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RESOLVING REVERSE-PAYMENT SETTLEMENTS WITH THE SMOKING GUN OF STOCK PRICE MOVEMENTS

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Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements

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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: (1) obscure the amount of the reverse payment; and (2) 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 Essay 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.

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I. INTRODUCTION

In a reverse-payment patent settlement, the patent holder pays the alleged infringer, who in turn agrees not to enter the market until an agreed date. Ending over a decade of conflicting lower court rulings, the Supreme Court in *FTC v. Actavis, Inc.* 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.[1] But application of this standard has often proven contentious because defendants usually: (1) obscure the amount of the reverse payment by coupling it with various business side deals; and (2) 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 Essay offers a method that can often cut through these difficulties by demonstrating and quantifying anticompetitive effects with a stock market event study. If the patent holder's stock market price jumps in response to an announcement of a reverse-payment settlement, then such a study shows that (absent proof of unexpected procompetitive efficiencies, including any

1. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

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: (1) the settlement exclusion period exceeded the expected litigation exclusion period; or (2) 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.[2] 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.[3]

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: (1) expected such an anticompetitive reverse-payment settlement all along; or (2) anticipated a risk of antitrust damages that offset the anticompetitive profits from the settlement. Further, stock market event studies of single events often require very large effects for statistical significance, and may fail to pick up substantial anticompetitive effects. The lack of a spike in a patent holder's stock market price accordingly cannot disprove anticompetitive effects, but the existence of one can prove such effects.

When abnormal stock market returns in response 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 claim 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 net amount of the reverse payment can only be used to estimate a floor on anticompetitive damages that assumes the patent holder earned zero profits from settlement.

2. *See infra* Part III.B.

3. *See infra* Part III.

II. THE CURRENT PROBLEM

Although a valid patent entitles a holder to exclude others from infringing the patent, a patent issued by the Patent and Trade Office is not necessarily a valid patent. Studies indicate that 48–73% of issued patents are held invalid in court.[4] A patent holder's entitlement to the monopoly profits that come from excluding entrants thus depends on the expected odds that the patent is valid and infringed. 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 is not only the very thing that patent settlements seek to avoid, but also produces bimodal results that do not capture the expected patent odds at the time of settlement.[5] Scholarship prior to *Actavis* addressed these concerns by proving that, without any inquiry into the patent merits, a court can determine 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 period 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: (1) market power; and (2) that the settlement

4. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at vi (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf ("Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute."); *see also* ADAM GREENE & D. DEWEY STEADMAN, RBC CAPITAL MKTS., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 1 (2010), http://amlawdaily.typepad.com/pharmareport.pdf (noting that patent holders lose 48% of the cases with generic entrants); Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006) (providing data that demonstrates that patent holders lose approximately 70% of the time).

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, 290–92, 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. *See* 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. *See* Elhauge & Krueger, *supra* note 5, at 297–304, 325–26. Elhauge and Krueger further explained why risk aversion should not count as a procompetitive justification. *Id.* at 311–12.

exceeded the optimal patent reward for innovation (assuming patent law has been optimized) if the settling entrant is not judgment proof.[7]

Actavis is in accord with 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 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 exceeds anticipated litigation costs shows market power, obviates the need to inquire into the patent merits, and indicates that the settlement exclusion period exceeds what is merited by the expected patent odds.[9] Unfortunately, application of this standard has proven contentious because: (1) side deals can obscure the reverse-payment amount; (2) defendants argue that the payments are justified to avert risk; and (3) one can infer only a highly conservative floor on damages from the reverse-payment amount.

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 absence of the patent holder's authorized generic roughly

7. Elhauge & Krueger, *supra* note 5, at 293–304, 307–11.

8. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

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, 649–50 (2009); *see also* Aaron Edlin et al., *Activating* Actavis, ANTITRUST, Fall 2013, at 16, 18 ("[T]he 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.

doubles the first-filing generic's revenue during its generic exclusivity period, 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 pay 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 scholars argue that 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 courts do admit risk aversion as a justification, it would

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. BUREAU OF COMPETITION, FED. TRADE COMM'N, 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, at 1 (2013), https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

12. *See* FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 104–06 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

13. *See, e.g.*, Barry C. Harris et al., *Activating* Actavis*: A More Complete Story*, ANTITRUST, Spring 2014, at 83, 85 & n.16 (2014); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 665–67 (2004).

14. *See* Elhauge & Krueger, *supra* note 5, at 312.

15. *Id.*

16. Edlin et al., *supra* note 10, at 20; *see also* Aaron Edlin et al., Actavis *and Error Costs: A Reply to Critics*, ANTITRUST SOURCE, Oct. 2014, at 1, 4–7.

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 litigation would have resulted without the reverse-payment settlement, one can calculate a lower bound on this delay by dividing *X*, the excess amount of payment (i.e., the amount by which the reverse payment exceeds avoided litigation costs), by *M*, the extra profits per day the patent holder gains by selling as a monopolist rather than against entrant competition.[17] If a no-payment settlement would have resulted without the reverse-payment settlement, a lower bound on this delay can instead be calculated by dividing *R*, the reverse-payment amount, by *M*.[18] 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 the joint gains from settlement, but the existing methods provide no direct means of calculating this amount.

III. THE PROMISE OF STOCK MARKET EVENT STUDIES

This Essay shows that 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

17. Elhauge and Krueger proved that this was true in a model where litigation had some positive length. *See* Elhauge & Krueger, *supra* note 5, at 299–300. They also proved that if at-risk entry occurred during litigation, or would have occurred without settlement, then 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. *See id.* at 301–02 (Given the definition of *X* and *M* noted in text, *X* replaces *A* and *M* replaces $P_N - P_Y$ from how the formulas were expressed in Elhauge and Krueger, *supra*.). The first lower bound was later confirmed in a simpler model that assumed instantaneous litigation by Edlin et al., *supra* note 10, at 23.

18. Elhauge and Krueger proved that for a strong patent (i.e., one with no at-risk entry) the minimum settlement period with a reverse payment is $\theta+(1-\theta)L+X/M$. Elhauge & Krueger, *supra* note 5, at 299–300. Without a reverse payment, the minimum settlement period is $\theta+(1-\theta)L+C/M$, where *C* equals the patent holder's anticipated litigation costs. *See Id.* at 314. Likewise, they proved that for a weak patent (i.e., with at-risk entry) the minimum settlement period with a reverse payment is $\theta+X/M$ and without a reverse payment is $\theta - C/M$. *Id.* at 301, 317. For both strong and weak patents, the difference between the settlement period with and without a reverse payment is $(X+C)/M$, which is the same as R/M.

our methodology without implicating agreements which are or might come under antitrust scrutiny.[19]

An earlier paper by some of us applied event-study methods to 68 drug patent settlements over the period 1993–2013, 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.[20] The latter finding disproved any claim that the stock market systematically underestimates expected litigation exclusion periods because of any market underestimations of 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 an indication of 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.[21] The above results, therefore, 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.

As William 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

19. 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 (Jan. 5, 2015, 8:21 PM), http://www.law360.com/articles/608357/law360-s-pay-for-delay-cheat-sheet-for-2015.

20. *See generally* Keith M. Drake, Martha A. Starr & Thomas G. McGuire, *Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?*, 22 INT'L J. ECON. BUS. 173 (2015).

21. 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% ($p = 0.42$). This result was not presented in our earlier paper.

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

method for quantifying the dollar value of an unexpected event,[23] such as a patent litigation settlement.

A. THE GLAXO–GENPHARM ZANTAC SETTLEMENT

In 1983, Glaxo launched Zantac (ranitidine), a histamine$_2$-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 agreed not to launch a generic product before 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. Below, Figure 1 reports Glaxo's market capitalization (the total market value of Glaxo's shares) for the seven trading days before and after

23. *Id.* at 122. *See generally* Eugene F. Fama, *Efficient Capital Markets: A Review of Theory and Empirical Work*, 25 J. FIN. 383 (1970); A. Craig MacKinlay, *Event Studies in Economics and Finance*, 35 J. ECON. LITERATURE 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).

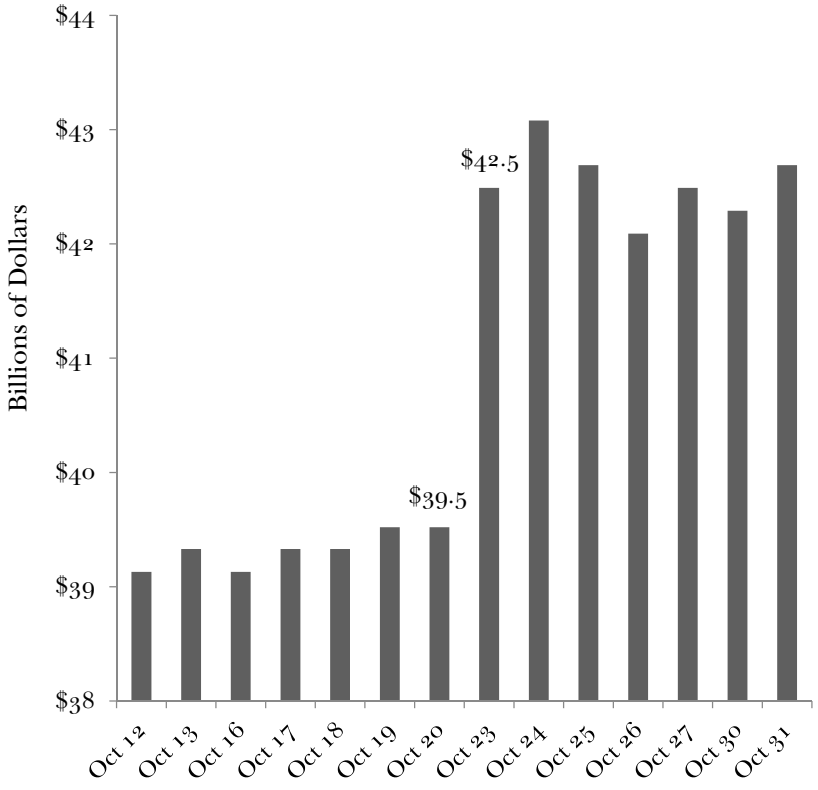
25. *See* Complaint, Glaxo Inc. v. Genpharm Pharmaceuticals Inc., No. 1:92-cv-01831-FAK (D. Md. June 30, 1992).

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, *supra* note 10, at 649; Hemphill, *supra* note 24, at 1569. 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* Tom Stevenson, *Patent Deal Prompts Glaxo Share Surge*, INDEPENDENT (Oct. 23, 1995), http://www.independent.co.uk/news/business/patent-deal-prompts-glaxo-share-surge-1579190.html; *see also* Derek Pain, *Market Report—Glaxo Brings Welcome Relief on a Demoralising Day*, INDEPENDENT, Oct. 24, 1995. But the U.S. market made up approximately 55% of Zantac sales, so we focus on it. *Compare* Hemphill, *supra* note 24, at 1569 (stating that Glaxo had approximately $2 billion in U.S. sales), *with* Daniel Green, *Glaxo Shares Rise as It Settles Patent Case*, FIN. TIMES, October 24, 1995 (reporting Glaxo as having worldwide sales of $3.6 billion).

27. At the time of the settlement, financial analysts estimated the payment to be as much as $50 million. *Glaxo Wellcome PLC: Settlement of Patent Case Spurs Drug Maker's Shares*, WALL STREET J., Oct. 24, 1995, at B4 [hereinafter *Glaxo Wellcome PLC*]. However, the payment size can be inferred from an FTC study and publicly available information, and was actually $132.5 million. Hemphill, *supra* note 24, at 1569 n.63. 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. *See* Stevenson, *supra* note 26.

the Zantac settlement. The $3 billion bump on the settlement announcement day (October 23) is maintained for days afterward.

Figure 1. Glaxo Market Capitalization Around Settlement Date of October 23, 1995



News reports linked the stock price increase directly to the settlement. For example, a report in the *Wall Street Journal*, entitled "Glaxo Shares Rise on Settlement of Zantac Suit," stated: "Glaxo Wellcome PLC shares surged 7% after the British drug maker unveiled an out-of-court settlement ending a protracted legal challenge to U.S. patents on blockbuster antiulcer drug Zantac."[28]

28. *See Glaxo Wellcome PLC*, *supra* note 27.

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 of the settlement, rule out or control for other factors influencing stock prices, and test whether a given stock price increase might be explained away 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 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]

For example, Laura Panattoni examined the stock price reaction to pharmaceutical patent holders winning or losing patent litigation, and she concluded 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 an 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 did not react to the announcement in terms of elevated trading volume or price change.[34] 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

29. *See* Fama, *supra* note 23, at 416.

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

31. *See, e.g.*, Drake, Starr, & McGuire, *supra* note 20; Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126 (2011); Ruben Jacobo-Rubio et al., The Private Value of Entry and Deterrence in the U.S. Pharmaceutical Industry (Jan. 14, 2014) (unpublished manuscript), https://media.terry.uga.edu/socrates/contact/documents/2014/01/24/value-entry-deterrence_Jan-11-2014.pdf.

32. *See* Panattoni, *supra* note 31, at 130. For a similar study, see Jacobo-Rubio et al., *supra* note 31.

33. *See* Drake, Starr & McGuire, *supra* note 20, at 175. Cash payments from the brand to the generic, contemporaneous business arrangements, and no-authorized-generic clauses were regarded as indications of "payments" from the patent holder to the generic. *Id.* at 181–82.

34. *Id.* at 189–93.

announcement.[35] On average, patent holder stock prices went up six percent.[36] A "control group" of settlements without a reverse payment was not associated with a significant increase in patent holder stock price.[37] This methodology isolates the effect of the information contained in the presence of a 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 the reverse-payment agreements were generally anticompetitive.

An event study should satisfy certain criteria to support valid causal inference.[38] 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. Below, 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.

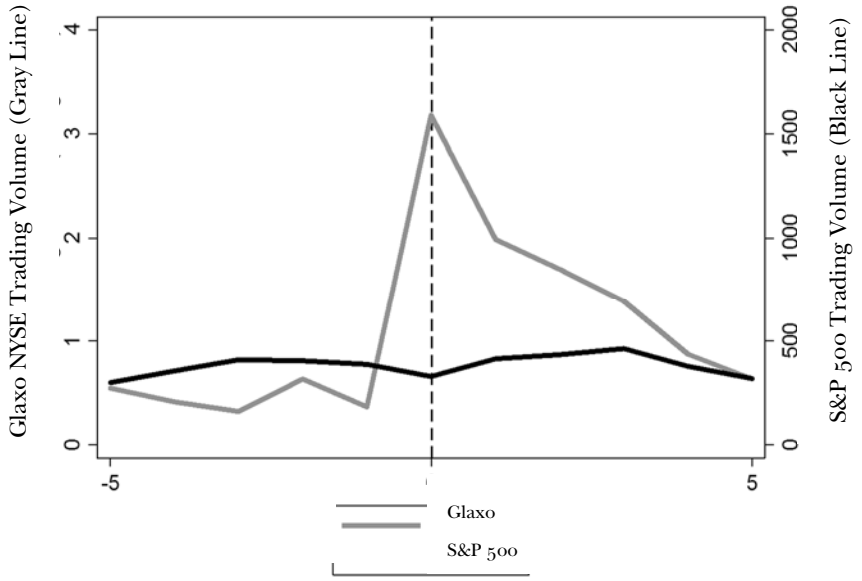
35. *Id.* at 175.

36. *Id.*

37. *Id.*

38. Sanjai Bhagat & Roberta Romano, *Event Studies and the Law: Part I: Technique and Corporate Litigation*, 4 AM. L. ECON. REV. 141 (2002); *see also* MacKinlay, *supra* note 23, at 14–16.

Figure 2. Trading Volume in Glaxo Shares Around the Announcement of Settlement, October 23, 1995 (Millions of Trades)



C. *AN EVENT STUDY OF THE GLAXO–GENPHARM SETTLEMENT*

For this Essay, we used event-study methods as described by MacKinlay[39] and concluded that the settlement announcement resulted in a large increase in Glaxo's stock value that cannot be explained by normal market movement. To estimate baseline Glaxo stock price movement, we first calculated the daily expected returns using data from 120 trading days before the event window.[40] 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 the settlement announcement.[41] We tested the statistical significance of the difference 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

39. *See* MacKinlay, *supra* note 23, at 14–16.

40. 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. The constant term estimated in that model is $\hat{\alpha}$, and $\hat{\beta}$ is the estimated coefficient on MR^t.

41. The abnormal return is the difference between the actual return and the expected return: $A^t = R^t - E[R^t]$. 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 note 40, *supra*.

returns during the prior 120 days. To test the robustness of the results to the choice of the event window, we also conducted analyses using alternative event windows which include both one day before and after as well as two days before and after the event, making these three- and five-day event windows, respectively. Longer event windows may capture a multi-day effect, but have the disadvantage of potentially capturing noise unrelated to the event of interest.

Results from the event study strongly indicate that the settlement announcement led to a sudden, multi-billion dollar increase in Glaxo's market value. We found 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.[42] It is highly unlikely that 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 nine percent ($p < 0.001$ 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. As noted above, there was no other simultaneous news about Glaxo that could explain this sharp jump in Glaxo stock.

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's showing of some unexpected procompetitive efficiency for which the settlement was reasonably necessary, the statements that "the settlement increases expected patent holder profits" and "the agreement delays entry beyond the date expected with litigation" are economically equivalent. An event study showing an increase in future expected profits thus shows that the agreement is anticompetitive. The event study in this Essay, therefore, shows that the Glaxo–Genpharm settlement was anticompetitive. Crucially, it does so without having to calculate the amount of the reverse payment—thereby avoiding any evidentiary issues associated with this test.

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

42. This result is from a regression in which daily returns of the S&P 500 are included as a regressor (as described in note 40, *supra*) and the equation in note 41, *supra*.

a reverse payment is present.[43] It also conflicts with the evidence showing that reverse-payment settlements produce no statistically significant decrease in generic stock market prices in the industry overall.[44] In an individual case, an event study showing that the generic stock price did not drop significantly would also contradict this alternative explanation. However, a generic stock drop would not suffice to establish this alternative explanation, because such a drop could instead reflect the stock market's conclusion that the settlement was anticompetitive in a way that created expected antitrust liability for the generic that exceeded its share of the anticompetitive profits created by the settlement.

A more serious limitation of this form of analysis is that a stock market event study might *under*estimate anticompetitive effects. To the degree that investors already anticipated an anticompetitive reverse-payment settlement, those anticompetitive profits would already have been impounded into the stock price, so an event study may not find any significant effect even though the settlement was anticompetitive. Even if an anticompetitive reverse-payment settlement was 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.

An event study might also 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 0.05 or 0.10). This could happen for a number of reasons. First, the increase in future expected profits may be small in relation to the random fluctuation of the patent holder's stock price, limiting the statistical "power" of the test.[45] A *p*-value of less than 0.10 allows us to reject the null hypothesis of no effect because there is less than a ten percernt 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.[46] Second, criteria for a valid event study might

43. *See supra* text accompanying note 21.

44. *See supra* note 21 and accompanying text (noting in the study of a large number of settlements that the average effect on the generic stock price was positive but not statistically significant).

45. 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* Drake, Starr & McGuire, *supra* note 20, at 191–93; Panattoni, *supra* note 31, at 140.

46. *See* JEFFREY M. WOOLDRIDGE, INTRODUCTORY ECONOMETRICS: A MODERN APPROACH 788–90 (3d ed. 2006).

not be satisfied. News of the settlement could trickle out rather than burst upon the scene, which would undermine the concept of an "event window." Investors may correctly anticipate that a settlement involving a reverse payment would occur, so the announcement would 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 true.

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 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 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.[47] Absent such a showing, an event study showing a stock price jump suffices to show anticompetitive effects without any need to quantify those costs. If the patent holder can make this showing, then the event study still identifies anticompetitive effects as long as the total increase in stock market capitalization exceeds the patent holder's avoided future litigation costs. Because a statistically significant increase in stock market capitalization is usually much higher than the reverse-payment amount, this will generally be easier to demonstrate 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.[48]

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.[49] In any event, to the extent it has any application, it is limited to cases where: (1) no settlement would

47. *Cf.* Elhauge & Krueger, *supra* note 5, at 303 (discussing the implications of an entrant's pessimism or optimism regarding patent strength).

48. *See id.* at 307.

49. *See supra* Part II.B.

have resulted without a reverse payment because the settling entrant is unreasonably optimistic; and (2) management risk aversion is so high that the managers of the patent holder 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.[50] However, if that were the case, then expected patent holder profits should fall. An event study that instead shows that expected patent holder profits rose thus contradicts 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 business side deals separately from any patent settlement. Moreover, many business side deals are concessions to the settling entrant (like agreeing not to sell an authorized generic) that can only decrease patent holder profits, which 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 the Zantac settlement, the business side deal was to supply ranitidine to the generic for the first two years after the settlement allowed generic entry.[51] 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. Therefore, the reverse-payment settlement was not reasonably necessary for this side deal. 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 conservatively assumes all joint gains from settlement would have gone to the settling entrant. If 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

50. Edlin et al., *supra* note 10, at 18–20. 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.

51. *See* Stevenson, *supra* note 26.

extra profits per day that the patent holder gains by selling as a monopolist rather than against entrant competition. If 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. Call the present value of those additional profits PV. Adding this PV that the patent holder gains to what is paid to the settling entrant produces a (still conservative) estimate of the total additional anticompetitive profits from the settlement.[52] If patent litigation would have resulted without the reverse-payment settlement, a higher (but still conservative) lower bound of $(PV + X)/M$ of anticompetitive delay can be estimated, and if a settlement without a reverse payment would have resulted instead, a higher (but still conservative) lower bound of $(PV + R)/M$ can be estimated.

To illustrate, consider 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 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 reasonably be 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 that M is $5.2 million per day.[53] If we assume that, without the reverse-payment settlement, a no-payment settlement would have occurred, then under existing methods the lower bound would be only ($50 million) / ($5.2 million per day) = 10 days. Summing the lower bound estimate of market capitalization increase of $2.93 billion with the reverse payment allows us to

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

53. Financial analysts believed Zantac would earn Glaxo approximately $2 billion in profits during the year after the settlement. *See, e.g.*, Stevenson, *supra* note 26. We assume Glaxo profits would fall by 95% without patent protection based on data for Zantac reported in Ernst Berndt et al., *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, *in* SCANNER DATA AND PRICE INDEXES 229 (Robert C. Feenstra & Matthew D. Shapiro eds., 2003). Other studies indicate the drop in profits can be lower, especially for drugs with lower sales. *See, e.g.*, Elhauge & Krueger, *supra* note 5, 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).

see that a better (albeit still conservative) lower bound is ($2.93 billion + $50 million) / ($5.2 million per day) = 573 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 (573 days), or December 30, 1995.

IV. CONCLUSION

Studying the movement of the patent holder's stock price at the time the patent holder announces a reverse-payment settlement can contribute to an economic analysis of the settlement's 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 is 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 accruing to the patent holder.

The event study of stock prices has promise for several reasons. Including the anticompetitive profits that 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 keep the lion's share of anticompetitive profits, then focusing only on what the patent holder transfers to the entrant misses most of the anticompetitive delay of entry. 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, calling event studies the "smoking gun" of reverse-payment settlements.