unfounded.

After considering your comments, the Commission has determined not to accept your suggestion that Paragraphs IV.A and IV.B be deleted. The Commission, however, has modified Paragraph IV.B by adding language to clarify that those restrictions apply as long as the existing Perrigo/Abbott supply agreement, any extension of that supply agreement, or any later supply agreement, is in effect. The Commission has decided not to delete Paragraph IV.A, and not to delete Paragraph IV.B as long as Perrigo and Abbott have a supply agreement in effect, because, as we explain below, the relief incorporated in those paragraphs appropriately addresses competitive concerns arising from the merger and is well within the "wide latitude" the Commission has in fashioning effective remedies.¹

WLF's comments appear to overlook the nature of the competitive concerns created by the transaction. These concerns arose because (1) at the time of the proposed consent, Perrigo was a uniquely positioned potential seller of a generic version of AndroGel, a leading testosterone gel product, and (2) Paddock had a supply relationship with the manufacturer of

¹ Jacob Siegel Co. v. FTC, 327 U.S. 608, 612-13 (1946).

branded AndroGel (Abbott Laboratories) allowing Paddock to share in revenues from sale of the branded product. Perrigo, unlike other potential generic AndroGel competitors (including Paddock), had neither been sued for patent infringement nor agreed to refrain from launching a generic product until 2015.² Perrigo was thus positioned to market a generic AndroGel product upon receipt of FDA approval of its product.

In light of the supply relationship between Paddock and Abbott, Perrigo's acquisition of Paddock threatened to substantially lessen competition by reducing Perrigo's incentives to compete with a generic version of AndroGel. As noted in the Commission's Analysis to Aid Public Comment, Paddock has served as a backup supplier of branded AndroGel under an agreement reached in 2006. The initial term of this agreement runs through September 30, 2012, and the agreement is extendable. Thus, Perrigo, via the deal with Paddock, has the potential to share in branded AndroGel revenues under the supply agreement in two ways -- through a \$2-million-per-year service fee, and also through additional fees Abbott would pay should it order product under the agreement. Perrigo's merger with Paddock created a partnership with Abbott that could have undermined Perrigo's incentives to develop and market its generic AndroGel product at the earliest opportunity. Specifically, Abbott could extend the supply agreement with Paddock, and the \$2 million-per-year service fee and additional fees for product supply could have compensated Perrigo -- now the owner of Paddock -- for delaying its entry into the market, whether as part of a patent settlement, if there were a lawsuit, or simply as an extension of the supply agreement in the absence of a lawsuit.

Harm to competition from arrangements that could reduce a company's incentives to vigorously compete is a well-recognized antitrust concern.³ The harm here could be particularly acute, as available evidence suggests that entry by a producer of generic AndroGel would save consumers hundreds of millions of dollars annually. The proposed order addresses these concerns. Paragraph IV.A. of the proposed order prohibits Perrigo from receiving \$2 million annual payments from Abbott under the Paddock back-up supply agreement. Paragraph IV.B. prohibits Perrigo from agreeing to delay its entry with its generic AndroGel in exchange for anything of value, with an exception for patent settlements in which Perrigo receives

² This changed on October 31, 2011, when Abbott sued Perrigo for patent infringement. *See* "Perrigo Confirms Filing for Testosterone Gel 1.0 and Announcement of Patent Infringement Lawsuit by Abbott" (Nov. 2, 2011), *available at* http://www.perrigo.com/uploadedFiles/Investors/Press_Releases/ANDRO.pdf; *contrast* WLF Comment at 10 ("WLF is at a loss to comprehend how any such lawsuit might come about."). The lawsuit was dismissed on December 28, 2011, following a settlement limited by the terms of Paragraph IV.B of the order in the form accepted by the Commission for public comment. Under the terms of Paragraph 18 of the Agreement Containing Consent Order, Respondents were obligated to honor the consent order, and the limitations of Paragraph IV.B, even though the order was not final.

³ See, e.g., Federal Trade Commission and United States Department of Justice, Antitrust Guidelines for Collaborations Among Competitors, § 2.2 (April 2000), available at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf (agreements among competitors may "reduce the participants' ability or incentive to compete independently.").

nothing more than reasonable litigation expenses. Paragraph IV.B. thus ensures that Perrigo's acquisition of the pre-existing supply agreement, including potentially substantial fees it could receive for supplying product to Abbott, does not result in delayed entry or termination of Perrigo's generic product.⁴

WLF's various criticisms do not address the nature or extent of the competitive concern generated by the transaction. For example, WLF asserts that neither Perrigo nor Paddock currently markets a competing generic version of AndroGel; that is correct, but is of no moment. The Commission routinely and appropriately acts to protect consumers from future harm to competition. WLF also argues that Perrigo is unlikely to obtain FDA approval, but such a statement is mere speculation and provides no basis for the Commission to ignore the significant potential harm to consumers from the merger.

WLF also makes a number of assumptions that are simply wrong. WLF mistakenly asserts that under the terms of the supply agreement the only source of potential revenues is the \$2 million per year flat payment. WLF is also incorrect in asserting that a risk of harm would arise only if Abbott sued Perrigo for patent infringement. WLF suggests that, absent such a patent suit, any payment would simply be a naked restraint of trade, which, it argues, no company would entertain. While the Commission agrees that such an agreement, absent a patent settlement, would indeed be a naked restraint of trade, it is not correct that no company would enter into such an agreement. Indeed, there is at least one recent instance of a branded

⁴ The modification adds language at the beginning of Paragraph IV.B. That paragraph, as modified, limits the effect of Paragraph IV.B to those times when Respondents are party to an AndroGel back-up supply agreement, whether or not that supply agreement has been triggered. Thus, Paragraph IV.B remains in effect at least through September 30, 2012, when the initial term of back-up supply agreement will end. If that agreement is extended, Paragraph IV.B will continue in effect, at least through the new expiration date. If the agreement is not extended beyond September 30, Paragraph IV.B will at that time not apply, unless and until Abbott and Perrigo enter into a new supply agreement. If they do, Paragraph IV.B - under the terms of the order as originally drafted and now also as modified - will continue to apply.

⁵ See, e.g., In re Watson/Arrow, No. C-4276, Analysis to Aid Public Comment, at 1 (Dec. 2, 2009), available at http://www.ftc.gov/os/caselist/0910116/0910116watsonanal.pdf ("The proposed acquisition would eliminate significant future competition by reducing the number of potential generic suppliers in each of the relevant markets."); In re Teva/IVAX, No. C-4155, Analysis to Aid Public Comment, at 4 (Jan. 23, 2006), available at http://www.ftc.gov/os/caselist/0510214/0510214analysis.pdf ("[T]he proposed acquisition would eliminate important future competition in several markets"); In re Baxter/Wyeth, Docket No. C-4068, Analysis to Aid Public Comment (Dec. 20, 2002), available at http://www.ftc.gov/os/2002/12/baxter-wyethanalysis.htm ("The proposed Consent Agreement preserves future competition" in several markets.).

product manufacturer, outside of patent litigation, paying its potential generic competitor to supply the brand rather than compete.⁶ With the incentives created by the pre-existing supply agreement, which Perrigo acquired, and the harm such a naked restraint could cause, an order provision limiting that possibility is appropriate. Moreover, contrary to WLF's assumption, Abbott did indeed sue Perrigo. *See supra* note 2.

With respect to WLF's concerns about the nature of the proposed relief, a straightforward form of relief would, of course, be to end the supply relationship between Perrigo and Abbott on a going-forward basis. On the understanding that such a termination was not easily accomplished due to existing contractual obligations and given the interest of the merging parties in proceeding as quickly as possible with the acquisition, the Commission included the alternative, more limited relief discussed above. The provision, which Perrigo and Paddock agreed to, is narrowly tailored to the specific overlap created by the merger. WLF's accusations that the proposed relief amounts to a "lawless" "extra-judicial" "stealth campaign" against pay for delay agreements are simply at odds with the facts here.

Separately, WLF makes a baseless and false allegation that FTC staff attorneys demanded that Paddock terminate a joint defense agreement, so that staff would be able to gain access to privileged documents. The Commission could justifiably ignore such allegations when they are limited to nothing more than an unsupported comment in a letter, but nonetheless elects to respond. There is absolutely no truth to any part of the allegation. Commission staff conducted itself with the highest degree of professionalism during the entire investigation.

For the above reasons, the Commission sees no reason to modify the order as you have suggested. We nevertheless appreciate your interest in this matter.

By direction of the Commission, Commissioner Ohlhausen not participating.

Donald S. Clark Secretary

⁶ See Complaint for Injunctive and Other Equitable Relief, FTC v. Warner Chilcott Holdings Co., No 05-2179 (D.D.C. Nov. 7, 2005), available at http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf (challenging agreement not to compete on drug with no patent protection).