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New FTC Chairman Leibowitz Will Seek the Demise of Pharmaceutical “Pay-for-Delay” Settlements

President Obama’s appointment of Jon Leibowitz as the Chairman and head of the Federal Trade Commission (“FTC” or “Commission”) will likely precipitate the resolution of a lingering antitrust question in the pharmaceutical industry: Does it violate the antitrust laws for a branded drug company to settle a patent infringement lawsuit by paying an alleged generic infringer millions of dollars not to market its lower-cost version of the drug? Courts generally permit such payments so long as they don’t “settle” sham litigation or exceed the scope of the patent protection. Chairman Leibowitz has called these judicial decisions “misguided,” however. He, President Obama, and their like-minded friends in Congress prefer the FTC’s historically favored approach that would deem anticompetitive any agreement where a brand pays a generic a large sum to delay entry.

Strong presidential and congressional support will likely embolden new FTC Chairman Leibowitz to press his agenda of eliminating pay-for-delay settlements. In the past, Leibowitz has vehemently attacked the courts’ rulings.¹ In his March 2009 Letter from the Chairman, he described eliminating these settlements as a “leading priority” for the Commission.² He and the FTC apparently have like-minded friends in Congress; on March 25, 2009 Representatives Rush, Waxman, and Dingell among others co-sponsored a House bill that

would essentially ban pay-for-delay settlements.³ President Obama concurs. As a senator, he co-sponsored a bill nearly identical to the House legislation.⁴ Moreover, while campaigning for the presidency, Obama promised that his “administration [would] ensure that the law effectively prevents anticompetitive agreements that artificially retard the entry of generic pharmaceuticals onto the market”⁵ Thus supported, Leibowitz will likely push the Commission to continue challenging pay-for-delay settlements and press Congress for legislation overturning the court’s “misguided” opinions.

¹ Jon Leibowitz, Comm’r, Fed. Trade Comm’n, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They’re B-a-a-a-ck!* at 1, Remarks at the Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust (Apr. 24, 2006), available at <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>.

² Fed. Trade Comm’n, *The FTC in 2009: Federal Trade Commission Annual Report*, Letter from the Chairman, (March 2009), available at <http://www.ftc.gov/opa/2009/03/annualrpt.shtm>.

³ Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. § 2 (1st Sess. 2009).

⁴ Preserve Access to Affordable Generics Act, S. 316, 110th Cong. § 3(2) (1st Sess. 2007); 153 Cong. Rec. S11505 (daily ed. Sept. 12, 2007).

⁵ Senator Barack Obama, Statement for the American Antitrust Institute at 2, available at http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf.

The Statutory Backdrop and Policy Issues Impacting Reverse Payment Settlements

In 1984, Congress passed the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act to accomplish two goals: (1) facilitate and expedite the marketing of generic drugs and (2) promote new drug innovation. To accomplish these goals, the Hatch-Waxman Amendments created two ways to obtain Food and Drug Administration (“FDA”) approval to market prescription drugs: a new drug application (“NDA”) and an abbreviated new drug application (“ANDA”). NDAs are submitted by manufacturers of branded drugs and are required to contain full clinical data establishing the drug’s safety and effectiveness, while ANDAs are submitted by formulators of generic drugs that rely on the safety and effectiveness data in the NDA and do not present duplicative clinical data.⁶

NDA holders must submit patent information to the FDA. A generic drug company filing an ANDA for a drug subject to an unexpired patent may certify that the patent is invalid, unenforceable, or will not be infringed by its product – known as a “Paragraph IV certification.” The patent owner has 45 days after the “ANDA-IV” is filed to initiate a patent infringement lawsuit, if it so chooses. If the patent holder files a lawsuit, the FDA may not approve the ANDA-IV for 30 months or such shorter or longer period as the court may order. Upon a court order that the patent is invalid, unenforceable, or not infringed or the expiration of the 30 months, the FDA may approve the generic drug. To encourage generic drug companies to challenge patents, Congress awarded the first generic company to file an ANDA-IV 180-days exclusivity before the FDA may approve subsequent generic applications.⁷

To obtain an earlier market entry date, generic drug companies continue to challenge patents. However, it has become increasingly common for branded drug companies and generic drug companies to settle those

patent lawsuits rather than litigate – an outcome not contemplated by Hatch-Waxman. These settlement agreements typically include (1) an agreed upon date in the future when the generic may market its product (sometimes before the patent expires and sometimes well after it expires) and (2) a payment from the branded drug company to the generic drug company in the form of cash or as part of an ancillary agreement.⁸ Settlements involving either form of payment are often referred to as “reverse payment settlements” or “pay-for-delay settlements.”

The debate concerning reverse payment settlements touches on key policy issues at the heart of Hatch-Waxman.

- *Innovation.* Reverse payment settlements can both promote and discourage innovation. Branded drug companies argue that if patent settlements are routinely found to violate the antitrust laws and removed as a meaningful option, then patent protection will be less certain, making them less willing to invest in innovation in the long term.⁹ On the other hand, the FTC and consumer groups argue that antitrust policy spurs innovation by encouraging firms to out-compete one another by developing superior products.¹⁰ If pay-for-delay settlements are never scrutinized, drug companies will have less incentive to develop new, presumably better, products.
- *Judicial Economy.* Reverse payment settlements also implicate a general policy that favors settlements because they have the potential to resolve disputes more efficiently than trial. Settlements save parties legal fees and remove the

⁸ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006).

⁹ See Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489, 549-50 (2007); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006); Hemphill, *supra* note 8, at 1574-75.

¹⁰ Fed. Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* at Executive Summary 1-2 (Oct. 2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

⁶ Cf. 21 U.S.C. § 355(b) with § 355(j).

⁷ *Id.* at § 355(j).

risk of an adverse judgment. They also save the courts, and thereby the taxpayers, time and resources. The more these settlements are disfavored, the less these benefits will be realized.¹¹

- *“Earliness” of Generic Entry.* Proponents of reverse payment settlements argue that they promote early generic entry. Because patents are presumptively valid, the settling parties argue that “early” is any time before the patent’s expiration. The FTC contends that reverse payment settlements do not necessarily promote early entry because it measures “earliness,” not by the patent’s expiration date, but by looking at when the generic would have agreed to enter absent a cash payment from the brand.¹²
- *Incentives for Early Generic Entry.* Some opponents argue that in certain circumstances reverse payment settlements undermine the incentives for generics to challenge patents to obtain early entry. For example, in a situation where a first ANDA-IV filer settles a patent case and retains its right to the 180-day exclusivity period, the financial incentives for other generics to challenge the patent are reduced. This is because subsequent ANDA-IV filers that challenge the patent and prevail will immediately face fierce competition and lower profits as all other generics rapidly enter. Thus, after expending resources litigating, it does not receive the 180 days of duopoly profits as compensation for its efforts. By settling with the first ANDA-IV filer, the brand can effectively nullify the financial incentives that Congress created for generics to challenge patents.¹³

While the issue of reverse payment settlements exposes deep fissures between the FTC’s view and the courts’

¹¹ See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005); Hemphill, *supra* note 8, at 1574.

¹² Opinion of the Commission at 26, *In the Matter of Schering-Plough Corp., et al.*, 136 F.T.C. 956 (2003), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

¹³ See Hemphill, *supra* note 8, at 1583-86.

holdings, there are some areas of agreement. Both seem to agree:

- *First*, that an agreement violates the antitrust laws when the date for generic entry extends beyond the expiration of the patent;¹⁴
- *Second*, that an agreement settling “sham” patent litigation violates the antitrust laws;¹⁵
- *And finally*, that if a branded drug company made a large cash payment to a cash-strapped generic that otherwise could not afford to bring its version of the drug to market, the settlement might increase competition by enabling the generic to enter.¹⁶

The FTC and the courts vehemently disagree, however, on whether a settlement that provides for (1) generic entry within the patent term, and (2) a large cash payment from the brand to the generic violates the antitrust laws.

FTC’s Position: Reverse Payment Settlements Violate the Antitrust Laws

The FTC favors a rule that would hold presumptively invalid any reverse payment settlement if it is shown to involve a large cash payment (or a disguised payment) from the brand to the generic in exchange for delayed entry.¹⁷ This is based on the following rationale: The branded drug company will almost always stand to lose more from the falling prices caused by generic entry than the generic entrant will profit. Thus, the brand can afford

¹⁴ *In re Tamoxifen*, 466 F.3d at 213.

¹⁵ E.g., Opinion of the Commission, *supra* note 12, at 33; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008).

¹⁶ Opinion of the Commission, *supra* note 12, at 37.

¹⁷ See Opinion of the Commission, *supra* note 12, at 12-14, 29; Fed. Trade Comm’n, *Barriers to Generic Entry* at 12-13, Prepared Statement Before the S. Special Comm. on Aging (July 20, 2006), available at <http://www.ftc.gov/os/2006/07/P052103BarriersToGenericEntryTestimonySenate07202006.pdf>; Fed. Trade Comm’n, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution* at 18, Prepared Statement Before the S. Comm. on the Judiciary (Jan. 17, 2007), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

to pay the generic not to bring its version to market. Accordingly, when a cash payment is involved, the FTC believes that it is reasonable to assume the existence of offsetting consideration, namely delayed generic entry.¹⁸

The FTC's approach requires determining whether a cash payment has been made – a straightforward inquiry when the agreement explicitly provides: *I, brand, will pay you, generic, millions of dollars to stop infringing my patent and not to market your product until my patent is about to expire.*¹⁹ The analysis is more difficult when ancillary agreements are involved.²⁰ For example, the FTC recently filed a complaint against Watson Pharmaceuticals, Par Pharmaceutical Companies, Paddock Laboratories, and Solvay Pharmaceuticals. In its complaint, the FTC stated that part of the parties' settlement agreement provided that generic-Par would co-promote brand-Solvay's drug by making sales calls.²¹ Internal documents allegedly indicated that the parties themselves recognized that the sales calls were being grossly overpriced in the settlement agreement.²² The difference between the amount agreed to and the fair market value of the sales calls, the FTC claims, was simply a disguised cash payment for delayed entry.²³

The FTC contends that it is *not* necessary to litigate the validity of the patent to prove that the payment was “in exchange for” delayed entry.²⁴ Instead, the FTC would look to evidence of the *parties' assessment* of the patent at the time of settlement to determine whether the patent legally excluded generic entry or the payment illegally prevented competition in violation of the antitrust laws.²⁵

Under the FTC's analysis, patent holders are entitled to monopoly profits during the life of the patent reduced by the probability that the patent is invalid.²⁶ In settlements without cash payments, this is the outcome that the parties' negotiations would produce in theory.²⁷ For example, if both the generic and the brand believed that there was a 60% chance that the brand's patent was invalid, and there were ten years left in the patent term, the settlement they would reach would involve the generic entering in roughly four years (assuming costless and instantaneous litigation for simplicity). Any more than four years, and the generic could do better by litigating. Any less, and the brand would prefer litigation.

When cash payments are involved, however, it becomes necessary to determine the parties' assessment of the patent's validity to “tease out” the effect that the cash payment had on the date that they agreed the generic would enter.²⁸ To use the above example: if the parties had agreed on entry in six years with a \$2 million cash payment, knowing the parties' assessment of the probability that the patent is invalid would help the Commission to “back into” when they would have agreed to generic entry absent the cash payment. The relevant inquiry, according to the FTC, is not whether the settlement allowed for generic entry before the end of the patent term, but whether it promoted earlier generic entry than would have come about absent the cash payment.²⁹ Under the FTC's approach, once it is proved that the parties would likely have agreed to earlier generic entry absent the cash payment, the burden would shift to the settling parties to demonstrate a procompetitive justification for the cash payment.

¹⁸ Opinion of the Commission, *supra* note 12, at 25-26.

¹⁹ See generally C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey* 15 (Columbia Law Sch., Working Paper, 2007), available at <http://www.ssrn.com/abstract=969492>.

²⁰ First Amended Complaint at 14-15, *FTC v. Watson Pharm., Inc.*, No. 09-598 (C.D. Cal. Feb. 12, 2009).

²¹ *Id.* at 18.

²² *Id.* at 20.

²³ *Id.* at 19.

²⁴ Opinion of the Commission, *supra* note 12, at 29-35.

²⁵ *Id.* at 25-26; Corrected Brief of Amicus Curiae Fed. Trade Comm'n at 16-17, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, No. 2008-1097 (Fed. Cir. 2008) available at <http://www.ftc.gov/ogc/briefs.shtml>

²⁶ Corrected Brief of Amicus Curiae Fed. Trade Comm'n, *supra* note 25, at 27.

²⁷ Opinion of the Commission, *supra* note 12, at 25-26.

²⁸ *Id.* at 7.

²⁹ *Id.* at 26.

Court Holdings: Reverse Payment Settlements Do Not Violate the Antitrust Laws

After considering the issue of whether reverse payment settlements are generally anticompetitive, the Federal, the Second, and the Eleventh Circuits have all adopted approaches essentially contrary to the FTC's. These circuit courts have found that reverse payment settlements do not violate the antitrust laws if the alleged anticompetitive effects are within the scope of patent protection. When assessing reverse payment settlements, these courts have examined: "(1) the scope of the exclusionary power of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects" in the relevant market.³⁰

In the most recent decision on point, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,³¹ the Federal Circuit Court of Appeals held that the anticompetitive effects of reverse payment settlements between Bayer and generic manufacturers were "within the exclusionary power of [Bayer's] patent," and thus, the presumptive validity of the patent protected the parties to the settlement agreements from antitrust challenges.³² The Federal Circuit held that "in the absence of evidence of fraud before the PTO or sham litigation, a court need not consider the validity of the patent as part of the antitrust analysis,"³³ citing the Second and Eleventh Circuits in agreement. The court explicitly rejected the FTC's approach of weighing the "uncertainty of patent validity" and the "'expected value' of the lawsuit" in a rule of reason analysis.³⁴ Instead, the court held that a patent holder should be able to choose settlement as an efficient "means of [patent] enforcement" without undergoing such scrutiny.³⁵

The federal circuit courts' decisions also disagree with the FTC on key policy issues. The courts cite maintaining patent protections and promoting innovation as a key rationale. The Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation* concluded that the plaintiffs had failed to state an antitrust claim because in the absence of sham litigation, a patent holder should be able to "protect" its "lawful monopoly" through settlement and should not have its patent deemed invalid based on its "fear of losing it."³⁶ The *Tamoxifen* court reasoned that "[r]ules severely restricting patent settlements might . . . heighten the uncertainty surrounding patents and might delay innovation."³⁷

The courts also cite encouraging settlement as another key policy rationale for their decisions. Like the Federal Circuit in *Cipro*, the Second Circuit in *Tamoxifen* pointed to the "principle that 'courts are bound to encourage' the settlement of litigation."³⁸ Likewise, the Eleventh Circuit has reasoned that public policy strongly favors the "efficiency-enhancing" gained by patent settlements, noting that "a patentee confident in the validity of its patent might pay a . . . substantial sum" to avoid the "caustic environment of patent litigation," an environment which "may actually decrease product innovation by amplifying the period of uncertainty" around the enforceability of a patent.³⁹ Hence, the effect of a settlement to actually bring finality to patent litigation is central to the Eleventh Circuit's reasoning, and where an agreement between a patentee and a generic manufacturer does not in fact resolve an infringement action but rather prolongs a dispute and delays generic entry, it may be found *per se* illegal.⁴⁰

³⁰ *Schering-Plough Corp.*, 402 F.3d at 1066 (citing *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1312 (11th Cir. 2003)).

³¹ 544 F.3d 1323 (Fed. Cir. 2008).

³² *Id.* at 1336.

³³ *Id.*

³⁴ *Id.* at 1337.

³⁵ *Id.*

³⁶ 466 F.3d 187, 209-10 (2d Cir. 2006).

³⁷ *Id.* at 202.

³⁸ *Id.* at 230.

³⁹ *Schering-Plough Corp.*, 402 F.3d at 1072, 1075.

⁴⁰ *Id.* at 1066 n.14.

Chairman Leibowitz Will Challenge Reverse Payments Until the Courts Yield or Congress Acts

Chairman Leibowitz has been a vocal opponent of reverse payment settlements. In conjunction with the FTC's decision to bring its lawsuit against Watson and others, then-Commissioner Leibowitz said: "Eliminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today."⁴¹ In 2007, he stressed to the Senate: "If these decisions are allowed to stand, drug companies will enter into more and more of these agreements and prescription drug costs will continue to rise rapidly. . . . It's a win-win deal for the companies. But it's a lose-lose proposition for consumers, who are left footing the bill."⁴² Chairman Leibowitz has also said: "fixing [the problem could] . . . help pay for health care reform."⁴³

As part of his policy to eliminate "pay-for-delay" settlements Chairman Leibowitz will likely employ a three-pronged approach: (1) file lawsuits challenging reverse payment settlements; (2) encourage Congress to pass legislation to eliminate reverse payment settlements; and (3) make increased use of the FTC's regulatory power to revoke the 180-day exclusivity period for first ANDA-

IV filers if it finds that the settlement agreement is anticompetitive.⁴⁴

The FTC and Chairman Leibowitz have demonstrated their commitment to gaining traction for their approach with the judiciary; they continue to file claims in hopes of obtaining a favorable decision. On February 12, 2009, for instance, the Commission filed a complaint against Watson, Par, Paddock, and Solvay Pharmaceuticals alleging violations of both Section 1 and Section 2 of the Sherman Act. Such claims may not be futile. For instance, a vigorous dissent accompanied the Second Circuit's majority opinion in *Tamoxifen*. Among other things, like the FTC, the *Tamoxifen* dissent took issue with the majority's apparent holding that only agreements settling "sham" litigation were apt to be anticompetitive.⁴⁵ Also, while it is frequently distinguished, in *Cardizem* the Sixth Circuit held a reverse payment settlement to be anticompetitive.⁴⁶

⁴¹ Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Concurring Statement in re *FTC v. Watson Pharm.* at 1-2 (Feb. 2, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090202watsonpharm.pdf>.

⁴² Jon Leibowitz, Comm'r, Fed. Trade Comm'n, *Anticompetitive Patent Settlements in the Pharmaceutical Industry* at 1, Oral Statement Before the S. Comm. on the Judiciary (Jan. 17, 2007), available at <http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf>.

⁴³ *FTC Commissioner Thinks Obama Administration Will Help Stop Agreements to Delay Generics*, Kaiser Daily Health Policy Report (kaisernetwork.org, Menlo Park, CA), Feb. 23, 2009, available at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=57111.

⁴⁴ See Leibowitz, *supra* note 43, at 1; Leibowitz, Comm'r, Fed. Trade Comm'n, *Barriers to Generic Entry* at 2, Oral Statement Before the S. Special Comm. on Aging (July 20, 2006), available at <http://www.ftc.gov/speeches/leibowitz/060720oralstatementliebowitz.pdf>; Jon Leibowitz, Comm'r, Fed. Trade Comm'n, *Health Care and the FTC: The Agency as Prosecutor and Policy Wonk* at 6, Remarks at the Antitrust in HealthCare Conference (May 12, 2005), available at <http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf>.

⁴⁵ 466 F.3d at 228.

⁴⁶ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003). See also, e.g., *In re Tamoxifen*, 466 F.3d at 213-14.

Also evident is Chairman Leibowitz's success in urging Congress to take action. In 2006, he suggested that Congress pass a law that would either ban payments above a *de minimis* amount in pharmaceutical patent infringement settlements or repudiate the circuits' *Schering* and *Tamoxifen* decisions.⁴⁷ Congress is apparently listening. On March 25, 2009, Representatives Rush, Waxman, and Dingell introduced H.R. 1706 that would make it illegal for anyone to be a party to an agreement where a brand pays a generic anything of value to delay entry. It would also give the FTC rulemaking authority to further restrict pay-for-delay settlements.⁴⁸ In

⁴⁷ Leibowitz, *supra* note 1, at 9.

⁴⁸ *See supra* note 3.

2007, Senators Kohl, Grassley, Leahy, Schumer, Feingold and Obama supported nearly identical legislation.⁴⁹

Now that one of Leibowitz's Senate allies has moved to the White House, he can expect even stronger support for the policy that he and the Commission favor. Leibowitz has said that attempting to curb pharmaceuticals' anticompetitive behavior is like playing "whack-a-mole."⁵⁰ Now that President Obama has put him in charge of the FTC, he will likely challenge pay-for-delay settlements until either the courts or Congress provides a permanent resolution.

⁴⁹ *See supra* note 4.

⁵⁰ Leibowitz, *Health Care and the FTC*, *supra* note 44, at 9.

This memorandum is intended only as a general discussion of these issues. It should not be regarded as legal advice. We would be pleased to provide additional details or advice about specific situations if desired.

If you wish to receive more information on the topics covered in this memorandum, you may contact your regular Shearman & Sterling contact person or any of the following:

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