A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech[1]

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We offer this brief statement in response to the June 23, 2009 speech by Federal Trade Commission Chairman Jon Leibowitz titled "'Pay-for-Delay' Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution)."[4]

We have both written papers analyzing the economics of "reverse payment" patent settlements.[5] In our research, we both reached the plain and important conclusion that it is too simplistic to conclude that *all* reverse payment patent settlements harm consumers, as the Chairman claimed in his speech.[6] Our research papers describe the economic conditions under which reverse payment patent settlements may harm consumers and the conditions under which reverse payment patent settlements may actually produce *more competition*, thereby *increasing* consumer welfare. It is therefore entirely inappropriate, from an economic perspective, to deem such settlements "pay-for-delay," since they very well may actually produce earlier entry of generic pharmaceuticals than entry that would occur if such settlements were banned.

Our research shows, and the Chairman's speech itself corroborates that reverse payments often foster settlements of pharmaceutical patent challenges that would otherwise be driven to protracted litigation. Such settlements likely induce generic entry well before the expiration of the challenged patents.[7] The litigation that would result if reverse payments were prohibited would be lengthy, costly to the judicial system and to those paying the bills for pharmaceuticals, and disruptive. The litigation costs borne by pharmaceutical firms would eventually be passed on to consumers in the form of higher drug prices or reduced R&D activity. That litigation would often affirm the challenged patent and the patent's infringement by the challenger. In these cases entry would be delayed until well past the time it would have occurred under a reverse payment patent settlement. That is why a blanket rule against reverse payments would, with some significant frequency, be the cause of significantly delayed generic competition and socially costly litigation that settlements could otherwise avert.

The remainder of this statement focuses on the Chairman's announcement of an internal FTC analysis that claims that eliminating reverse payment patent settlements would save American consumers approximately $3.5 billion per year in drug costs.[8] Since this analysis became available just yesterday, our statement reflects an initial reaction to it. We intend to prepare a more complete and thorough assessment of the FTC study over the next few weeks. Nonetheless, our initial conclusion is that the FTC study suffers from a number of evident flaws. But before turning to the details, it is important to emphasize that the FTC study, at least implicitly, agrees that a ban of reverse payments would stultify settlements increasing the number of lengthy litigations. Such

an increase in protracted litigation activity may, in some cases, delay significantly generic competition. At the same time, the FTC study asserts that *on average* the ban would be harmful to consumers, notwithstanding the potential negative impacts on consumers and the prevalence of litigation that would be forced to proceed as a result of the ban. It is our conclusion that the assumptions underlying the FTC study are far too unreliable to provide support for the proposed ban on reverse payment settlements, in view of their acknowledged beneficial impacts occurring at least a significant fraction of the time.

1. The FTC Study's Conclusion That Reverse Payment Patent Settlements Delay Generic Entry by 17 Months Is Not Reliable

The FTC study concludes that reverse payments delay entry of generic pharmaceutical manufacturers by an average of 17 months (or 1.42 years) because, according to the FTC analysis, generic entry under patent settlement agreements with reverse payments is 17 months later than entry under agreements without reverse payments. As a matter of economics, there is no sound rationale for assuming that the inclusion of a payment from the branded to the generic manufacturer as part of the settlement agreement *caused* the observed differences in entry dates by the generic manufacturers. The reason: Settlements with and without reverse payments may differ systematically in certain aspects of the underlying patent disputes. For example, if settlements with reverse payments occur when the branded manufacturer possesses a stronger patent than in settlements without reverse payments, later entry under the reverse payment settlements may simply reflect the average difference in patent strengths rather than any payment for delay. Similarly, patent settlements with and without reverse payments may differ in the average patent life remaining or the point in time after an initial challenge at which the settlement is reached. Such differences would render invalid the comparison of entry delay between the two types of settlements.[9] By ignoring the fact that the universe of settlements that involved a payment from the branded to the generic manufacturer may differ in important respects from the universe of settlements without such payments, the FTC study has dangerously oversimplified the analysis. It is just not possible to make reliable inferences about the effect of reverse payments on entry delay without properly accounting for the other salient differences between the two categories of settlements.

More generally, the Chairman's speech ignores the fact that patent settlements with reverse payments may actually accelerate generic competition for numerous drugs. We understand and have examined the highly simplified economic models that can inappropriately lead to the conclusion that reverse payment settlements will always reduce competition. But overly simple economic models ignore important economic realities that can make reverse payment settlements procompetitive. Such realities include, but are not limited to, (a) risk aversion, (b) information asymmetries, (c) differences in expectations, and (d) differences in discount rates.

In fact, our analyses show that under certain conditions, without a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers. If reverse

payment settlements are banned in these cases, the parties may be unable to reach settlement and may litigate the dispute to the end. Such litigation engenders significant delays in the possibilities for competition, even if the generic manufacturer were ultimately to prevail as patent litigation may persist over an extended period of time and generic competition may not commence until after all litigation has been completed. And if the generic manufacturer were to lose the litigation, entry would occur only after – and perhaps long after – entry would have occurred in the presence of a patent settlement with a reverse payment.

2. The FTC Study's Conclusion That Consumers Save 77% With Generic Entry Following a Patent Settlement Overstates The Savings

The FTC study estimates the average consumer savings from a "mature generic market relative to pre-generic levels are approximately 77%..." (p. 12) This estimate overstates the benefits of earlier generic competition. The FTC study simply assumes that following generic entry under a patent settlement agreement that consumers will have the benefit of a "mature generic market" where there would be numerous generic entrants. However, the reality is that not all markets will exhibit the effects of a "mature generic market." For example, for many drugs, there would likely be only a few generic competitors, and in some cases, there may be just one generic competitor. A Congressional Budget Office (CBO) study and many other analyses, including an FTC report on follow-on biologics from earlier this month,[10] have found that the effect on prices and market share depend critically on the number of generic entrants.[11] The effect of fewer generic entrants on generic drug prices is generally much smaller than the 85-percent price effect assumed by the FTC in this study: For example, the CBO study found that the price effect was roughly 40 percent with fewer generic entrants,[12] whereas the FTC report on follow-on biologics cited evidence that one to five generic entrants led to price discounts of 10 to 40 percent.[13] The FTC report on follow-on biologics also shows that the assumption in this study about the market share erosion from branded to generic manufacturers (90 percent in the first year) is at the high end of the empirical evidence.[14] Fixing these flaws in the FTC analysis would significantly reduce its estimate of consumer savings.

3. The FTC Study Ignores The Social Costs of Banning Reverse Patent Settlements

The FTC study ignores the social costs of banning reverse payments. The Chairman appears to agree that banning reverse payments will reduce the likelihood of patent dispute settlements and increase the frequency of patent litigation: The study states, "Over the 2004 to 2008 time period, the percentage of drugs that settled per year (not including injectibles) increased from 7% to 18%, with most of the increase following the Eleventh Circuit's *Schering* decision. Since this post *Schering* era is probably a better reflection of likely future settlement patterns, it seems appropriate and conservative to use the 15% per year average from this period in the estimate calculations." (p. 14) By acknowledging that the Court's decision approving a reverse payment settlement has led to *more* settlements, the FTC has implicitly acknowledged that the increase in reverse

payment settlements has correspondingly *reduced* litigation. The study also acknowledges that some reverse payment settlements would be litigated without reverse payments.[15] The reduction in litigation is a clear benefit to society, which is completely ignored in the FTC analysis.

The FTC study also ignores other (potentially large) social costs that increased patent litigation would impose on society. The greater frequency of protracted litigation in patent disputes may have the effect of discouraging patent challenges by generic drug firms because they would be more costly for the generic firms if the prospect of settlement were reduced. Patent challengers are often small pharmaceutical firms that may lack the capital to withstand a long, drawn-out patent fight in court. Faced with a greater likelihood of expensive and protracted litigation, these firms may simply forgo the challenge. Well-resourced generic companies may also have different business calculations about challenging patents in the face of protracted litigation with little possibility of an out-of-court resolution. Thus, under a ban of reverse payments, rather than having a settlement that enables entry prior to patent expiration, there may be no challenge of the patent at all, and consumers would receive no benefit of accelerated generic competition. Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition can be substantial.

The prospect of facing patent challenges and more frequent protracted litigation to defend patents may also discourage investments in innovation to develop new drugs in the first place. Thus, taking some potentially procompetitive settlement options off the table would narrow the effective patent protection provided to branded manufacturers and, on the margin, could lower incentives to invest in new medicines in the future.

4. Conclusions

We understand that designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core it depends upon the validity of the patent claims. What is clear is that under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and consumers. Our economic analyses have shown that an outright prohibition of reverse payment settlements, as advocated by the FTC Chairman in his speech, would harm consumer welfare in a range of circumstances. Patent settlements between branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any patent settlement agreement between a branded pharmaceutical company and a generic applicant be provided to the FTC and the DOJ. And as the Chairman accurately articulated, our judicial system has been working hard in this area to create a framework for the case-specific adjudication of allegations that particular settlements are anticompetitive. But painting all settlements with the same brush, as the Chairman advocates, is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying a logical economic framework to the facts specific to that settlement.

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[4] See http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf (downloaded on June 23, 2009).

[5] "Reverse payments" (as the term has been typically used in the analysis of patent settlements) is any net consideration from a holder of a drug patent to the challenger of the patent that is part of a settlement of the patent challenge.

[6] Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry," forthcoming in *Annals of Health Law*, available at http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=bret_dickey (downloaded on June 23, 2009); Robert Willig and John Bigelow, "Antitrust Policy Toward Agreements that Settle Patent Litigation," *The Antitrust Bulletin*, pp. 655-698, (Fall 2004); and John Bigelow and Robert Willig, "'Reverse Payments' in Settlements of Patent Litigation: Schering Plough, K-Dur and the FTC," *The Antitrust Revolution: Economics, Competition, and Policy*, 5th Edition (2008).

[7] *See, e.g., Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[8] It is worth noting that the study's estimate of consumer savings from a ban on reverse payment patent settlements implicitly assumes that eliminating anticompetitive settlements can only be achieved by banning reverse payments. The study does not provide a basis for this assumption. Alternatively, it may be possible to deter anticompetitive patent settlement agreements that include reverse payments through the examination of settlements by antitrust enforcement agencies.

[9] Moreover, every patent dispute and every settlement has some unique features that are difficult to account for in comparing settlements.

[10] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf (downloaded on June 24, 2009).

[11] *See, e.g.*, Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, available at http://www.cbo.gov/doc.cfm?index=655&type=0&sequence=0 (downloaded on June 23, 2009).

[12] *Id.*

[13] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf (downloaded on June 24, 2009), page 12 and fn. 37.

[14] *Id*, page 13 and fn. 38, citing evidence of a market share erosion of 50 to 90 percent.

[15] The FTC study states, "This does not mean that we are assuming that all settlements with payments would 'become' settlements without payments if the former were banned. Some would; others might involve litigation of the patent." (p. 13)