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Abstract

The Supreme Court recently held that in reverse payment settlements of drug patent disputes, anticompetitive effects can be inferred if the reverse payment exceeds the patent holder's anticipated litigation costs, absent some offsetting justification. Application of this standard is problematic because defendants usually (a) obscure the amount of the reverse payment and (b) claim their settlement was justified by risk aversion. Further, even if a net reverse payment can be proven, it is little help in estimating the period of delay or damages. This Article offers another type of evidence that demonstrates and quantifies anticompetitive effects. An otherwise unexplained bump in the patent holder's stock price shows that the settlement created new future profits by extending the period without generic competition beyond what the stock market expected. The stock market test has several advantages: it rebuts the risk aversion claim (which cannot explain the stock price rise); it more effectively (though still conservatively) captures damages than the magnitude of the reverse payment; and, finally, it relies on the behavior of objective traders rather than deal makers with well-understood incentives to obscure the presence of a payment. We conduct a stock market event study on one of the early instances of a reverse-payment settlement to illustrate how the method works.

Keywords: patent, antitrust, settlement, reverse payment, patent settlement, event study, risk aversion, damages

JEL: C72, K00, K10, K11, K20, K21, K29, K30, K39, K40, K41, K49, L12, L40, L41, L42, L49

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Ending over a decade of conflicting lower court rulings, the Supreme Court in *FTC v. Actavis, Inc.*² held that reverse-payment patent settlements deserve antitrust scrutiny under a rule-of-reason approach, where anticompetitive effects are inferred if the amount of the reverse payment exceeds the patent holder's anticipated litigation costs, absent some offsetting justification. But application of this standard has often proven contentious because defendants usually (a) obscure the amount of the reverse payment by coupling it with various business side deals and (b) claim their settlement was justified by risk aversion. Further, proving the full amount of damages can be difficult because the difference between the reverse payment amount and anticipated litigation costs can only be used to calculate the minimum possible anticompetitive injury if the patent holder obtained none of the joint gains from settlement, which is far lower than the full amount of anticompetitive injury.

This Article offers a method that can often cut through these difficulties: demonstrating and quantifying anticompetitive effects with a stock market event study. If the patent holder's stock market price jumps in response to announcement of a reverse payment settlement, then such a study shows that (absent proof of unexpected procompetitive efficiencies, including any associated with the side deals) the settlement must have produced a settlement exclusion period that exceeded what the stock market expected. This means that either (a)

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² 133 S.Ct. 2223 (2013).

the settlement exclusion period exceeded the expected litigation exclusion period or (b) the stock market underestimated the expected litigation exclusion period because it underestimated the patent strength and patent holder bargaining power. But the latter claim of market misestimation is generally inconsistent with evidence showing that without reverse payments, patent holder stock market prices do not jump.³ Further, if such market misestimations were the explanation, then reverse payment settlements should generally decrease the stock market prices of the settling entrant. In fact, the evidence shows that they do not.⁴

Thus, a jump in the patent holder's stock market price in response to a reverse payment settlement should suffice to show anticompetitive effects. This test is conservative because the patent holder stock price might not increase in response to an anticompetitive reverse payment settlement if the stock market (a) expected such an anticompetitive reverse payment settlement all along or (b) anticipates a risk of antitrust damages that offsets the anticompetitive profits from the settlement. Further, stock market event studies often require very large effects for statistical significance, and thus may fail to pick up substantial anticompetitive effects. The lack of a spike in a patent holder's stock market price thus cannot disprove anticompetitive effects. But the existence of one can prove such effects.

When abnormal stock market returns to a news event can be reliably estimated, this stock market test cuts through any need to resolve disputes about the amount of a reverse payment. A jump in the patent holder stock market price means the stock market must have concluded that the settlement exclusion period exceeded the expected litigation exclusion period in a way that increased profits. This stock market test also rebuts the usual claim that risk aversion caused the patent holder to settle for less than the expected exclusion because that could not explain why the stock market concluded that the settlement increased patent holder profits. Finally, a stock market test can provide a truer test of the full magnitude of anticompetitive effects because it at least includes some (albeit conservative) estimate of the patent holder's profits from settlement, whereas the amount of net reverse payment can only be used to estimate a low floor on anticompetitive damages that assumes the patent holder earned zero profits from settlement.

³ See *infra* Part II.

⁴ See *infra* Part II.

I. THE CURRENT PROBLEM

Reverse payment settlements raise the concern that the entrant (usually a generic drug company) has been paid to stay out of the market longer than merited by the expected outcome of patent litigation. The main difficulty that had split the lower courts before *Actavis* was that it seemed difficult to determine whether the settlement exclusion period exceeded the expected litigation exclusion period without engaging in a judicial inquiry into the patent merits, which was not only the very thing that patent settlements seek to avoid, but also would produce bimodal results that do not capture the expected patent odds at the time of settlement.⁵ Scholarship prior to *Actavis* proved that without any inquiry into the patent merits, one can infer that the settlement exclusion period exceeds the expected litigation exclusion period whenever the reverse payment amount exceeds the patent holder's anticipated litigation costs, absent some procompetitive justification for which the settlement was reasonably necessary.⁶ The basic intuition is that a patent holder would not pay more than its anticipated litigation costs unless it obtained a longer exclusion than it could obtain through litigation by incurring those litigation costs. This scholarship also showed that a reverse payment of this size sufficed to show both (a) market power and (b) that the settlement exceeded the optimal patent reward for innovation (assuming patent law has been optimized) if the settling entrant is not judgment proof.⁷

Actavis seems to follow this scholarship, holding that “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

⁵ Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 285-89 (2012) (summarizing the prior conflict among the circuits).

⁶ *Id.* at 283, 290-292, 297-312. Carl Shapiro was the first to argue that reverse payments that exceed litigation costs presumptively produce settlement exclusion periods that exceed the expected litigation exclusion periods, but he assumed instantaneous litigation and thus no possibility of at-risk entry during such litigation, and he concluded that this presumption could be rebutted by showing risk aversion or varying party estimates of the patent odds. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003). Elhauge and Krueger proved that the same proposition holds even if one considers the length of litigation, at-risk entry during that litigation, and varying party estimates of the patent odds. Elhauge & Alex Krueger, *supra* note 5, at 297-304, 325-326. Elhauge and Krueger further explained why risk aversion should not count as a procompetitive justification. *Id.* at 311-312.

⁷ Elhauge & Alex Krueger, *supra* note 5, at 293-304, 307-311.

from other services for which it might represent payment, and the lack of any other convincing justification.”⁸ The Court also concluded (like this prior scholarship) that a net reverse payment that exceeded anticipated litigation costs itself showed market power, obviated the need to inquire into the patent merits, and indicated that the settlement exclusion period exceeded what was merited by the expected patent odds.⁹ Unfortunately, application of this standard has proven contentious for the following reasons.

a. Obscuring the Amount of Reverse Payment. Although early reverse payment settlements involved naked cash payments, more recent reverse payments have involved business side deals that obscure the amount of the reverse payment.¹⁰ For example, the settling entrant might receive payments that are coupled with co-marketing or manufacturing agreements, so that determining the size of the net payment requires quantifying the extent to which the cash payments exceed the market value of the entrant services. Or the reverse payment might be made in the form of product licenses or intellectual property transfers, requiring quantifying the extent to which the value of those patent holder rights exceed whatever the entrant provides in return. One provision, commonly attached to reverse payment settlements in drug markets, is for the patent holder to agree not to launch its own “authorized generic” version of the drug during the 180 days that the first-filing generic gets to be the exclusive generic entrant.¹¹ The generic’s

⁸ *Actavis*, 133 S.Ct. at 2237.

⁹ *Id.* at 2236-37.

¹⁰ See C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649-650 (2009) [hereinafter Hemphill, *An Aggregate Approach*.] See also Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28(1) ANTITRUST 16, 18 (Fall 2013) (“the complexity is the result of the defendants’ own actions. The elephant in the room here merits naming. The parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature. Ordinarily, a genuinely valuable fee-for-service deal could be kept separate from the settlement to avoid antitrust problems. A degree of skepticism is therefore warranted with regard to complex reverse-payment settlements where the parties justify the large payments by subsidiary consideration.”)

¹¹ Although no other generic can receive FDA approval to launch during the first-filer’s 180-day exclusivity period, the patent holder can launch its own “authorized generic” at any time. In 2012, 19 of the 40 potential pay-for-delay agreements included a promise by the patent holder not to launch an authorized generic for some period of time, see Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug*,

revenue roughly doubles during the 180-day generic exclusivity period if no authorized generic is launched, allowing the patent holder to make a “reverse payment” without any money changing hands.¹² Furthermore, the reverse payment must be compared to the patent holder’s expected future litigation costs, which themselves must be estimated.

b. Claiming Risk Aversion as a Justification. Defendants often argue that reverse payment settlements are “justified” by managerial risk aversion. Supporting authors argue that the reverse payment could, theoretically, be a “risk premium” that managers at the patent holder are willing to make in order to avoid the uncertainty associated with litigation.¹³ This justification is controversial both factually and normatively. Active capital markets for large publicly traded companies should generally enforce profit-maximizing behavior by management on behalf of shareholders and thus deter managerial risk aversion that decreases shareholder profits.¹⁴ We are aware of no empirical evidence supporting the risk-aversion hypothesis on the part of managers of large pharmaceutical companies. Even if such risk aversion did explain a settlement, some argue it should not be an admissible “justification” because allowing reverse payments that foster such risk-averse decisions inefficiently lowers shareholder returns and incentives to invest in innovation.¹⁵ Others stress that unless the settling entrant is unreasonably optimistic about its odds of winning the patent trial, the less restrictive alternative of settling without a reverse payment can equally achieve this risk reduction, resulting in a shorter settlement exclusion period and thus less harm to competition.¹⁶ Nonetheless, defendants have actively argued otherwise and if

Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012: A Report by the Bureau of Competition, (January 2013), retrieved from: <http://www.ftc.gov/news-events/media-resources/mergers-and-competition/pay-delay>.

¹² See FTC, *Authorized Generic Drugs: Short Term Effects and Long Term Impact*, (August 2011), at 104-105.

¹³ See, e.g., Robert Willig & John Bigelow, *Antitrust Policy toward Agreements that Settle Patent Litigation*, 49 *Antitrust Bull.*, 655 (2004); Barry Harris, Kevin Murphy, Robert Willig & Matthew Wright, *Activating Actavis: A More Complete Story*, 28(2) *ANTITRUST*, 83 (Spring 2014).

¹⁴ See Elhauge and Kreuger, *supra* note 5, at 312.

¹⁵ *Id.* at 312.

¹⁶ Edlin, Hemphill, Hovenkamp, & Shapiro, *Activating Actavis*, *supra* note 10, at 4.C; Edlin, Hemphill, Hovenkamp, & Shapiro, *Actavis and Error Costs*, *ANTITRUST SOURCE* 1, 4-7 (2014).

courts do admit risk aversion as a justification, it would complicate every case because management can always claim to be risk averse and the degree of any alleged risk aversion would be hard to quantify.

c. Calculating Damages. Even when the above hurdles can be cleared, thus establishing an anticompetitive reverse payment settlement, a private plaintiff has the additional difficulty of calculating the amount of damages. A key ingredient in this calculation is estimating the period by which entry was delayed. The current literature indicates that if one assumes litigation would have resulted without the reverse payment settlement, one can calculate a lower bound on this delay by dividing what we will call X , the excess amount of payment (i.e., the amount by which the reverse payment exceeds avoided litigation costs), by what we will call M , the extra profits per day the patent holder gains by selling as a monopolist rather than against entrant competition.¹⁷ If one assumes a settlement with no reverse payment would have resulted without the reverse payment settlement, one can instead calculate a lower bound on this delay by dividing R , the reverse payment amount, by M .¹⁸ Thus, in both cases, existing methods require calculating the amount of the reverse payment, which can be difficult. Moreover, in both cases, these existing methods provide only a highly conservative lower bound because they assume that the patent holder gains nothing from the settlement and in effect transfers all joint profits from the settlement to the settling entrant through the payment. It is more realistic to assume the patent holder also captures some of

¹⁷ Elhauge and Krueger proved that this was true in a model where litigation had some positive length. Elhauge & Krueger, *supra* note 5, at 300-301. They also proved that if at risk entry during litigation would have occurred, the lower bound would be even higher, namely $X/M + \theta L$, where θ is the patent holder's estimate of the patent odds and L is the anticipated length of litigation. *Id.* at 301. The first lower bound was later confirmed in a simpler model that assumed instantaneous litigation by Edlin, Hemphill, Hovenkamp, & Shapiro, *Activating Actavis*, *supra* note 10, at 23.

¹⁸ Elhauge & Krueger proved that for a strong patent (i.e., with no at risk entry) the minimum settlement period with a reverse payment was $\theta + (1 - \theta)L + X/M$ and without a reverse payment was $\theta + (1 - \theta)L - C/M$, where C = the patent holder's anticipated litigation costs. Elhauge & Krueger, *supra* note 5, at 300, 314. Likewise, they proved that for a weak patent (i.e., with at risk entry) the minimum settlement period with a reverse payment was $\theta + X/M$ and without a reverse payment was $\theta - C/M$, *id.* at 301, 317. The difference in both cases is $(X+C)/M$, which is the same as R/M .

the joint gains from settlement, but these existing methods provide no direct means of calculating this amount.

II. THE PROMISE OF STOCK MARKET EVENT STUDIES

An earlier paper by some of us applied event-study methods to 68 drug patent settlements over the period 1993 to 2013, finding that settlements with an indication of a reverse payment from the patent holder to the generic entrant were associated with an immediate, large and statistically significant increase in the patent holder stock price (on average and after adjustment for trends and overall market changes), whereas settlements with no indication of a reverse payment were not associated with such a stock price change.¹⁹ The latter finding disproved any claim that the stock market systematically underestimates expected litigation exclusion periods because it underestimates the patent strength and patent holder bargaining power. Further, if such market underestimations explained why reverse payment settlements significantly increase patent holder stock prices, we would expect those reverse payment settlements to significantly decrease generic stock market prices. These data instead show that the settlements with reverse payments did not produce a statistically significant decrease in generic stock prices, but rather produced a statistically insignificant increase in the stock market prices of publicly traded generics.²⁰ These results thus indicate that, for the pharmaceutical industry overall, reverse-payment settlements were a pay-for-delay, increasing the expected profits of the patent holder by extending the expected time of selling without generic competition.

The current paper shows that such stock price movements can be used to establish anticompetitive effects and damages in individual cases, illustrating the approach by applying it to the 1995 settlement between Glaxo and GenPharm concerning Zantac (ranitidine). We chose an old settlement so as to illustrate our

¹⁹ Keith Drake, Martha Starr, & Thomas McGuire, *Do “Reverse Payment” Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay-for-Delay?*, INTERNATIONAL JOURNAL OF ECONOMICS AND BUSINESS, forthcoming.

²⁰ For example, using the market model and an event window that includes the day before and after the settlement announcement, the average cumulative abnormal return to generics was 1.2% (p=0.42).

methodology without implicating agreements which are or might come under antitrust scrutiny.²¹

As Schwert explains in a frequently cited article, financial events (here, the announcement of a settlement agreement) “result in a current change in security prices, and the price change is an unbiased estimate of the value of the change in future cash flows to the firm.”²² In other words, the change in stock prices associated with an event is an estimate of the present value of the additional future profits. Random fluctuations can affect stock prices (a factor event-study methods are designed to address), and investors’ expectations, while rational and informed, are also subject to error. Nonetheless, as long as the requirements for an event study are met, the change in stock prices is an unbiased, informative, and frequently used method for quantifying the dollar value of an unexpected event.²³

a. The Glaxo-GenPharm Zantac Settlement. In 1983, Glaxo launched Zantac (ranitidine), a histamine₂-receptor antagonist that reduces stomach acid and is meant to treat and prevent ulcers, heartburn, and other gastrointestinal disorders. Zantac became the top-selling prescription drug in the United States during the mid-1990s with sales of more than \$2 billion per year.²⁴ In February 1991, GenPharm Pharmaceuticals filed an abbreviated new drug application with the FDA, claiming that it was eligible to market a generic version of Zantac on December 5, 1995.²⁵ Glaxo sued GenPharm for patent infringement. On October 23, 1995, the day the patent trial was scheduled to begin, the companies announced a settlement, under which GenPharm acknowledged that Glaxo’s patents were valid and would be infringed, and agreed not to launch a generic product before

²¹ Antitrust litigation continues for numerous high-profile reverse payment cases. For a summary, see Melissa Lipman, *Law360’s Pay-For-Delay Cheat Sheet for 2015*, Law360, (January 2015), retrieved from: <http://www.law360.com/articles/608357/law360-s-pay-for-delay-cheat-sheet-for-2015>.

²² William Schwert, *Using Financial Data to Measure Effects of Regulation*, 24(1) J. L. & ECON. 121, 122 (April 1981).

²³ Schwert, *supra* note 22; Eugene Fama, *Efficient Capital Markets: A Review of Theory and Empirical Work*, 25(2) J. FINANC. 383 (May 1970); Craig MacKinlay, *Event Studies in Economics and Finance*, 35 J. ECON. LIT. 13 (1997).

²⁴ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U L. REV. 1553, 1569 (2006) [hereinafter Hemphill, *Paying for Delay*].

²⁵ See the Complaint, *Glaxo Inc., et al., v GenPharm Pharmaceuticals Inc.*, No. 1:92-cv-01831-FAK.

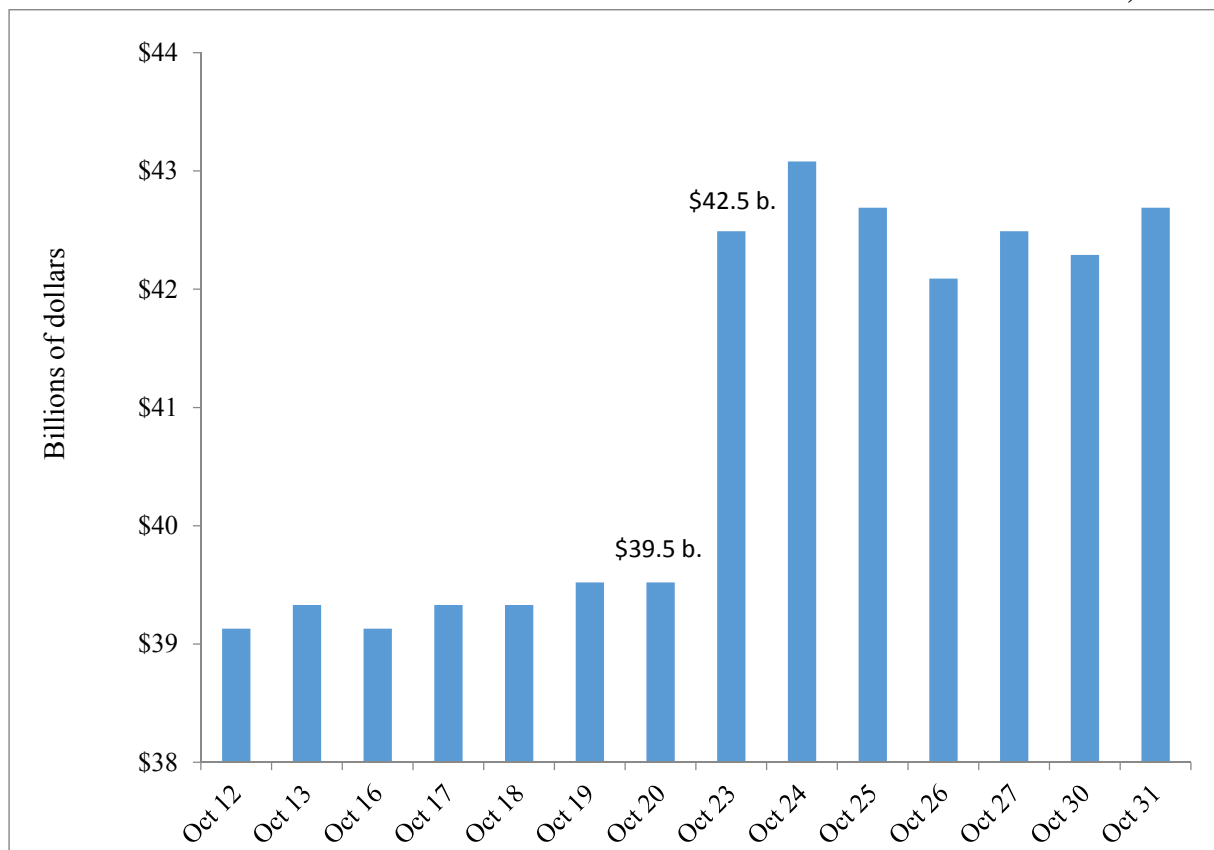
July 25, 1997.²⁶ In return Glaxo paid GenPharm an undisclosed cash amount, which analysts estimated to have been as much as \$50 million and may have been even higher.²⁷

Glaxo's stock price increased 7.5% on the day the settlement was announced. Figure 1 reports Glaxo's market capitalization (the total value of Glaxo's shares) for seven trading days before and after the Zantac settlement. The \$3 billion bump on the settlement announcement day (October 23rd) is maintained for days afterward.

²⁶ Although it avoided antitrust challenge, the FTC and others point to the Zantac settlement as one of the first reverse payment settlements. See Hemphill, *Paying for Delay*, *supra* note 24, at 1569; Hemphill, *An Aggregate Approach*, *supra* note 10, at 649. The settlement may have also affected generic entry in other product or geographic markets because GenPharm also agreed that Glaxo's "form 2" patent (which expired in 2002) was valid, and the settlement also resolved patent litigation in Canada, Britain, and Australia. See Stephen Moore, *Glaxo Shares Rise on Settlement of Zantac Suit*, Wall Street Journal Europe, October 24, 1995. Also see *Market Report – Glaxo Brings Welcome Relief on a Demoralising Day*, The Independent – London, October 24, 1995. U.S. sales made up 78% of Glaxo's combined sales from the countries included in the Zantac settlement, so we focus on the U.S. market. See Glaxo Wellcome PLC., Annual Report (Form 20-F), at 25 (Mar. 21, 1997).

²⁷ At the time of the settlement, financial analysts estimated the payment to be as much as \$50 million, see *Business Brief – GLAXO WELLCOME PLC: Settlement of Patent Case Spurs Drug Maker's Shares*, The Wall Street Journal, October 24, 1995. However, Hemphill, *Paying for Delay*, *supra* note 24, at 1569, explains how the payment size can be inferred from an FTC study and publically available information, and was actually \$132.5 million. Glaxo also agreed to sell specified quantities of ranitidine to GenPharm between 1997 and 1999, raising some questions about whether the cash amount should be adjusted up or down by the net value of this business side deal.

FIGURE 1
GLAXO MARKET CAPITALIZATION AROUND SETTLEMENT DATE OF OCTOBER 23, 1995



News reports linked the stock price increase directly to the settlement, noting the elimination of imminent risk of generic entry. For example, one report stated:

“the market took the view that Glaxo had made a realistic judgment in reaching a Zantac settlement. Its profits would have been hit if it had lost the case. The deal is seen as removing nagging worries...”²⁸

b. Using Event-Study Methods to Estimate the Increase in Stock Value.

While the stock price rise on the day of the announcement is evident from the raw data, event study methods refine the estimated effect, rule out or control for other factors influencing stock prices, and test whether a given stock price increase might be explained by random fluctuation. Event studies rely on the efficient market hypothesis, that share prices quickly incorporate all available information about a company’s future profits, to attribute the change in firm market value to the

²⁸ See Moore, *supra* note 26.

event.²⁹ Examples of event studies are abundant in economics, legal studies,³⁰ and other fields, and have been applied to health care and pharmaceutical industries, including to patent litigation.³¹ Laura Panattoni examined the stock price reaction to pharmaceutical patent holders winning or losing patent litigation, concluding that investors closely monitor trials and that their expectations about different possible outcomes are reflected in the stock price of the patent holder.³² Panattoni found that patent holders' share prices increased after winning patent litigation and decreased after losing patent litigation, supporting the proposition that before a decision, expected earnings lie between the expected earnings from winning or losing patent litigation.

An earlier paper by some of us studied announcements of drug patent settlements (as opposed to court decisions), with the purpose of testing whether settlements with indication of a reverse payment were associated with a stock price jump.³³ When the parties settled the patent litigation with an agreed-upon date of generic entry and no indication of a reverse payment, the patent holder's stock market did not react to the announcement -- in terms of elevated trading volume or price change. By contrast, when a settlement agreement did include indication of a reverse payment, both trading volume and stock price went up significantly in a short time horizon around the announcement. On average, patent holder stock prices went up 6%. A "control group" of settlements without a reverse payment were not associated with a significant increase in patent holder stock price. This methodology isolates the effect of the information contained in the presence of a

²⁹ See Fama, *supra* note 23.

³⁰ Event studies are commonly used in investigation of fraud and securities cases. See Sanjai Bhagat & Roberta Romano, *Event Studies and the Law: Part II: Empirical Studies of Corporate Law*, 4(2) AM. LAW ECON. REV., 380 (2002).

³¹ Laura Panattoni, *The Effect of Paragraph IV decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126 (2011); Jacobo-Rubio, Ruben, John L. Turner, and Jonathan Williams. *Pharmaceutical Patent Litigation: Measuring the Value of Generic Entry Rights and Brand Deterrence*, unpublished manuscript, University of Georgia, Department of Economics, (June 2013); Drake, Starr, & McGuire, *supra* note 19.

³² See Panattoni, *supra* note 31. For a similar study, see Jacobo-Rubio, Turner & Williams, *supra* note 31.

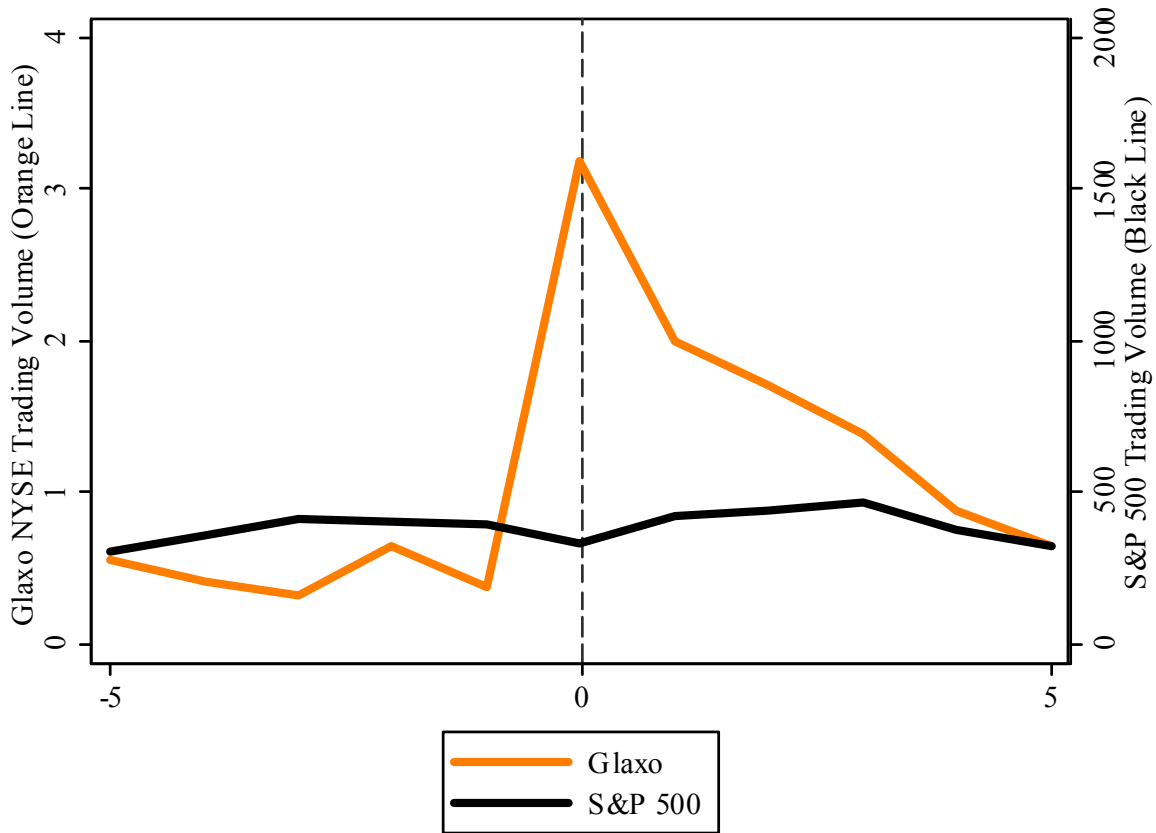
³³ See Drake, Starr & McGuire, *supra* note 19, at 9 and 25-26. Cash payments, contemporaneous business arrangements, and no-authorized generic clauses were regarded as indications of "payments" from the patent holder to the generic.

reverse payment from other reasons possibly accounting for the patent holder stock price jump which would have affected all drug patent settlements equally. The stock price increase when there was a reverse payment signals that these agreements extended the time the patent holder could sell without generic competition and that, overall, the reverse-payment agreements were anticompetitive.

An event study should satisfy certain criteria to support valid causal inference.³⁴ First, the “event” should be dated clearly; if not, the short event window within which to study the change in stock value cannot be reliably determined. Figure 2 shows the trading volume for Glaxo stock in the days leading up to and following the settlement announcement. The dramatic spike in volume, absent in the trading volume for the stock market overall, confirms that the announcement constituted “news” to traders on the day of the announcement. Second, the presence of other events or “news” on the date of the announcement should be ruled out; otherwise, it might be these other events, rather than the event of interest, are responsible for the value change. And third, there should be suitable data to estimate the daily random variation in stock value, and to control for other factors, such as market or industry-wide news that also influence stock prices. We ensured all of these criteria were satisfied prior to conducting a study of the Glaxo-GenPharm settlement.

³⁴ Sanjai Bhagat & Roberta Romano, *Event Studies and the Law: Part I: Technique and Corporate Litigation*, 4(1) AM. LAW ECON. REV., 141 (2002). See also MacKinlay, *supra* note 23.

FIGURE 2
TRADING VOLUME IN GLAXO SHARES AROUND THE ANNOUNCEMENT OF SETTLEMENT,
OCTOBER 23, 1995



c. An Event Study of the Glaxo-GenPharm Settlement. We use event study methods as described by MacKinlay.³⁵ To estimate baseline Glaxo stock price movement, we first calculate the daily expected returns using data from 120 trading days before the event window.³⁶ We then calculate the “abnormal return”—the indication of how the announcement affects stock prices – as the difference between the actual return earned by Glaxo and the expected return on the day of

³⁵ See MacKinlay, *supra* note 23.

³⁶ We calculate the expected return, $E[R^t]$, as $\hat{\alpha} + \hat{\beta}MR^t$ where $\hat{\alpha}$ and $\hat{\beta}$ are coefficients estimated from a linear regression of the Glaxo stock return on day t on the market returns on that day, MR^t . The percentage changes in the Standard & Poor’s 500 Stock Price index measures market returns. $\hat{\alpha}$ is the constant term estimated in that model and $\hat{\beta}$ is the estimated coefficient on MR^t .

the settlement announcement.³⁷ The statistical significance of the difference is tested with a t-statistic equal to the ratio of the abnormal return during the event window (e.g. on October 23, 1995) over the standard deviation of the daily abnormal returns during the prior 120 days. To test the robustness of the results to the choice of the event window, we also conduct analyses using alternative event windows which include one day before and after and two days before and after the event, making these three and five-day event windows, respectively. Longer event windows may capture a multiday effect, but have the disadvantage of potentially capturing noise unrelated to the event of interest.

We find that overall movement in the stock market does not explain the movement in Glaxo's stock price on the announcement day. Glaxo's stock price increased 7.5% on the day of the settlement announcement over the daily return from the S&P 500.³⁸ It is highly unlikely a bump this size occurred by chance ($p < 0.001$). These results are insensitive to the choice of event window; the cumulative abnormal return in Glaxo's stock price for the two longer event windows is even bigger, approximately 9% ($p < 0.001$ for both). Corresponding increases in Glaxo's market capitalization range between \$2.93 and \$3.49 billion for the single and multi-day event windows. In sum, results from the event study strongly indicate that the settlement announcement led to a sudden, multi-billion dollar increase in Glaxo's market value.

d. How the Event Study Proves Anticompetitive Effects. An increase in the patent holder stock value upon announcement of a reverse payment settlement constitutes a statistical test of the hypothesis that the agreement was anticompetitive. Absent a defendant showing of some unexpected procompetitive efficiency for which the settlement was reasonably necessary, the statements “the settlement increases expected patent holder profits” and “the agreement delays entry beyond the date expected with litigation” are economically equivalent. An

³⁷ The abnormal return is the difference between the actual return and the expected return: $A^t = R^t - E[R^t]$. For the market model used here, the expected return is based on the corresponding event window market return and the OLS estimates of $\hat{\alpha}$ and $\hat{\beta}$ from the equation in *supra* note 36.

³⁸ This result is from a regression in which daily returns of the S&P 500 are included as a regressor (as described in *supra* note 36) and the equation in *supra* note 37. In event studies, this is referred to as a Market Model.

event study showing an increase in future expected profits thus shows that the agreement is anticompetitive. The event study above shows that the Glaxo-GenPharm settlement was anticompetitive. Moreover, it does so without having to calculate the amount of the reverse payment.

One might object that investors might have underestimated the strength of the patent holder's patents and bargaining power, which would make them "surprised" by the favorable terms of a settlement. However, this alternative explanation conflicts with the finding from our earlier paper that there is no systematic correlation between settlements and stock price movements unless a reverse payment is present.³⁹ It also conflicts with the evidence showing that reverse payment settlements produce no statistically significant decrease in generic stock market prices, but rather produce a statistically insignificant increase in generic stock prices.⁴⁰ In an individual case, one might also be able to contradict this alternative explanation with an event study showing that the generic stock price did not have the drop such an explanation would imply.

A more serious problem is that a stock market event study might underestimate anticompetitive effects. To the degree that investors already anticipated an anticompetitive reverse payment settlement, those anticompetitive profits would have already been impounded into the stock price, and thus an event study may not find any significant effect even though the settlement was anticompetitive. Even if an anticompetitive reverse payment settlement were not anticipated in advance, investors might conclude that while news of it raises direct business profits, it also produces an offsetting increase in expected antitrust liability for the settlement. If so, then an anticompetitive reverse payment may fail to raise stock market prices precisely because the market expected antitrust law to correctly ascertain its anticompetitive nature and penalize the corporation accordingly.

In addition, an event study might erroneously fail to find anticompetitive effects when the observed change in the patent holder's stock price does not meet standard levels of statistical significance (e.g., p-values less than .05 or .10). This could happen for a number of reasons. The increase in future expected profits may

³⁹ See text accompanying *supra* note 19.

⁴⁰ See *supra* note 20 and accompanying text.

be small in relation to the random fluctuation of the patent holder's stock price, limiting the statistical "power" of the test.⁴¹ A p-value of less than 0.10 allows us to reject the null hypothesis of no effect because there is less than a 10% chance we would have obtained the statistical results in question if the null hypothesis were true, but a p-value of higher than 0.10 does not allow us to affirmatively conclude that the null hypothesis of no effect is true.⁴² Or, criteria for a valid event study might not be satisfied. News of the settlement might have trickled out rather than burst upon the scene, undermining the concept of an "event window." Investors may have correctly anticipated that a settlement involving a reverse payment would occur, so the announcement did not constitute news at all. Other events may have occurred around the same time as the settlement, so the estimated abnormal return may not reflect the effect of the settlement alone. As we noted earlier, the Zantac settlement satisfied criteria for an event study and the additional profits made up a significant share of Glaxo profits, so the danger of erroneously failing to capture an anticompetitive effect in this case was low, but this will not always be the case.

If, in spite of the above, an event study does show an abnormal increase in the share price, that suffices to prove anticompetitive effects, absent a defendant showing of some unexpected procompetitive efficiency for which the reverse payment settlement was reasonably necessary. We consider such claimed efficiencies next.

e. Assessing Procompetitive Efficiencies. The most common alleged procompetitive efficiency is avoiding litigation costs. However, a reverse payment settlement would be reasonably necessary to achieve such an unexpected avoidance of litigation costs only if settlement without a reverse payment were not possible or expected, which will only be in cases where the settling entrant was unreasonably optimistic about its odds of patent victory.⁴³ Absent such a showing,

⁴¹ The two prior empirical studies of drug patent court decisions and settlements segmented the cases into those in which the sales volume of the drug in question comprised a smaller and larger share of the overall patent holder sales. When the share was low, stock price movements were smaller and less likely to pass tests of statistical significance. See Panattoni, *supra* note 31, at 140; Drake, Starr & McGuire, *supra* note 19, at 27.

⁴² JEFFREY WOOLDRIDGE, *INTRODUCTORY ECONOMETRICS* 788-790, 793 (3d ed. 2006).

⁴³ Elhauge & Krueger, *supra* note 5, at 303.

an event study showing a stock price jump can suffice to show anticompetitive effects without any need to quantify anticipated litigation costs. If the patent holder can make this showing, then the event study still shows anticompetitive effects as long as the total increase in stock market capitalization exceeds the patent holder's avoided future litigation costs. Because the increase in stock market capitalization is usually much higher than the reverse payment amount, this will generally be easier to show than showing that the reverse payment amount exceeded the patent holder's avoided future litigation costs. For example, in Glaxo, it is implausible that avoiding future litigation costs could possibly explain a market capitalization increase of \$2.93 billion given that the most that had ever been spent on any drug patent litigation was \$15 million.⁴⁴

The next most common alleged justification is that management risk aversion might justify the reverse payment. As noted above, this claim is controversial both empirically and normatively.⁴⁵ In any event, to the extent it has any application it is limited to cases where (a) no settlement would have resulted without a reverse payment because the settling entrant is unreasonably optimistic and (b) management risk aversion is so high that they are willing to sacrifice expected corporate profits by not only paying the reverse payment but also accepting a settlement exclusion period that is less than the expected litigation exclusion period.⁴⁶ However, if that were the case, then expected patent holder profits should fall. Thus, an event study showing that instead expected patent holder profits rose disproves any alleged risk aversion justification.

Finally, defendants may claim that business side deals coupled with their settlements have procompetitive efficiencies. However, any such efficiencies can be attributed to the reverse payment settlement only if the settlement was reasonably necessary for that side deal. In the typical case this will not be true because nothing prevents the firms from entering into the business side deal separately from any patent settlement. Moreover, many business side deals are

⁴⁴ See Elhauge & Krueger, *supra* note 5, at 307.

⁴⁵ See *supra* p. 5.

⁴⁶ Edlin, Hemphill, Hovenkamp, & Shapiro, *Actavis and Error Costs*, *supra* note 16, at 4-7. Even in such cases, calling such a reverse payment "justified" is controversial because it allows a settlement that decreases expected corporate profits and thus lowers the returns to innovation below the level deemed optimal by patent law. Elhauge & Krueger, *supra* note 5, at 312.

concessions to the settling entrant (like agreeing not to sell an authorized generic) that can only decrease patent holder profits and thus cannot explain an event study showing a stock price increase. Even when the settlement is reasonably necessary for the business side deal in question, it will often be implausible that the side deal could have generated unexpected efficiencies large enough to explain a large increase in capitalized stock value. For example, in Glaxo, the business side deal was to supply ranitidine to the generic for the first two years after the settlement allowed generic entry.⁴⁷ Even if such a supply arrangement were really efficient, rather than a vehicle for delivering an additional side payment, such a supply arrangement could have equally been used after the patent period ended through patent litigation or a settlement without a reverse payment. The reverse payment settlement thus did not seem reasonably necessary for this side deal. Moreover, even if it were, it is implausible that a two-year contract to supply ranitidine to the generic could have possibly produced \$2.93 billion in unexpected efficiencies that would explain the stock price rise.

f. Calculating Damages. As described above, one can calculate a highly conservative lower bound on the period of delay associated with a reverse payment settlement if one assumes all joint gains from settlement would have gone to the settling entrant. If one assumes litigation would have resulted without the reverse payment settlement, the conservative lower bound on delay is X/M , the amount by which the reverse payment exceeds avoided litigation costs divided by the extra profits per day the patent holder gains by selling as a monopolist rather than against entrant competition. If one assumes a settlement without a reverse payment would have resulted without the reverse payment settlement, the conservative lower bound is R/M , that is, the amount of reverse payment divided by M .

However, it is far more likely that the patent holder also gains something from the agreement, and this is where an event study adds to the story. The abnormal increase in the firm's market capitalization conveys information about how investors expect the deal to affect the patent holder's future profits. Letting this be PV (for present value of additional profits), we add what the patent holder gains to what is paid to the settling entrant to get a (still conservative) estimate of

⁴⁷ See *supra* note 27.

the total additional anticompetitive profits from the settlement.⁴⁸ If one assumes that without the reverse payment settlement, patent litigation would have resulted, one can estimate a higher (but still conservative) lower bound of $(PV+X)/M$, and if one assumes that instead a settlement without a reverse payment would have resulted, one can estimate a higher (but still conservative) lower bound of $(PV+R)/M$.

To illustrate, how many days of market exclusivity are associated with the lower bound estimates of a \$2.93 billion increase in Glaxo's market capitalization and a payment to the generic of \$50 million? To be conservative, we assume profits as a share of sales are the same in the U.S. as other countries involved, implying that 78% of the market capitalization increase, \$2.32 billion, can be attributed to delay in the U.S.⁴⁹ To figure the number of days we need an estimate of M , the rate of profits the patent holder makes selling as a monopolist rather than against generic competition, a number that can be reasonably estimated from reports of patent holder sales. Financial analyses conducted around the time of the settlement imply that Zantac would earn about \$1.9 billion more in profits per year for Glaxo when selling without generic competition, which means M is \$5.2

⁴⁸ It is still highly conservative because it assumes that before the announcement the stock market believed that there was zero chance of a reverse payment settlement and that after the announcement the stock market believed that there was zero chance of antitrust liability. *See supra* p. 2. Neither of these is likely to be true, but to whatever extent they are not true they make the damages conservatively low.

⁴⁹ *See supra* note 26. It is conservative to assume that profits are proportional to sales across these countries because prices are generally much higher in the United States, see Michelle Llamas, *Big Pharma Cashes in on Americans Paying (Higher) Prices for Prescription Drugs*, (Oct. 2014), available at <http://www.drugwatch.com/2014/10/15/americans-pay-higher-prices-prescription-drugs/>. Our calculation assumes that the delay period is uniform across countries. With more information on prices and costs across countries, the estimates here could be refined. For example, assuming the profit margin on Zantac is 95% in the US and 70% in the other countries involved, the U.S.'s proportion of profits would be 85%, and the delay period we calculate would be 41 days higher. The multi-country feature of the Zantac settlement is atypical and will not generally be problematic, *see* C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey*, unpublished manuscript, 6-11 (Mar. 2007), available at <http://ssrn.com/abstract=669492>, showing that the Zantac case was the only reverse payment settlement up to 2007 that included international licenses.

million per day.⁵⁰ If we assume that without the reverse payment settlement, a settlement without any reverse payment would have occurred, then under existing methods the lower bound would be only $(\$50 \text{ million})/(\$5.2 \text{ million/day}) = 10$ days. Summing the lower bound estimate of market capitalization increase of \$2.32 billion with the reverse payment allows us to see that a better (albeit still conservative) lower bound is $(\$2.32 \text{ billion} + \$50 \text{ million})/(\$5.2 \text{ million/day}) = 446$ days. With this estimate of the “delay” in hand, we can use the definition of a delay to estimate the “expected date of generic entry,” as the agreed upon date (July 25, 1997), less the delay (446 days), or May 5, 1996.

III. CONCLUSION

Study of the movements of the patent holder’s stock price at the time of an announcement of reverse payment settlement can contribute to an economic analysis of its competitive effects. An anticompetitive settlement generates additional anticompetitive profits for the patent holder by giving it more time to sell without entrant competition. Evidence about a reverse payment focuses on the part of any additional anticompetitive profits that are transferred to the settling entrant through that payment. Evidence from an event study of the patent holder stock price complements this form of evidence with an economic evaluation of the additional anticompetitive profits that were retained by the patent holder.

We believe the event study of stock prices has promise for several reasons. Including the anticompetitive profits the patent holder keeps rather than only the anticompetitive profits that the patent holder transfers is more accurate given that it seems certain that patent holders retain at least some share of any anticompetitive profits. Indeed, if (as seems likely) patent holders normally retain the lion’s share

⁵⁰ Financial analysts believed Zantac would earn Glaxo approximately \$2 billion in profits during the year after the settlement, see “Patent Deal Prompts Glaxo Share Surge,” *The Independent*, October 24, 1995. We assume Glaxo profits would fall by 95% without patent protection based on data for Zantac reported in Ernst Berndt, Margaret Kyle and Davina Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, in SCANNER DATA AND PRICE INDEXES 8, 229-273 (Jan. 2003). Other studies indicate the drop in profits can be lower, especially for drugs with lower sales. See Elhauge and Krueger at 316 (collecting literature, though only summarizing results with one generic entrant); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 43 (2005). (covering all numbers of entrants).

of anticompetitive profits, then focusing only on what the patent holder transfer to the entrant misses most of the story. Event studies also have the advantage of focusing on the behavior of rational investors who closely follow industry news, rather than on the behavior of deal-makers with well-understood incentives to disguise the true nature of their settlements. The predictions of the “anticompetitive hypothesis” are sharp and testable with publicly available data, meriting, we think, the label, the “smoking gun” of reverse-payment settlements.