Comparing Economic Impact Estimates of "Reverse Payment" Settlements

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Economic studies of "reverse payment" settlements have reached contradictory conclusions about the effect of this type of settlement on consumers. This analysis explains why existing economic research provides little evidence of the appropriateness of any given settlement involving consideration.

"Reverse payment" patent settlements (often called "pay-for-delay" deals) between brand and generic drug companies are receiving new scrutiny by the lower courts following the Supreme Court's ruling in *Federal Trade Commission v. Actavis*. In the 5–3 decision on June 17, 2013, the Court sided with neither the advocates of a scope-of-patent approach nor the proponents of a declaration of presumptive illegality.[1] Instead, the Court applied the rule of reason standard, meaning that pay-for-delay settlements — in 2012, 30 percent of all pharmaceutical patent settlements[2] — should be assessed individually.

Opponents of this type of patent settlement generally celebrated the decision but argue that the Court did not go far enough and that legislative action is necessary.[3] The Preserve Access to Affordable Generics Act (S. 214), introduced in February 2013 by Senator Amy Klobuchar (D-MN), would establish that any reverse payment settlement is presumed to be anti-competitive and would authorize the Federal Trade Commission (FTC) to initiate enforcement proceedings under the presumption of illegality unless the parties disprove the claim of anti-competitiveness.

Against this backdrop, two reports — one from the IMS Institute for Healthcare Informatics[4] and one from U.S. PIRG and Community Catalyst[5] — were released, each purporting to measure the economic consequence of pay-for-delay settlements. A third estimate, from the FTC, is often cited in discussions of the economic impact of permitting this type of settlement.[6] Though all three reports examine the same issue, each reaches a different — even contradictory — conclusion. In light of these reports' conflicting findings — as well as the renewed interest in legislation restricting reverse payment settlements and the impact of the Supreme Court's decision on parties currently engaged in patent litigation — an objective understanding of the costs and benefits of this type of settlement is essential.

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In this analysis, we undertake the goal of providing a clear assessment of these economic impact estimates. Toward this end, we compare and contrast the methodologies, key assumptions, and primary findings of the three reports. Evaluating the strengths and weaknesses of the reports' economic arguments, we outline the limitations unique to each report as well as the overarching shortcoming common to all three. We conclude by arguing that the Supreme Court's ruling on pay-for-delay settlements is sufficient and appropriate for promoting competitiveness in the pharmaceutical industry.

COMPARISON OF ECONOMIC IMPACT ESTIMATES

The parameters, findings, and assumptions of the three reports differ across the board, as **Table 1** delineates. Beyond the differences in conclusions, time periods studied, and number of drugs analyzed, the methodologies vary as well. But the fundamental difference among the economic impact estimates derives from whether a report assumes that pay-for-delay settlements:

1) yield savings by allowing generics to enter the market before brand patents would have expired, or

2) deny savings by delaying generic entry beyond when generics would have entered the market had the patent challenger prevailed in court.

TABLE 1. PARAMETERS, FINDINGS, AND ASSUMPTIONS OF ECONOMIC IMPACT ESTIMATES

	IMS Institute for Healthcare Informatics	U.S. PIRG/ Community Catalyst	Federal Trade Commission
Study Parameters	33 drugs with settlements between 2005 and 2012.	20 drugs with pay-for-delay settlements between 1993 and 2012.	Unspecified number of drugs with settlements between January 1, 2004, and September 30, 2009.
Primary Findings	Savings from all 33 settlements total $25.5 billion. Future savings, from 2013 until the date of patent expiry, total $61.7 billion. Settlements involving reverse payments are responsible for $11.8 billion to $13.6 billion in savings to date and future savings.*	For the 20 drugs analyzed, brand drug companies brought in a total of $98 billion in sales between the time of the reverse payment settlements and the point of generic entry.	Pay-for-delay settlements cost U.S. consumers $35 billion over a decade.
Key Assumptions	Settlements provide savings by allowing generic market entry before brand patents would have expired. Savings are calculated from date of generic entry through 2012 and from January 2013 to patent expiry. Savings attributable to pay-for-delay are calculated using the generic success rate in patent challenges (48%) and the percentage of settlements with consideration (26–30%).	The period of time between a pay-for-delay settlement and generic entry is caused by the reverse payment. Brand drug prices are assumed to grow at an annual rate of 10%.	Pay-for-delay settlements are responsible for delaying generic entry on average 17 months. Cost is calculated assuming an average delay in generic entry of 17 months, average price discrepancy between brands and generics of 85%, and generic penetration rate of 90%.

Source: *Matrix Global Advisors analysis based on reports by IMS Institute for Healthcare Informatics (June 2013), U.S. PIRG and Community Catalyst (July 2013), and Federal Trade Commission (January 2010).*

** Some media coverage of the IMS report confused the total estimate with the estimate of savings arising from reverse payments alone. See, for example, PharmaceuticalCommerce.com, "'Pay for Delay' Patent Settlements Have Saved Payers $25.5 Billion during 2005–2012, says IMS Health Institute," July 9, 2013.*

The FTC and U.S. PIRG/Community Catalyst reports assume that pay-for-delay settlements prevent lower-cost generic drugs from entering the market as early as they otherwise would. In fact, the latter assumes that, absent a settlement agreement, generic entry would have occurred on the day the settlement was executed. Conversely, the IMS report assumes that settlements allow generics to enter the market sooner than they otherwise would because there is no guarantee that a generic manufacturer would win a patent challenge. Thus, the IMS report calculates savings beginning with the date of generic entry. Clearly, there is a fundamental contradiction in the reports' underlying assumptions, as demonstrated by the fact that the IMS report claims savings for consumers over seven of the exact drugs for which the U.S. PIRG/Community Catalyst report asserts the opposite.[7]

This contradiction points to a methodological flaw inherent in all three reports: all three fail to establish causality between pay-for-delay settlements and the date of generic entry. Instead, each report espouses a predetermined conclusion about whether such settlements lead to generic entry sooner or later than would otherwise occur. As described in **Table 2**, other shortcomings unique to each report include lack of statistical rigor, failure to account for market and regulatory dynamics, and methodological inconsistencies.

TABLE 2. SHORTCOMINGS AND METHODOLOGICAL FLAW OF ECONOMIC IMPACT ESTIMATES

	IMS Institute for Healthcare Informatics	U.S. PIRG/ Community Catalyst	Federal Trade Commission
Shortcomings	Calculates savings to date without adjusting for brand patent expiry dates that fell before the end of 2012. By the report's own parameters, savings to date should be calculated as future savings are calculated — through scheduled patent expiry. Calculates savings based on generic volumes after generic entry, which could lead to an inflated savings estimate. The lower cost of the generic likely induces higher utilization relative to brand utilization prior to generic entry.	Assumes that, absent a reverse payment settlement, the generic entry date would be the settlement date, neglecting regulatory, judicial, or logistical factors that may delay generic entry. Quantifies the effect of reverse payment settlements on brand sales, not consumers, despite being ostensibly concerned about drug companies' anti-consumer behavior.	Does not control for other factors that may contribute to the finding that generic entry following a reverse payment settlement is on average 17 months later than generic entry following a settlement without a reverse payment.
Methodological Flaw	Fails to construct a proper "but for" analysis, where generic entry in the absence of pay-for-delay settlements can be objectively assessed.		

Source: *Matrix Global Advisors analysis based on reports by IMS Institute for Healthcare Informatics (June 2013), U.S. PIRG and Community Catalyst (July 2013), and Federal Trade Commission (January 2010).*

ANALYSIS

In 2010, economists Bret Dickey, Jonathan Orszag, and Laura Tyson warned that "painting all settlements with the same brush is likely to harm consumers."[8] Despite coming to different conclusions, the three economic impact estimates analyzed here do just that when they assume that reverse payment settlements can be lumped together and categorically declared pro-competitive (e.g., IMS) or anti-competitive (e.g., FTC and U.S. PIRG/Community Catalyst).

This does not mean that an insightful economic study on this topic is impossible. Rather, a well-constructed economic analysis of reverse payment settlements would:

1) consider the causality between a reverse payment and the date of generic entry, and

2) determine the likely generic entry date in the absence of a reverse payment.

Essential to any economic study of the issue is the recognition that an individual drug patent settlement involving payment from one party to another cannot be deemed pro- or anti-competitive without full consideration of all aspects of the patent dispute and settlement agreement.

Indeed, the Supreme Court acknowledged this relativity with its decision to apply the "rule of reason" to these cases. As Justice Stephen Breyer noted in the Court's majority opinion, "The likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[9]

CONCLUSION

At its heart, the Supreme Court's decision rejects the oversimplified analyses of the three reports discussed above. However, these reports can be considered as representative of two ends of a spectrum — one end being a state of affairs in which settlements are all pro-competitive, and the other in which settlements are all anti-competitive. Neither of these "bookend" scenarios is realistic, but this perspective is useful for understanding the wide range of potential costs or benefits of pay-for-delay settlements.

Nevertheless, this view does not change our two basic conclusions on the issue: First, the Supreme Court's rule of reason decision is adequate and appropriate. Second, S. 214 or any other attempt to go beyond the Court's decision is unnecessary and potentially harmful. Depending on the circumstances, pay-for-delay settlements could be anti-competitive, pro-competitive, or neutral in their effects on consumers and should therefore be assessed on a case-by-case basis.

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NOTES

[1] Joining Justice Breyer in the majority opinion were Justices Kennedy, Ginsburg, Sotomayor, and Kagan. Justice Alito was recused.

[2] Federal Trade Commission (FTC) Bureau of Competition, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012," available at www.ftc.gov/os/2013/01/130117mmareport.pdf.

[3] For example, Community Catalyst responded to the decision thus: "We are heartened by the court's acknowledgement that pay-for-delay deals allow powerful brand-name patent holders and generic companies to divide the spoils of higher drug prices, leaving consumers to pay the balance. . . . The Supreme Court has opened the door for Congress to take action, and now it must." Community Catalyst, "SCOTUS Opens Door for FTC, Congress to Stop Collusive Pay-for-Delay Deals," news release, June 17, 2013.

[4] IMS Institute for Healthcare Informatics, "Impact of Patent Settlements on Drug Costs: Estimation of Savings," June 2013, available at www.gphaonline.org/media/cms/Impact_of_Patent_Settlements_on_Drug_Costs_Estimation_of_Savings_070813_FINAL_81.pdf.

[5] U.S. PIRG and Community Catalyst, "Top Twenty Pay-for-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers," July 2013, available at www.uspirg.org/sites/pirg/files/reports/Top_Twenty_Pay_For_Delay_Drugs_USPIRG.pdf.

[6] FTC, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," January 2010, available at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[7] These seven drugs are Adderall XR, Altace, Effexor XR, Lamictal, Lipitor, Wellbutrin XL, and Zantac. See also Kurt R. Karst, "Lies, Damned Lies, and Statistics: Another Report on Drug Patent Settlement Agreements," FDA Law Blog, July 11, 2013, available at www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/07/lies-damned-lies-and-statistics-another-report-on-drug-patent-settlement-agreements-.html.

[8] Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry," *Annals of Health Law* 19, no. 2 (Winter 2010): 399.

[9] *Federal Trade Commission v. Actavis, Inc., et al.,* 570 U.S. 756 (2013).

ABOUT MGA

Matrix Global Advisors (MGA) is a Washington, DC–based economic policy consulting firm that was founded by Alex Brill in 2007. MGA engages in consulting and analysis on a range of health care, tax, and other policy matters. Through knowledge of the legislative and regulatory process and the application of analytical tools, MGA has advised and conducted analyses for health insurers, hospitals, drug manufacturers, trade associations, investment banks, and others.

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