Perrigo Paddock, File No. 111-0083

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FEDERAL TRADE COMMISSION

Concerning

REQUESTS FOR COMMENTS ON PROPOSED CONSENT AGREEMENT REGARDING ALLEGED ANTICOMPETITIVE EFFECTS OF PERRIGO'S ACQUISITION OF PADDOCK LABORATORIES

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Submitted Electronically
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex D)
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: FTC Proposed Consent Agreement Regarding Alleged Anticompetitive Effects of Perrigo's Acquisition of Paddock Laboratories -- Comments Perrigo Paddock, File No. 111-0083
76 Fed. Reg. 45801 (August 1, 2011)

Dear Commissioners:

The Washington Legal Foundation (WLF) appreciates this opportunity to submit these comments to the Federal Trade Commission (FTC) in connection with the FTC's proposed Consent Agreement with Perrigo Co. and Paddock Laboratories, Inc. WLF is a non-profit public interest law and policy center based in Washington, D.C. with supporters nationwide. WLF promotes free-market policies through litigation, administrative proceedings, publications, and advocacy before state and federal government agencies, including the FTC.

The proposed Consent Agreement arises in connection with Perrigo's agreement to purchase substantially all of the assets of Paddock. As set forth below, WLF strongly objects to one provision of the Consent Agreement, relating to future competition in the market for testosterone gel. The Consent Agreement would: (1) restrict Perrigo/Paddock's right to receive payments in connection with the 2006 settlement of patent infringement litigation filed against Paddock; and (2) bar Perrigo from accepting money to settle hypothetical future patent infringement litigation that might be filed against it by the patent holder for AndroGel, a brand-name testosterone gel currently marketed by Abbott Laboratories. The FTC contends that this provision is necessary because, in its absence, Perrigo's acquisition of Paddock would substantially lessen competition in the market for testosterone gel. The FTC provides no support for its contention, a contention that is belied by all available evidence.

Indeed, the FTC's decision to insist upon the provision can only be explained as an effort to expand its campaign against so-called "reverse payment" settlements of patent disputes between brand-name drug manufacturers and generic drug manufacturers. WLF does not dispute the FTC's right to carry on that campaign in the courts, albeit we note that every

federal appellate court to address the issue has rejected the FTC's position regarding the antitrust implications of such settlements. But WLF strenuously objects to the FTC's lawless efforts to punish companies that have entered into reverse payment settlements, when the punishment arises (as here) in contexts to which past settlements have no conceivable relevance and in which there is no possibility that competition could be threatened. The Commission needs to understand that with great power comes great responsibility. Given the FTC's ability to disrupt Perrigo's acquisition of Paddock, it is unsurprising that Perrigo would not contest the testosterone gel provision. But simply because the FTC can insist on such provisions does not mean that it should do so when there is neither a legal nor a factual basis for the provisions. WLF requests that the Commission eliminate all references to the testosterone gel issue before approving the Consent Agreement.

I. *Interests of the Washington Legal Foundation*

The Washington Legal Foundation is a public interest law and policy center based in Washington, D.C., with members and supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. To that end, WLF regularly appears before federal and State courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government. WLF has frequently appeared as *amicus curiae* in the federal courts to address the proper scope of the antitrust laws. *See*, *e.g., Pacific Bell Tel. Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009); *Weyerhaeuser Co. v. Ross-Simmons Hardware Lumber Co.*, 549 U.S. 312 (2007); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 127 (2007). In particular, WLF filed briefs in several of the principal federal appeals court cases that are addressing or have addressed the "reverse payment" patent settlement issue discussed herein. *See, e.g., In re K-Dur Antitrust Litigation*, No. 10-2077 (3d Cir., dec. pending); *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005), *cert denied,* 548 U.S. 919 (2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

WLF is filing these comments due to its interest in promoting the efficient settlement of patent disputes, as well as its interest in ensuring that federal agencies do not take actions in excess of their statutory mandate. WLF has no ties with any of the pharmaceutical companies involved in this matter and has not discussed its comments with them. WLF takes no position regarding the propriety of provisions of the Consent Agreement other than those relating to testosterone gel.

II. FTC's Statutory Authority

Federal law authorizes the FTC to prevent businesses and individuals (with certain limited exceptions) from "using unfair methods of competition in or affecting commerce and

unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(2). The FTC "shall have no authority" to declare an act or practice unfair unless it is "likely to cause substantial injury to consumers," *and* the injury "is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n). It is empowered to issue cease-and-desist orders, ordering individuals and entities not to engage in acts or practices it determines to be in violation of the FTC Act. 15 U.S.C. § 45(b).

III. Perrigo's Agreement to Purchase Paddock

Both Perrigo and Paddock are corporations that have been engaged in the manufacture and sale of generic prescription drugs. On January 20, 2011, Perrigo and Paddock signed an agreement whereby Perrigo agreed to purchase substantially all of Paddock's assets for $540 million. The Commission responded by filing a Complaint, alleging that the effects of the acquisition might be "to substantially lessen competition and to tend to create a monopoly in the relevant markets," in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. In support of its allegations, it cited the market for testosterone gel; competition in that market allegedly would be lessened:

> [B]y (1) increasing the likelihood and degree of coordinated interaction between Perrigo and Abbott in the market for testosterone gel; (2) increasing the likelihood that the combined entity would forego or delay the launch of Perrigo's product in the testosterone gel market; and (3) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's independent entry into the testosterone gel market.

Complaint 4-5.

The Complaint failed to mention that neither Paddock nor Perrigo held an FDA-approved ANDA (Abbreviated New Drug Application) for a testosterone gel product, and thus neither was authorized to enter the market. The Complaint also failed to mention that the only testosterone product on the market, Abbott Laboratories's AndroGel, is protected by an Abbott patent that will not expire until 2020. It also failed to mention that when Perrigo filed an ANDA for a testosterone gel product in 2009, Solvay Pharmaceuticals, Inc. (Abbott's predecessor-in-interest on the AndroGel patent) announced that it would not file a patent infringement suit against Perrigo because it had determined that Perrigo's proposed product did not violate the AndroGel patent (because the product's formulation was distinct from the formulation protected by the patent).

Despite the absence of evidence that either Paddock or Perrigo has ever competed in the testosterone gel market or that the combined entity is likely to do so in the foreseeable future,

the FTC insisted that the Consent Agreement include the provision to which WLF objects. The Commission's contention that the provision is necessary to prevent a lessening of competition is belied by the absence of evidence of past competition, the absence of evidence of likely competition in the foreseeable future, and the absence of evidence that Abbott has any plans to, or grounds for, seeking to prevent Perrigo's entry into the market.

IV. Paddock's Patent Litigation Settlement with Solvay

The FTC's concern regarding lessened competition in the testosterone gel market apparently stems from a patent litigation settlement agreement entered into between Solvay and Paddock. The Patent and Trademark Office (PTO) in January 2003 issued a patent to Solvay (the "'894 patent") for the gel formulation used in AndroGel; that patent is not set to expire until August 2020. In May 2003, Paddock filed an ANDA for generic AndroGel. The ANDA included a Paragraph IV certification, *i.e.,* an assertion that the patent protecting the brand-name drug (the '894 patent) was invalid and/or was not infringed by Paddock's proposed generic version of AndroGel.

Solvay responded to the Paragraph IV certification by filing a patent infringement suit against Paddock in August 2003. Apparently in anticipation of expensive patent infringement litigation, Paddock in July 2003 entered into an agreement with Par Pharmaceuticals, Inc. whereby, in return for a share of the profits from marketing the generic product, Par agreed to share Paddock's litigation costs and to sell the generic product once it was approved for marketing. The filing of Solvay's infringement lawsuit placed an automatic 30-month stay on any FDA approval of Paddock's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

By December 2005 following extensive discovery, the parties had filed summary judgment motions on the validity of the '894 patent.[1] In September 2006, while the motions were still pending, Solvay and Paddock entered into a settlement agreement, a settlement that was memorialized as a consent judgment by the U.S. District Court for the Northern District of Georgia. Although the '894 patent (if upheld) would have excluded Paddock from the market until 2020, Solvay agreed pursuant to the settlement to permit Paddock to begin marketing its generic product no later than February 2016, and Paddock agreed not to market its product until then (or a somewhat earlier date, depending on the actions of Watson and

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[1] Although FDA had granted preliminary approval to Paddock's ANDA by early 2006 and although the 30-month stay had expired, FDA did not give final approval to Paddock's ANDA because Paddock was only the second generic company to file an ANDA for generic AndroGel. That first filer was Watson Pharmaceuticals, Inc. As the first filer, Watson was entitled to a 180-day exclusivity period for the marketing of generic AndroGel. 21 U.S.C. § 355(j)(5)(B)(iv).

other generic manufacturers). In conjunction with the litigation settlement, Solvay entered into an agreement with Par whereby: (1) Solvay would share profits on AndroGel with Par and Paddock worth about $6 million annually to Par and about $2 million annually to Paddock); (2) Par agreed to promote AndroGel to primary care physicians; and (3) Paddock agreed to serve as a backup supplier of AndroGel.[2]

The FTC asserts, "Par agreed to delay introducing a generic version of AndroGel in exchange for, among other things, payment under a backup supply agreement." 76 Fed. Reg. at 45803. That statement is highly misleading, because it makes no mention of the '894 patent, which bars anyone from introducing a generic version of AndroGel until 2020. Paddock and Par (which eventually purchased the ANDA from Paddock) cannot be said to have "delayed" introducing a generic product unless one assumes (contrary to the presumption of patent validity) that the '894 patent is invalid. By entering into a settlement agreement of Solvay's patent infringement litigation, Paddock and Par ensured that generic competition began four (and perhaps five) years *earlier* than if the infringement litigation had not settled and the courts had upheld the '894 patent.

V. FTC's Unsuccessful Lawsuit Against Paddock and Par

For many years, the FTC has maintained its position that pharmaceutical patent settlements that entail payments from the patent holder to the alleged infringer violate the antitrust laws because of their alleged tendency to lessen competition. Because the litigation settlement between Solvay and Paddock entailed the payment of money from Solvay to Paddock, the FTC began an investigation of the circumstances surrounding the settlement. In 2009, the FTC filed suit against Solvay, Paddock, Par, and Watson (which had entered into a separate patent litigation settlement with Solvay), alleging violation of the Sherman Act and § 5(a) of the FTC Act.

In February 2010, a federal district court in Atlanta dismissed the FTC's claims under Fed.R.Civ.P. 12(b)(6) for failure to state a claim upon which relief could be granted. *In re: Androgel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010). Relying on Eleventh Circuit precedent, the district court ruled that because the FTC did not allege that the

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[2] The FTC's "Analysis of Agreement Containing Consent Orders to Aid Public Comment" states that the agreement between Par and Solvay "has since been transferred to Paddock." Analysis at 3. That statement is incorrect. A September 13, 2006 agreement between Par and Solvay provided that Solvay would pay Par for, *inter alia*, providing backup supplies of AndroGel. Simultaneously, Par signed a letter to Paddock, designating Paddock as its Designee under the backup supply agreement. The backup supply agreement is no longer in effect.

patent settlements exceeded the scope of the '894 patent (*e.g.*, did not allege that the generic drug companies agreed not to compete even after the patent's 2020 expiration date), "it does not matter that the Defendants settled their patent disputes with reverse payments." *Id.* at 1379. The FTC has appealed that dismissal to the U.S. Court of Appeals for the Eleventh Circuit.

VI. Perrigo's ANDA for Generic AndroGel

Many years after the Solvay/Paddock patent litigation settlement and well before Perrigo began any negotiations to purchase Paddock, Perrigo in 2009 submitted its own ANDA for a generic version of AndroGel, along with a Paragraph IV certification that its proposed drug would not infringe the '894 patent. That certification triggered Solvay's obligation to file a patent infringement suit within 45 days (or else forfeit its right to a 30-month stay of issuance of the ANDA). On July 17, 2009, Solvay (through its Unimed Pharmaceuticals subsidiary) issued a press release announcing that it would not be filing an infringement suit. Solvay explained that it decided not to file suit against Perrigo because, according to the Paragraph IV certification, Perrigo's proposed testosterone gel product "contains a different formulation than the formulation protected by the AndroGel patent." Solvay explicitly contrasted the Perrigo ANDA with the ANDAs previously filed by Paddock and Watson, which "purported to be identical to the AndroGel formulation."

Of course, in order to obtain FDA approval for its pending ANDA, Perrigo will need to demonstrate *inter alia* that its proposed generic drug is "bioequivalent" to AndroGel – despite having a different formulation than the formulation protected by the '894 patent. Although it has been pending with FDA for more than two years, Perrigo's ANDA has not yet been approved. Indeed, FDA has given no indication that the ANDA will ever be approved. If it is approved, Abbott (Solvay's successor under the '894 patent) would not be absolutely barred from filing a patent infringement suit; but: (1) Abbott has given no indication that it is contemplating such a suit; and (2) any infringement claim would be undercut by Solvay's prior statements about the Perrigo ANDA and its several-year delay in filing suit.

VII. The FTC's Complaint and the Proposed Consent Agreement

Pursuant to a purchase agreement dated January 20, 2011, Perrigo agreed to purchase substantially all of Paddock's assets for $540 million. Following an investigation, the FTC issued a Complaint alleging that the acquisition might substantially lessen competition in several relevant markets, including the market for testosterone gel. In support of that allegation, the Commission cited the AndroGel backup supply agreement (pursuant to which Solvay was paying about $2 million annually to Paddock) and the Perrigo ANDA (which, if approved, could result in Perrigo's entry into the testosterone gel market). The FTC alleged that Perrigo's acquisition of Paddock's assets (including Paddock's rights under the backup

supply agreement) increased the likelihood that Perrigo/Paddock would "forego or delay the launch of Perrigo's product in the testosterone gel market" and would "delay or eliminate the substantial additional price competition that would have resulted" from such a launch.

Under the proposed Consent Agreement, Paddock/Perrigo agreed: (1) not to accept further payments under the backup supply agreement after its initial term expires in September 2012; and (2) not to settle any patent infringement suit that Solvay/Abbott might file against it in the future, under terms that include the payment of funds (other than reasonable litigation expenses) from Solvay/Abbott to Paddock/Perrigo. Although not required by the proposed Consent Agreement, Paddock/Perrigo (without waiting until September 2012) has terminated the backup supply agreement and is no longer accepting any funds under that agreement.

VIII. The FTC Has Failed to Demonstrate That the Consent Agreement Is Necessary to Prevent the Likelihood of Substantial Injury to Consumers

The provision regarding the testosterone gel market should be removed from the proposed Consent Agreement because the FTC lacks statutory authority to restrict Perrigo/ Paddock's activities in that market. The FTC has not shown and cannot show that there is any likelihood of substantially lessened competition in the testosterone gel market as a result of Perrigo's acquisition of Paddock's assets. In the absence of any evidence suggesting such a likelihood, the FTC has "no authority" to act. 15 U.S.C. § 45(n).

The FTC's concerns regarding the testosterone gel market apparently arose because Paddock entered into a "reverse payment" patent litigation settlement with Solvay in September 2006. Under the terms of the settlement, Paddock was permitted to enter the market with a generic version of AndroGel in either 2015 or 2016 (Solvay's '894 patent does not expire until 2020), and Solvay agreed to pay Paddock about $2 million per year for serving as a backup supplier of AndroGel. The FTC has taken the position that such settlements are suspect under the antitrust laws – the FTC contends that whatever the agreed date for generic entry, the parties would have agreed to an earlier entry date (thereby increasing competition) had no money been paid by the patent holder to the alleged infringer.

As the FTC is well aware, its views regarding the antitrust implications of "reverse payment" patent litigation settlements have been rejected by the federal courts on numerous occasions. *See, e.g., In re: Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 208-09 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005), *cert. denied,* 548 U.S. 919 (2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003). Indeed, a federal district court in Georgia has determined that the patent settlement entered into between Solvay and Paddock did not violate the antitrust laws and that the payment from Solvay to Paddock was not relevant to the antitrust

analysis. *In re: AndroGel Antitrust Litigation (No. II)*, 687 F. Supp. 2d at 1379. WLF does not fault the FTC for sticking to its guns and continuing to litigate. Even though (in light of the Eleventh Circuit's prior decisions in *Schering-Plough* and *Valley Drugs*) the FTC is almost certain to lose its appeal from the *AndroGel Antitrust Litigation* decision, there is always a chance that the Supreme Court will eventually hear the issue and decide it in the FTC's favor. The FTC is under no obligation to acquiesce in the court decisions handed down to date.

The FTC's inappropriate actions in this case suggest, however, that the Commission has been blinded by its unwavering belief in the justness of its legal position. Unable to prevail against Paddock in the courts, the FTC has determined to use its power in an inappropriate, bullying manner in order to let the world know that it really, really objects to "reverse payment" patent litigation settlements. WLF respectfully suggests that the FTC carefully examine whether its conduct in this case meets the high standards normally adhered to by the Commission.

Most disturbing to WLF are (unconfirmed) reports of inappropriate settlement demands conveyed by FTC officials while Perrigo and Paddock were attempting to convince the FTC to approve Perrigo's acquisition. We understand that FTC officials demanded, as a condition of settlement, that Paddock terminate its joint defense agreement with Par – an action that would have given the FTC access to a large number of documents currently protected by the attorney-client privilege. We can understand why FTC lawyers, intent on overturning their defeat in federal court antitrust litigation, would want to gain access to those documents. But we cannot fathom any legitimate reason for such a demand. Certainly, the existence of a joint defense agreement between Par and Paddock had little if any relevance to the issue that was before the Commission: whether Perrigo's acquisition of Paddock would substantially lessen competition. Simply because the extraordinary power wielded by the FTC means that many companies will accede to its demands is not a legitimate reason for the FTC to make demands that undermine the attorney-client privilege.

Moreover, the explanations provided by the FTC for demanding that Perrigo/Paddock enter into the Consent Agreement make little sense. The FTC contended that the acquisition would substantially lessen competition by:

> (1) increasing the likelihood and degree of coordinated action between Perrigo and Abbott in the market for testosterone gel; (2) increasing the likelihood that the combined entity [*i.e.*, Perrigo and Paddock] would forego or delay the launch of Perrigo's product in the testosterone gel market; and (3) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's independent entry into the testosterone gel market.

Complaint at 3-4. But when the FTC discusses the lessening of competition in the testosterone gel market, it overlooks the fact that AndroGel's formulation is protected (until 2020) by a patent issued by the PTO and thus there has never been *any* competition in that market. Indeed, the only reason that there is likely to be any competition prior to 2020 is that Paddock, by aggressively litigating its patent infringement defense for several years, persuaded Solvay to enter into a settlement agreement that permits Paddock (and now Par) to market its generic drug five years in advance of the patent's expiration.

The FTC asserts that the existence of the backup supply agreement (among Paddock, Par, and Solvay), somehow affects the likelihood that Perrigo will delay the launch of Perrigo's generic product. That assertion is without merit. First, the FTC's position presupposes that Perrigo possesses a product that it is capable of launching. That supposition is demonstrably untrue. It has been two years since Perrigo filed its ANDA, but Perrigo has yet to receive even preliminary approval for the ANDA from FDA. By all indications, Perrigo is having difficulty demonstrating that its testosterone gel formulation is bioequivalent to AndroGel; in the absence of such a demonstration, it will never gain approval of its ANDA. ANDA proceedings are undertaken in secret, so the FTC cannot possibly have any considered basis for concluding that the Perrigo ANDA will be approved. Yet, in the absence of evidence suggesting that the ANDA will be approved, the FTC has no basis for concluding that Perrigo's acquisition of Paddock will cause "substantial injury to consumers" in the testosterone gel market.

Second, the FTC's substantial-injury-to-consumers conclusion is wildly at odds with the economics of marketing generic versions of popular drugs such as AndroGel. The FTC's theory apparently proceeds as follows: Perrigo would not want to do anything to cut off the $2 million annual income steam that it was entitled to receive from Abbott/Solvay, and launching a generic drug would reduce the need for a backup source for AndroGel – thereby endangering Perrigo's income stream. Yet, in light of AndroGel's popularity, manufacturers of generic AndroGel are likely to earn tens of millions of dollars each year, even if several generic manufacturers end up entering the market. Given the economic incentives for Perrigo to launch its product, it is highly doubtful that Perrigo would delay marketing based solely on a fear that doing so might endanger the $2 million income stream.

Third, the FTC's Complaint presupposes that, in the absence of the Consent Agreement, Perrigo/Paddock and Solvay/Abbott would be willing to enter into a conspiracy in restraint of trade, in apparent violation of the antitrust laws. There is no pending patent litigation, so any payment from Solvay/Abbott to Perrigo/Paddock could not be explained as a bona fide settlement of disputed litigation. Rather, any such payment could only be offered as a naked inducement to persuade Perrigo/Paddock not to compete in the testosterone gel market. The FTC has presented no evidence to suggest that any of the companies involved has a predisposition to offer or accept payment under those conditions. And as the FTC concedes,

the backup supply agreement was scheduled to expire next year, so any payments beyond that date would need to be pursuant to a new agreement among the parties.

Fourth, the only realistic scenario under which Solvay/Abbott might be persuaded to make payments to Perrigo/Paddock would be in connection with the settlement of patent litigation between Solvay/Abbott and Perrigo. Yet, WLF is at a loss to comprehend how any such lawsuit might come about. In connection with its 2009 ANDA, Perrigo filed a Paragraph IV certification stating that its proposed generic product should be approved immediately because it did not infringe the '894 patent. That filing opened the door for Solvay to file a patent infringement lawsuit had it disagreed with Perrigo's certification. Yet, Solvay announced in July 2009 that it would *not* be filing suit, based on Perrigo's assurances that its proposed testosterone gel product contained a different formulation than the formulation protected by the '894 patent. By failing to file suit in 2009, Solvay forfeited its right to obtain a stay of FDA's approval of the ANDA, and Perrigo's product could be on the market right now if FDA had determined that the ANDA was properly approvable. Of course, Solvay/Abbott are not prohibited from changing their minds and filing a belated patent infringement suit, but the FTC has cited no evidence that Solvay/Abbott are contemplated doing so, and WLF is aware of none. The pendency of any such suit would do nothing to prevent the marketing of Perrigo's product. Moreover, Solvay would have a difficult time explaining to the judge hearing any such suit why, if it really believed that Perrigo's testosterone gel product infringed the '894 patent, it did not file suit in 2009. Accordingly, in the absence of any evidence suggesting that Solvay/Abbott is likely to file a patent infringement lawsuit against Perrigo, the FTC has no basis for demanding (as a means of preventing practices that are "likely to cause substantial injury to consumers") that Perrigo/Paddock sign a Consent Agreement promising not to accept a "reverse payment" in connection with a settlement of a hypothetical lawsuit by Solvay/Abbott. Moreover, even if there were evidence that Solvay and Abbott are contemplating a patent infringement lawsuit, the FTC has no reason to assume that the hypothetical lawsuit would be resolved through settlement and that the settlement terms would include a monetary payment from Solvay/Abbott to Perrigo.

The FTC's decision to nonetheless force Perrigo/Paddock to accept the AndroGel-related provisions of the Consent Agreement is an abuse of the Commission's powers. The FTC obviously feels very strongly that "reverse payment" patent litigation settlements are harmful to competition. The Commission has available to it several authorized methods of pursuing its policy goal, include urging Congress to adopt legislation prohibiting "reverse payment" settlements or bringing enforcement actions against entities that have entered into such settlements. But it is wholly inappropriate for the FTC, having lost in the courts in its efforts to have the Paddock/Par/Solvay settlement declared illegal, to retaliate by threatening to block the Perrigo acquisition of Paddock unless Perrigo agrees in advance never to enter into a reverse payment settlement of a hypothetical patent infringement lawsuit.

The FTC may someday prevail in the courts on its contention that the antitrust laws prohibit pharmaceutical companies from entering into reverse payment patent litigation settlements. But until that time arrives, the FTC should cease attempting to browbeat pharmaceutical companies into complying with its policy goals through use of extra-judicial enforcement methods not authorized by statute.

CONCLUSION

WLF respectfully requests that the FTC remove from the Consent Agreement the provisions related to future competition in the market for testosterone gel. The FTC has not shown that there is any likelihood of substantially lessened competition in the testosterone gel market as a result of Perrigo's acquisition of Paddock. In the absence of evidence suggesting such a likelihood, the FTC has no authority to act.

Sincerely,

Daniel J. Popeo
Chairman and General Counsel

Richard A. Samp
Chief Counsel