

A FRAMEWORK FOR ESTIMATING DAMAGES IN REVERSE PAYMENT CASES

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Abstract

Patent disputes between brand and generic pharmaceutical manufacturers are often settled with compensation from the brand (the patent holder) to the generic (the alleged infringer), along with restrictions on the generic's entry date. Such agreements are known as "reverse payment" settlements. The effect of a reverse payment settlement on market outcomes depends importantly on the unobserved strength of the brand's patent. To quantify the effect of a reverse payment settlement, we propose using bargaining theory to estimate the unobserved patent strength from the observed settlement. The estimated patent strength can then be used to construct counterfactuals without reverse payments. Applying the framework to the Lamictal case, we find that the settlement reached by the brand and generic manufacturer cost buyers over \$100 million relative to the settlement that would have been reached had a reverse payment not been an option, and over \$1.3 billion relative to the expected outcome under continued litigation.

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The 1984 Hatch-Waxman Act established a mechanism through which generic pharmaceutical manufacturers can be approved to market generic versions of branded drugs.¹ Generic manufacturers are required to file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) that demonstrates that the drug as produced by the generic is bioequivalent to the branded drug. Successfully establishing bioequivalence, however, does not immediately trigger approval. Branded drugs are typically covered by one or more patents that protect them from generic competition. To file for approval to market a generic prior to the expiration of these patents, generics must make a Paragraph IV certification, claiming that the patents are invalid or will not be infringed by the generic product. Brand manufacturers are notified of Paragraph IV challenges and typically sue for patent infringement. As in other patent litigation contexts, the brand and generic often settle prior to the resolution of the case in court. Generally speaking, such settlements can be characterized by two components: (1) the date the generic may begin marketing the drug, and (2) some form of consideration from one party to the other.

Settlements in which the brand pays the generic are known as “reverse payment” settlements, or “pay-for-delay” settlements, as labeled by the FTC. Such payments are considered reverse because the firm whose intellectual property is allegedly infringed makes the payment. Pay-for-delay comes from an argument that the payment from brand to generic is in exchange for a later generic entry date. The FTC has been investigating reverse payment settlements since the late 1990s, contending that they are anticompetitive and therefore violate antitrust law.² In 2013, the U.S. Supreme Court took up the issue in *FTC v. Actavis*,³ ruling that reverse payment settlements are subject to antitrust scrutiny but not presumptively unlawful, and directed courts to apply the rule of reason to determine whether a given settlement violated antitrust law.⁴

In this article we develop a framework to estimate the impact of a given reverse payment settlement on the timing of generic entry, relative to continued litigation and/or a counterfactual

¹ For more information about the approval process, see, e.g., SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS (2012).

² See, e.g., FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010).

³ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

⁴ *Id.* at 2226.

settlement that does not contain a reverse payment.⁵ The core idea of the approach is to impose structure on the relationship between patent strength and settlement choice, and then use the observed settlement choice to infer the unobserved patent strength. The inferred patent strength can then be used to predict the expected outcome of continued litigation, as well as the settlement that would have been chosen had a reverse payment not been an option—outcomes central to the quantification of any damages from a reverse payment settlement.

To illustrate the framework, we apply it to the drug Lamictal (lamotrigine), an anticonvulsant developed by GlaxoSmithKline (GSK). Generic manufacturer Teva (TEV) filed a Paragraph IV challenge to produce generic lamotrigine prior to the expiration of GSK's patents, and GSK subsequently sued TEV for patent infringement.⁶ The firms settled in February 2005, with TEV agreeing not to enter until July 2008 and GSK agreeing not to compete with its own generic when TEV entered. In 2012, a class of purchasers sued GSK and TEV alleging that the settlement was anticompetitive.⁷ Our results suggest that the settlement increased total wholesale spending on lamotrigine tablets by over \$100 million relative to the settlement GSK and TEV would have reached had a reverse payment not been an option, and by over \$1.3 billion relative to the expected outcome under continued litigation. Because these results are based on data that may be less complete than what would be available in an actual litigation, we emphasize that these estimates should be taken with some caution. The primary purpose of the exercise is to illustrate how our proposed framework can be applied.

We view our primary contribution to the literature on reverse payment settlements as providing a practical framework for estimating damages in specific cases. Most prior academic work focuses on determining the potential antitrust liability of reverse payment settlements. If the broad takeaway from that work is that reverse payment settlements can be—but are not necessarily—anticompetitive, it is an important next step to look at individual cases and try to understand the underlying economics determining firms' settlement choices. In addition, our framework allows for damages estimation without directly examining the validity of the patent, which can be complex and time consuming. While the decision in *Actavis* indicates that an examination of patent

⁵ These are the two counterfactual benchmarks in Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Actavis and Error Costs: A Reply to Critics*, ANTITRUST SOURCE (Oct. 2014), www.americanbar.org/content/dam/aba/directories/antitrust/oct14_edlin_10_21f.authcheckdam.pdf.

⁶ *In re Lamictal Direct Purchaser Antitrust Litig.*, Civ. No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012).

⁷ *Id.*

strength is “normally not necessary”⁸ to determine whether a settlement is anticompetitive—instead relying on payment size as a proxy (the “*Actavis* inference”⁹)—quantification of any relevant damages requires an estimate of what would have happened in the absence of the settlement, which, in turn, likely requires an estimate of patent strength.

More broadly, this article contributes to a growing literature that applies structural econometric methods to topics in competition policy and, more specifically, to situations in which outcomes are determined via bargaining. A foremost example in this literature is merger simulation. Recent developments in merger simulation include methods using bargaining theory to predict merger effects in markets in which prices are negotiated.¹⁰ We adapt similar methods to the study of reverse payments.

I. BACKGROUND

A. REVERSE PAYMENT INCENTIVES

Under Hatch-Waxman, a key incentive for generics to challenge patents is that the first Paragraph IV challenger is given a 180-day exclusivity period during which it is the only generic manufacturer permitted to market the drug.¹¹ This exclusivity period begins on the earlier of when (a) the generic begins marketing the drug or (b) a court rules the brand’s patent to be invalid or not infringed.¹² Because generic competition quickly drives down generic prices and profits, 180-day exclusivity grants the first generic a secure period during which substantial profits can be earned, thereby encouraging patent challenges. Research has found that the prevalence of patent challenges increased dramatically following the enactment of Hatch-Waxman, and especially after the 1998

⁸ *Actavis*, 133 S. Ct. at 2236.

⁹ See Edlin et al., *supra* note 5, at 1.

¹⁰ Gautam Gowrisankaran, Aviv Nevo & Robert Town, *Mergers When Prices Are Negotiated: Evidence from the Hospital Industry*, 105 AM. ECON. REV. 172 (2015); Kate Ho & Robin S. Lee, *Insurer Competition in Health Care Markets*, 85 ECONOMETRICA 379 (2017). Other applications of bargaining models in the literature include, e.g., Gregory S. Crawford & Ali Yurukoglu, *The Welfare Effects of Bundling in Multichannel Television Markets*, 102 AM. ECON. REV. 643 (2012); Matthew Grennan, *Price Discrimination and Bargaining: Empirical Evidence from Medical Devices*, 103 AM. ECON. REV. 145 (2013).

¹¹ 21 U.S.C. § 355(j)(5)(B)(iv)

¹² What counts as a court decision has been the subject of considerable debate. For instance, some have argued that the exclusivity period should start only after appeals have been exhausted. Others have argued that any court decision in favor of the generic should immediately trigger the exclusivity period. See, e.g., *Mylan Pharm. v. Shalala*, 81 F. Supp. 2d 30, 37 (D.D.C. 2000).

decision in *Mova v. Shalala*,¹³ which expanded the set of circumstances under which generics could receive 180-day exclusivity.

With or without 180-day exclusivity, a fundamental insight concerning brand/generic patent litigation is that the brand typically has far more to lose than the generic has to gain. Both brand and industry profits decrease sharply once a generic has entered.¹⁴ Because industry profits are larger under monopoly, firms locked in patent litigation may have incentives to use reverse payments to divide up monopoly rents, compensating the generic in a way that maintains industry profits.¹⁵

While reverse payment settlements do not preclude other generics from challenging the brand's patent, settlements with the first Paragraph IV challenger establish obstacles to future challengers. First, the expected payoffs from later patent challenges are far smaller because 180-day exclusivity is only granted to the first challenger. Second, the FDA is often prevented from approving other ANDAs for the same drug until the first challenger's 180-day exclusivity period has expired. Thus, if the first challenger's exclusivity period is not triggered or forfeited, delaying the entry of the first challenger may effectively delay all generic entry.¹⁶ Moreover, even if there are multiple challengers, continued monopoly is likely capable of benefiting everyone involved—except consumers.

Given these incentives, the FTC began closely investigating reverse payment settlements in the late 1990s. One of the first and most prominent reverse payment cases is *Schering-Plough*,

¹³ *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). For further information on trends in patent challenges, see, e.g., FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002) [hereinafter *FTC, GENERIC DRUG ENTRY*]; C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613 (2011).

¹⁴ See, e.g., Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, in *HANDBOOK OF HEALTH ECONOMICS* 763 (Mark V. Pauly, Thomas G. McGuire & Pedro P. Barros eds., Vol. 2 2011).

¹⁵ This basic argument has been developed in numerous articles. See, e.g., John P. Bigelow & Robert D. Willig, "Reverse Payments" in *Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC (2005)*, in *THE ANTITRUST REVOLUTION* 248 (John E. Kwoka, Jr. & Lawrence J. White eds., 5th ed. 2009); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 *ANN. HEALTH L.* 367 (2010); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 *TEX. L. REV.* 283 (2012); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *RAND J. ECON.* 391 (2003).

¹⁶ For further discussion of this approval bottleneck, see, e.g., Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"*, 78 *FORDHAM L. REV.* 1075 (2009).

which was first tried in early 2002 before an FTC administrative law judge.¹⁷ The FTC alleged that settlement agreements between Schering-Plough, the brand manufacturer of the drug K-Dur, and Upsher-Smith and ESI Lederle, two generic manufacturers, were anticompetitive. While both sides agreed that later entry by Upsher and ESI—i.e., a longer period of Schering monopoly—would maximize total profits from sales of K-Dur, the defense argued that Schering’s payments to Upsher and ESI need not have been for the purpose of delaying generic entry. For instance, Schering may have been willing to make payments to eliminate uncertainty (if risk averse) or to avoid litigation costs. Under these circumstances and others, it can be shown that there are settlements that the brand and generic manufacturers prefer to continued litigation and that result in generic entry earlier than the date expected from continued litigation.¹⁸ The possibility that a reverse payment settlement could be procompetitive has been successfully advanced to argue against a per se ban on reverse payments.¹⁹

B. THE DEFINITION OF DELAY

Implicit in the discussion above is a definition of delay as the time difference between the generic entry date under the settlement and the expected generic entry date under continued litigation. That said, the negotiated generic entry date can, in principle, be compared to at least four benchmarks: (1) the expected generic entry date under continued litigation, based on the probability that the brand’s patent would be upheld at trial;²⁰ (2) the generic entry date under continued litigation, determined by the validity of the brand’s patent; (3) the expiration of the brand’s patent; and (4) the generic entry date the firms would have agreed to as part of a settlement not containing a reverse payment.

While benchmark (1) treats the brand’s patent as probabilistically valid, benchmarks (2) and (3) do not. According to benchmark (2), the effect of a reverse payment directly hinges on patent

¹⁷ Schering-Plough Corp., 136 F.T.C. 1092 (2002) (initial decision), *rev’d*, Comm’n Decision, 136 F.T.C. 956 (2003) (Comm’n decision and final order), *review granted, order vacated sub nom.* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

¹⁸ See, e.g., Bigelow & Willig, *supra* note 15; Dickey et al., *supra* note 15; Barry C. Harris et al., *Activating Actavis: A More Complete Story*, ANTITRUST, Spring 2014, at 86.

¹⁹ See, e.g., FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237–38 (2013).

²⁰ There is a potential distinction here between (a) firms’ beliefs about this probability at the time of settlement negotiations and (b) the actual probability. See, e.g., Bigelow & Willig, *supra* note 15, at 267–68. The framework we propose attempts to uncover firms’ subjective beliefs about the strength of the brand’s patent, rather than its actual strength, though these coincide if firms have correct beliefs.

validity. If the brand's patent is valid, all settlements with entry prior to patent expiration are considered to have caused negative delay. If the patent is invalid, all settlements with entry after the conclusion of the trial are considered to have caused entry to be delayed. Using benchmark (2), the reverse payment case would likely require deciding the original patent infringement case, which has been described as a "turducken task."²¹ Benchmark (3) asserts that because the brand holds a valid patent, any settlement with entry prior to patent expiration falls within the exclusionary scope of the patent. Benchmark (4) allows the counterfactual without reverse payments to include alternative settlements rather than forcing continued litigation.

The appropriate benchmark for determining the competitive impact of a reverse payment settlement has been the subject of considerable debate. In March 2005, after several initial decisions in the *Schering-Plough* case, the Eleventh Circuit Court ruled that Schering's settlements with Upsher and ESI fell "within the patent's exclusionary power,"²² which some have interpreted as embracing the date of patent expiration as the proper counterfactual benchmark.²³ Decisions in other reverse payment cases also seemingly endorsed the date of patent expiration as the counterfactual benchmark, at least insofar as the relevant patent was not clearly a sham:

Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.²⁴

In 2012, the Third Circuit Court of Appeals rejected this "scope of the patent" logic, instead viewing reverse payments as "*prima facie* evidence of an unreasonable restraint of trade,"²⁵ placing the burden on the settling firms to demonstrate that the payment was for some purpose other than delaying the entry of the generic. The Supreme Court, in *Actavis*, also rejected the scope

²¹ *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012), *rev'd and remanded sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

²² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005).

²³ *See, e.g., Actavis*, 133 S. Ct. 2223.

²⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005); *see also, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006).

²⁵ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *cert. granted, judgment vacated sub nom.* *Merck & Co. v. La. Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013).

of the patent logic, but directed courts to apply the rule of reason rather than the “quick look” approach favored by the Third Circuit Court.²⁶

Our understanding of the current consensus among economists and lawyers is that brand patents are viewed as probabilistically valid and that benchmarks (1) and (4)—the expected date of generic entry under continued litigation and the date of generic entry the firms would have agreed to as part of a settlement not containing a reverse payment—are the appropriate standards by which reverse payment settlements should be judged.²⁷ In line with that consensus, the framework we propose is well-suited to estimate damages using both benchmarks. The framework is uniquely suited to applying benchmark (4), which requires identifying the counterfactual settlement the firms would have reached had they not been able to enter into a settlement that included a reverse payment.

C. NON-CASH PAYMENTS

In many reverse payment cases the payment from brand to generic is not in cash. In the *Schering-Plough* case, for instance, Schering paid Upsher \$60 million to license several products from Upsher. The FTC contended that the payment was not commensurate with the value of the licenses and instead was made for the purpose of delaying Upsher’s entry. Both the FTC administrative law judge and the Eleventh Circuit Court rejected the FTC’s argument, however, finding that the payment arguably reflected a fair price for the licenses.²⁸

Given the need for plaintiffs in a reverse payment case to demonstrate a transfer of value, settlements after the FTC’s initial action in *Schering-Plough* unsurprisingly shifted away from cash and toward side deals. According to settlement information collected by the FTC, for the majority of settlements prior to the *Schering-Plough* case that involved restrictions on generic entry and some kind of payment from the brand to the generic, the payment took the form of cash.²⁹ After the FTC’s action in *Schering-Plough*, the number of settlements involving cash payments

²⁶ *Actavis*, 133 S. Ct. at 2226.

²⁷ See Edlin et al., *supra* note 5, at 4.

²⁸ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1070 (11th Cir. 2005).

²⁹ See FTC, *GENERIC DRUG ENTRY*, *supra* note 13, at 31–32.

declined steeply.³⁰ Moreover, the vast majority of recent settlements involving cash now explicitly specify that the payment is to cover litigation fees.³¹

One important form of non-cash compensation is a “no authorized generic” (no-AG) commitment. In the *Lamictal* case, which we examine in Part III, compensation from the brand to the generic was in the form of a no-AG commitment. As discussed earlier, Hatch-Waxman encourages Paragraph IV challenges by awarding 180 days of marketing exclusivity to the first generic manufacturer with a Paragraph IV certification. This rule does not apply to the branded manufacturer itself, which is allowed to produce or license its own authorized generic. The presence of an authorized generic has been found to decrease first-filer generic revenues substantially,³² and, thus, a commitment by the brand not to launch an authorized generic is valuable to a generic manufacturer.³³ Indeed, the commitment not to launch an authorized generic has been a popular component of patent settlements. In 75 of the 198 settlements that the FTC labeled as potential pay-for-delay agreements between 2007 and 2014 (nearly 40 percent), compensation from the brand to the generic included a no-AG commitment.³⁴

Whether the Supreme Court’s decision in *Actavis* applies to no-AG commitments (and other non-cash transfers) is still being disputed in the courts. At least two decisions in the *Lamictal* case held that no-AG commitments should not be considered reverse payments,³⁵ and only in 2015 did

³⁰ See, e.g., FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, www.ftc.gov/policy/reports/policy-reports/commission-and-staff-reports [hereinafter FTC, SETTLEMENT AGREEMENTS]; Michael A. Salinger, Pauline Ippolito & Joel Schrag, *Economics at the FTC: Pharmaceutical Patent Dispute Settlements and Behavioral Economics*, 31 REV. INDUS. ORG. 85 (2007).

³¹ See FTC, SETTLEMENT AGREEMENTS, *supra* note 30, FY 2013–2014.

³² In an extensive study of authorized generics, the FTC found that competing with an authorized generic during the 180-day exclusivity period decreased the wholesale revenues of the first-filer generic by 39.6–52.0%, depending on the specification. FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 59 (2011) [hereinafter FTC, AUTHORIZED GENERIC DRUGS].

³³ Authorized generics are also relevant outside of the 180-day exclusivity period. In fact, approximately two-thirds of authorized generics that were launched between 2001 and 2008 were not marketed during a 180-day exclusivity period. See *id.* at 27. For instance, if a branded manufacturer grants a generic manufacturer a license to produce a patent-protected drug, it also has the option to launch an authorized generic to compete with that generic (regardless of any FDA-mandated exclusivity). An agreement not to do so—giving the generic an exclusive license to produce a generic version of the drug—can also be considered a no-AG commitment.

³⁴ See FTC, SETTLEMENT AGREEMENTS, *supra* note 30.

³⁵ *In re Lamictal Direct Purchaser Antitrust Litig.*, Civ. No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012), *adhered to on reconsideration*, 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom.* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

an appeals court find that the no-AG agreement in the *Lamictal* case falls under *Actavis*.³⁶ In addition to whether *Actavis* applies to no-AG commitments, there is also the issue of quantifying the value of the no-AG commitment. In the *Effexor XR* case, which also featured a no-AG commitment, the district court ruled that while no-AG commitments were subject to antitrust scrutiny, the plaintiffs’ estimate of the value of the no-AG commitment was “vague and amorphous”³⁷ and dismissed the case.

D. EMPIRICAL LITERATURE

While several prior empirical studies have examined large samples of drugs to estimate the average impact of reverse payment settlements,³⁸ empirical work on practical approaches to estimating damages is—to our knowledge—limited to one study, by Thomas McGuire et al.³⁹ This study suggests using an event study analysis of the brand stock price to estimate the profits gained by the brand as a result of a reverse payment settlement, and then dividing that estimate by an estimate of the difference in daily profits that the brand earns under monopoly versus competition with a generic entrant. The authors argue that this ratio can be interpreted as the length of extended monopoly (in days) that the brand gained from the settlement.⁴⁰ Damages can then be estimated based on the duration of extended monopoly and observed or estimated price differences between the branded drug and the generic(s).

In our view, the framework we propose in this article is complementary to the ideas of McGuire et al. For a variety of well-known reasons, event study analyses will not always detect causal effects.⁴¹ For example, news of the settlement may not be sudden, or the settlement could

³⁶ *King Drug Co. v. Smithkline Beecham*, 791 F.3d 388, 409 (3d Cir. 2015).

³⁷ *In re Effexor XR Antitrust Litig.*, Civ. No. 11-5479, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014).

³⁸ See, e.g., Keith Drake, Martha Starr & Thomas McGuire, *Do “Reverse Payment” Settlements Constitute an Anticompetitive Pay-for-Delay?* 22 INT. J. ECON. BUS. 173 (2015); FED. TRADE COMM’N, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* (2010); Eric Helland & Seth A. Seabury, *Are Settlements in Patent Litigation Collusive? Evidence from Paragraph IV Challenges* (Nat’l Bureau of Econ. Research, Working Paper No. 22194, 2016).

³⁹ Thomas McGuire, Keith Drake, Einer Elhauge, Raymond Hartman & Martha Starr, *Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements*, 101 IOWA L. REV. 1581 (2016).

⁴⁰ This calculation is based on research analyzing the period of delay caused by reverse payment settlements in the context of stylized theoretical models. See, e.g., Aaron Edlin et al., *Activating Actavis*, ANTITRUST, Fall 2013, at 16; Elhauge & Krueger, *supra* note 15.

⁴¹ See, e.g., S.P. Kothari & Jerold B. Warner, *Econometrics of Event Studies*, in HANDBOOK OF CORPORATE FINANCE: EMPIRICAL CORPORATE FINANCE (B. Espen Eckbo ed., 2006).

have already been fully priced in by investors. The approach we propose may prove especially useful in cases where event study analysis is not suitable. In addition, by using a structural model of settlement choice, the framework allows for identification of alternative settlements that do not include reverse payments.

II. FRAMEWORK FOR ESTIMATING DAMAGES

A. OVERVIEW

Evaluating the impact of a reverse payment settlement on market outcomes requires an estimate of when generic entry likely would have occurred absent the settlement. The strength of the brand's patent—i.e., the probability that the brand's patent would be upheld in court—is a key determinant of the answer to this question. Absent the at-issue settlement, the patent infringement trial could have continued or the parties could have reached an alternative settlement that did not include a reverse payment. Had the trial continued, the patent would have been invalidated or upheld. A weak patent is more likely to be invalidated, resulting in earlier generic entry. A strong patent is more likely to be upheld, resulting in later generic entry. Similarly, in settlement negotiations, a weak patent is more likely to lead to settlement terms favorable to the generic (i.e., earlier generic entry), while a strong patent is more likely to lead to settlement terms favorable to the brand (i.e., later generic entry).

A major obstacle to determining when generic entry likely would have occurred absent a reverse payment settlement is that the strength of the brand's patent is not directly observable. Our proposed framework attempts to overcome this obstacle. The fundamental idea is to use a formal bargaining model to express settlements as a function of estimable objects and the unknown strength of the patent and then use the model to back out the strength of the patent from the observed settlement. Using the estimated patent strength, we then can conduct a counterfactual analysis of when generic entry likely would have occurred absent the settlement and use the results to assess the impact of the reverse payment settlement on market outcomes.

B. BARGAINING MODEL BACKGROUND

While it is intuitive that a negotiated settlement will reflect the strength of the patent, backing out patent strength from an observed settlement requires an explicit model that connects patent strength to settlement choice—it is the structure of the model that allows the observed settlement to be traced back to the patent strength that generated it.

We begin by introducing some notation and terminology. A settlement s can be characterized by (1) a generic entry date and (2) some form of consideration running from the brand to the generic (e.g., a no-AG commitment). Denote the brand’s payoff from reaching a given settlement s as $\pi_B(s)$ and its payoff if a settlement is not reached as $\pi_B^{\text{trial}}(p)$, where p is the strength of the brand’s patent (i.e., the probability the patent would be upheld in court). The brand’s gain from reaching a given settlement is its payoff under the settlement compared to its payoff without a settlement (continued litigation): $\pi_B(s) - \pi_B^{\text{trial}}(p)$. Likewise, the generic’s payoff from reaching settlement s is $\pi_G(s)$ and its payoff if a settlement is not reached is $\pi_G^{\text{trial}}(p)$. The generic’s gain from reaching the settlement is its payoff under the settlement compared to its payoff without a settlement: $\pi_G(s) - \pi_G^{\text{trial}}(p)$.

The Nash bargaining solution, originally proposed by John Nash and commonly employed in the economics literature, proposes a way that agreements are selected in two-player bargaining games.⁴² Specifically, the Nash bargaining solution can be obtained by maximizing the “Nash product” subject to the constraint that the solution delivers weakly higher payoffs to both players than what they can receive outside of the negotiation. In the reverse payment context, denoting the brand’s bargaining power by the parameter $\lambda \in [0,1]$, Nash bargaining solves:

$$\begin{aligned} \max_{s \in S} & \left[\pi_B(s) - \pi_B^{\text{trial}}(p) \right]^\lambda \left[\pi_G(s) - \pi_G^{\text{trial}}(p) \right]^{1-\lambda} \\ \text{s. t. } & \pi_B(s) - \pi_B^{\text{trial}}(p) \geq 0 \\ & \pi_G(s) - \pi_G^{\text{trial}}(p) \geq 0 . \end{aligned}$$

The first expression above is the bargaining power-weighted geometric mean of the brand and generic’s gains from a settlement s , given a patent strength p . The second and third expressions require that the settlement delivers payoffs to the brand and generic that are at least as large as their payoffs from not reaching a settlement. These inequalities are typically referred to as “incentive compatibility” constraints.

⁴² John F. Nash Jr., *The Bargaining Problem*, 18 *ECONOMETRICA* 155 (1950). Nash bargaining satisfies certain axioms that are thought to be desirable (e.g., Pareto optimality), and can also be micro-founded in an alternating-offers non-cooperative model. *See, e.g.*, Ken Binmore, Ariel Rubinstein, & Asher Wolinsky, *The Nash Bargaining Solution in Economic Modeling*, 17 *RAND J. ECON.* 176 (1986). To our knowledge, Nash bargaining was first applied to the analysis of reverse payments in an article by Jeremy Bulow. Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in *INNOVATION POLICY AND THE ECONOMY* (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2004). Nash bargaining has also been applied in several other empirical studies in the economics literature. *See supra* note 10.

According to the Nash bargaining solution, if the brand has all the bargaining power ($\lambda=1$), the brand will be able to get the generic to agree to the settlement for which the brand's gain $\pi_B(s) - \pi_B^{\text{trial}}(p)$ is largest, subject to the generic's incentive compatibility constraint. If the generic has all the bargaining power ($\lambda=0$), the generic will be able to get the brand to agree to the settlement for which the generic's gain $\pi_G(s) - \pi_G^{\text{trial}}(p)$ is largest, subject to the brand's incentive compatibility constraint. More generally, if the brand's bargaining power is λ , the brand and generic will agree to the settlement for which $[\pi_B(s) - \pi_B^{\text{trial}}(p)]^\lambda [\pi_G(s) - \pi_G^{\text{trial}}(p)]^{1-\lambda}$ is largest, subject to the incentive compatibility constraints.

C. OPERATIONALIZING THE BARGAINING MODEL

To use the model to predict the settlement the brand and generic will reach, the three elements of the model need to be measured: (1) brand and generic payoffs under different potential settlements, $\pi_B(s)$ and $\pi_G(s)$; (2) brand and generic payoffs absent a settlement as a function of patent strength, $\pi_B^{\text{trial}}(p)$ and $\pi_G^{\text{trial}}(p)$; and (3) the bargaining power parameter, λ .⁴³

1. Brand and Generic Settlement Payoffs

The payoff to each firm under a given settlement is the net present value of the expected stream of profits covering three periods: (1) the period prior to the entry of the generic during which the brand earns monopoly profits and the generic earns zero profit; (2) the period following the entry of the generic during which the settling generic is the only generic in the market (if applicable) and the firms compete in a duopoly (potentially with an authorized generic); and (3) the period during which additional generics enter and both brand and generic profits typically fall precipitously. These payoffs can be estimated with transaction data and/or firm forecasts of prices and quantities.⁴⁴

⁴³ Risk aversion can also be incorporated into the modeling. *See infra* Part III.E.3.

⁴⁴ Assumptions about the timing of additional generic entry are also necessary. Because the profits of the brand and generic typically plummet as additional generics enter, the assumed timing of additional generic entry can have a significant impact on the estimated payoffs. Besides profits from drug sales, the settlement payoffs must also include the valuation of any other settlement features besides the generic's entry date. If the alleged reverse payment is in the form of cash, for instance, valuation of the cost to the brand and the benefit to the generic is immediate. If the compensation to the generic takes another form, such as a no-AG commitment, valuation is more complex.

2. *Brand and Generic Trial Payoffs*

Brand and generic expected profits absent a settlement depend on the strength of the patent. If the patent is upheld at trial and there are no other Paragraph IV challengers, the brand earns monopoly profits and the generic earns zero profit until the patent expires. If the patent is invalidated, the firms first compete in a duopoly (potentially with an authorized generic) for the 180-day exclusivity period following immediate generic entry (if applicable).⁴⁵ Additional generics may then enter if they have received FDA approval. Estimates of brand and generic profits in each of these situations can be constructed using observed transaction data and/or internal firm projections. Expected profits absent a settlement can then be calculated as a probability weighted average of (a) profits if the patent is upheld and (b) profits if the patent is invalidated.

3. *Bargaining Power*

The bargaining power parameter can be thought of as capturing any unmodeled factors that affect the negotiated settlement. If all payoff-relevant differences between the brand and generic have been explicitly and accurately estimated, an assumption of symmetric bargaining power ($\lambda=0.5$) can be motivated by an argument that the negotiated settlement should be invariant to firm labels—i.e., holding the payoffs constant, swapping the identities of the firms should not affect the negotiated settlement. That said, it is not feasible to model everything that might affect a negotiation, and the bargaining power parameter will pick up the effect of any relevant omitted factors, such as differences in negotiating skill, any asymmetries in public relations costs (e.g., if a large reverse payment is more likely to turn into a public relations issue), etc. While there is some empirical evidence suggesting that brands may have more bargaining power than generics in settlement negotiations,⁴⁶ in practice we believe symmetric bargaining power is a reasonable starting assumption.

⁴⁵ It is possible that the generic may not be able to enter right away (e.g., if the generic has not received tentative FDA approval) and/or that the challenging generic does not have 180-day exclusivity.

⁴⁶ Unlike brand stock prices, generic stock prices do not exhibit statistically significant increases at the time of reverse payment settlements. These results suggest that any economic rents that were generated by the settlement (and that were not already priced into the stocks) accrue largely to the brand, which is consistent with the brand having higher bargaining power. *See* McGuire et al., *supra* note 39, at 1588.

4. Multiple Paragraph IV Challengers

While the *Lamictal* case that we analyze in Part III involves only a single Paragraph IV challenger, cases with multiple Paragraph IV challengers present additional difficulties. In such cases, the brand's payoff from settling with one Paragraph IV challenger may depend on the terms of the brand's settlement (or failure to reach a settlement) with another Paragraph IV challenger. Similar considerations apply to the challenging generics' payoffs. Some academic work has explored situations in which multiple, interacting settlement negotiations occur simultaneously,⁴⁷ but whether such methods can be appropriately and tractably applied to the reverse payment context is unclear. While a full development of methods for cases with multiple Paragraph IV challengers is beyond the scope of this article, it is an important caveat that the approach described here is most directly relevant to cases with only a single Paragraph IV challenger. In cases with multiple Paragraph IV challengers, modifications to account for the presence of multiple negotiations may be required.

D. USING THE OPERATIONALIZED BARGAINING MODEL TO ESTIMATE PATENT STRENGTH AND THE IMPACT OF THE REVERSE PAYMENT SETTLEMENT ON MARKET OUTCOMES

Given measures of brand and generic settlement and trial payoffs and an assumed value of the bargaining power parameter, the bargaining model can be used to predict the settlement the brand and generic would reach under different possible patent strengths.⁴⁸ Each such predicted settlement can then be compared to the observed settlement. By repeating this analysis for all possible patent strengths, the patent strength for which the settlement predicted by the model most closely matches the observed settlement can be estimated. This patent strength is said to rationalize the observed settlement.

While brand and generic settlement and trial payoffs likely can be readily estimated, the bargaining power parameter may be more elusive empirically. In circumstances in which one is not comfortable making an assumption about bargaining power, the set of patent strengths that rationalize the observed settlement can be estimated using the incentive compatibility constraints

⁴⁷ See, e.g., Allan Collard-Wexler, Gautam Gowrisankaran & Robin Lee, "*Nash-in-Nash*" Bargaining: A Microfoundation for Applied Work (Nat'l Bureau of Econ. Research, Working Paper No. 20641, 2014); Henrick Horn & Asher Wolinsky, *Bilateral Monopolies and Incentives for Merger*, 19 RAND J. ECON. 408 (1988); Roger B. Myerson, *Graphs and Cooperation in Games*, 2 MATHEMATICS OF OPERATIONS RESEARCH 225 (1977).

⁴⁸ I.e., for each possible patent strength, the model can be used to solve for the settlement for which the Nash product is largest.

alone. The logic is as follows. To have been willing to enter into the settlement, the expected profits of the brand and generic each must have been larger with the settlement than without a settlement—i.e., the settlement must have been incentive compatible. By modeling the expected profit of the brand with and without a settlement, an inference can be drawn about the strongest possible patent strength for which the settlement would have been incentive compatible for the brand. And by modeling the expected profit of the generic with and without a settlement, an inference can be drawn about the weakest possible patent strength for which the settlement would have been incentive compatible for the generic. The actual patent strength lies somewhere between the weakest and strongest possible patent strengths for which the settlement would have been incentive compatible for both firms.

Damages can be estimated using the estimates of patent strength. Total spending under the observed settlement can be compared to expected spending under continued litigation, using the patent strength estimates to weigh the outcomes of the brand’s patent being upheld or invalidated. The counterfactual settlement the brand and generic would have reached had a reverse payment not been an option also can be estimated by restricting the set of possible settlements in the bargaining model.

E. STYLIZED EXAMPLE

Consider the following stylized example featuring a no-AG commitment.⁴⁹ A brand and generic manufacturer were locked in a litigation over a patent that had 100 months until expiration when they entered into a settlement in which (a) the generic was allowed to enter at month 60 and (b) the brand committed not to market an authorized generic (i.e., the brand made a no-AG commitment).

Assume that the expected profits under different market configurations were as follows:

	Expected Profits per Month	
	Brand	Generic
Monopoly	\$120 million	\$0
Duopoly with authorized generic	\$40 million	\$40 million
Duopoly with no authorized generic	\$20 million	\$60 million
Competition	\$0	\$0

⁴⁹ This example is a variant of the models presented in Bigelow & Willig, *supra* note 15, and Edlin et al., *supra* note 5.

To see what can be inferred about the strength of the patent given the observed settlement, we first consider the incentive compatibility constraints, which require that each firm's expected profit with the settlement is greater than its expected profit without a settlement. Under the settlement, the brand gets 60 additional months of monopoly profits and then 40 months of no authorized generic duopoly profits: $60 * \$120 \text{ million} + 40 * \$20 \text{ million} = \$8 \text{ billion}$. Absent a settlement, if the brand wins the patent infringement trial, it gets 100 months of monopoly profits: $100 * \$120 \text{ million} = \12 billion . If it loses the patent infringement trial, it gets 100 months of authorized generic duopoly profits: $100 * \$40 \text{ million} = \4 billion .⁵⁰ Thus, the brand's expected profit absent a settlement is $p * \$12 \text{ billion} + (1-p) * \4 billion . The brand's incentive compatibility constraint requires that $\$8 \text{ billion} \geq p * \$12 \text{ billion} + (1-p) * \4 billion , which implies that $p \leq 0.5$. If the brand's patent was sufficiently strong—i.e., if the brand had better than a 50 percent chance of winning the trial—it would not have agreed to let the generic enter at month 60 and to the no-AG commitment.

A similar calculation can be performed for the generic. The generic's expected profit under the settlement is $40 * \$60 \text{ million} = \2.4 billion . Its expected profit absent a settlement is $(1-p) * 100 * \$40 \text{ million}$. The generic's incentive compatibility constraint requires that $\$2.4 \text{ billion} \geq (1-p) * 100 * \40 million , which implies that $p \geq 0.4$. If the brand's patent was sufficiently weak—i.e., if the brand had less than a 40 percent chance of winning the trial—the generic would not have agreed to wait 60 months before entering.

Thus, analysis of the incentive compatibility constraints indicates that the strength of the patent is between 0.4 and 0.5. Pinning down the actual patent strength within this range requires an assumption or evidence about bargaining power. If the brand was able to negotiate the settlement most favorable to it, then the patent strength that rationalizes the observed settlement is 0.4, the minimum patent strength for which the generic is willing to settle with the brand (with entry at month 60 and a no-AG commitment). Alternatively, if the generic was able to negotiate the settlement most favorable to it, then the patent strength that rationalizes the observed settlement is 0.5, the maximum patent strength for which the brand is willing to settle with the generic. More generally, as the brand's bargaining power decreases from 1 to 0, the estimate of patent strength

⁵⁰ The assumption that duopoly will continue until patent expiration if the brand's patent is invalidated may not hold in practice, but is a standard assumption in stylized theoretical analyses of reverse payments.

increases from 0.4 to 0.5. This pattern is illustrated in Figure 1, which plots the estimate of patent strength as a function of the brand’s bargaining power.

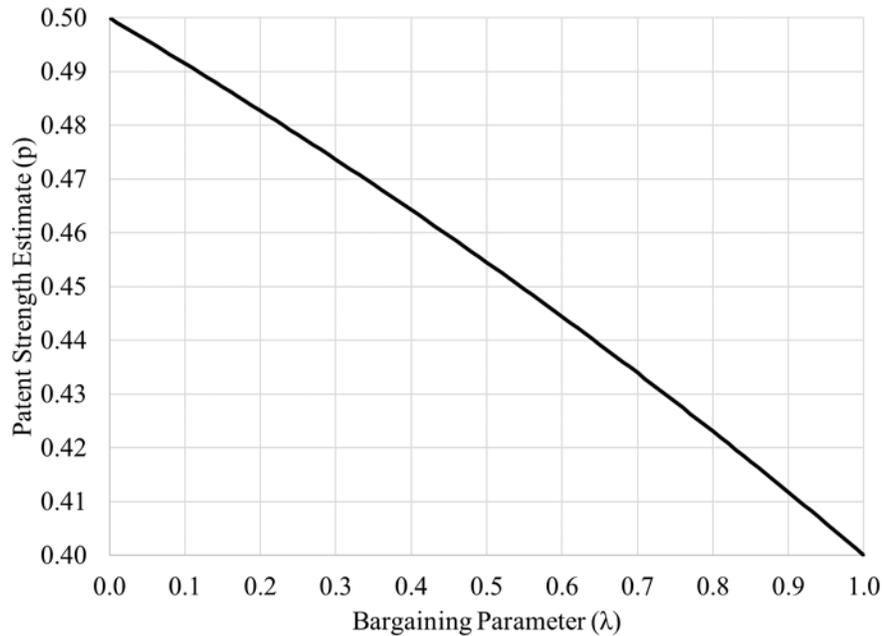


FIGURE 1: THE IMPACT OF BARGAINING POWER

Turning to damages, suppose production costs are zero so that the profit numbers also reflect consumer spending. Suppose also that there are no changes in total quantity sold so that spending differences reflect price differences.⁵¹ Spending is equal to $60 \times \$120 \text{ million} + 40 \times \$80 \text{ million} = \$10.4 \text{ billion}$ under the observed settlement. If the brand’s bargaining power was such that the estimate of patent strength is 0.45, then expected spending absent the settlement is $0.45 \times 100 \times \$120 \text{ million} + (1 - 0.45) \times 100 \times \$80 \text{ million} = \$9.8 \text{ billion}$. Damages are therefore $\$10.4 \text{ billion} - \$9.8 \text{ billion} = \$600 \text{ million}$ with trial as the counterfactual benchmark. Absent no-AG commitments (i.e., taking away reverse payment settlements) the firms always settle with a generic entry date equal to the expected generic entry date from continued litigation—in the model, this is the only incentive compatible settlement. Therefore, given a patent strength of 0.45, the generic enters at month 45. Spending under this alternative settlement is equal to $45 \times \$120 \text{ million} + 55 \times \$80 \text{ million} = \$9.8 \text{ billion}$. Damages are therefore also equal to $\$600 \text{ million}$ with an alternative settlement as the counterfactual benchmark, though in general the two damages estimates need not be the same.

⁵¹ Even without a change in total quantity sold there is a shift between brand consumption and generic consumption. That said, assuming there are no meaningful quality differences between brand and generic, the difference in spending (without any quality adjustment) remains a reasonable measure of damages.

III. APPLICATION TO THE *LAMICTAL* CASE

We now apply the framework laid out in Part II to the drug Lamictal (lamotrigine), an anticonvulsant used in the treatment of epilepsy and bipolar disorder. In the main quantitative analysis, we abstract away from several complicating factors to simplify the presentation. We also emphasize that some of the assumptions we make for the *Lamictal* case may not generalize to other reverse payment cases. Reverse payment settlements can be highly idiosyncratic, and one of the takeaways of our results for *Lamictal* is that these details can matter a great deal when assessing the effects of a settlement.

A. BACKGROUND

GlaxoSmithKline (GSK) began producing Lamictal tablets in 1994 and a chewable tablet form (“chewables”) in 1998.⁵² The primary patent protecting Lamictal from generic competition was U.S. Patent No. 4,602,017 (the ‘017 patent), which expired in late January 2009.⁵³ In 2002, Teva (TEV) filed a Paragraph IV application seeking approval to sell generic lamotrigine (both tablets and chewables). GSK subsequently sued TEV for patent infringement, which culminated in a bench trial beginning in January 2005. Before a final ruling on the validity of the ‘017 patent, however, GSK and TEV reached a settlement in mid-February 2005. The settlement had the following components:⁵⁴ (1) TEV was allowed to market generic lamotrigine chewables beginning in June 2005; (2) TEV was allowed to market generic lamotrigine tablets beginning in July 2008, six months prior to the expiration of the ‘017 patent; and (3) GSK agreed not to launch authorized generic versions of Lamictal.⁵⁵

⁵² FDA ORANGE BOOK, <https://www.accessdata.fda.gov/scripts/cder/ob/>. Based on our calculations, sales of chewables are far lower than sales of tablets. In 2007, for instance, sales of Lamictal tablets exceeded \$2 billion while sales of chewables were around \$80 million.

⁵³ The original patent expired in July 2008 but GSK was granted a pediatric exclusivity extension of six months, which extended the effective patent life to late January 2009. We assume that GSK and TEV knew in early 2005 that pediatric exclusivity would be granted.

⁵⁴ *In re Lamictal Direct Purchaser Antitrust Litig.*, Civ. No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012), *adhered to on reconsideration*, 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom.* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

⁵⁵ From the publicly available court documents we have reviewed, it is unclear whether GSK agreed not to launch authorized generics during TEV’s 180-day exclusivity period, until January 2009, or ever. To our knowledge, GSK never launched an authorized generic for chewables or tablets, so we assume this was covered by the settlement.

In February 2012, a class action lawsuit was brought against GSK and TEV alleging that the settlement was unlawful and had resulted in higher prices for lamotrigine tablets than would have prevailed in the absence of the settlement. In December 2012, the district court dismissed the case, ruling that the settlement was not subject to antitrust scrutiny because it did not involve a cash payment from GSK to TEV.⁵⁶ The plaintiffs appealed and the appeals court remanded the case back to the district court following the Supreme Court's decision in *Actavis*. In January 2014, the district court affirmed its dismissal,⁵⁷ which the plaintiffs again appealed. In June 2015, the Third Circuit overturned the dismissal,⁵⁸ a decision that GSK and TEV appealed to the Supreme Court. The Supreme Court declined to review the case in November 2016.⁵⁹

B. DATA

The IMS National Sales Perspectives (NSP) dataset—which, according to IMS, captures 100 percent of the U.S. pharmaceutical market—provides information about lamotrigine sales for the years 2005 to 2013. The NSP data capture transactions between drug manufacturers and wholesalers.⁶⁰ A row in the raw data is a unique combination of national drug code (NDC) and month. NDCs are quite granular, identifying package size and dosage strength in addition to manufacturer and delivery form (e.g., the type of tablet). We collapse the data to the level of manufacturer-delivery form-month, thereby aggregating over different package sizes and dosage strengths.

Table 1 breaks out average prices and shares by manufacturer for lamotrigine tablets. TEV priced at around 80 percent of GSK's price and took 60 percent of the market when it entered. After other generics entered, GSK's share fell to about 9 percent, while TEV maintained almost 30 percent of the market. TEV's share translated into much lower revenues, however, as generic prices fell precipitously. As of December 2013, more than 70 percent of TEV's revenues from

⁵⁶ Lamictal MDL Litig., Civ. No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012).

⁵⁷ Lamictal MDL Litig., 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom.* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

⁵⁸ King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 404 (3d Cir. 2015).

⁵⁹ Smithkline Beecham Corp. v. King Drug Co. of Florence, Inc., 137 S. Ct. 446 (2016).

⁶⁰ The data do not account for rebates paid by drug manufacturers to payers and therefore likely overstate manufacturer revenues.

selling lamotrigine tablets had been generated during the first six months in which it was the only generic on the market.

TABLE 1: LAMOTRIGINE TABLET PRICES AND SHARES

Measure	Period	Months	GSK	TEV	Other Generics
Price (\$/pill)	Monopoly	2/2005-6/2008	\$3.34		
	Duopoly	7/2008-12/2008	\$3.41	\$2.84	
	Competition	1/2009-12/2013	\$4.38	\$0.18	\$0.08
Share (% of pills)	Monopoly	2/2005-6/2008	100.0%		
	Duopoly	7/2008-12/2008	39.7%	60.3%	
	Competition	1/2009-12/2013	9.3%	29.6%	61.1%

Notes: Prices are in PPI-deflated 2/2005 dollars. "Other Generics" combines 7+ generic manufacturers other than TEV.

C. MODEL

We assume GSK and TEV had two types of settlements available to them when negotiating in February 2005: (1) an agreement in which TEV would begin marketing generic lamotrigine at an agreed upon date and GSK *would not* launch an authorized generic, and (2) an agreement in which TEV would begin marketing generic lamotrigine at an agreed upon date and GSK *would* launch an authorized generic. We assume cash transfers were not feasible because they likely would have attracted antitrust scrutiny. Because the chewable segment is quite small relative to the tablet segment, we focus on the agreed upon entry date for tablets and ignore chewables.

1. Settlement Payoffs

We model the payoffs to each possible settlement—i.e., the combination of TEV’s entry date and whether GSK makes a no-AG commitment—as the expected profits from sales of lamotrigine tablets up until the expiration of the ‘017 patent in January 2009 plus five years afterwards.⁶¹ For simplicity we assume zero time discounting. We estimate that during monopoly, GSK makes sales of \$189.7 million per month. We estimate that during duopoly and without an authorized generic in the market, GSK makes \$58.6 million and TEV makes \$103.4 million per month. We estimate

⁶¹ While TEV entered at the end of July 2008 and patent expiration occurred at the end of January 2009, for simplicity we push these dates forward a week so that we model TEV’s entry date as occurring at the beginning of August 2008 and the patent expiring at the beginning of February 2009.

that after other generics enter, GSK makes \$25.8 million and TEV makes \$1.9 million per month.⁶² These estimates are constructed from the IMS NSP data under the assumption of negligible production costs, in which case the reported sales can be considered to be estimates of profits.

For profits with an authorized generic in the market—a market configuration not observed in the data—we use estimates from the FTC’s report on authorized generics.⁶³ In actual cases, estimates may be obtainable from firm projections around the time of the settlement. The FTC report found that, on average, competition from an authorized generic reduces the first generic’s share by 30.2 percent and its price by 13.5 percent.⁶⁴ Applying these adjustments to the duopoly numbers reported above, we estimate that GSK would have made \$85.6 million (including authorized generic profits) and TEV would have made \$62.4 million per month with an authorized generic in the market. We estimate that after other generics enter, GSK would have made \$26.4 million and TEV would have made \$1.3 million per month.

To construct the settlement payoffs, we also need to make an assumption about whether generics other than TEV would have been able to enter at the conclusion of TEV’s 180-day exclusivity period, or, alternatively, not until the expiration of the ‘017 patent. These two possibilities are equivalent for the observed settlement because TEV began producing 180 days prior to the expiration of the ‘017 patent. More generally, however, there can be a large difference between the conclusion of TEV’s 180-day exclusivity period and the expiration of the ‘017 patent.

Importantly, all settlements leave the ‘017 patent intact. Review of FDA tentative approval letters indicates that all generic manufacturers besides TEV who filed for approval to produce generic lamotrigine tablets did so with Paragraph III certifications,⁶⁵ allowing for FDA approval only upon the expiration of all relevant patents. Furthermore, because TEV was the first Paragraph IV filer, the payoff to another generic from successfully invalidating the ‘017 patent would have been substantially smaller. These facts suggest that other generics may not have been able to enter the market prior to patent expiration, even if GSK and TEV had reached a settlement with TEV entering the market more than 180 days prior to patent expiration. The experience of chewables

⁶² We estimate that all other generics jointly make \$2.6 million per month.

⁶³ FTC, AUTHORIZED GENERIC DRUGS, *supra* note 32.

⁶⁴ *Id.* at 48 tbl. 3-2, 59 tbl. 3-7. Table 3-2 is the effect on prices, and Table 3-7 is the effect on revenues; the effect on shares can be calculated from these two results (assuming no effect on total quantity). Once other generics enter, we assume that the authorized generic has no effect on generic prices but continues to take share from TEV.

⁶⁵ We obtained all relevant FDA approval letters via a Freedom of Information Act request.

supports this argument. TEV’s 180-day exclusivity for chewables expired several years prior to the expiration of the ‘017 patent, but no other generic manufacturer was given final approval by the FDA until the day the patent expired. For the main results, we therefore assume that other generics would not have entered prior to the expiration of the ‘017 patent, even if TEV had entered more than 180 days prior to patent expiration.

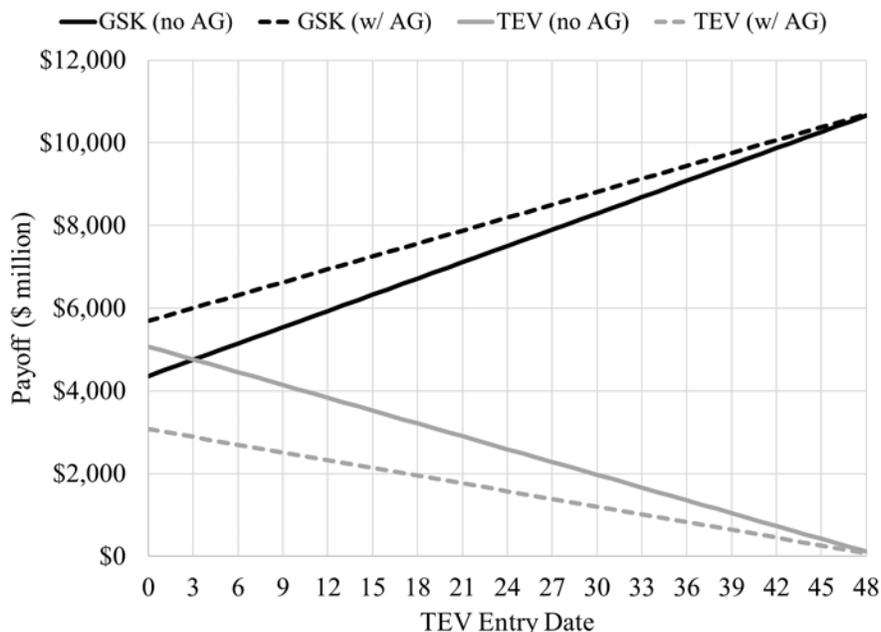


FIGURE 2: GSK AND TEV SETTLEMENT PAYOFFS

Figure 2 plots the estimated settlement payoffs. The black lines give GSK’s payoffs and the gray lines give TEV’s payoffs. The solid lines are the payoffs when GSK makes a no-AG commitment and the dashed lines are the payoffs when GSK does not make a no-AG commitment.⁶⁶ While it is not immediately apparent visually, the slope of GSK’s payoffs is steeper than TEV’s, which indicates that GSK loses more from TEV’s entry than TEV gains. In addition, the vertical distance between the payoffs with and without an authorized generic is greater for TEV than for GSK, which indicates that TEV loses more from the presence of an authorized generic than GSK gains. These two facts generate mutually beneficial settlements in which GSK makes a no-AG commitment in exchange for later entry by TEV.

⁶⁶ For an example of how to construct a point on these lines, consider GSK’s payoff from a settlement with TEV entering at month 21 and without a no-AG commitment. GSK’s payoff from this settlement is equal to $21 * \$189.7 \text{ million} + 27 * \$85.6 \text{ million} + 60 * \$26.4 \text{ million} = \$7,879 \text{ million}$.

2. Trial Payoffs

To construct the trial payoffs, we need to make an assumption about whether TEV would have been able to enter immediately in the scenario in which GSK's patent was ruled to be invalid. When GSK and TEV were negotiating a settlement in February 2005, the judge in the patent infringement case stated that he would likely reach a determination "in the course of the next week."⁶⁷ At that time TEV had not received tentative approval from the FDA, and TEV did not receive final approval until August 2006. If TEV had won in court in February 2005, the ruling would have triggered TEV's 180-day exclusivity well before TEV was likely to receive FDA approval. Therefore, we assume that if GSK's patent was invalidated, TEV would have entered at the same time as other generics in August 2006 (without 180-day exclusivity),⁶⁸ and if the patent was upheld, all generics including TEV would have entered when the patent expired in January 2009.

3. Bargaining Power and Risk Aversion

We also need to make assumptions about bargaining power and risk aversion. For the main results we assume symmetric bargaining power: $\lambda=0.5$. (We discuss asymmetric bargaining power in Part III.E.2.) Risk aversion is relevant in determining the payoffs the firms receive from continued litigation. If the firms are risk averse, then a settlement delivering the same expected payoff as continued litigation will be preferred to litigation because it does not carry the uncertainty of the trial outcome. In the economics literature, risk preferences are typically estimated using choice data (among risky options) paired with revealed preference logic and a model of decision making under uncertainty.⁶⁹ It is unclear whether similar methods can be applied in the reverse payment context.⁷⁰ Absent evidence suggesting significant risk aversion, we assume that GSK and TEV were risk neutral. (We discuss the effects of risk aversion in Part III.E.3.)

⁶⁷ *In re Lamictal Direct Purchaser Antitrust Litig.*, Civ. No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012), *adhered to on reconsideration*, 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom. King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

⁶⁸ According to FDA documents, at least two other generic manufacturers (Roxane and Genpharm) received tentative approval from the FDA in the summer of 2006.

⁶⁹ See, e.g., Levon Barseghyan et al., *Estimating Risk Preferences in the Field*, J. ECON. LIT. (forthcoming).

⁷⁰ There are also theoretical arguments suggesting that publicly traded firms should not be particularly risk averse because shareholders can diversify risk by altering their investment portfolio. See, e.g., DAVID BESANKO ET AL., *ECONOMICS OF STRATEGY* 474 (5th ed. 2010).

D. RESULTS

To find the predicted settlement as a function of patent strength p , we solve the Nash bargaining problem for each p between 0 and 1 (in steps of 0.01). We then take those p that rationalize the observed settlement (TEV’s entry date and GSK’s no-AG commitment) and compute counterfactual outcomes for the two counterfactual benchmarks: (1) continued litigation and (2) an alternative settlement that does not include a no-AG commitment.

TABLE 2: LAMICTAL PATENT STRENGTH, DELAY, AND DAMAGES ESTIMATES

	Benchmark	Min	Average	Max
Patent Strength	--	0.640	0.665	0.690
Delay (months)	Trial	3.30	4.05	4.80
	Settlement	1.00	2.00	3.00
Δ Spending (\$ million)	Trial	\$1,315.9	\$1,435.5	\$1,555.0
	Settlement	\$125.4	\$167.1	\$208.8

Table 2 reports the results. All patent strengths between 0.64 and 0.69 rationalize the observed settlement.⁷¹ We therefore report estimates for the minimum, maximum, and average values of p that rationalize the observed settlement. The remaining rows of the table report statistics comparing outcomes under the observed settlement to outcomes under the two counterfactual benchmarks.

Based on the patent strengths that rationalize the observed settlement, we predict that entry would have occurred 3.3–4.8 months earlier (in expectation) had the patent infringement trial continued. We also find that GSK and TEV would have agreed to a settlement in which TEV entered 1–3 months earlier had a no-AG commitment not been allowed. The primary reason for the difference in entry dates between the two counterfactuals is that the model suggests that TEV realizes substantial gains even from settlements that do not include no-AG commitments, as these settlements ensure duopoly by leaving the ‘017 patent intact. Specifically, TEV’s profits during duopoly (with or without an authorized generic in the market) are roughly 50 times larger than

⁷¹ The reason that multiple patent strengths rationalize the observed settlement is due to modeling time in months. Using finer time units (e.g., weeks or days) would tighten the interval of rationalizing patent strengths.

after other generics enter.⁷² Given our assumption that TEV would not have been able to enter in February 2005 had the `017 patent been ruled invalid, TEV does not receive a single month of duopoly even if it successfully invalidates the `017 patent. TEV is therefore willing to agree to settlements with relatively late entry dates even when GSK is not able to make a no-AG commitment.

The estimated effect of the settlement on spending—which can be interpreted as a measure of damages—indicates an even larger difference between the two counterfactual benchmarks.⁷³ With an alternative settlement as the counterfactual benchmark, we estimate that the observed settlement increased spending by \$125.4–\$208.8 million. With continued litigation as the counterfactual benchmark, the corresponding estimates are \$1,315.9–\$1,555.0 million, an order of magnitude larger. This stark difference is again primarily generated by the impact of a settlement that leaves the `017 patent intact compared to the possibility of the patent being invalidated at trial. Settlements that allow GSK to market an authorized generic still delay the entry of *other* generics. While TEV is able to enter the market, other generics and the intense downward pricing pressure they bring are kept off the market until patent expiration in January 2009. If the `017 patent is invalidated at trial, on the other hand, other generics enter in August 2006, leading to large reductions in overall spending.

E. DISCUSSION OF MODELING ASSUMPTIONS

While these results suggest that the Lamictal settlement resulted in at least \$100 million in increased spending on lamotrigine tablets, the analysis rests on assumptions that are by no means unassailable. In actual cases, plaintiffs and defendants would likely benefit from examining a variety of assumptions to explore the sensitivity of the results to changes in underlying assumptions. We discuss several (though not all) such possible extensions.

1. *The Duration of Duopoly*

Construction of the settlement payoffs requires assumptions about the timing of the entry of generics other than the generic challenging the patent. In the analysis above, we assumed other

⁷² Without an authorized generic in the market, TEV earns \$103.4 million per month during duopoly versus \$1.9 million per month during competition. With an authorized generic in the market, TEV earns \$62.4 million per month during duopoly versus \$1.3 million per month during competition.

⁷³ The data does not indicate any meaningful changes in total quantity upon generic entry, so the change in spending is essentially fully attributable to price.

generics would not have been able to enter until patent expiration, even if TEV had entered more than 180 days prior to patent expiration. If 180 days of generic exclusivity were all that was possible, the payoffs would have been substantially different. In particular, if TEV had only received 180 days of generic exclusivity, then all it loses from delaying entry by an extra month is one month of profit under competition—less than \$2 million (compared to profits of \$60+ million per month during duopoly).

Though not incorporated into the model above, the total quantity of lamotrigine tablets sold nearly doubled over the 2005–2009 period. If TEV foresaw this strong market growth and 180 days of generic exclusivity was all that was possible, TEV may actually have preferred to enter *later* (i.e., later than immediate entry) so that duopoly would occur in a larger market. In that case, even extremely weak patents may lead to settlements with generic entry close to patent expiration—with or without reverse payments—as the generic may be happy to wait and let the market grow. Similar considerations may arise in other cases.

2. *Bargaining Power*

To understand the impact of bargaining power, consider patent strength inference using only the incentive compatibility constraints. If the difference between the minimum and maximum possible patent strength implied by these constraints is relatively small, then the assumed bargaining power will not have a large impact on the estimate of patent strength and corresponding damages. If the difference is large, however, the assumed bargaining power will have a bigger impact. How much can be inferred from the incentive compatibility constraints alone will vary from case to case. In the numerical example in Part II.E, for instance, analysis of the incentive compatibility constraints determined patent strength to be between 0.4 and 0.5, and in counterfactual settlement negotiations without reverse payments there was only a single settlement satisfying the incentive compatibility constraints for each patent strength (with entry equal to the expected generic entry date from trial).

In the Lamictal analysis, on the other hand, the incentive compatibility constraints are much less informative. While GSK's incentive compatibility constraint indicates that patent strength is no stronger than 0.83, the observed settlement is incentive compatible for TEV even with a patent strength of zero. This result can primarily be traced back to our assumptions about the timing of TEV's entry and the duration of duopoly had GSK's patent been invalidated at trial. Upon invalidating GSK's patent, we assumed TEV would not have been able to enter until August 2006

(because it had not yet received FDA approval) and would not have enjoyed any period of generic exclusivity during which it would have earned duopoly profits. If upon winning at trial TEV would have been the only generic in the market from August 2006 to patent expiration in January 2009, TEV's incentive compatibility constraint would imply a patent strength of at least 0.65, and GSK's incentive compatibility constraint would imply a patent strength no higher than 0.74.⁷⁴ In general, the extent to which the incentive compatibility constraints bind may depend crucially on the underlying details of each case.

It is also worthwhile to highlight that the sensitivity of the results to changes in assumed brand bargaining power may depend on the counterfactual benchmark. Patent strength is estimated to be weaker if the brand's bargaining power is assumed to have been higher, and the weaker patent strength yields higher damages when continued litigation is the counterfactual benchmark. With an alternative settlement as the counterfactual, on the other hand, the stronger brand bargaining power but weaker patent strength tend to have offsetting effects on the counterfactual settlement.⁷⁵

3. Risk Aversion

Risk aversion has been posited as a reason why settlements with reverse payments might not be anticompetitive, as a payment from brand to generic may be to eliminate risk rather than delay entry.⁷⁶ Risk aversion can be incorporated into the proposed framework by applying a concave transformation to the payoffs.⁷⁷ With risk aversion, firms will prefer the guarantee of a settlement

⁷⁴ To see that TEV's delayed approval is not as important quantitatively, suppose instead that TEV would have been able to enter immediately had it successfully invalidated GSK's patent, but with only 180 days of exclusivity. In that case, it remains that the observed settlement—with TEV entering 3.5 years later but not competing with an authorized generic during 180-day exclusivity—is preferred by TEV to continued litigation even for a patent strength of zero. The reason is that the value of the no-AG commitment—which increased TEV's profits by over \$40 million per month during duopoly (according to our estimates)—far exceeds the additional 3.5 years of competition profits that TEV would have received from immediate entry.

⁷⁵ For example, assuming $\lambda=0.75$ in the Lamictal analysis, the average patent strength rationalizing the observed settlement is 0.345, compared to 0.665 with $\lambda=0.5$. With continued litigation as the counterfactual, the estimated effect of the observed settlement on spending is nearly \$3 billion—more than double the estimate for $\lambda=0.5$. With an alternative settlement as the counterfactual, on the other hand, the estimated effect on spending is the same as it is for $\lambda=0.5$. Over all bargaining powers, damages estimates range from \$125.4 to \$208.8 million for the alternative settlement counterfactual and \$646.4 to \$4,615.4 million for the continued litigation counterfactual.

⁷⁶ See, e.g., Bigelow & Willig, *supra* note 15.

⁷⁷ For instance, assuming Constant Absolute Risk Aversion (CARA) utility, firms can be modeled as evaluating a monetary payoff x according to $u(x) = -\exp(-rx)$, where r determines the strength of risk aversion. Because this function is concave, firms will prefer settlements with certainty that deliver the same expected monetary payoff as continued litigation. Formally, given patent strength p , trial payoffs x_1 and x_2 , and any concave $u(\cdot)$,

over the uncertainty of continued litigation. In general, adding risk aversion to the model will have different effects on the two counterfactual benchmarks. If brand risk aversion is strong enough, for instance, it may be that the observed reverse payment settlement involves generic entry prior to the expected generic entry date from continued litigation—i.e., negative delay. With an alternative settlement as the counterfactual, however, the brand is still able to eliminate risk and may settle for an even earlier entry date if it does not have the ability to make a reverse payment.⁷⁸

4. *Other*

The analysis can potentially be modified in several other ways. First, we assume GSK and TEV shared the same belief about the probability of the '017 patent being upheld in court. In principle, the firms can be permitted to have different beliefs about patent strength. The Nash bargaining model could then be used to uncover pairs of patent strength beliefs that rationalize an observed settlement. For pairs where the firms differ in their assessment of patent strength, any patent strength between the two beliefs would seem like a reasonable choice to calculate the expected trial outcome.

Second, we completely abstract away from chewables. The observed settlement allowed TEV to market generic lamotrigine chewables beginning in June 2005, which yielded a long duopoly period for chewables, during which we estimate TEV earned in excess of \$150 million. This aspect of the settlement agreement, which was extremely favorable to TEV, may have contributed to a later entry date for tablets—profits from chewables are potentially a form of compensation for forgone profits from tablets.

Last, much of the settlement payoff modeling can be refined to account for factors like time discounting, litigation costs, more nuanced changes in prices and shares (e.g., TEV's share in the data decreasing smoothly upon the entry of other generics rather than falling sharply), and potential effects of an authorized generic on brand pricing and quantity (as modeled above, the authorized generic only affects generic sales). Other cases likely present additional possible complications not considered here. As long as these complications can be tractably incorporated into the payoffs

$u(px_1 + (1 - p)x_2) \geq pu(x_1) + (1 - p)u(x_2)$. For a rigorous development of risk aversion in economic modeling, see, e.g., Andreu Mas-Colell, Michael Whinston & Jerry Green, *MICROECONOMIC THEORY* (1995).

⁷⁸ For a similar argument, see Edlin et al., *supra* note 5.

that enter the bargaining model, the proposed framework is likely versatile in being able to accommodate case-specific idiosyncrasies.

IV. CONCLUSION

In *Actavis*, the Supreme Court ruled that reverse payment settlements are subject to antitrust scrutiny under the rule of reason. In cases where a reverse payment has been found to be unlawful, quantifying the impact on market outcomes requires estimating the counterfactual, which depends on the unobserved strength of the brand's patent. In this article we propose a framework to infer patent strength from an observed settlement. The estimated patent strength can then be used in counterfactual analyses that compute the expected outcome from continued litigation or restrict the types of settlements available to firms, permitting quantification of damages.

Applying the framework to the *Lamictal* case, our results suggest that the settlement cost buyers of lamotrigine tablets over \$100 million relative to the settlement that would have been reached had a reverse payment not been an option, and over \$1.3 billion relative to the expected outcome under continued litigation. While these estimates are specific to the *Lamictal* case and should be taken with some caution, they suggest that the FTC is rightly wary of the effects of reverse payment settlements on consumer welfare. In addition, the results highlight that the assumed counterfactual benchmark—continued litigation or an alternative settlement that does not include a reverse payment—can have a major impact on the estimated effect of the settlement. We are optimistic that the framework can be applied in other reverse payment cases to more fully understand the economics of settlement choice and to quantify any relevant damages.