A Framework for Estimating Damages in Reverse Payment Cases*

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Abstract

Patent disputes between branded and generic pharmaceutical manufacturers are often settled with financial 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. To quantify the effect of reverse payment settlements on market outcomes, we propose using bargaining theory to infer the unobserved patent strength from the firms' observed settlement choice. The estimated patent strength can then be used to construct a counterfactual world without reverse payments. Applying our framework to the Lamictal case, we find that the settlement the firms reached likely cost buyers of lamotrigine tablets $100+ million in the form of higher drug prices, though the estimated magnitude of the effect depends crucially on the assumed counterfactual benchmark: continued litigation or an alternative settlement without a reverse payment.

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1 Introduction

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

Settlements in which the brand pays the generic are known as "reverse payment" settlements, or "pay-for-delay" settlements (as labeled by the Federal Trade Commission (FTC)). The usage of "reverse" comes from the fact that the firm whose intellectual property is allegedly being infringed upon is the one doing the paying, rather than the firm who is allegedly doing the infringing. "Pay-for-delay" comes from the argument that payments from brand to generic are in exchange for a later entry date by the generic than would have prevailed in a counterfactual world without the settlement. The FTC has been investigating reverse payment settlements since the late 1990s, contending that they are anticompetitive and in violation of antitrust law. In 2013, the Supreme Court took up the issue in *FTC v. Actavis*, ruling that reverse payment settlements are subject to antitrust scrutiny but not presumptively unlawful. Instead, the Supreme Court directed courts to apply the "rule of reason" to determine whether the settlement in question was in violation of antitrust law.

In this paper, we develop a framework to estimate how much a given reverse payment settlement delayed (or possibly hastened) the onset of generic competition, relative to the expected entry date from continued litigation and/or to a counterfactual settlement that does not contain a reverse payment (the two counterfactual benchmarks stated in Edlin et al. (2014)). The core idea of the approach is to impose structure on the way that patent

[1] For more information about the approval process, see for example Thaul (2012).

strength maps to settlement choice. Once this structure is in place, the firms' observed settlement choice can be used to infer what they must have believed about patent strength in order to rationalize that settlement choice. The backed-out patent strength can then be used to predict the expected outcome from trial as well as the settlement that would have been chosen if reverse payments had been disallowed, outcomes that are central to the quantification of any damages from the settlement.

To illustrate the approach, we apply the framework to the case of Lamictal (lamotrigine), an anticonvulsant developed by the British firm GlaxoSmithKline (GSK). Generic manufacturer Teva (TEV) filed a paragraph IV challenge to produce lamotrigine prior to the expiration of GSK's patents, and was subsequently sued by GSK. The firms settled in February 2005, with GSK conceding not to compete with its own generic upon TEV's entry and TEV agreeing to stay out of the market until July 2008 (more details about the negotiated settlement are given in section 4). In 2012, GSK and TEV were sued by a class of purchasers who alleged that the settlement was anticompetitive.

Our results indicate that the settlement increased total wholesale spending on lamotrigine tablets by $100+ million, but that the estimated effect is highly sensitive to the assumed counterfactual benchmark. When assuming continued litigation as the counterfactual benchmark, the estimated change in spending resulting from the settlement is 6+ times higher than when assuming an alternative settlement without a reverse payment as the benchmark. Moreover, the results suggest that the timing of TEV's entry was substantially delayed (by 5 or more months) compared to TEV's expected entry date from continuation of the patent infringement trial, but that given the opportunity to reach an alternative settlement without a reverse payment, the equilibrium settlement may still have involved TEV entering in July 2008 – the same time as under the reverse payment settlement. The reasons for this stark difference between the two counterfactual benchmarks are examined further in section 4. Since these results are based on data that is likely far more incomplete than what would be available in an actual litigation, we emphasize that the exact numbers we estimate should be taken with caution; the primary purpose of the case is to illustrate how the framework we develop can be practically applied, and how case-specific idiosyncrasies can affect the results.

We view our primary contribution to the existing literature on reverse payment settlements as providing a practical framework for estimating damages in specific cases. Most prior academic work examines reverse payment settlements with an eye toward determining what the antitrust standing of such settlements should be. If the broad takeaway from that

work is that reverse payment settlements can be but are not necessarily anticompetitive (an interpretation in line with the Supreme Court's *FTC v. Actavis* decision), and therefore need to be examined on a case-by-case basis, it is an important next step to look at individual cases and try to better understand the underlying economics determining firms' settlement choices. In addition, our approach allows for damages estimation without examining the validity of the patent directly – direct examination of patent validity is an extremely complex and time-consuming process.[2] While the Supreme Court's decision in *FTC v. Actavis* indicates that an examination of patent strength is "normally not necessary"[3] to determine whether a settlement is anticompetitive – instead relying on payment size as a proxy (the "*Actavis* inference" (Edlin et al. (2014))) – quantification of any relevant damages does seem to require an estimate of what would have happened in the absence of the settlement, which in turn presumably requires an estimate of patent strength.

More broadly, the paper contributes to a growing literature that applies structural econometric methods to topics in competition policy, and more specifically situations in which outcomes are determined via bargaining. A foremost example in this literature is merger simulation. Recent developments in merger simulation include Gowrisankaran et al. (2015), who utilize bargaining theory to predict merger effects in a market in which prices are negotiated (hospital services). We adapt similar methods to the study of reverse payments.

The paper proceeds as follows. Section 2 provides additional background about the history of reverse payment settlements and existing academic work on the topic. Section 3 presents the general framework for estimating damages. Section 4 applies the framework to the case of Lamictal. Section 5 concludes.

2 Background

In this section, we summarize the relevant institutional background and the history of reverse payments, along with related academic work. Rather than provide a comprehensive description of the legal history, we instead focus on a handful of major developments and on the issues most relevant to our paper.

[2]From the Supreme Court's decision in *FTC v. Actavis*: "The Circuit's related underlying practical concern consists of its fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. Any such litigation will prove time-consuming, complex, and expensive." *FTC v. Actavis*, 570 U.S. ___ (2013), Docket No 12-416, Syllabus p. 3.

[3]Ibid.

2.1 Reverse payment incentives

Under the 1984 Hatch-Waxman Act, a key incentive for generics to challenge patents is that the first paragraph IV challenger is given an 180-day exclusivity period during which it is the only generic firm permitted to produce the drug. This exclusivity period begins on the date that (a) the generic begins marketing the drug, or (b) a court rules the brand's patent to be invalid or not infringed,[4] whichever date is earlier. Since generic competition quickly drives down generic prices and in turn profits, 180-day exclusivity grants the first generic a secure period during which substantial profits can be earned, thereby incentivizing patent challenges. Past research has found that the prevalence of patent challenges increased dramatically in the wake of the Hatch-Waxman Act, and especially after the 1998 decision in *Mova v. Shalala* which expanded the set of circumstances under which generics would receive 180-day exclusivity.[5]

With or without 180-day exclusivity, a fundamental insight concerning brand-generic patent litigation is that the brand has far more to lose than the generic has to gain. Once a generic has entered, and in particular after any relevant generic exclusivity has ended, not only do brand profits sharply decrease, but *industry* profits sharply decrease. Since maintenance of the brand's monopoly increases industry profits, firms locked in patent litigation may have incentives to use reverse payments to divvy up monopoly rents, compensating the generic in a way that does not destroy joint profits. This basic argument has been developed in numerous existing articles: e.g., Shapiro (2003); Dickey et al. (2010); Elhauge and Krueger (2012); Bigelow and Willig (2013); Edlin et al. (2014).

While any such agreements do not preclude other generic firms from challenging the brand's patent, settlements with the first paragraph IV challenger do establish obstacles to future challengers. First, since 180-day exclusivity is only granted to the first challenger, the expected payoffs from patent challenges are far lower for future generics. Second, until a generic's 180-day exclusivity period has expired, the FDA is often prevented from approving other ANDAs for the same drug. Therefore, if the first challenger's exclusivity period is not triggered (or forfeited), delay in that generic's entry may effectively delay all generic competition.[6] Moreover, even if there are multiple challengers, it remains the case that

[4]What precisely counts as a "court decision" has been the subject of considerable debate. For instance, whether the start of the exclusivity period can be delayed until appeals are exhausted, or if earlier court decisions finding in favor of the generic immediately trigger exclusivity.

[5]For further information on trends in patent challenges, see for example FTC (2002), Filson and Oweis (2010), and Hemphill and Sampat (2011).

[6]See Patel (2009) and the articles cited therein for further discussion of this approval "bottleneck."

continued monopoly is likely capable of benefiting everyone involved (i.e., to the extent that the generics can be compensated for lost generic sales) – 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 the K-Dur case, which was initially tried in early 2002 before an FTC administrative law judge. The FTC alleged that settlement agreements between Schering-Plough, the branded manufacturer of the drug, and two generic producers, Upsher-Smith and ESI Lederle, 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 the generics need not have been for the purpose of inducing delay. 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 both firms prefer to continued litigation *and* that result in earlier generic entry than the expected generic entry date from trial (Dickey et al. (2010); Bigelow and Willig (2013); Harris et al. (2014)). The existence of these incentive compatible, consumer-friendly settlements was (and has since been) successfully advanced to argue against a per se ban on reverse payments.

2.2 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, there are at least four different benchmarks with which the negotiated generic entry date can be compared:

1. The expected generic entry date under continued litigation, computed using the probability that the brand's patent would be upheld at trial[7]
2. The generic entry date under continued litigation, determined by the validity of the brand's patent
3. Patent expiration
4. The generic entry date that the firms would have agreed upon as part of a settlement not containing a reverse payment

[7]As noted in Bigelow and Willig (2013), there is a potential distinction here between (a) firms' beliefs about this probability at the time of settlement negotiations and (b) the actual probability. Our approach attempts to uncover firms' subjective beliefs about the strength of the brand's patent, rather than the actual strength (though these coincide if firms have correct beliefs).

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 validity. If the brand's patent is valid, all settlements with entry no later than patent expiration have negative delay, whereas if the patent is invalid, all settlements with entry past the conclusion of the trial are considered to have delayed generic entry. Using benchmark (2), the reverse payment case would likely require deciding the original patent infringement case, which has been described as a "turducken task."[8] Benchmark (3) asserts that, since the brand holds a valid patent, any settlement with entry no later than 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 as in benchmarks (1) and (2).

Which benchmark should be used for determining anticompetitiveness has been the subject of considerable debate. In March 2005, after several initial decisions in the case, the Eleventh Circuit Court ruled that Schering's settlements with Upsher and ESI fell "within the patent's exclusionary power,"[9] which some observers interpreted as embracing benchmark (3). Decisions in the *Valley Drug*, *Taxmoxifen*, and *Ciprofloxacin* cases also seemingly endorsed benchmark (3), 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."[10]

In 2012, the Third Circuit Court (in the K-Dur case) rejected this "scope of the patent" logic, instead viewing reverse payments as "*prima facie* evidence of an unreasonable restraint of trade,"[11] placing the burden on the settling firms to demonstrate that the payment was for some purpose other than delaying the generic's entry. In *FTC v. Actavis*, the Supreme Court also rejected the scope 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.

Our understanding of current practice is that brand patents are viewed as probabilistically valid, and that benchmarks (1) and (4) are the appropriate standards by which reverse payment settlements should be judged (Edlin et al. (2014)). In line with current practice, our

[8] *FTC v. Watson Pharmaceuticals*. No. 10-12729, April 25, 2012, p. 39.

[9] *Schering-Plough v. FTC*. No. 04-10688, March 8, 2005, p. 34.

[10] *In re: Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), March 31, 2005, at 535.

[11] *In re: K-Dur Antitrust Litigation*. No. 10-2077, July 16, 2012, p. 33.

approach is well-suited to estimate damages according to both benchmarks. Our approach is uniquely suited for applying benchmark (4), which requires formulating a counterfactual settlement that the firms would have reached had they been unable to make reverse payments.

2.3 Non-cash payments

An additional complicating factor in many reverse payment cases is that the payment from brand to generic is not in the form of cash. In the K-Dur case, for instance, Schering paid Upsher $60 million to license several products from Upsher. The FTC contended that this payment was not commensurate with the value of the licenses, and instead was made for the purposes of delaying Upsher's entry. However, both the FTC administrative law judge and the Eleventh Circuit Court rejected the FTC's argument, in effect concluding that no reverse payment had occurred.[12] Given the need for plaintiffs in a reverse payment case to demonstrate that a transfer of value actually occurred, settlements after the FTC's initial action in K-Dur unsurprisingly shifted away from cash and toward side deals. According to settlement information collected by the FTC and reported in FTC (2002), for the majority of settlements prior to the K-Dur case that involved (a) restrictions on generic entry and (b) some kind of payment from the brand to the generic, the payment took the form of cash. After the FTC's action in K-Dur, on the other hand, the number of settlements involving cash payments steeply declined.[13] Moreover, the vast majority of recent settlements involving cash now explicitly specify that the payment is for the purposes of covering litigation fees.

One important form of compensation besides cash is what is called a "no authorized generic" (no-AG) commitment. In the Lamictal case, which we examine in section 4, compensation from the brand to the generic is in the form of a no-AG commitment. As discussed earlier, the Hatch-Waxman Act incentivizes 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, however, who is allowed to produce or license its own generic product: an "authorized generic." Competing with an authorized generic has been found to substantially decrease first-filer generic revenues,[14] and

[12]Schering's settlement with ESI, on the other hand, did contain a direct cash payment.

[13]Source: FTC Bureau of Competition. Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2004 to FY 2014. Also see Salinger et al. (2007) for more information about the characteristics of settlements over time.

[14]FTC (2011) conducts an extensive study of authorized generics, including both quantitative analysis and detailed qualitative arguments drawing on internal pharmaceutical firm documents. They find that competing with an AG during 180-day exclusivity decreases the wholesale revenues of the first-filer generic

thus commitments by the brand not to launch an authorized generic are valuable to generic manufacturers.[15] Indeed, the commitment not to launch an authorized generic has been a popular component of patent settlements. In 75 of the 198 settlements (nearly 40%) that the FTC labeled as potential pay-for-delay agreements between 2007 and 2014, compensation from the brand to the generic took the form of a no-AG commitment.[16]

It is still being disputed in the courts whether the Supreme Court's decision in *FTC v. Actavis* applies to no-AG commitments (and other non-cash transfers). Several decisions in the Lamictal case denied that no-AG commitments should be considered reverse payments (e.g., "there are only a few scattered indications that the Supreme Court intended its holding to apply to non-monetary payments"[17]), and only in 2015 did an appeals court rule that the no-AG agreement in the Lamictal case falls under *Actavis*, ruling that "no-AG agreements are likely to present the same types of problems as reverse payments of cash."[18] On top of 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 features a no-AG commitment, the judge ruled that no-AG commitments were subject to antitrust scrutiny but that the plaintiffs' estimate of the value of the no-AG commitment was "vague and amorphous," and dismissed the case.[19]

2.4 Empirical literature

While there have been several prior empirical studies examining large samples of drugs in order to estimate the average impacts of reverse payment settlements (e.g., FTC (2010), Drake et al. (2015), and Helland and Seabury (2016)), empirical work on practical approaches to estimating damages is – to our knowledge – limited to one study: McGuire et al. (2016). McGuire et al. (2016) suggest using an event study analysis of the brand stock price to estimate the supracompetitive profits gained by the brand as a result of the reverse payment

by 39.6%-52.0%, depending on the specification.

[15] Authorized generics are also relevant outside of 180-day exclusivity. In fact, FTC (2011) reports that approximately two-thirds of AGs that were launched between 2001 and 2008 were *not* marketed during an 180-day exclusivity period. 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 brand – can also be considered a no-AG commitment.

[16] Source: FTC Bureau of Competition. Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2007 to FY 2014.

[17] *In re: Lamictal Direct Purchaser Antitrust Litigation.* No. 12-cv-995 (WHW), January 24, 2014, p. 14.

[18] *King Drug Company v. Smithkline Beecham.* No. 14-1243, June 26, 2015, p. 32.

[19] *In re: Effexor XR Antitrust Litigation.* No. 11-5479 (PGS) (LHG), October 6, 2014, p. 38.

settlement, and then dividing that estimate by an estimate of the profit difference for the brand between continued monopoly and competition with a generic entrant to convert those supracompetitive profits into an equivalent duration of extended monopoly.[20] 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 approach we propose in this paper is complementary to the ideas of McGuire et al. (2016). For a variety of well-known reasons (e.g., see Kothari and Warner (2008)), event study analyses will not always be capable of detecting causal effects. For example, news of the settlement may not be sudden, or the settlement could 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 utilizing a structural model of settlement choice, our approach requires plaintiffs and defendants to be completely explicit about the factors determining settlement choice, and as a result permits the estimation of alternative settlement terms had reverse payments been disallowed.

3 Approach to Estimating Damages

We now turn to the discussion of the basic framework for estimating damages in reverse payment cases. We begin with a high level description of the idea in this section and then apply the framework to the Lamictal case in section 4.

3.1 General framework

Denote the set of possible settlements over which the firms are negotiating by $\mathcal{Z}$, and denote the subset of such settlements that contain a reverse payment by $Z_R \subset \mathcal{Z}$. In any given case, suppose that the settlement chosen by the firms (z^*) contains a reverse payment (i.e., $z^* \in Z_R$). Evaluating the competitive effect of the settlement and quantifying any relevant damages involves comparing outcomes (e.g., the generic's entry date) under z^* to outcomes under various counterfactuals: specifically, (1) continued litigation and (2) an alternative settlement not containing a reverse payment (i.e., if only settlements in $\mathcal{Z} - Z_R$ were available).

Patent strength is a key input to both counterfactual questions. Continued litigation will

[20] This calculation is based on prior work analyzing the period of delay caused by reverse payment settlements in the context of stylized theoretical models, e.g. Elhauge and Krueger (2012) and Edlin et al. (2013).

result in very different outcomes for sham patents vs. ironclad ones, and the settlement that firms choose when unable to make reverse payment settlements will also presumably depend on the strength of the patent – in negotiations, the value of each firms' outside option (continued litigation) depends on the likelihood that the patent will be upheld. Unfortunately, patent strength is not directly observed. To overcome this problem, the fundamental idea of the approach is to explicitly model settlement choice as a function of patent strength p (i.e., the probability that the brand's patent will be upheld). Once this model is in place, patent strength estimates can be backed out from the observed settlement by finding the patent strength(s) p such that the settlement chosen in the model is the same as the observed settlement. With the rationalizing patent strength(s) in hand, counterfactual analyses like estimating the expected outcome from continued litigation and/or restricting the firms to settlements not containing a reverse payment can be conducted.

Implementing the approach in practice requires careful modeling of the function through which firms are assumed to choose settlements. This function will incorporate the payoffs that the negotiating firms receive as a function of available settlements, the payoffs that firms expect to receive from continued litigation (the outside option to settling), and the process through which firms choose settlements given those payoffs. A standard approach in the economics literature to model negotiations is to assume that the firms negotiate through "Nash bargaining," a solution concept to two-player bargaining games initially proposed by Nash (1950).[21,22,23] The use of Nash bargaining in other litigation contexts (e.g. in estimating reasonable royalty rates) has proven controversial, with some courts rejecting its use.[24] A thorough discussion of this point is beyond the scope of this paper, though we note that some economic model of settlement choice – an analysis of the various possible rationales for reverse payments – underlies essentially all arguments about the competitive effects of reverse payments. Nash bargaining (potentially allowing for asymmetric bargaining power) provides a framework in which the economic fundamentals of the situation (e.g., payoffs from settling, outside options, etc.) and how those fundamentals map to settlement choice are explicitly modeled.

[21]To our knowledge, Nash bargaining was first applied to the analysis of reverse payment settlements by Bulow (2004).

[22]In applied work, Nash bargaining has been used in recent empirical articles such as Crawford and Yurukoglu (2012), Grennan (2013), and Gowrisankaran et al. (2015).

[23]Many applications require modeling the outcome of many simultaneous bargains, and typically use the "Nash-in-Nash" solution suggested by Horn and Wolinsky (1988), the microfoundations of which are examined by Collard-Wexler et al. (2015). The Lamictal case consists of only a single bargaining game, but the Nash-in-Nash concept may prove useful in cases with multiple paragraph IV challengers.

[24]For example, Oracle Am., Inc. v. Google Inc., 798 F. Supp. 2d 1111 (N.D. Cal. 2011).

The Nash bargaining solution, which can be microfounded in an alternating-offers model (e.g., see Binmore et al. (1986)), is obtained by maximizing the so-called "Nash product" subject to the incentive compatibility constraints that the chosen settlement delivers weakly higher payoffs to both firms than their outside options:

$$\begin{aligned} \max_{z \in \mathcal{Z}} \; & \left[\pi_B(z) - \pi_B^{trial}(p)\right]^{\lambda} \left[\pi_G(z) - \pi_G^{trial}(p)\right]^{1-\lambda} \\ s.t. \; & \pi_B(z) - \pi_B^{trial}(p) \geq 0 \\ & \pi_G(z) - \pi_G^{trial}(p) \geq 0 \,. \end{aligned} \tag{1}$$

$\mathcal{Z}$ is the set of settlements over which the firms are negotiating. Brand and generic payoffs as a function of the settlement z are denoted by $\pi_B(z)$ and $\pi_G(z)$, respectively. The outside option to a settlement is continued litigation, with payoffs as a function of the patent strength p denoted by $\pi_B^{trial}(p)$ and $\pi_G^{trial}(p)$. λ is a bargaining power parameter; at the extremes, setting $\lambda = 1$ is equivalent to the brand making a take-it-or-leave-it settlement offer to maximize its payoff subject to the generic's incentive compatibility constraint, and vice-versa for $\lambda = 0$. Intuitively, Nash bargaining selects the settlement that maximizes "gains from trade" – more precisely, the settlement that maximizes the bargaining power-weighted geometric mean of the firm-specific gains from trade (payoffs in excess of outside options).

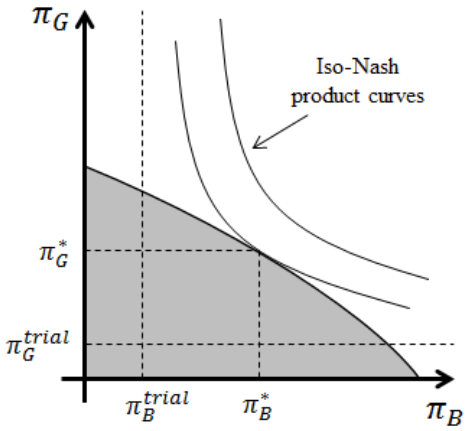

Figure 1: Nash bargaining Brand profits are on the x-axis and generic profits are on the y-axis. The shaded region gives the feasible payoffs from settlements in $\mathcal{Z}$, and the dashed lines at π_B^{trial} and π_G^{trial} denote the value of each firm's outside option. The "iso-Nash product curves" plot combinations of π_B and π_G that generate the same value of $[\pi_B - \pi_B^{trial}]^{\lambda}[\pi_G - \pi_G^{trial}]^{1-\lambda}$. The Nash bargaining solution is the feasible settlement that sits on the highest iso-Nash product curve, delivering payoffs π_B^* and π_G^*.

A graphical representation of Nash bargaining is given in Figure 1. The solution to the Nash bargaining problem is the feasible settlement that delivers the highest Nash product,

which in the picture is given by the tangency point between the set of feasible settlements and the iso-Nash product curve. For some intuition about how the model can be used to make inferences about patent strength, consider the effect of an increase in patent strength on the chosen settlement; as patent strength increases, the iso-Nash product curve at each point steepens,[25] pushing the tangency point in Figure 1 down and to the right – a settlement less favorable to the generic and more favorable to the brand. Our approach can be thought of as "inverting" this intuition; if the observed settlement is extremely favorable to the brand, for instance, then the brand's patent was likely strong.

3.2 Discussion

Of course, the precise meaning of words like "extremely favorable" and "strong" in the preceding sentence is central to the accurate quantification of damages. These particulars heavily depend on the specifics of the functions π_B, π_G, π_B^{trial}, and π_G^{trial}, as well as the bargaining parameter λ. The details of modeling these functions will likely vary substantially from case to case, e.g. if the alleged reverse payment was in the form of cash or some sort of implicit payment, if the challenging generic will receive paragraph IV exclusivity, if there are multiple generic challengers, if the firms are risk averse, if the challenging generic has an approved ANDA, etc. Given these case-specific idiosyncrasies, it is difficult to make general statements about how various case characteristics will combine to indicate the likely strength of the brand's patent (and the resulting counterfactual outcome). That said, it is possible to intelligently speculate about plausible key forces, and how the magnitude of those forces might be estimated from available data.

Two important quantities affecting settlement incentives are (a) the profit gain to the brand of continued monopoly and (b) the profit loss to the generic of staying off the market. Both quantities can likely be estimated (or even are directly observable) from firm documents, either from sales projections or actual transaction data. For instance, the size of a cash payment relative to these quantities will be indicative of how long monopoly would need to be extended to rationalize the brand making the payment, and how long the generic would be willing to stay off the market in order to receive the payment. The potential impact of case-specific details on these calculations is immediate – for example, if the generic does not have paragraph IV exclusivity, its profit loss from staying off the market will be substantially

[25] This effect can be verified formally by applying the implicit function theorem to the objective function in (1) to determine the slope of the iso-Nash product curves, and then differentiating that slope with respect to the patent strength p.

attenuated. The calculations will also be further complicated by reasons for payment besides affecting the timing of the generic's entry (litigation costs, risk aversion, etc.), but the core idea remains the same.[26]

In cases with no-AG commitments, additional relevant quantities are the brand's loss from not launching an AG and the generic's gain from not competing with an AG. Unlike a cash payment, these values are not directly observable, and therefore need to be estimated from other sources. In the Lamictal example in section 4 below, we utilize estimates from the FTC about the average effects of authorized generics, though ideally firm documents can provide more direct evidence about firm projections of the impact of an AG. When the generic loses more from facing an AG than the brand gains, no-AG commitments will often offer straightforward Pareto improvements under which the generic is willing to delay entry in exchange for a no-AG commitment by more than enough to compensate the brand for lost AG profits.[27] In general, the more that an AG cuts into generic profits, the more willing the generic will be to delay entry in exchange for a no-AG commitment. Inverting this logic to make a statement about patent strength, given an observed generic entry date and a no-AG commitment by the brand, the more that an AG reduces generic profits, the lower the patent strength needed to rationalize the observed settlement.

It is also important to acknowledge the role of the bargaining parameter λ in determining settlement choice. Going back to Figure 1, increases in the brand's bargaining power steepen the iso-Nash product curves while increases in the generic's bargaining power flatten them. The effects of changes in bargaining power on settlement choice are therefore similar to

[26]Another obstacle in models with cash payments is rationalizing generic entry prior to patent expiration. If joint surplus (brand plus generic) increases in the entry date of the generic and cash payments are costless, it is generally optimal in the model for the firms to agree to generic entry at patent expiration, maximizing the pie then using the cash payment to split it.

In practice, however, some settlements feature both a cash reverse payment and generic entry prior to patent expiration. To rescue the method, one possibility is to add a function that captures expected antitrust liability to the payoff functions. For instance, if a large cash payment and/or generic entry close to patent expiration is likely to attract antitrust scrutiny, then it may no longer be the case that maximal delay will increase joint surplus, as such a settlement would also maximize antitrust risk. Accurate specification of the functional form of this liability will depend on the details of the given case (e.g., documents uncovered during discovery may point to the extent to which firm executives were concerned with antitrust liability), as well as the time period during which the settlement was reached. For instance, the first generation of reverse payment settlements primarily featured (a) cash payments and (b) generic entry at patent expiration (FTC (2002)). For these cases, the basic model may be entirely suitable, whereas for later cases involving cash payments and generic entry prior to patent expiration, modifications may be needed. Another option is to use only the incentive compatibility constraints for inference, which eliminates the need for an explicit model of settlement choice (at the cost of coarser estimates).

[27]No-AG commitments may still be used even when the AG is worth more to the brand than the generic, though the logic is somewhat more complex.

changes in patent strength, such that the assumed bargaining power can potentially have a major impact on the estimated patent strength. We further discuss the interpretation of the bargaining parameter and the impact of changes in the bargaining parameter on the results in the context of the Lamictal case in section 4. In addition, if one is uncomfortable taking any stance on bargaining power, another option is to use only the incentive compatibility constraints for inference. Assuming that stronger patents increase brand trial payoffs and decrease generic trial payoffs, the two inequality constraints in (1) will provide an interval of patent strengths for which the observed settlement is incentive compatible, with the brand's incentive compatibility constraint delivering the upper bound and the generic's incentive compatibility constraint delivering the lower bound. Using only incentive compatibility rather than a full model of settlement choice comes at a cost, however. First, since less structure is imposed on settlement choice, the set of patent strengths that are consistent with the model will be larger. Second, the increased coarseness in estimating patent strength will pass through to the counterfactual analysis; for example, the set of incentive compatible alternative settlement choices without reverse payments is potentially much larger than the set that is consistent with Nash bargaining (which imposes additional structure).

4 Application: Lamictal

We now apply the framework laid out in section 3 to the example of Lamictal (lamotrigine), an anticonvulsant used in the treatment of epilepsy and bipolar disorder. Many of the assumptions we make are specific to the Lamictal case, and may not generalize to other reverse payment cases. Reverse payment settlements can be highly idiosyncratic, and one of the takeaways from our results for Lamictal is that these details can matter a great deal when assessing the effects of the settlement.

4.1 Background

GlaxoSmithKline (GSK) began producing Lamictal tablets in 1994, and later added a chewable tablet form ("chewables"). In 2007, sales of Lamictal tablets exceeded $2 billion, while revenues from chewables were far lower, around $80 million.[28] The primary patent protecting Lamictal (both tablets and chewables) from generic competition was U.S. Patent No.

[28]It is somewhat unclear to us why tablets and chewables are not more substitutable, but all indications in the data suggest that the two markets operate quite independently of one another.

4,602,017 (the '017 patent), which expired in late January 2009.[29] In 2002, Teva (TEV) filed a paragraph IV application with the FDA seeking approval to sell generic Lamictal (both tablets and chewables). GSK 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, GSK and TEV reached a settlement in mid-February 2005 with the following components:[30]

- TEV was allowed to market generic Lamictal tablets beginning in July 2008, six months prior to the expiration of the '017 patent
- TEV was allowed to market generic Lamictal chewables beginning in June 2005
- GSK agreed not to launch authorized generic versions of Lamictal until January 2009[31]

In February 2012, a class-action lawsuit was brought against GSK and TEV, alleging that the settlement reached was unlawful and resulted in higher prices for lamotrigine tablets than would have prevailed in the absence of the agreement. In December 2012, the district court dismissed the case, arguing that the settlement was not subject to antitrust scrutiny because it did not involve a cash payment from GSK to TEV. The plaintiffs appealed, and the appeals court remanded the case back to the district court following the Supreme Court's decision in *FTC v. Actavis*. In January 2014, the district court affirmed its dismissal, which the plaintiffs again appealed. In June 2015, the Third Circuit overturned the dismissal,[32] a decision which GSK and TEV appealed to the Supreme Court in February 2016.[33]

4.2 Model

We assume that 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

[29] The original patent actually expired in July 2008, but GSK was granted a six-month pediatric exclusivity extension, extending the effective patent life to late January 2009. We assume that GSK/TEV knew that pediatric exclusivity would be granted.

[30] *In re: Lamictal Direct Purchaser Antitrust Litigation.* Case 2:12-cv-00995-WHW-CLW Document 105. The court documents we utilize, such as this one, are all publicly available.

[31] From the court documents we have reviewed, it is somewhat unclear whether GSK agreed not to launch AGs during TEV's 180-day exclusivity periods, until January 2009, or ever. To our knowledge, GSK never launched an AG for either chewables or tablets, so we assume that this was either what was written in the settlement or that this was common knowledge between GSK and TEV.

[32] *King Drug Company v. Smithkline Beecham.* No. 14-1243, June 26, 2015.

[33] *Smithkline Beecham v. King Drug Company.* No. 15-1055, February 19, 2016.

(2) an agreement in which TEV would begin marketing generic lamotrigine at an agreed upon date and GSK *would* launch an authorized generic. Since the chewable market is extremely small relative to the tablet market, we focus on the agreed upon entry date for tablets. Chewables are incorporated into the model, but are modeled much less explicitly than tablets, as a form of cash payment (see section 4.4.3 for more details). Other cash transfers are assumed to be infeasible, or likely to attract considerable antitrust scrutiny. Given the challenges to date in litigating cases involving no-AG commitments, we believe it is a reasonable simplifying assumption that, at the time of many such settlements, the negotiating firms believed that there was only a negligible risk of antitrust liability. Therefore, we assume that GSK/TEV acted as if the no-AG commitment carried zero expected antitrust liability.[34]

Each possible settlement is characterized by a pair $(\tau, ag) : \tau \in [0, 48], ag \in \{N, Y\}$ (no,yes),[35] where $\tau = 0$ corresponds to immediate entry and $\tau = 48$ corresponds to entry at patent expiration.[36] The net present value of profits to each firm (as of February 2005) from sales of lamotrigine tablets depend on the entry date of TEV and the presence or absence of an authorized generic. We denote these payoffs by the functions $\pi_{GSK}(\tau, ag)$ and $\pi_{TEV}(\tau, ag)$. The payoffs to continuing the trial (the expected value of the NPV of profits from trial) depend on the probability that GSK's patent would be upheld ($p =$"patent strength"), and are denoted by the functions $\pi^{trial}_{GSK}(p)$ and $\pi^{trial}_{TEV}(p)$.

These four functions, the construction of which we discuss in section 4.4, define a two player bargaining game. We are interested in the mapping from patent strength p to the equilibrium settlement (τ^*, ag^*) (or going to trial if no incentive compatible settlement exists). Under Nash bargaining, the equilibrium settlement is given by the solution to:

$$\max_{(\tau,ag)} \left[\pi_{GSK}(\tau, ag) - \pi^{trial}_{GSK}(p)\right]^{\lambda} \left[\pi_{TEV}(\tau, ag) - \pi^{trial}_{TEV}(p)\right]^{1-\lambda} \tag{2}$$

$$s.t.\ \pi_{GSK}(\tau, ag) - \pi^{trial}_{GSK}(p) \geq 0$$

$$\pi_{TEV}(\tau, ag) - \pi^{trial}_{TEV}(p) \geq 0\,.$$

[34]The effect of adding antitrust liability to settlements with no-AG commitments largely depends on which firm is expected to bear the cost. For instance, if GSK disproportionately bears the cost, then it receives more favorable settlement terms for all patent strengths, since incurring an extra cost from settlement is in effect equivalent to an increase in the value of GSK's outside option (taking the outside option avoids incurring the cost) – as a result, weaker patents rationalize the observed settlement.

[35]As presented here and in future sections, one unit of time is a month. It is straightforward to discretize time more finely, e.g. by week or day.

[36]To be completely correct, patent expiration actually occurs closer to $t = 47.75$ 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.

By solving (2) for many values of p, we find the set of patent strengths that rationalize the observed settlement choice, $P^* \equiv [\, p \mid (\tau^*, ag^*) = (42, N)]$. This set contains our estimates of the firms' subjective beliefs about the probability of GSK winning at trial. To predict the settlement that would have been chosen absent the ability of GSK to make no-AG commitments, we restrict the set of feasible settlements to $(\tau, Y) : \tau \in [0, 48]$ and allow the firms to renegotiate, holding the bargaining parameter λ constant. In the final step, we calculate the difference in total spending on lamotrigine tablets resulting from the observed settlement compared to the counterfactual settlement (or to the expectation of continued litigation), which can be interpreted as an estimate of damages from the settlement.[37,38]

4.3 Data

Information about lamotrigine prices and quantities are taken from the IMS National Sales Perspectives™ (NSP) dataset – which captures 100% of the U.S. pharmaceutical market – for the years 2005 to 2014. The NSP data is derived from direct sales from roughly 100 pharmaceutical companies and indirect sales from over 500 distribution centers. The data is therefore much more accurate in estimating the revenues received by pharmaceutical firms than data sources at the retail level (such as the IMS National Prescription Audit™, the Medical Expenditure Panel Survey, etc.). One important limitation of the data is that revenues in the data do not include rebates from drug manufacturers to payers, and are therefore an upper bound to the true revenues. 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). For the analysis, we collapse this data to the level of manufacturer-form-month, combining the data from different package sizes and dosage strengths.

Figure 2 plots the total quantity (in millions of pills) of lamotrigine tablets sold by month, as well as the average price paid per pill (in producer price index (PPI)-deflated

[37] One possible objection to the interpretation of the spending difference as damages is that the extra profits may fuel welfare enhancing R&D and that these benefits are not captured by the model. We are unable to evaluate this claim quantitatively, though we note that the direction of the effect is not determinate. For example, Hemphill and Sampat (2013) (drawing on empirical work in Hemphill and Sampat (2011)) argue that the ability to make reverse payment settlements primarily increases the return to innovations covered by weaker, secondary patents (e.g., extended release formulations). Increasing the return of such innovations relative to others may distort R&D incentives in a way that actually reduces welfare.

[38] Our spending estimates are restricted to lamotrigine *tablets*. This is consistent with an interpretation of damages in which any potential gains realized by chewable buyers cannot be used to offset harm done to tablet buyers. Aggregate spending estimates would require a fuller model of the chewable market than we present here.

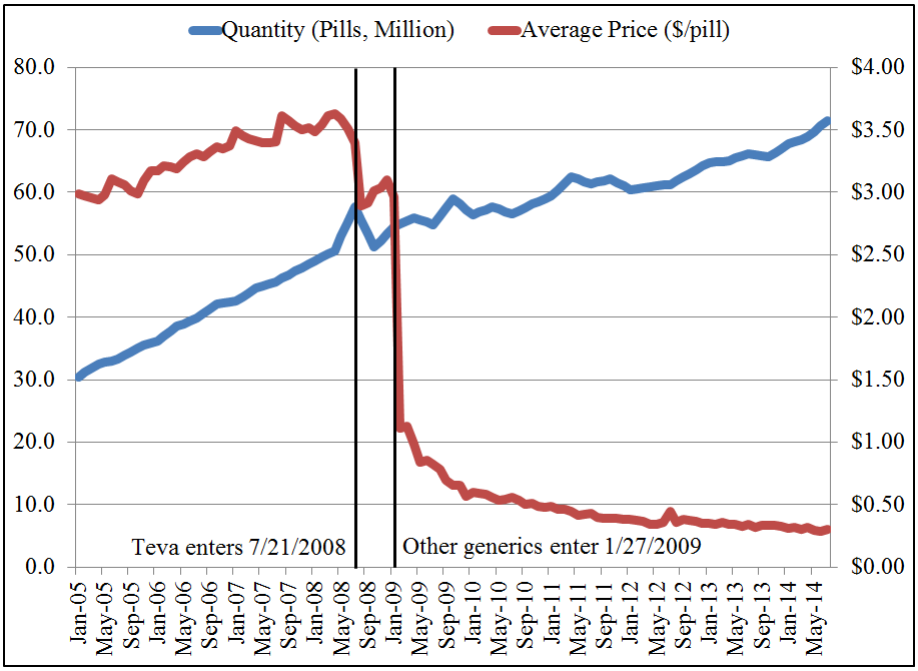

Figure 2: Lamotrigine Tablet Sales, 2005-2014 Total wholesale quantity (in millions of pills) is plotted on the left y-axis, while the average price per pill is plotted on the right y-axis.

2/2005 dollars). At the peak of the market when only GSK's Lamictal was available, GSK sold over 50 million pills a month at over $3.50 a pill, earning monthly revenues in excess of $175 million. Average prices fall by about 16% after TEV enters (comparing the average price during the 6 months where TEV is the only generic on the market with the 6 months prior). Once additional generics enter, the average price paid plunges as consumers switch to generic. By the end of 2010, industry revenue was less than 15% of what it was at its peak, even as total quantity continued to grow.

Table 1 breaks out average prices and shares by manufacturer. When TEV enters, it prices about 17% below GSK and takes nearly two-thirds of the market. Once all other generics enter, GSK's share further diminishes. TEV, while well below its share during duopoly, maintains about a quarter of the market. This share translates into much lower revenues, however, as generic prices fall to around 10 cents or less per pill once many generics enter the market. As of November 2014, more than 80% of TEV's revenues from selling lamotrigine tablets were generated during the six months in which it was the only generic on the market.

We close this section by noting that the strength of the assumptions needed to estimate the payoff functions depends on the quality of available data. Firm projections of market size, estimates of the profits foregone by not launching an authorized generic, actual transaction data, etc. would improve the accuracy of the payoffs that enter the bargaining game,

Table 1: Shares and Prices by Manufacturer

Statistic	Period	Months	GSK	TEV	Other Generics
Shares (% of total pills)	Monopoly	01/2005-07/2008	100.0%		
	Duopoly	08/2008-01/2009	33.0%	67.0%	
	Competition	02/2009-11/2014	8.3%	28.0%	63.7%
Prices ($ per pill)	Monopoly	01/2005-07/2008	$3.34		
	Duopoly	08/2008-01/2009	$3.39	$2.81	
	Competition	02/2009-11/2014	$4.56	$0.11	$0.07

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

presumably allowing for more precise counterfactual predictions. While such detailed data may not ever be publicly available, it is likely obtainable by plaintiffs' and defendants' experts as part of a litigation, which is where we envision the real-world application of the approach.

4.4 Constructing the payoff functions

Recall that the payoffs entering the bargaining game contain the firms' expected NPV of profits as a function of the settlement. We build these payoffs from the ground up, modeling the flow profits to each firm at each month $t = 0, 1, 2, ...$, where $t = 0$ corresponds to February 2005 (the month in which the settlement was reached). Denote total quantity at time t by Q_t, the share of firm i (GSK or TEV) at time t by s_{it}, the price of firm i at time t by p_{it}, the marginal cost of firm i at time t by c_{it}, and the (monthly) discount factor of firm i by δ_i. The payoff of a given settlement (τ, ag) to firm i is then:

$$\pi_i(\tau, ag) = \sum_{t=0}^{\infty} \delta_i^t \cdot (p_{it} - c_{it}) \cdot (s_{it} \cdot Q_t) \tag{3}$$

While the notation is suppressed, the elements on the right-hand-side of (3) will often condition on the settlement (τ, ag). Suppose that TEV enters right away with the settlement $(\tau, ag) = (0, N)$. $t = 0$ will then be duopoly competition between GSK and TEV. For all settlements with $\tau > 0$, on the other hand, GSK will have a monopoly at $t = 0$. We adjust prices and quantities to reflect these competitive differences. To do so, we fit curves that capture the observed trends in the data (which are assumed to be commonly known to GSK and TEV), and then adjust these curves to reflect how different competitive conditions might

have changed behavior, calibrating the adjustments using estimates from the literature. For example, using estimates from FTC (2011), we assume that facing an authorized generic during duopoly would have reduced TEV's share by 30% and its price by 14%. We believe that this approach accurately captures the essence of how the market works, with the understanding that the functional forms we employ are only reduced form representations of the exact mechanisms at play. In the subsections below, we discuss several particularly important issues – the duration of duopoly, trial outcomes, chewables, bargaining power, and risk aversion – in constructing the payoff functions. Further details about price and share patterns in the data, the exact functional forms and parameter values we use, etc. are given in section 6.1 in the appendix.

4.4.1 The duration of duopoly

One crucial question when constructing the payoff functions is when other generics besides TEV would have been able to enter the market. In particular, would other generics have been able to enter at the conclusion of TEV's 180-day exclusivity period, or not until the expiration of GSK's '017 patent? For the observed settlement, in which TEV began producing six months prior to patent expiration, these two outcomes are equivalent. More generally, however, there can be a large difference between these two possibilities. Suppose TEV had entered more than six months prior to patent expiration; would duopoly between GSK and TEV have lasted only six months, or continued until patent expiration?

Importantly, all settlements leave GSK's '017 patent intact. Review of FDA tentative approval letters obtained under a Freedom of Information Act request indicates that all generic manufacturers besides TEV who filed for approval to produce generic lamotrigine tablets did so with paragraph III certifications, allowing for FDA approval only upon the expiration of all relevant patents. Furthermore, since TEV was the first paragraph IV filer, the payoff to other generics of successfully invalidating the '017 patent would have been substantially diminished. These facts suggest that other generics may not have been able to enter the market prior to patent expiration even if GSK/TEV had reached a settlement with TEV entering the market more than six months prior to patent expiration. The experience of chewables 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 manufacturers were given final approval by the FDA until the day the patent expired, on which several manufacturers were approved. That said, the market for chewables is considerably smaller than the market for tablets, so the outcome for chewables may not be fully representative of what would have

happened for tablets.

Rather than take a definitive stance, we present results under both assumptions: for all settlements, (1) duopoly between GSK and TEV until patent expiration, and (2) duopoly for at most six months (less if TEV enters less than six months prior to the expiration of the '017 patent).[39]

4.4.2 Trial payoffs

Another important wrinkle in the Lamictal case is that TEV likely would not have been able to exercise its 180-day exclusivity had it successfully invalidated GSK's patent. At the time GSK/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."[40] At this time, TEV had not received tentative approval from the FDA, and they were not finally approved until much later, in August 2006. If TEV had won in court, the ruling would have triggered TEV's 180-day exclusivity, well before TEV was likely to receive FDA approval. Therefore, if GSK's patent was invalidated, we assume that TEV would have entered at the same time as other generics (without 180-day exclusivity) in August 2006 ($t = 18$).[41,42] If the patent was upheld, we assume that all generics including TEV would have entered at patent expiration ($t = 48$). Both outcomes are assumed to have been foreseen by GSK and TEV.

Since TEV's lack of an approved ANDA may have had a substantial impact on the bargaining outcome, we also perform the analysis assuming that TEV would have been able to enter right away had it successfully invalidated GSK's patent. While we do not believe this assumption to be correct in the Lamictal case, it nonetheless sheds light on an important factor affecting settlement negotiations.

4.4.3 Chewables

Modeling the choice of two entry dates – one for tablets and one for chewables – is conceptually straightforward (e.g., by constructing the chewable analogs of equation (3) and then

[39] In *Nostrum v. FDA*, the court ruled that 180-day exclusivity does not apply beyond the life of the relevant patent(s).

[40] *In re: Lamictal Direct Purchaser Antitrust Litigation.* Case 2:12-cv-00995-WHW-CLW Document 105.

[41] It is possible that TEV would have pushed the FDA for earlier approval had it successfully invalidated GSK's patent, but we do not have data to attempt to estimate the magnitude of any such effect.

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

combining the two). However, rather than complicating the model with multiple, potentially interacting entry dates, we instead make the simplifying assumption that the chewable part of the settlement can be represented by a lump-sum transfer from GSK to TEV. Given the size of the tablet market relative to chewables, we suspect that the "full" model yields results similar to what we report here.

According to the NSP data, TEV was making $3 to $5 million per month selling chewables during duopoly (5/2005 to 1/2009), compared to a couple hundred thousand dollars per month by the end of 2014. In total, we estimate that TEV will make roughly $200 million selling chewables (in 2/2005 dollars). The observed settlement, in which TEV was allowed to market lamotrigine chewables beginning in June 2005, yielded a long duopoly period for chewables, during which TEV earned about $160 million. We assume, conservatively, that this aspect of the settlement represented a $75 million transfer from GSK to TEV. We then include the value of this payment (a benefit to TEV and a cost to GSK) in all settlement options containing a no-AG commitment. If the true value of the chewable settlement was higher, our estimates of patent strength will tend to be biased upwards, as we will understate the amount of time TEV was willing to delay entry for tablets in order to receive the early entry date for chewables.

4.4.4 Bargaining power and risk aversion

Besides the estimated profit functions, bargaining power and risk aversion also affect the equilibrium outcome of the bargaining game. For the results in section 4.5, we assume that $\lambda = 0.5$ (symmetric bargaining power). To the extent possible, payoff relevant differences between firms – e.g. in discount rates, outside options, etc. – should be explicitly modeled and incorporated into the payoff functions (equation (3)). The symmetry assumption can then be motivated by an argument that the negotiated settlement should be invariant to swapping the firms.[43] That said, it is infeasible to explicitly model *everything* that might affect the negotiation; the bargaining parameter then captures any unmodeled differences between firms that may affect the bargaining outcome, e.g. differences in negotiating skill. There is some empirical evidence suggesting that brands may have more bargaining leverage than generics in settlement negotiations; for instance, McGuire et al. (2016) report that, 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

[43] I.e., the label "GSK" or "TEV" should arguably not affect the bargaining outcome. See Binmore et al. (1986) for further discussion on this point.

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. Given the clear possibility that bargaining power may not be symmetric, we also examine the case of asymmetric bargaining power in section 4.6.

Risk aversion is relevant in determining the value that 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 since 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.[44] It is unclear whether similar methods can be fruitfully applied in the reverse payment context. Absent evidence suggesting significant risk aversion,[45] in the main results we assume that both firms are risk neutral; we analyze the effects of risk aversion in section 4.6.

4.5 Results

We discuss results for four models corresponding to different specifications of (a) the duration of duopoly and (b) whether or not TEV had an approved ANDA at the time of the settlement:

1. Duopoly until patent expiration, no approved ANDA
2. Six months of duopoly (at most), no approved ANDA
3. Duopoly until patent expiration, approved ANDA
4. Six months of duopoly (at most), approved ANDA

For each specification, we solve the maximization problem (2) for each p between 0 and 1 (in steps of 0.01) to find the equilibrium settlement as a function of p. We then take the p that rationalize the observed settlement $(42, N)$ and compute counterfactual outcomes for the two benchmarks discussed in section 2: (1) if GSK/TEV could only negotiate over τ (disallowing no-AG commitments) and (2) if no settlement was allowed (continuing the patent infringement trial). Table 2 reports the results. The four columns of the table correspond to the four sets of assumptions listed above. For every specification, there is a range of patent strengths that rationalizes the observed settlement; the first row of the

[44] See Barseghyan et al. (2015) for a review of this literature.

[45] There are also theoretical arguments suggesting that publicly traded firms should be risk neutral since shareholders can diversify risk by altering their portfolio (e.g., see Goldberg (2013)).

Table 2: Baseline Results

		(1)	(2)	(3)	(4)
			Duration of Duopoly		
		Pat. Exp.	6 mos.	Pat. Exp.	6 mos.
	Counter-		TEV Approved ANDA?		
Statistic	factual	No	No	Yes	Yes
p	–	0.63 (0.028)	0.33 (0.013)	0.75 (0.018)	0.38 (0.008)
Delay	τ-only	1.60 (0.096)	0.00 (0.000)	1.75 (0.144)	0.00 (0.000)
	Trial	5.10 (0.84)	14.25 (0.39)	6.24 (0.86)	23.76 (0.40)
Δ Spending	τ-only	\$176 (11.5)	\$105 (10.9)	\$183 (12.5)	\$105 (10.9)
	Trial	\$1,274 (105.3)	\$2,476 (85.3)	\$1,174 (89.8)	\$3,119 (88.0)
%Δ Spending	τ-only	2.1% (0.002)	1.2% (0.001)	2.1% (0.002)	1.2% (0.001)
	Trial	17.0% (0.019)	41.4% (0.023)	15.5% (0.016)	62.6% (0.034)

Notes: Delay is measured in months. Total spending is in millions of dollars and is calculated using a yearly discount factor of 0.92. Bootstrapped standard errors are given in the parentheses. Standard errors are calculated by drawing from the estimated asymptotic variance/covariance matrix of the estimated parameters underlying the payoff functions and re-estimating the settlement choice model.

table gives the simple average. The remainder of the table reports statistics about outcomes under $(42, N)$ compared to outcomes under (1) renegotiation without no-AG commitments ("τ-only") and (2) continued litigation ("Trial"). The set of rows labeled "Delay" gives the average difference in TEV's entry date. "Δ Spending" and "%Δ Spending" give the average difference in total spending on lamotrigine tablets, both in absolute and percentage terms (damages).

The table reveals several interesting patterns. First, all else constant, TEV having an approved ANDA increases the patent strengths that rationalize the observed settlement. This result stems from the fact that having an approved ANDA increases the value of TEV's outside option to settling, as winning the patent infringement case would then result in TEV's immediate entry. When TEV has a stronger outside option, GSK needs a stronger patent to achieve the observed settlement. The effect on delay and spending, however, is ambiguous; while the stronger patent increases the probability of GSK monopoly, in the event that TEV successfully invalidates GSK's patent, TEV enters immediately rather than in August 2006.

Second, if duopoly between GSK and TEV lasts no more than six months, patent strength falls by around half and delay is *zero* for both τ-only counterfactuals. The reason for this

stark difference can be traced to the shape of TEV's payoff function when duopoly does not persist for more than six months. In particular, since the majority of TEV's profits are generated during its 180-day exclusivity period (around 80% according to our estimates), essentially the only cost to TEV of delaying entry is time discounting. In fact, since the lamotrigine market was growing quickly during the period – total tablets sold increased by more than 70% between February 2005 when the settlement was reached and July 2008 when TEV entered – our estimates imply that, when six months of exclusivity is all that is possible, delays in TEV's entry were mutually beneficial.[46] The bigger the market, the more valuable TEV's exclusivity period.

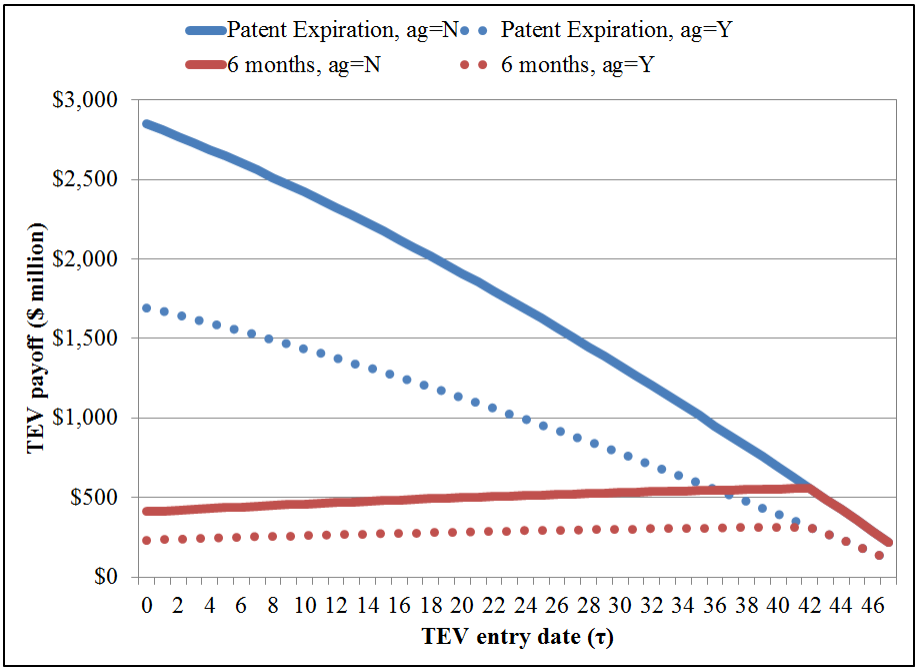

Figure 3: TEV Payoffs TEV's payoff given its entry date is plotted when duopoly persists until patent expiration (blue lines) or for six months at most (red lines), and as a function of whether an authorized generic is present (dotted lines) or not (solid lines).

To further illustrate this point, Figure 3 plots TEV's payoff as a function of its entry date and the presence/absence of an authorized generic, assuming duopoly until patent expiration and alternatively six months of duopoly at most. When duopoly persists until patent expiration, the stakes are much higher and TEV's payoff exhibits the expected decreasing shape, since every month of later entry corresponds to one less month of duopoly. When generic exclusivity lasts six months at most, on the other hand, TEV's payoff actually increases the

[46] Of course, for the market growth to affect the negotiated settlement, it needs to have been foreseen by the firms. Firm documents containing sales projections will likely be highly informative in assessing the reasonableness of this assumption.

later it enters due to the larger market size more than compensating TEV for the lost time value of money. This increasing pattern continues until $\tau = 42$, where the length of TEV's exclusivity period begins to shorten, resulting in a sharp decrease in TEV's payoff. The upshot of this pattern is that, if six months of exclusivity is all that was possible, it may be that delays in TEV's entry benefited both firms. As a result, even extremely weak patents rationalize the observed settlement $(42, N)$, as the negotiation over TEV's entry date is not rivalrous until $\tau = 42$. For the same reason, even when taking away no-AG commitments, TEV is still willing to delay entry until six months prior to patent expiration, leading to zero delay for the τ-only counterfactual (though spending is still higher with the no-AG commitment due to higher prices during exclusivity).

Third, there are large differences in the estimated effect of the settlement depending on the counterfactual benchmark used. For the case where duopoly lasts six months at most, this difference follows immediately from the discussion above. Weak patents imply early generic entry from continued litigation (in expectation), whereas the predicted alternative settlement in the absence of no-AG commitments still involves TEV entry only six months prior to patent expiration. As a result, the spending estimates for the τ-only counterfactual are only a small proportion of the estimates for the trial counterfactual. The same pattern (though to a somewhat lesser degree) is present when duopoly persists until patent expiration, but for a different reason. In that case, settlements over TEV's entry date alone still meaningfully delay "generic entry"; 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. If GSK's patent is invalidated at trial, overall spending sharply decreases. This sharp decrease is generated not only by the cessation of GSK's monopoly, but also by the early entry of other generics besides TEV (after six months). Even for weak patents, TEV therefore prefers to settle and leave GSK's patent intact, which results in a long period of duopoly and correspondingly higher spending.

4.6 Extensions

The results of the baseline specification suggest that GSK/TEV's settlement resulted in higher spending on lamotrigine tablets, though the estimated size of that effect heavily depends on the assumed counterfactual benchmark. In this section, we explore the sensitivity of the results to changes in (a) bargaining power and (b) firm risk preferences. For both extensions, we assume that duopoly extends until patent expiration for all settlements and that TEV did not have an approved ANDA at the time of settlement. Readers interested in

further modifications to the settlement choice model can e-mail either author for access to the relevant code.

4.6.1 Bargaining power

The results in the prior section assume that GSK and TEV have equal bargaining power, $\lambda = 0.5$. While we believe this is a natural and salient specification given the difficulties in attempting to estimate the degree to which one firm is more capable at extracting surplus in negotiations than the other, it is also important to examine the sensitivity of the results to changes in λ. Figure 4 plots patent strength and damages estimates as λ varies from 0.2 (TEV strong bargaining power) to 0.8 (GSK strong bargaining power).

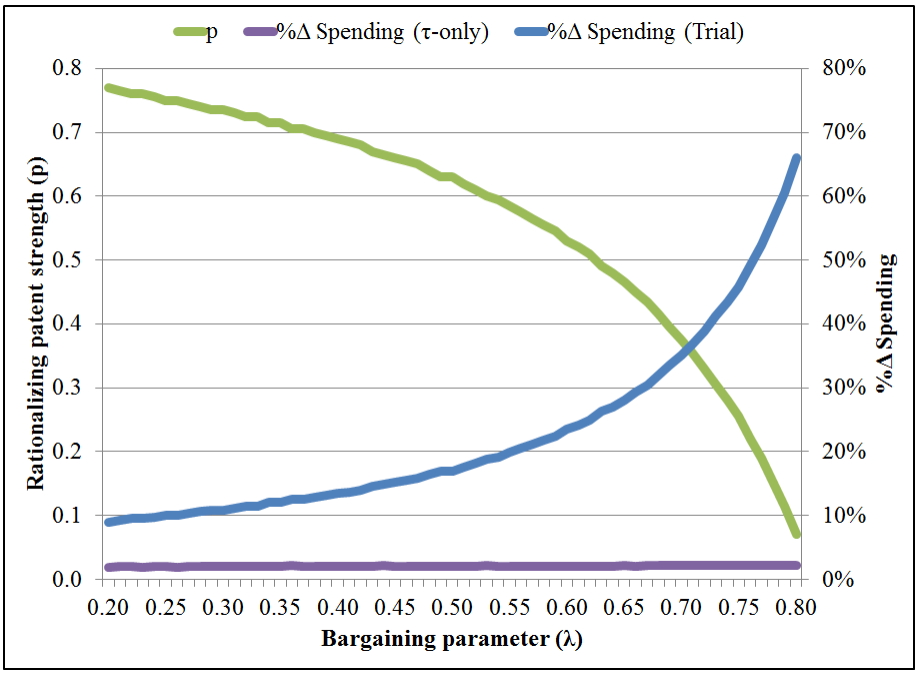

Figure 4: Varying Bargaining Power The figure plots patent strength and damages estimates as a function of GSK's assumed bargaining power (λ). The mean patent strength that rationalizes the observed settlement is on the left y-axis, and the corresponding damages estimates are on the right y-axis. The flat purple line uses an alternative settlement without a reverse payment as the counterfactual benchmark, and the curved blue line uses continued litigation as the counterfactual benchmark.

As GSK's bargaining power increases, it is able to reach more favorable settlement terms for all patent strengths. Therefore, the patent strengths that rationalize the observed settlement decrease as GSK's bargaining power increases. The figure illustrates the major impact that bargaining power can have on the estimate of patent strength, with patent strength

ranging from 0.77 (for $\lambda = 0.2$) to 0.07 (for $\lambda = 0.8$).[47]

The large differences in patent strength imply correspondingly large differences in damages for the trial counterfactual, ranging from less than 10% (around $700 million) to more than 60% (more than $3 billion). The effect of the changes in patent strength for the τ-only counterfactual (which allows renegotiation but without no-AG commitments), on the other hand, is far more muted. Intuitively, in the counterfactual settlement negotiations, the changes in the assumed bargaining power roughly offset the corresponding changes in the implied patent strength[48] – when GSK has a weak patent it has strong bargaining power (and vice versa). Since GSK and TEV are predicted to have strong incentives to settle even absent the ability of GSK to make a no-AG commitment, these countervailing forces result in the estimated delay of TEV's entry increasing only slightly as λ increases. These results again emphasize the potential importance of the assumed counterfactual benchmark in quantifying competitive effects.

4.6.2 Risk aversion

Risk aversion has been posited as an important reason why settlements with reverse payments might not be anticompetitive; a payment from brand to generic may be for the purposes of eliminating risk rather than delaying entry. To investigate this possibility, we assume that the firms evaluate outcomes according to the Constant Absolute Risk Aversion (CARA) utility function $u(x) = -e^{-rx}$. In the presence of risk aversion, the firms prefer settlements with guaranteed payoffs over facing the uncertainty of the trial outcome. Table 3 displays the results for two chosen values of r, along with the baseline of risk-neutrality ($r = 0$) for comparison purposes. Higher values of r are associated with more severe risk aversion.

As risk aversion increases, the patent strength that rationalizes the observed settlement also increases. The key reason for this result is that GSK faces substantially more risk than TEV: the difference between winning and losing at trial is nearly $4 billion for GSK and around $10 million for TEV.[49] When the firms are risk-averse, TEV is able to use the fact that GSK faces more risk to extract additional concessions relative to the baseline case, unless GSK's patent is stronger. For the trial counterfactual, the higher estimated patent strength implies a much shorter delay in generic entry. In fact, for $r = 0.0006$ (which

[47] For $\lambda \geq 0.83$, the observed settlement cannot be rationalized by the model; one interpretation of this result is as an upper bound on GSK's bargaining power.

[48] This effect is not present in the trial counterfactual because there is no renegotiation for the bargaining power to affect.

[49] TEV has more at stake from trial in the case where it has an approved ANDA, but even then GSK still faces considerably more risk (in absolute terms).

Table 3: Risk Aversion

Statistic	Counter-factual	r (Gamble Interpretation) 0 ($5,500)	0.0002 ($5,278)	0.0006 ($4,900)
p	–	0.63 (0.028)	0.71 (0.025)	0.85 (0.017)
Delay	τ-only	1.60 (0.096)	1.80 (0.112)	1.67 (0.177)
	Trial	5.10 (0.836)	2.70 (0.741)	-1.50 (0.521)
Δ Spending	τ-only	$176 (11.54)	$185 (11.70)	$179 (12.82)
	Trial	$1,274 (105.3)	$959 (93.5)	$407 (73.8)
%Δ Spending	τ-only	2.1% (0.002)	2.2% (0.002)	2.1% (0.002)
	Trial	17.0% (0.019)	12.3% (0.016)	4.9% (0.010)

Notes: The "Gamble Interpretation" of r gives the certainty equivalent (in millions) of a gamble paying $4,000 million ($4 billion) 50% of the time and $7,000 million ($7 billion) the other 50% of the time. Bootstrapped standard errors are given in the parentheses.

corresponds to the firms being indifferent between receiving $4.9 billion with certainty and a 50/50 gamble between $4 billion and $7 billion), the observed settlement is estimated to have *negative* delay compared to trial. Spending is still higher under the observed settlement, however, because under the settlement "generic entry" refers to TEV alone, while under the trial counterfactual other generics enter at the same time as TEV. Even though this occurs 1.5 months later in expectation, the decreased generic prices upon generic entry more than compensate for the later entry date.

While incorporating strong risk aversion generates negative delay and greatly reduces the estimated spending effects for the trial counterfactual, the results for the τ-only counterfactual are largely unchanged. Since the τ-only counterfactual allows renegotiation of a settlement, GSK is still able to eliminate risk even when unable to make reverse payments. The resulting settlement features an earlier counterfactual entry date, even when the patent is relatively strong. This result mirrors an argument made by Edlin et al. (2014); in the presence of risk aversion, incentive compatible reverse payment settlements with entry dates prior to the expected entry date from trial may exist, but in such cases the firms will settle for an even earlier entry date if not allowed to make reverse payments.

To further illustrate this point, Figure 5 plots equilibrium settlements as a function of patent strength for the case where $r = 0.0006$. For sufficiently strong patents ($p > 0.6$), TEV's negotiated entry date is earlier than its expected entry date from continued litigation, even when allowing no-AG commitments. That said, regardless of the patent strength, TEV's negotiated entry date when allowing no-AG commitments is always later than when

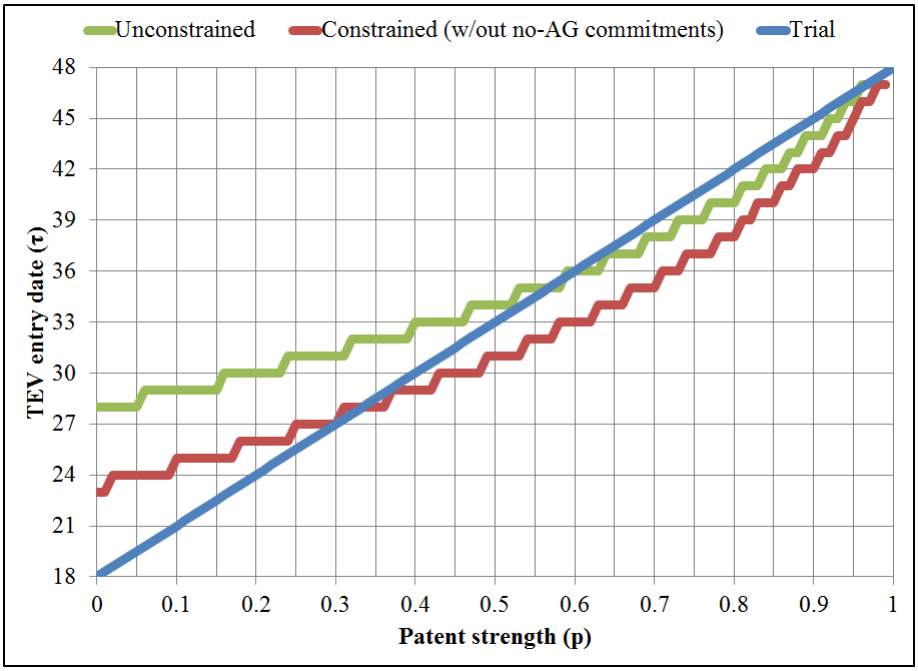

Figure 5: Settlements with Strong Risk Aversion (r=0.0006) Unconstrained settlements (the green line) allow no-AG commitments, while constrained settlements (the red line) do not. The trial (blue) line plots the expectation of TEV's entry date from continued litigation ($t = 18$ if GSK's patent is invalidated and $t = 48$ otherwise).

no-AG commitments are disallowed, since alternative settlements without reverse payments still allow the firms to eliminate uncertainty about the outcome of the patent litigation. These contrasting results further accentuate the importance of the assumed counterfactual benchmark; the estimated effect of the settlement can vary greatly depending on whether or not the firms are allowed to renegotiate in the but-for world.

5 Conclusion

In its 2013 *FTC v. Actavis* decision, the Supreme Court ruled that reverse payment patent settlements are subject to antitrust scrutiny under the rule of reason. Quantifying the impact of a given reverse payment settlement requires knowledge of patent strength, which is unobserved. In this paper, we developed a framework to infer patent strength from the firms' observed settlement choice. The estimated patent strength can then be used in counterfactual analyses that restrict the types of settlements available to firms, permitting quantification of damages.

Applying the framework to the specific case of Lamictal (lamotrigine), we estimate that

the settlement reached, which featured a no-AG commitment by the brand, cost buyers of lamotrigine tablets $100+ million. While these estimates are specific to the Lamictal case – and should be taken with some caution given the relative paucity of available data – more broadly they indicate that the FTC is rightly wary of the effects of reverse payment settlements on consumer welfare. In addition, the results highlight that case-specific idiosyncrasies (e.g., whether the generic has an approved ANDA) and the assumed counterfactual benchmark – continued litigation or an alternative settlement without a reverse payment – can have a major impact on the estimated effect of the settlement. We are optimistic that our basic framework can be applied in other reverse payment cases to more fully understand the economics of settlement choice and to quantify any relevant damages.

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6 Appendix

6.1 Functional forms used to construct the payoff functions

In this section, we more precisely describe the way we model the components of GSK and TEV's payoff functions (equation (3)). In the interest of brevity, the presentation is somewhat condensed; please feel free to contact either of us with questions. A table with the full set of parameter values used in the baseline results is given in section 6.2.

6.1.1 Total quantity

Examining Figure 2, there is essentially no quantity response when TEV enters or when other generics do, despite sizable decreases in price. With this in mind, we model the total quantity (in millions of pills) of lamotrigine demanded at time t, Q_t, as evolving exogenously according to:[50]

$$Q_t = Q_0 + (Q_\infty - Q_0) \cdot \left(1 - \exp(-\beta_Q \cdot t)\right). \tag{4}$$

Q_0 is initial quantity at $t = 0$, Q_∞ is the saturation quantity, and β_Q determines the rate at which total quantity approaches Q_∞. The parameters Q_0, Q_∞, and β_Q are estimated by non-linear least squares on the observed industry quantity data.

6.1.2 Shares

The next step is to determine what share of total quantity is received by each firm in each month conditional on the settlement (τ, ag). Denote the end of duopoly by t_c, which is $t = 48$ for the case where duopoly extends to patent expiration and $t = \min(\tau + 6, 48)$ for

[50] Of course, modeling total quantity as evolving exogenously is a major simplifying assumption. For instance, one commonly held view for why industry quantity does not go up when the price falls upon generic entry is that the brand simultaneously ceases marketing the drug (Scott Morton and Kyle (2012)). In a more complete model, GSK's marketing behavior and the effect on total quantity would endogenously respond to the timing of generic entry. Since we do not have data on drug advertising, however, we are unable to add advertising to our model. If anything, we suspect that this simplification yields an *over*estimate of patent strength (and therefore an underestimate of delay). In a model with advertising, TEV will be relatively more willing to delay entry in order to let the market grow, even when GSK's patent is weak. This effect is shut off in our model, implying that GSK needs a stronger patent to achieve the same delay in TEV's entry.

Similarly, the chosen settlement might affect the timing of the launch of a next-generation product by GSK, which would also presumably affect demand for lamotrigine tablets. Indeed, GSK's extended release version of Lamictal tablets was approved by the FDA in June 2009, just a few months after other generics besides TEV began producing immediate release tablets. However, Lamictal XR and XR generics have failed to gain significant traction, accounting for less than 4% of total lamotrigine pills sold as of the end of 2014 while the market for the immediate release tablets has continued to grow.

the case where duopoly lasts at most six months. The functional form of shares depends on whether the market is in monopoly ($t < \tau$), duopoly ($\tau \leq t < t_c$), or competition ($t \geq t_c$), and whether $ag = N$ or $ag = Y$.

During monopoly, GSK's share is 1. During duopoly and without an authorized generic ($ag = N$), GSK's share is modeled to be a constant denoted by s_d^{GSK}. When other generics enter, GSK's share is given by a fraction (α_s^{GSK}) of its share in duopoly and then declines (at rate β_s^{GSK}) toward its estimated long-run value (s_∞^{GSK}, about 4% of total lamotrigine tablets sold). Formally:

$$s_{GSK,t}(\tau, N) = \begin{cases} 1 & \text{if } t < \tau \\ s_d^{GSK} & \text{if } \tau \leq t < t_c \\ s_\infty^{GSK} + (s_{t_c,n}^{GSK} - s_\infty^{GSK}) \cdot \exp\big(-\beta_s^{GSK} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{5}$$

where $s_{t_c,n}^{GSK} = \alpha_s^{GSK} \cdot s_{GSK,t_c-1}(\tau, N)$.

Without an authorized generic, TEV's share during duopoly is simply $1 - s_d^{GSK}$. During competition, TEV's share is modeled as following the same functional form as GSK, though with different parameters:

$$s_{TEV,t}(\tau, N) = \begin{cases} 0 & \text{if } t < \tau \\ 1 - s_{GSK,t}(\tau, N) & \text{if } \tau \leq t < t_c \\ s_{\infty,n}^{TEV} + (s_{t_c,n}^{TEV} - s_{\infty,n}^{TEV}) \cdot \exp\big(-\beta_s^{TEV} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{6}$$

where $s_{t_c,n}^{TEV} = \alpha_s^{TEV} \cdot s_{TEV,t_c-1}(\tau, N)$, and

$$s_{\infty,n}^{TEV} = \underline{\ell}_s + (\ell_s - \underline{\ell}_s) \cdot \frac{1 - \exp(-\beta_{fm} \cdot (t_c - \tau))}{1 - \exp(-\beta_{fm} \cdot 6)}.$$

ℓ_s gives TEV's long-run share if it enters 6 months prior to competition, which we observe in the data. $\underline{\ell}_s$ is what TEV's long-run share would have been if it had entered at patent expiration at the same time as other generics (e.g., see Hollis (2002) and Yu and Gupta (2014) for studies of first-mover advantage in the pharmaceutical industry). β_{fm} determines the path through these two points, including whether TEV's long-run share could have been even higher had it entered earlier than observed. We estimate the parameters governing shares when there is no authorized generic from the observed data using non-linear least squares.

For settlements without no-AG commitments ($ag = Y$), we modify the shares to account for the effect of the AG. During duopoly, competition with the AG is assumed to reduce

TEV's share by a fixed fraction γ^{TEV} relative to its share when not competing with an AG. γ^{TEV} is fixed (at 0.302) using estimates from FTC (2011) about the effects of AG competition. The AG gets TEV's lost share plus any extra share lost by GSK due to the presence of the AG (determined by the parameter γ^{AG}). When all other generics enter, GSK's share decreases as with $ag = N$ settlements, but with a different starting point. The same goes for TEV's share, but also potentially with a different lower asymptote ($s_{\infty,y}^{TEV}$) to reflect the loss of any long-run share advantage that may have been gained by not facing AG competition during duopoly. During competition, the AG maintains a fixed proportion of TEV's share.

$$s_{GSK,t}(\tau, Y) = \begin{cases} 1 & \text{if } t < \tau \\ 1 - s_{TEV,t}(\tau, Y) - s_{AG,t}(\tau, Y) & \text{if } \tau \leq t < t_c \\ s_{\infty}^{GSK} + (s_{t_c,y}^{GSK} - s_{\infty}^{GSK}) \cdot \exp\big(-\beta_s^{GSK} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{7}$$

where $s_{t_c,y}^{GSK} = \alpha_s^{GSK} \cdot s_{GSK,t_c-1}(\tau, Y)$.

$$s_{TEV,t}(\tau, Y) = \begin{cases} 0 & \text{if } t < \tau \\ (1 - \gamma^{TEV}) \cdot s_{TEV,t}(\tau, N) & \text{if } \tau \leq t < t_c \\ s_{\infty,y}^{TEV} + (s_{t_c,y}^{TEV} - s_{\infty,y}^{TEV}) \cdot \exp\big(-\beta_s^{TEV} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{8}$$

where $s_{t_c,y}^{TEV} = \alpha_s^{TEV} \cdot s_{TEV,t_c-1}(\tau, Y)$, and

$$s_{\infty,y}^{TEV} = \underline{\ell}_s + \theta_s(\ell_s - \underline{\ell}_s) \cdot \frac{1 - \exp(-\beta_{fm} \cdot (t_c - \tau))}{1 - \exp(-\beta_{fm} \cdot 6)}.$$

$$s_{AG,t}(\tau, Y) = \begin{cases} 0 & \text{if } t < \tau \\ \frac{\gamma^{TEV}}{1-\gamma^{TEV}} \cdot s_{TEV,t}(\tau, Y) \cdot (1 + \gamma^{AG}) & \text{if } \tau \leq t < t_c \\ \frac{\gamma^{TEV}}{1-\gamma^{TEV}} \cdot s_{TEV,t}(\tau, Y) & \text{if } t \geq t_c \end{cases} \tag{9}$$

θ_s determines how much any possible first-mover advantage for TEV is taken away by facing AG competition during duopoly. When $\theta_s = 0$, facing an AG takes away the entire advantage, so that TEV's long-run share after facing AG competition is identical to its share if it had entered at the same time as other generics. When $\theta_s = 1$, TEV's long-run share is unaffected by AG competition. For the results reported in the text, we essentially follow Berndt et al. (2007), who argue that "long-run prices and shares are likely essentially unaffected by authorized generics." TEV's long-run share and slight price premium (as shown in Table 1) are thus assumed to persist even if TEV had faced AG competition, or if TEV had entered closer to patent expiration.

As an example of the share paths for $ag = Y$ settlements, shares over time for the settlement $(\tau, ag) = (42, Y)$ are displayed in Figure 6. For comparison purposes, the corresponding shares for $ag = N$ are tracked by the dotted lines.

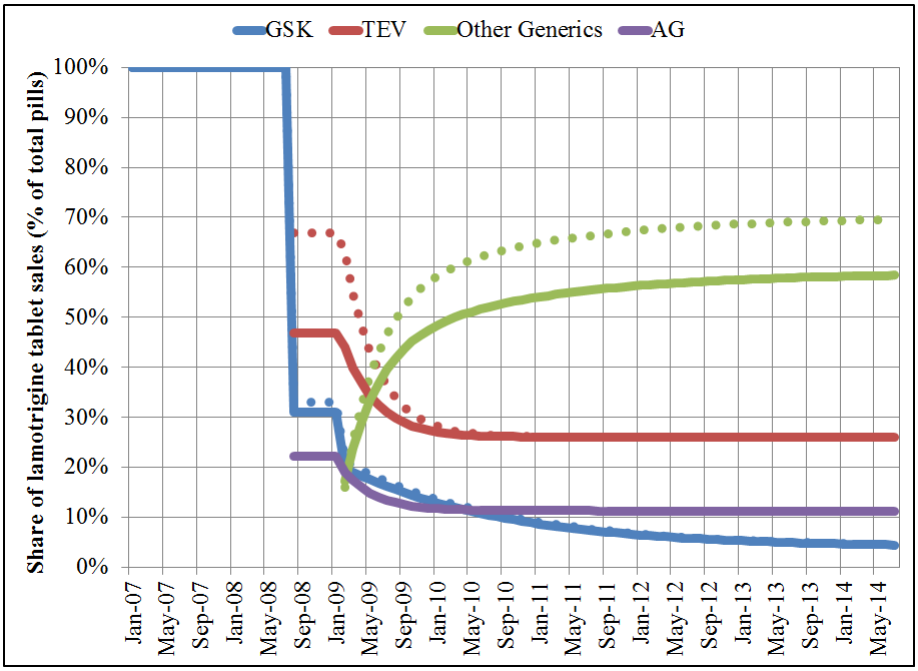

Figure 6: Shares for $(\tau, \mathbf{ag}) = (\mathbf{42}, \mathbf{Y})$, 2007-2014: The solid lines track shares for $(\tau, ag) = (42, Y)$ while the dotted lines track shares for $(\tau, ag) = (42, N)$

6.1.3 Prices

We begin by discussing prices for settlements with no-AG commitments ($ag = N$). In the data, GSK's price increases consistently over time except for a slight decline during the 6 months that TEV is the only generic on the market. After other generics enter, it appears that GSK's price returns to trend. We model this pattern as:

$$p_{GSK,t}(\tau, N) = \begin{cases} p_0^{GSK} + \beta_p^{GSK} \cdot t & \text{if } t < \tau \\ \rho_d^{GSK} \cdot (p_0^{GSK} + \beta_p^{GSK} \cdot t) & \text{if } \tau \leq t < t_c \\ \min(\bar{p}, p_0^{GSK} + \beta_p^{GSK} \cdot t) & \text{if } t \geq t_c \,. \end{cases} \tag{10}$$

ρ_d^{GSK} determines how much GSK's price falls from trend during duopoly. $\bar{p}$ is a choke price which prevents GSK's price from increasing indefinitely, which we set to \$10 per pill.

During duopoly, we impose that TEV prices at a constant fraction (ρ_d^{TEV}, about 0.83) of GSK's price. During competition, TEV's price is assumed to follow a decreasing pattern

with the same functional form as shares but with different parameters:

$$p_{TEV,t}(\tau, N) = \begin{cases} \cdot & \text{if } t < \tau \\ \rho_d^{TEV} \cdot p_{GSK,t}(\tau, N) & \text{if } \tau \leq t < t_c \\ p_{\infty,n}^{TEV} + (p_{t_c,n}^{TEV} - p_{\infty,n}^{TEV}) \cdot \exp\big(-\beta_p^{TEV} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{11}$$

where $p_{t_c,n}^{TEV} = \alpha_p^{TEV} \cdot p_{TEV,t_c-1}(\tau, N)$, and

$$p_{\infty,n}^{TEV} = \underline{\ell}_p + (\ell_p - \underline{\ell}_p) \cdot \frac{1 - \exp(-\beta_{fm} \cdot (t_c - \tau))}{1 - \exp(-\beta_{fm} \cdot 6)}\,.$$

When an authorized generic is present, we again utilize estimates from FTC (2011). Prices with an AG are shifted up/down from their levels without an AG, with different adjustments allowed during duopoly and competition. In line with estimates in FTC (2011), the AG is assumed to match TEV's price.

$$p_{GSK,t}(\tau, Y) = \begin{cases} p_{GSK,t}(\tau, N) & \text{if } t < \tau \\ (1 - \sigma_d^{GSK}) \cdot p_{GSK,t}(\tau, N) & \text{if } \tau \leq t < t_c \\ \min\big(\bar{p}, (1 - \sigma_c^{GSK}) \cdot p_{GSK,t}(\tau, N)\big) & \text{if } t \geq t_c \end{cases} \tag{12}$$

$$p_{TEV,t}(\tau, Y) = \begin{cases} \cdot & \text{if } t < \tau \\ (1 - \sigma_d^{TEV}) \cdot p_{TEV,t}(\tau, N) & \text{if } \tau \leq t < t_c \\ p_{\infty,y}^{TEV} + (p_{t_c,y}^{TEV} - p_{\infty,y}^{TEV}) \cdot \exp\big(-\beta_p^{TEV} \cdot (t - t_c)\big) & \text{if } t \geq t_c \end{cases} \tag{13}$$

where $p_{t_c,y}^{TEV} = \alpha_p^{TEV} \cdot p_{TEV,t_c-1}(\tau, Y)$, and

$$p_{\infty,y}^{TEV} = \underline{\ell}_p + \theta_p(\ell_p - \underline{\ell}_p) \cdot \frac{1 - \exp(-\beta_{fm} \cdot (t_c - \tau))}{1 - \exp(-\beta_{fm} \cdot 6)}\,.$$

$$p_{AG,t}(\tau, Y) = \begin{cases} \cdot & \text{if } t < \tau \\ (1 + \sigma^{AG}) \cdot p_{TEV,t}(\tau, Y) & \text{if } \tau \leq t < t_c \\ (1 + \sigma^{AG}) \cdot p_{TEV,t}(\tau, Y) & \text{if } t \geq t_c \end{cases} \tag{14}$$

$\underline{\ell}_p$ and θ_p play the same role for prices as $\underline{\ell}_s$ and θ_s do for shares. For the results reported in the text, the AG is assumed to have no effect on TEV's price outside of duopoly (as with shares).

6.1.4 Model fit

Figure 7 compares the fitted shares (for $\tau = 42$) to the observed shares for the period 1/2007-7/2014. Figure 8 does the same for prices. All curves that we fit (total quantity, shares, and prices) have R-squared values in excess of 0.95.

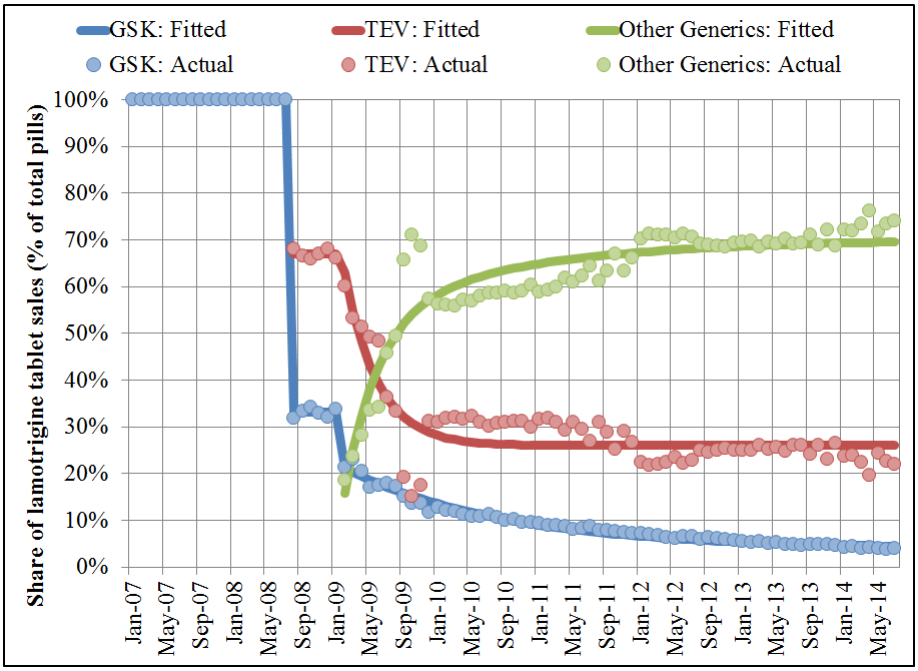

Figure 7: Fitted and Actual Shares, 2007-2014

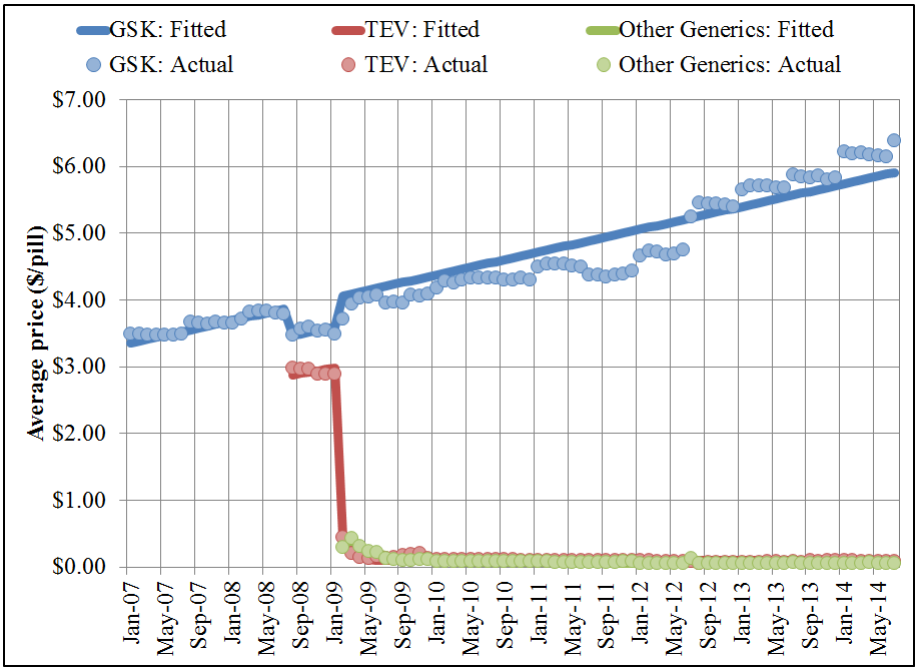

Figure 8: Fitted and Actual Prices, 2007-2014

6.1.5 Trial payoffs

With either trial outcome, we assume that GSK launches an authorized generic (since its profits are higher when doing so). The difficulty with constructing the trial payoffs is shares and prices in the first month of competition, which as modeled above often depend on the values in the last month of duopoly. With trial outcomes, the market may transition from monopoly directly to competition (e.g., if GSK's patent is upheld). If so, for GSK we set $s_{t_c,y}^{GSK} = \alpha_s^{GSK} \cdot s_d^{GSK}$ and assume that prices continue to behave according to equation (12). For TEV, we set $s_{t_c,y}^{TEV} = \underline{\ell}_s$ and $p_{t_c,y}^{TEV} = \underline{\ell}_p$.

6.1.6 Marginal costs and discount factors

As more and more generics enter the market, generic prices are expected to fall toward marginal costs. Given long-run generic prices in the data of 5 to 6 cents per pill, we set marginal costs for both firms equal to 5 cents per pill. For discount factors, we set $\delta_{GSK} = \delta_{TEV} = 0.90^{1/12}$, values in line with empirical estimates of the (yearly) cost of capital for pharmaceutical firms in Giaccotto et al. (2011) and Harrington (2012).

6.1.7 Authorized generic profit sharing

When branded manufacturers launch an AG, they typically share the profits with the generic firm who markets it. From a review of firm documents, FTC (2011) finds that the brand typically receives between 50 and 92 percent of AG profits. We denote this profit-sharing parameter by ψ_{AG} and set it to 0.75.

6.2 Parameter values for the baseline results

	Parameter	Type*	Baseline Value	Standard Error
Quantity	Q_0	1	29.722	(2.113)
	Q_∞	1	76.666	(5.935)
	β_Q	1	0.015	(0.004)
Shares	s_d^{GSK}	1	0.331	(0.004)
	α_s^{GSK}	1	0.638	(0.011)
	s_∞^{GSK}	1	0.039	(0.002)
	β_s^{GSK}	1	0.053	(0.003)
	α_s^{TEV}	1	0.942	(0.054)
	ℓ_s	1	0.260	(0.006)
	$\underline{\ell}_s$	3	0.260	–
	β_s^{TEV}	1	0.258	(0.043)
	θ_s	3	1.000	–
	γ^{TEV}	2	0.302	–
	γ^{AG}	3	0.100	–
Prices	p_0^{GSK}	1	2.702	(0.052)
	β_p^{GSK}	1	0.028	(0.001)
	ρ_d^{GSK}	1	0.891	(0.030)
	$\bar{p}$	3	10.000	–
	ρ_d^{TEV}	1	0.829	(0.006)
	α_p^{TEV}	1	0.146	(0.009)
	ℓ_p	1	0.098	(0.003)
	$\underline{\ell}_p$	3	0.098	–
	β_p^{TEV}	1	0.963	(0.165)
	σ_d^{GSK}	2	0.077	–
	σ_c^{GSK}	3	0.000	–
	σ_d^{TEV}	2	0.135	–
	σ^{AG}	2	0.000	–
	θ_p	3	1.000	–
Others	c_{GSK}	3	0.050	–
	c_{TEV}	3	0.050	–
	c_{AG}	3	0.050	–
	δ_{GSK}	2	0.991	–
	δ_{TEV}	2	0.991	–
	ψ_{AG}	2	0.750	–
	β_{fm}	3	1.000	–

*Notes: Type 1 parameters are estimated from the IMS data. Type 2 parameters are calibrated based on information in FTC (2011) and other industry/academic sources. Type 3 parameters are calibrated to reflect what we believe to be reasonable assumptions about the operation of the market. Some of these parameters are more certain than others. For instance, that marginal costs are around 5 cents is supported by generic pricing in the competition period, which should approach marginal cost. We are less certain when calibrating parameters such as GSK's choke price ($\bar{p}$). Parameter values are rounded to three decimal places. Standard errors are only available for estimated parameters, and all estimates are significant at the 1% level.