Most Drug Manufacturers Use Reverse Payment Settlements to Divide the Market

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Abstract

The purpose of this paper is to examine the effects of reverse payment settlements on competition in the market for pharmaceutical drugs. I approached this study by constructing two novel datasets; one includes patent disputes that were resolved through reverse payment settlements, and the other includes patent disputes that were resolved in trial. On average, a reverse payment settlement leaves consumers with 26.3 fewer months of competition than a trial would. As courts' legal framework for handling reverse payment settlements evolves, it is crucial to bear in mind the pervasive tendency for drug manufacturers to abuse these deals.

Section I: Introduction

Pharmaceutical drugs tend to be extremely expensive, because many of them are patented. And demand is highly inelastic, since millions of consumers depend on pharmaceutical drugs for their health and well-being. So it is vitally important that the laws regulating drug patents are sound, and that they only arrange monopolies in cases where it is truly deserved. Precisely for this reason, lawmakers and courts should take a much closer look at reverse payment settlements. Indeed, it is highly likely that drug manufacturers abuse reverse payment settlements in order to artificially extend the duration of their monopolies. But courts have done a poor job of identifying these abuses. And most of the scholarly literature on this subject has failed to convincingly prove/disprove the prominence of abuse in reverse payment settlements. It is therefore worthwhile to carefully examine the nature of these settlements, and attempt to understand their effects on the market for pharmaceutical drugs.

The mechanics of how reverse payment settlements work are somewhat complex. So I will begin my study by providing some background on these deals, in Section II. In Section III, I will review the existing literature on reverse payment settlements, and emphasize the methodological shortcomings that are apparent in most papers. I will then present my dataset and explain my methodology, in Sections IV and V, respectively. In Section VI, I will discuss the ways in which this study could and should be expanded upon, in future work. I then conclude in Section VII.

Section II: Background

Reverse payment settlements are a highly controversial practice. They enable drug manufacturers to prevent legal challenges to their patents, by compensating challengers in exchange for abandoning their charges. Such agreements can effectively immunize drug manufacturers from patent challenges, and unnaturally extend the duration of monopolistic drug prices. It is therefore alarming that reverse payment settlements have become so common, and the issue definitely warrants further scrutiny. This section will offer some background on the history, intent and dangers of reverse payment settlements.

Reverse payment settlements are a specific variant of out-of-court settlements that occur between pharmaceutical companies, after one company challenges the validity of the other's patent. The logistics of how these patent challenges and settlement negotiations occur are complicated. But they are worth articulating, in order to best understand their alarming antitrust implications.

If a drug manufacturer feels that an existing drug patent is fundamentally weak and should not have been issued, it can file an Abbreviated New Drug Application (ANDA), using "paragraph IV certification". The filing drug manufacturer (hereafter referred to as "the challenger"), has to prove that it can produce a generic version of the patented drug, and submit its proof to the FDA. If the drug in question has any meaningful commercial value, the patent holding drug manufacturer (hereafter referred to as "the incumbent"), will sue the challenger for patent infringement. But instead of battling each other in court, the two parties often agree to a reverse payment settlement. Under this arrangement, the challenger promises not to market, sell or legally challenge the patented drug, in exchange for a sizeable payment (known as the reverse

payment), and an earlier patent expiration date. So the challenger agrees to abandon its case against the patent in question, and in return, the incumbent shortens the life of its patent as well as compensating the challenger.

Precisely because the incumbent usually shortens the life of its patent, reverse payment settlements can theoretically be procompetitive. This is especially the case if the two settling parties agree to shorten the patent's life by an amount that reflects its strength. In order to better understand this notion, it is worth considering a hypothetical example. If a drug patent has ten years remaining until it expires, and the settling parties agree that the patent faces, roughly, a 50% chance of being invalidated in court, then an ideal reverse payment settlement would shorten the remaining patent life by five years. And the reason this outcome is procompetitive is because the new, early patent expiration date loosely reflects the expected outcome of proceeding with the trial. In other words, if a patent has a one-in-two chance of being invalidated in trial, then an optimal settlement would cut the remaining patent life in half.

In understanding this point, it is important to recognize that all patents are inherently probabilistic. That is, every patent has a certain probability of being invalidated if it were to be challenged in trial. Indeed, the US Patent and Trademark does not have an infallible formula it applies when reading over patent applications. So no patent is black or white, and every patent has an underlying probability of invalidation.

Since reverse payment settlements often shorten the life of the patent in question there, is scope for these deals to be procompetitive. But because of various important nuances, in practice, reverse payment settlements hardly ever match the idyllic theoretical scenario. And there are two broad reasons for why this is the case. The first reason has to do with a regulation called the Hatch Waxman Act. This Act mandates that the first challenger to successfully

replicate a patented drug will enjoy 180 days of market exclusivity following the patent's expiration. So the first patent-challenger will enjoy six months of duopolistic market power upon its expiration – regardless of when the patent ends up expiring. (The other duopolist, of course, is the incumbent, who owned the patent and had operated as a monopoly until expiration).

The Hatch-Waxman Act was well-intentioned. Indeed, lawmakers wanted to create an incentive for companies to challenge drug patents that were fundamentally weak. And this objective is welfare-enhancing, because the US Patent and Trademark Office is notoriously understaffed, and tends to grant patents too liberally. What is more, when determining their decisions, patent clerks exercise discretion; they do not apply some robust, technical framework that definitively says "yes" or "no" to an application. So the verdicts on patent applications are imperfect, and they often arrange unwarranted monopolies for many pharmaceutical companies. And naturally, undeserved drug patents are massively harmful to consumers, because of the prohibitively high prices they enable. Therefore, regulatory incentives that promote patent challenges certainly benefit the market for pharmaceutical drugs. Precisely for this reason, most observers applauded the new incentives to challenge existing drug patents.

But the Hatch-Waxman Act came with unforeseen consequences. Indeed, though it dramatically increased the incentives to challenge patents for first ANDA filers, it simultaneously decreased the incentives for other challengers, who were not the first to replicate a drug, to pursue patent challenges. And this has much to do with the way in which the law is applied. Specifically, if the first challenger to file an ANDA does not invalidate the patent (either because it agreed to a reverse payment settlement, or because it lost in trial), it still enjoys the right to six months of market exclusivity following expiration, regardless of who or what caused the expiration. In other words, if firm B is the second challenger to replicate the drug, and firm B

successfully invalidates the patent in court, the firm A will still enjoy the 180 day duopoly market, even though firm B invalidated the patent. Unsurprisingly, this nuance is problematic. Any patent challenger that was not the *first* to replicate the drug is essentially fighting on behalf of the first challenger's profits, rather than its own. And this dramatically reduces the expected payoff to being the second (or third, or fourth, etc.) firm to challenge a patent.

These reduced expected payoffs for non-first ANDA filers have severe antitrust implications. Indeed, it is important that each drug patent faces more than one potential challenger. Because if, after the first patent challenge, the two parties agree to a reverse payment settlement, there should exist incentives for other additional challenges, in case the terms of the reverse payment settlement do not reflect the strength of the patent. To better understand this crucial notion, it is worth considering a hypothetical example. If two parties agree to a reverse payment settlement on an extremely weak patent, but choose only to shorten the patent life by one day, other pharmaceutical firms will theoretically exploit this opportunity, and challenge the same patent themselves. But if the payoff to being an additional challenger is laughably low, we are unlikely to ever see more than one meaningful patent challenger. And if the first patent challenge results in a reverse payment settlement with questionable terms, consumers will have to live with it. So the Hatch-Waxman Act raised the payoff of patent challenges for first challengers, at the expense of the payoffs to subsequent challengers. This condition greatly increases the incidence of anticompetitive reverse payment settlements.

The second key reason that reverse payment settlements tend not to be procompetitive is because there exists a strong temptation for the two settling parties to arrive at an agreement that divides the market. In order to understand why this temptation exists, it is important to reiterate the theoretical role that payments play in these settlements. The two parties *should* only bargain

over the revised patent expiration date. (The challenger would push for an earlier patent expiration date, while the incumbent would aim for a later one.) And the payment, in turn, *should* only serve two roles. The first is to compensate the generic for the legal fees it incurs. And the second role is to bridge any irresolvable gap regarding the revised patent expiration date. That is, if the two parties feel very differently about the underlying strength of the patent, and each insists on revised expiration dates that are distant from one another, then the monetary payment can bridge that gap.

But the temptation to use this monetary payment in additional ways is profound. And there is one simple reason for this temptation. Namely, a monopolist's profits are more than double the profits of a duopolist. This entails that the incumbent can use the reverse payment to comfortably compensate the challenger for the opportunity cost of staying out of the market, and still be better off than it would have been if it had lost the patent. To better understand this notion, it is worth considering another example. Let us assume that a drug patent that expires in ten years generates $100 million in monopoly profits, $40 million in duopoly profits and $10 million in competitive profits.

Figure I: Profits Under Different Market Arrangements

Market structure	Profits (million USD)
Monopoly	100
Duopoly	40
Competitive	10

If the two settling parties decide to cut the remaining patent life in half, the challenger will gain six months of duopoly profits, plus four and a half years of competitive profits. The incumbent, in turn, will lose five years of monopoly profits (in exchange 4.5 years of competitive

profits, plus half a year of duopoly profits). However, if the incumbent paid the challenger half a year of duopoly profits, plus 4.5 years of competitive profits, instead, then the incumbent would be much better off, and the challenger would be just as well off. In fact, abusing reverse payment settlements could even make both parties better off than if they only bargained over the patent's expiration date. Indeed, the incumbent could even offer, say, the equivalent of five years' worth of duopoly profits and still be far better off than it would be if the patent expired early.

Figure II: Analysis of Different Settlement Strategies

Settlement strategy	Profits for incumbent (million USD)	Foregone profits for incumbent (million USD)	Direct costs to incumbent (million USD)	Net gain for incumbent (million USD)	Gain for challenger (million USD)	Cost to challenger (million USD)	Net gain for challenger (million USD)
Patent expires five years early	65	500	0	-435	65	NA	65
Patent expires on time, but the incumbent compensates the challenger with 0.5 years of duopoly profits and 4.5 years of competitive profits	500	NA	65	435	65	NA	65
Patent expires on time, but the incumbent compensates the challenger with 5 years of duopoly profits	500	NA	200	300	200	NA	200

As Figure II reveals, both parties are far better off if they abuse the reverse payment settlement than if they bargain over the revised patent expiration date. In fact, the incumbent can get away with hardly any losses, while still compensating the challenger for the opportunity cost of staying out of the market. The profit figures in this example are hypothetical. But these conclusions hold as long as we assume the following condition:

(Monopoly profits) 0.5 < duopoly profits < competitive profits

There are virtually no scenarios in which these assumptions do not hold. So it is clear that there are powerful incentives to avoid any agreements that involve shortened patent durations. Indeed, it is evident that the "ideal reverse payment settlement", in which the parties agree to shorten the patent life by an amount that directly reflects its strength, is the least appealing arrangement for both negotiators. And the consequences of this reality are certainly damaging. Patents that attract legal challenges are most likely to have weak foundations than not. But because of reverse payment settlements, the two disputing parties almost never settle their differences by shortening the patent life in a way that matches its strength. Rather, an extremely strong incentive exists on both sides to keep the patent life as long as possible. And precisely because reverse payment settlements are frequently used in this market-dividing manner, weak drug patents endure far longer than they should, which unwarrantedly extends monopoly prices for drugs that many consumers cannot live without.

There is one important clarification worth reiterating. In theory, additional challengers could file an ANDA and challenge a patent's validity, after a reverse payment settlement already occurred. So it is fair to ask, if a reverse payment settlement really was unfair to consumers (and to other potential market entrants), would other drug companies not continue to challenge the patent until they were satisfied with the outcome? Unfortunately, the answer is no. After the first reverse payment settlement occurs, other meaningful challenges to that patent are unlikely. Indeed, I mentioned that the Hatch-Waxman Act greatly reduces the payoff to subsequent patent challenges, because of the 180-day exclusivity clause. So even if there were a second manufacturer that challenged a patent after a reverse payment settlement, the second challenger is going to spend very little on the legal battle (because of the low payoff). Indeed, the only meaningful challenges to drug patents are those that involve the first ANDA filer. This is the

only instance in which the challenger would find it worthwhile to dedicate a sufficient amount of time and money to the effort. So if a reverse payment settlement is anticompetitive and fundamentally unjust, given the underlying strength of the patent, we cannot rely on subsequent patent challengers to correct for the mistake. Indeed, though theoretically reversible, a reverse payment settlement effectively dictates the fate of a given drug patent.

The final concern with reverse payment settlements is that the courts have not handled them effectively. But the prevailing framework that the courts originally used when contemplating the antitrust implications of a given reverse payment settlement is highly problematic. Indeed, until 2013, almost every court used the following standard when assessing the legality of such settlements: does the settlement in question grant market power beyond the exclusionary zone of the patent? In other words, the courts would consider whether the agreement leaves the incumbent with more market power than the patent originally afforded it. If the courts had concluded that it does not, then the settlement would not officially violate antitrust laws. On its face, this logic seems reasonable. After all, the incumbent had a patent that legally protected its market power, so as long as the reverse payment settlement remains within the boundaries of its patent, the outcome should be acceptable. But this simplistic logic is misleading, and the standard was deeply flawed, for two broad reasons. First, it presumes the validity of the patent precisely when the courts had every reason to question it. Indeed, reverse payment settlements only occur because one drug manufacturer believed that another's patent should not be valid. And the courts' framework implied that, absent a reverse payment settlement, the market for this patented drug would have looked exactly as it did when there was only one player, and there were no challengers in the picture at all. This makes very little sense. Because if a reverse payment settlement had not occurred, then the patent challenge would have

gone to trial, and might have been invalidated. So it is problematic for the courts to have presumed the validity of every patent by default.

Fortunately, this framework for analyzing reverse payment settlements has begun to change. Indeed, in 2013, in a legal battle between the Federal Trade Commission and Actavis, a drug manufacturer, the Supreme Court ruled that reverse payment settlements are not immune to antitrust liability.[1] Indeed, the Court ruled that the terms of a reverse payment settlement should be measured against procompetitive antitrust policies. And it also stressed that the size of the payment in reverse payment settlements should be taken into account when gauging these antitrust implications. So the framework that the courts apply when analyzing these settlements has evolved, in a positive direction. But there are three concerns to keep in mind as the new framework for analyzing these cases takes shape. First, the Supreme Court's ruling in *FTC v. Actavis* was far from unanimous. And the dissent was quite vocal, so the consensus on this matter is still quite weak. Second, many reverse payment settlements increasingly feature significant side deals, which serve as a substitute for monetary-payments. Indeed, the monetary payment is becoming largely irrelevant in these deals. And one of the most likely reasons for this is that settling firms know that it is harder to file successful antitrust suits against a reverse payment settlement if the monetary payment is small. This detail is vitally important, because in its ruling, The Supreme Court stressed the importance of the size of the reverse payment, when assessing the antitrust implications of these deals. If monetary payments become a thing of the past, though, this approach will fail to capture many reverse payment settlements' antitrust violations. The final concern worth raising is that the effects of the *FTC v. Actavis* precedent are still being borne out. Indeed, the Supreme Court did not leave lower courts with any specific

[1] 133 S. Ct. 2223 (2013)

guidelines on how to revise their frameworks for analyzing reverse payment settlements. In fact, in its ruling, The Supreme Court stated that it is up to the lower courts to develop this new approach. So the most important hurdle, in many regards, has yet to be overcome. And precisely for that reason, it is crucially important, and timely, to conduct and in depth study on the antitrust implications of reverse payment settlements.

Section III: Literature Review

Economic and legal scholars that have analyzed the controversies regarding reverse payment settlements easily fit into one of two categories. Roughly half insist that these settlements do not violate antitrust laws, while the other half passionately disagree. For the sake of simplicity, I will refer to the former as "defenders" (of reverse payment settlements), and to the latter as "opponents" (of reverse payment settlements).

Even as the discussion surrounding reverse payment settlements evolves, there has been little consensus on the issue between the two sides. And the scholars' unconvincing methodological approaches are principle reason for this polarization. Indeed, both defenders and opponents of reverse payment settlements have, for the most part, offered theoretical models that do not rely on real-world data. Often, the models are mere technical expressions of the conclusions and assumptions that the scholars hold. So it is not terribly surprising that most of the scholarly literature on this question has been unconvincing.

To be fair, the data on reverse payment settlements is scarce and often incomplete. The terms of these settlements are not publically available, and the details surrounding the negotiations are even harder to find, let alone verify. Further, the underlying strength of the drug

patents in question (which is to say, their probability of invalidation), is virtually unknowable. So the unconvincing methodologies are partly inevitable.

Despite the methodological shortcomings, the leading pieces of literature have meaningfully influenced the discussion regarding reverse payment settlements. So it is worth exploring this literature in some depth, in order to better understand the nature of this though-provoking debate. I begin with the leading arguments and papers in defense of reverse payment settlements.

Defenders of Reverse Payment Settlements

Broadly, there are three worthwhile arguments that have come out of the literature in defense of reverse payment settlements. The first is that the cash payment in these settlements serves as a crucial gap-bridging mechanism when the disputing parties disagree on the underlying strength of the patent.[2] To better understand this argument, it is helpful to reconsider the theoretically ideal reverse payment settlement. The two parties are expected to negotiate a new expiration date that reflects the strength of the patent. The weaker the patent, the earlier the revised the expiration date should be. But in order for these negotiations to be possible, the two disputing parties have to (at least partly) agree on the underlying strength of the patent. Otherwise, they will be unable to identify a mutually satisfactory revised patent expiration date. According to the defenders, the only way to bridge this theoretical gap is by including reverse payments in the agreement. Indeed, any gap between the two parties' perceptions of the patent's

[2] Robert Willig &John Bigelow, Antitrust Policy Towards Agreements that Settle Patent Litigation, Antitrust Bull, 2004

strength can be reconciled via compensation. So these payments are extremely important; without them, many settlements on patent disputes would theoretically be undoable.

Robert Willig (and like-minded theorists) offer no data to validate this claim in their papers. But their assumption is nevertheless a fair one. Indeed, the challenger is likely to understate the patent's strength, while the incumbent is likely to exaggerate it. And without a reverse payment, this gap might be irreconcilable. The problem with this theory, however, is that it does not prove that reverse payments are not *also used* in additional ways. Indeed, even though they *can* serve a perfectly legal function, there is no proof that settling parties do not use them to divide the market.

In addition to highlighting the gap between the disputing parties' perceptions, defenders of reverse payment settlements also extensively discuss the risks associated with patent trials. And this discussion of litigation risk is the second noteworthy contribution that comes out of the defenders' literature. They point out that firms are inherently risk-averse, and prefer to avoid patent trials wherever possible. This even applies to firms with strong patents. Indeed, the costs of losing a patent trial are enormously high, since many of these drugs offer billions of dollars in monopoly profits. And because it is reasonable to assume that reverse payments enable settlements that would otherwise have been infeasible, defenders argue that many firms would face nastier shocks and more expensive legal battles if it were not for these settlements.

Various economists have expanded on this idea to make an even more meaningful argument. They point out that, if reverse payment settlements were per se illegal, then the benefits to owning any drug patent would automatically diminish, since the value of a patent necessarily decreases if it cannot be protected via reverse payment settlement. So in the long run, various defenders insist that banning reverse payments will harm society and consumers, not just

drug manufacturers. Indeed, if the value of a patent falls, then the incentive to innovate diminishes.[3] In that vein, Daniel Crane, who first articulated this point, insists that the premise behind patents is completely analogous to the premise behind reverse payment settlements. Both raise prices in the short-run, but the long-run benefits to society outweigh these short-run costs. After all, reverse payment settlements, just like patents, increase the expected return on research and development.[4]

Crane's point is an interesting one, but his logic is unsound for two reasons. First, he does not sufficiently address the massive potential for disputing parties to abuse reverse payment settlements, and use them to divide the market. So even if his argument about the long-run costs of banning reverse payment settlements is reasonable, he leaves one of the most relevant questions unanswered. Indeed, Crane fails to account for the importance of dismantling undeserving monopolies. The second reason his logic is unsound is because his central analogy between patents and reverse payment settlements is misleading. The difference is that patents protect drugs that are theoretically unique. Even if the committee that examines and approves these patents is imperfect, they at least apply some scrutiny, and contemplate the societal harms and benefits of offering market protection. The terms of reverse payment settlements, on the other hand, are a product of corporate negotiations, and do not undergo comparable scrutiny. And finally, even though reverse payment settlements incentivize overall R&D, not all R&D is qualitatively the same. Indeed, if manufacturers know that they can immunize just about any drug from patent challenges, they might divert their resources to shallow and non-revolutionary R&D, rather than quality R&D. Indeed, if reverse payment settlements did not protect

[3] Crane, Daniel. "EXIT PAYMENTS IN SETTLEMENT OF PATENT INFRINGEMENT LAWSUITS: ANTITRUST RULES AND ECONOMIC IMPLICATIONS." Florida Law Review 54 (2002): 760.
[4] Ibid

fundamentally obvious drugs, pharmaceutical companies would probably have a stronger incentive to pursue more research that addresses wider health threats, even if the nominal level of R&D falls. So the claim about reducing incentives to innovate is dubious, at best. Overall, the defenders effectively highlight that there exist profound benefits of reverse payment settlements to drug manufacturers, even when they are not abused. But they still fail to properly acknowledge their far-reaching costs, and ignore the massive temptation for abuse.

The defenders raise a third and final point that has gained a lot of traction. Namely, they insist that most reverse payment settlements lead to deals that are welfare-enhancing for consumers, even in the short run, because of the incumbent's risk aversion, and the challenger's optimistic expectations. Robert Willig and John Bigelow first articulated this idea in their influential 2004 paper.[5] And it is worth unpacking their logic and assumptions in order to understand precisely what they are arguing. First, they assume that the incumbent is extremely risk-averse, and would pay a fairly high price to avoid a trial, given the uncertainty. For that reason, the defenders argue that the incumbent would agree to a revised patent expiration date that is *earlier* than the expected expiration date of entry under litigation. Next, they assume that the challenger is extremely optimistic about its chances of invalidating the patent in trial. The defenders assume this optimism because they believe that all companies willing to risk a trial must be somewhat overly-optimistic about their chances, in the first place. So, the defenders argue that the challenger would only accept a very early revised patent expiration date if it were to settle. And crucially, they insist that this date will still be earlier than the earliest acceptable entry date for the incumbent, even after accounting for the incumbent's risk aversion.

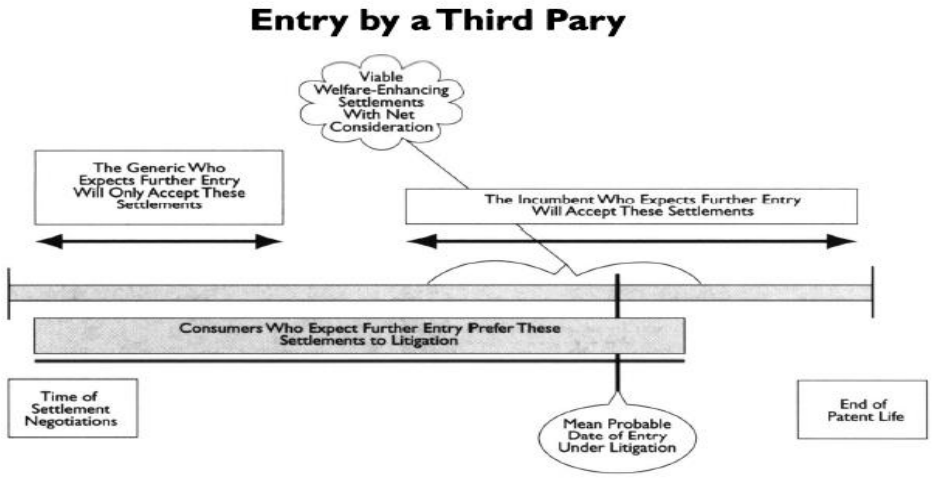
[5] Robert Willig &John Bigelow, Antitrust Policy Towards Agreements that Settle Patent Litigation, Antitrust Bull, 2004

Let us consider an example, to understand how this would work. Imagine that a challenger files an ANDA in 2020, for a patent that expires in 2030. And assume that the "true", underlying probability of invalidation for this patent is 50%. A fair reverse payment settlement would therefore revise the patent expiration date to 2025, from 2030, since reducing the patent life by 50% directly reflects the underlying probability of invalidation. According to the Willig-Bigelow theory, the incumbent will come pretty close to knowing the "true", underlying probability of invalidation, because it knows more about its patent than anyone else. But because the incumbent is risk-averse and desperately wants to avoid litigation, it would still agree to let its patent expire as early as 2024, rather than 2025, if that is what it takes to avoid a trial. The challenger, as the defenders assume, is extremely optimistic about its chances in trial. So the challenger might believe that the probability of invalidation is 70%, even though the "true" underlying probability of invalidation is 50%. In the challenger's eyes, therefore, a "fair" reverse payment settlement would revise the patent expiration date to 2023, from 2030 (since a 7 year reduction in patent life directly reflects the incumbent's belief that the patent has a 70% chance of invalidation).

If the two parties could only settle their dispute by negotiating over a revised patent expiration date, an agreement would be impossible, because of the gap in the disputing parties' beliefs. Indeed, the incumbent is willing to cut as much as six years off of its patent life, in order to avoid a trial. But the challenger insists that the patent life must be reduced by at least 7 years. So without a reverse payment, a settlement between these two parties would be impossible, and they would have to go to trial. But with a reverse payment settlement, the incumbent could impel the challenger to accept a revised expiration date in 2024, by compensating it for the opportunity cost of allowing the patent to exist one extra year. Crucially, if the dispute had gone to trial, the

expected patent expiration date would have been in 2025 (since the true probability of invalidation is 50%), which is *later* than the revised patent expiration date arising from the reverse payment settlement. And therefore, if we subscribe to Willig and Bigelow's assumptions, it is conceivable that by banning reverse payment settlements, we would block deals that are welfare-enhancing for consumers. Marc Schilkraut, who expanded on the Willig-Bigelow model in a later paper, offers a helpful diagram to depict this phenomenon:[6]

Figure III: Schidlkraut's Diagrammatic Representation of the Willig-Bigelow Theory



Some of the underlying assumptions that come out of the Willig-Bigelow model are not entirely unreasonable. Indeed, the incumbent is probably willing to pay a premium, in the form of reducing its patent's life, in order to avoid the risks associated with litigation. Even if the patent is strong, this assumption would still hold, because billions of dollars in profits are often at stake. In addition, the challenger is probably also optimistic about its chances of prevailing in

[6] Schilkraut, Marc. "Patent Splitting Settlements and the Reverse Payment Fallacy." Antitrust Law Journal 71 (2004).

trial, as the defenders suggest. But they definitely take this assumption of challenger optimism too far. Indeed, the literature in defense of reverse payment settlements portrays the challengers as though they are virtually clueless. And this is a stretch, for two reasons. First, any challenger would extensively consult with lawyers, before even beginning to replicate a patented drug. And these lawyers would definitely offer a reasonable estimate of the probability of invalidating the patent in question. Second, my dataset, which I present in the next section, revels that most of the parties that were challengers at one point, have also been involved in other disputes in which they are incumbents. So most of these firms have been on both sides of the table. The incumbent may know more about the patent than anyone else, because it owns it. But because most challengers have been in the incumbent's shoes in separate trials, it is careless to assume that challengers are irrational, and clueless, when it comes to assessing the probability of invalidation.

The Willig-Bigelow conclusions are also unconvincing for two other reasons. First, the model, like most others, completely ignores the strong temptation for the disputing parties to "divide the market". In my hypothetical example above, I noted that reverse payments allowed the incumbent to compensate the challenger for the opportunity cost of delaying the patent expiration date by one year more than the challenger originally felt was fair. But why would the incumbent stop there? Why not compensate the challenger for the opportunity cost of staying out of the market for even longer? It is certainly mutually beneficial for them to do so. As we discussed earlier, the patent holder can easily compensate the challenger for the opportunity cost of staying out of the market, in exchange for settling on an expiration date that is many years later than the expected expiration date under litigation. In fact, both parties have strong incentives engage in precisely this type of deal. So it is problematic that the Willig-Bigelow

model does not even consider whether the outcomes it discusses are likely to ever arise. Which brings me to the second problem with their conclusions. The Willig-Bigelow model relies entirely on hypothetical, diagrammatic models. There is no data to support their assumptions or conclusions, so it is impossible to verify whether the disputing parties actually behave in the way that these models suggest.

To sum up, the defenders of reverse payment settlements offer three broad insights. First, they stress the potential for these payments to serve as a mechanism for bridging the gap when the disputing parties disagree on the underlying strength of the patent. And this achievement is noteworthy, because it helps companies avoid the unnecessary risks and costs of litigation. Second, the defenders stress that banning reverse payment settlements discourages innovation, because it reduces the value of owning a patent, by raising the risk of litigation for all drug patents. And finally, a few defenders insist that reverse payment settlements have the potential to be welfare-enhancing, under various assumptions. While the assumptions and arguments that come out of these papers are not entirely illogical, they are still weak and very unconvincing. Indeed, the most significant problem throughout the literature is that the scholars fail to adequately account for the massive potential for companies to abuse reverse payment settlements. And even in cases where they recognize this possibility, they do nothing to verify its alleged unlikelihood. So there is a clear need for an empirical study that tests the precise role these reverse payments play in settlements between disputing firms.

Opponents of Reverse Payment Settlements

The opponents of reverse payment settlements vehemently insists that these deals violate anti-trust laws. And the scholars in this category make three central contributions to the discussion. First, and unlike the defenders, they highlight the massive temptation for disputing parties to abuse reverse payment settlements in order to divide the market. Second, they discuss the unlikelihood that additional firms will re-challenge a patent's validity, if it was already subject to a reverse payment settlement. And finally, one unique study points out that valuation rises more for firms announcing a reverse payment settlement, than it does for firms announcing a settlement that did not feature a reverse payment.

The opponents thoroughly discuss the deep temptation for disputing firms to abuse these payments. The point they have raised is that incumbents can easily compensate their challengers for the opportunity cost of staying out of the market, and still earn more than they would in a duopolistic (let alone competitive), market. This point is crucially important to understanding the implications of reverse payment settlements, but it is not fully acknowledged by everyone in the field. And the reason is that the opponents offer almost no evidence to prove how these incentives affect the decisions of disputing parties. Indeed, various influential papers, such as Michael Carrier's, rely entirely on persuasive logic. They do nothing more than emphasize that it is in both parties' interest to use reverse payment settlements in anticompetitive ways.[7] Some scholars take their analysis a step further, by theoretically modelling disputing firms' decision-making process.[8] But even though these models offer some empirical support to expose the

[7] Carrier, Michael. "UNSETTLING DRUG PATENT SETTLEMENTS: A FRAMEWORK FOR PRESUMPTIVE ILLEGALITY." Michigan Law Review 108:37 (2009): 753.
[8] Elhauge, Einer, and Alex Krueger. "Solving the Patent Settlement Puzzle." Texas Law Review 91:283 (2013)

potential harms of reverse-payment settlements, they do not test the conclusions with any observable data.

The second major point that comes out of the opponents' literature addresses the bottleneck that a reverse payment settlement creates for future patent challenges. This is the point that I raised in the background section, when first articulating the harms of these settlements. And just about every studies that opposes reverse payment settlements highlights this important detail. To reiterate, the Hatch Waxman Act creates a massive incentive for drug manufacturers to challenge each other's patents. But the incentive only applies to the *first* company to challenge the patent. The incentive for a company to challenge a patent as a second (or third, or fourth, etc.) challenger, in turn, is considerably reduced, because of the Hatch Waxman Act. Indeed, the first challenger to file an ANDA is awarded with 180 days of duopolistic market power, but this luxury does not apply to any of the other challengers that were not the first to file an ANDA. They only benefit if they manage to take the dispute to trial, and win. Crucially, though, even if a second patent challenger were to come along and invalidate a drug patent in trial, the *first* challenger is still the one that would enjoy the 180 days of duopolistic market power. And the literature in opposition to reverse payment settlements thoroughly emphasizes this crucial disincentive. Because it dramatically reduces the likelihood that additional challengers will come along to scrutinize existing reverse payment settlements. So if a reverse payment settlement appears extremely anticompetitive, we cannot expect other challengers from the marketplace to come in and correct for it. The Hatch-Waxman Act has made the payoffs much too low for this to happen. And even in instances where a settlement is challenged by other, uninvolved companies, the additional challengers are unlikely to spend enough on the challenge for it to be considered meaningful. In that way, the bottleneck largely

shields reverse payment settlements from legal challenges by other drug manufacturers, leaving no market mechanism to correct for anticompetitive settlements.

The final noteworthy contribution that opponents make comes from a 2014 paper by Keith Drake, Martha Starr and Thomas McGuire.[9] The three scholars analyze how companies' share prices have responded to the announcement of a reverse payment settlement. And they compare this with the market's response to companies announcing a patent settlement that did not feature a reverse payment. In theory, and if reverse payment settlements are no more anticompetitive than other settlements, both of these deals should have the same average effect on a company's share price. However, Drake, Starr and McGuire find that stock prices rose by 6% more for firms announcing a reverse payment settlement, than they did for firms announcing a non-payment settlement. In theory, if reverse payment settlements tend to extend monopolistic market arrangements, then this is precisely the result we would expect. Indeed, if a reverse payment settlement allows a company to preserve its monopoly profits for longer than it should, then the market will reward a company that engages in such a deal, by more than it would reward an incumbent that engages in a non-payment settlement. So the findings in this study definitely suggest that reverse payment settlements are at least perceived to extend monopolistic market arrangements by more than ordinary settlements.

Drake, Starr and McGuire offer a genuine contribution to the discussion. They are among the few scholars that attempt to verify the opponent's widely cited claims by examining data on various incumbents. Indeed, most studies have tended to rely on hypothetical models instead. But there is still a considerable weakness in their approach. Namely, they place too much faith in the

[9] Drake, Keith, Martha Starr, and Thomas McGuire. "Do Reverse Payment Settlements of Brand-Generic Patent Disputes In the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay." NBER 20292 (2014).

efficient market hypothesis. And this is problematic, because even though investors might *think* that reverse payment settlements artificially extend monopolistic market arrangements for incumbents, it does not prove that this is necessarily the case.

So the literature that opposes reverse payment settlements has shaped the discussion in interesting ways. The opponents have clarified some of the glaring potential harms of these settlements, which include the temptation for parties to divide the market, and the bottleneck on additional challenges. But barring a few minor exceptions, the opponents have not managed to produce convincing studies, because their claims are theoretical, rely on hypothetical models and use no data on settlements to test their conclusions. There is certainly room for more data-driven methodologies in this discussion. And this brings me to my next two sections, in which I outline and analyze observable data on reverse payment settlements.

Section IV: Data

My goal is to examine the terms of reverse payment settlements, and compare them to the outcomes of similar drug patent disputes that went to trial. I therefore compiled two categories of data for this study. The first features patent disputes that ended in reverse payment settlements, and the second features patent disputes that went to trial. In the first category, there are eighteen different reverse payment settlements, and 72 trials make up the second category. For the reverse payment settlements, I identify the disputing parties, the drug in question, the annual US sales of that drug in the fiscal year preceding the settlement, the date on which the settlement was announced, the revised patent expiration date and the original patent expiration date. In addition, I attempted to compile information regarding the size of the reverse payment, but this

information was only available for half of the observations included. For the disputes that went to trial, I identified the two parties involved, the drug in question, the winner of the trial, the annual US sales for the drug in the fiscal year preceding the trial, the date of the court decision and the original expiration date for that patent. With this information, I was able to infer the how many months of additional competition emerged out of each dispute.

I used two principal sources to compile the data on patent disputes that went to trial. The first source was a 2009 study by Laura Panattoni, in which she examines the circumstances surrounding a large number of drug patent trials.[10] Panattoni gathered most of her information from FDA publications (which summarize ANDA filings), and through LexisNexis® searches.[11] A number of these disputes went through complicated litigation processes that resulted in more than one District Court decision. In those instances, Panattoni selected the one decision that resolved the most uncertainty surrounding the dispute.[12] The other key sources I used consisted of corporate earnings reports, media archives and press releases. The earnings reports primarily helped supplement the information that came out of Panattoni's dataset.

The terms and details surrounding reverse payment settlements are difficult to identify, since the settling parties have no obligation to publicize this information. Indeed, publically available information on most reverse payment settlements is either limited or nonexistent. But some reverse payment settlements, particularly those involving blockbuster drugs, receive ample media attention. As such, my principal sources for data on reverse payment settlements were newspapers articles and press releases. I supplemented this information with data from Scott

[10] Panattoni, Laura. "The Effect of Paragraph IV Decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms." Journal of Health Economics 30 (2009): 131.
[11] Ibid
[12] Ibid

Hemphill's 2007 study, which also examines the nature and terms surrounding reverse payment settlements.[13] Hemphill's dataset offered helpful background on various settlements, and some information regarding the size of the reverse payment, as well as the revised patent expiration dates. His principal sources were similar to mine: he relied on press releases, trade publications, financial analyst reports and FTC reports.

There are a number of obstacles that complicate any attempt to compile a clean dataset on reverse payment settlements. Indeed, these settlements come in many forms, and have become increasingly complex and opaque in recent years. For one, many reverse payment settlements arise between more than two parties. This generally occurs when multiple generic manufacturers file an ANDA on the same day, and they all become entitled to the 180-day exclusivity. In a few cases, additional challenges arose after the patent had already been subject to a reverse payment settlement. (In most cases, those additional challenges also ended in reverse payment settlements). Examples from our dataset include Provigil and Adderall XR. In addition to these complex features, for many reverse payment settlements, the publically available records did not specify a revised patent expiration date. Because my analysis is impossible without information on these dates, this obstacle significantly limited the size and scope of my data.

Another challenge with understanding these settlements is that the deal making process has markedly evolved over the past decade. Indeed, most reverse payment settlements before 2005 were straightforward: the challenger promised to stay out of the market in exchange for ample compensation, and an earlier patent expiration date. But since 2005, many incumbents have compensated challengers in less straightforward ways. For instance, many incumbents have

[13] Hemphill, Scott. "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition." Columbia Law Review 109, no. 4 (2009).

provided value in the form of manufacturing, supply, inventory and even promotion for the challenger. Indeed, recent settlements usually feature a combination of monetary and non-monetary compensation from the incumbent to the challenger. And this has substantially complicated the analysis of reverse payment settlements, for a few reasons.

First and foremost, it has become impossible to gauge the true value of the reverse payment in most of these settlements. Not only are the forms of compensation often unspecified, but the monetary value of manufacturing agreements, or inventory exchanges are very difficult to quantify. As a consequence, I was unable to specify the size of the reverse payment for many of my observations. Second, even where information on the size of the reverse payment is available, it tends to grossly understate the true value, because most monetary reverse payments are combined with sizeable non-monetary compensation.

My data on reverse payments is therefore limited in scope. The details surrounding most reverse payment settlements are not publically available, or only partially available. What is more, the settlements that were detailed in publically available documents involved the most well-known and widespread drugs in the market. So small drugs manufactured by relatively small companies are undeniably under-represented. However, that does not undermine the analysis in this study. Indeed, the goal is to gauge the effect of reverse payment settlements on competition, and ultimately, consumers. Since these blockbuster drugs make up such a disproportionately large percent of overall drug purchases, my dataset is definitely useful for the purpose of this analysis.

Variables

Using the information I gathered, I calculated two key variables. The most important of these is the *number of additional months of competition* that came out of each settlement and each trial. I deduced this variable by simply calculating the number of months by which the patent in question was shortened. For the reverse payment settlement data points, the value of this variable depends upon the disputing parties' negotiation outcomes. For the disputes that ended in a trial (the second category of data), the *number of additional months of competition* depended upon outcome of the trial. If the incumbent prevailed in court, the *number of additional months of competition* was zero, since the patent remained valid, and its terms un-modified. In cases where the challenger prevailed in trial, the months that remain until the patent in question expired reflects the *additional months of competition*.

There is also an alternative approach to quantifying the anti-trust implications of reverse payment settlements, using the data I gathered. One could look at the *percent by which patent life was reduced*, for each reverse payment settlement and for each trial. For reverse payment settlements, this variable equals the amount by which patent life is extended, as a proportion of the remaining patent life. For instance, if the patent in question has ten years remaining until it expires, and the disputing parties agree to a revised patent expiration date in eight years, then the *percent by which patent life was reduced* is 20%. This variable is simply another way of representing the *number of additional months of competition*. But it is still a useful variable to consider, because in theory, the *percent by which patent life was reduced* should reflect the underlying probability of invalidation for each patent in question. For the disputes that ended in trial, the *percent by which patent life was reduced* is a binary variable, equaling either 0 or 100. The value is zero if the incumbent prevails in trial, and 100 if the challenger prevails. While the

percent by which patent life was reduced offers interesting insights, I will use the *number of additional months of competition* in the methodology section. The reason is that it impossible to run a hypothesis test if one of the means reflects an average of continuous outcomes, while the other reflects and average of a binary outcome.

Descriptive Statistics

Table I, on page 32 summarizes the terms surrounding the reverse payment settlements, and Table II, on page 33, summarizes the information surrounding the disputes that went to trial.

The figures that came out of these two categories of data were quite telling. The mean *additional months of competition* for disputes resolved via reverse payment settlement is 23.6, and the median is 10.0. The mean *additional months of competition* for disputes resolved in trial is 49.9, while the median is 18. It is important to note that the median additional months of competition for disputes resolved in trial is expected to be low, since this value is zero for all trials in which the incumbent prevailed (which was the outcome for just under half of the trials).

For the reverse payment settlements, the mean *percent by which patent life was reduced* is 22, and the median is 15. For the disputes that went to trial, the mean percent by which patent life was reduced is 53 (which directly reflects the mean outcome of the trials). The median *percent by which patent life was reduced* for disputes resolved in trial is 100, but because trials have binary outcomes, this particular figure is irrelevant.

The mean annual US sales for the drugs that were the subject of reverse payment settlements is $916 million, and the median is $365 million. The mean size of the reverse payment is $216 million, and the median is $73 million. It is necessary to reiterate, however, that

precise information regarding the size of the payments was difficult to find, and is only available for half of the observations. And because of the prevalence on non-monetary compensation in these settlements, the mean and median values for the payments are undoubtedly understated.

It is interesting to note that the reverse settlements offering the fewest *additional months of competition* disproportionately involved the drugs that generated the highest volumes of sales. On pages 35 and 36, I analyze the relationship between these two variables. The correlation coefficient is -0.38, and the R-squared value is 0.19. I also examine the relationship between the annual sales of a drug and the additional months of competition for the disputes resolved in trial. The correlation coefficient is -0.28 and the R-squared is 0.08.

Table I: Patent Disputes that were Resolved via Reverse Payment Settlement

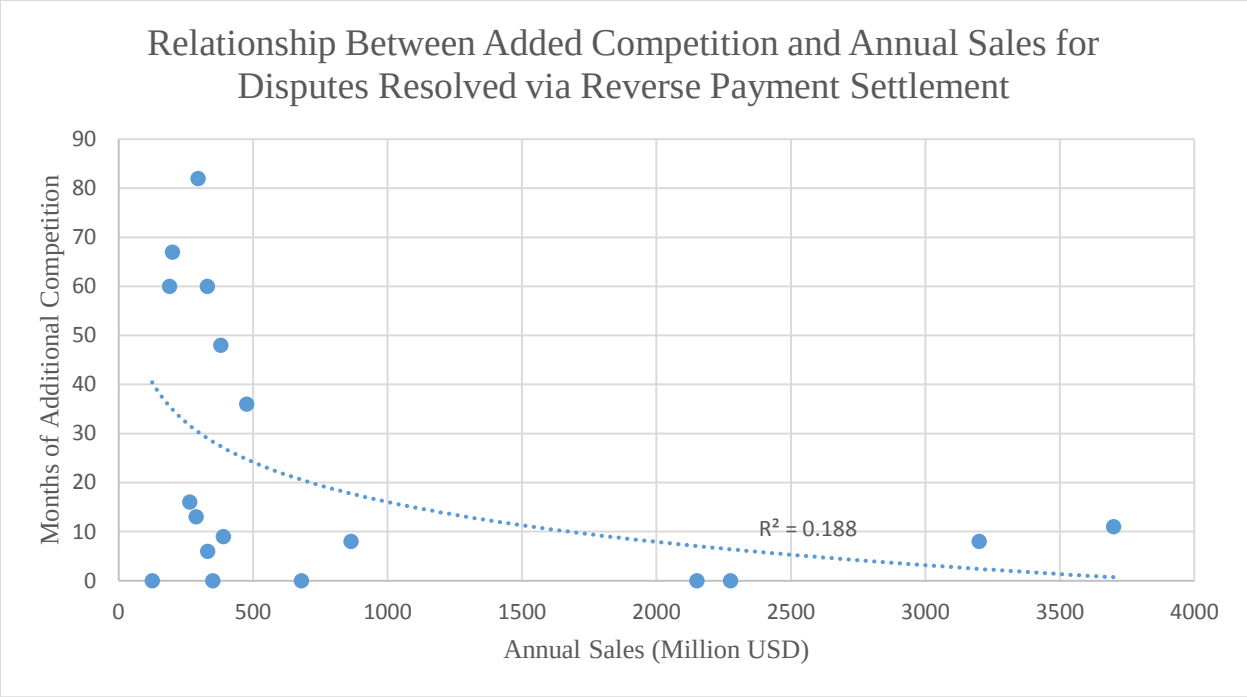
Observation	Drug	US sales (million USD)	Incumbent	Challenger	Payment Size (million USD)	Agreement Date	Revised Patent Expiration Date	Origil Patent Expiration Date	Percent by which the RPS Reduced Patent Life	Additional Months of Competition
1	AndroGel	330	Solvay	Watson	unknown	Jan-06	Jan-15	Jan-20	36%	60
2	Adderall XR	864	Shire	Barr	102	Aug-06	Apr-09	Dec-09	20%	8
3	Plavix	3,200	Bristol	Apotex	40	May-06	Apr-11	Dec-11	12%	8
4	Alphagan	200	Allergan	Alcon	unknown	Mar-06	Sep-09	Apr-15	61%	67
5	Provigil	476	Celpahon	Teva, Ranbaxy, Mylan and Barr	73	Dec-05	Oct-11	Oct-14	34%	36
6	Effexor XR	2,275	Wyeth	Teva	unknown	Dec-05	Jul-10	Jul-10	0%	0
7	Niaspan	380	Kos	Barr	unknown	Apr-05	Sep-13	Sep-17	32%	48
8	K-Dur	190	Schering	Upsher	60	Jun-97	Sep-01	Sep-06	54%	60
9	Cirpo	680	Bayer	Barr	398	Jan-97	Dec-03	Dec-03	0%	0
10	Zantac	2,150	Glaxo	Genpharm	133	Oct-95	Aug-97	Aug-97	0%	0
11	Buspar	288	Bristol	Schein	73	Dec-94	Nov-00	Dec-01	15%	13
12	Novladex	265	Zeneca	Barr	66	Mar-93	Aug-02	Dec-02	14%	16
13	Mirapex	389	Boehringer	Barr	unknown	Dec-08	Jan-10	Jan-10	35%	9
14	Aggrenox	331	Boehringer	Barr	unknown	Dec-08	Jan-15	Jan-16	7%	6
15	Nexium	3,700	AstraZeneca	Teva and Ranbaxy	1000 to Ranbaxy	Jan-08	Jan-14	Jan-15	13%	11
16	Nuvigil	296	Teva	Mylan	unknown	Apr-12	Jan-16	Jan-23	61%	82
17	Propecia	350	Merck	Teva	unknown	Oct-69	Oct-13	Oct-13	0%	0
18	Sinemet CR	125	Merck	Purepac	unknown	Jan-95	Jan-06	Jan-06	0%	0
Mean		**916**			**216**				**22%**	**23.6**
Median		**365**			**73**				**15%**	**10.0**
Std Dev		**1,112**			**314**				**21%**	**27.5**

Table II: Patent Disputes that were Resolved in Trial

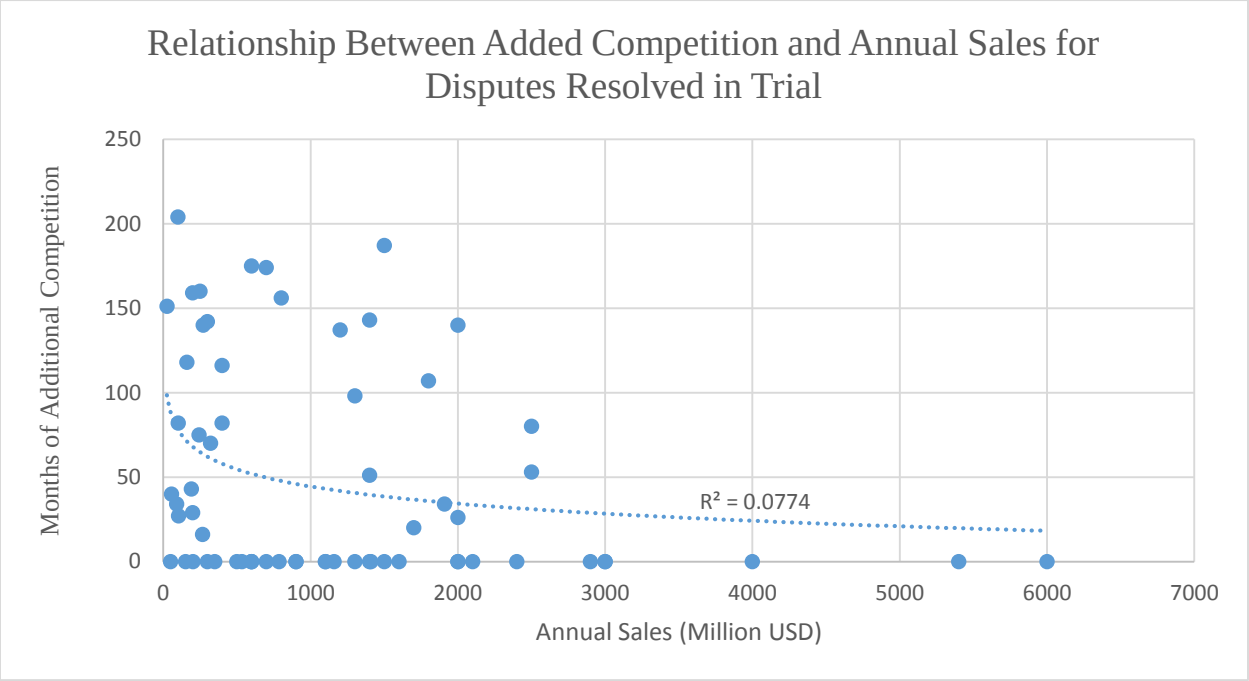
Observation	Drug	US sales (million USD)	Incumbent	Challenger	Winner	Numerical Expression of Trial Outcome (0=Challenger; 1=Incumbent)	Date of Decision	Expiration	Additional Months of Competition
1	Accupril	534	Pfizer	Teva	Challenger	0			0
2	Aciphex	1,300	Esai	Teva and Mylan	Challenger	0			0
3	Actos	3,000	Takeda	Alphapharm and Mylan	Challenger	0			0
4	Aculiar	50	Allergan / Roche	Apotex and Novex	Challenger	0			0
5	Adalat CC	270	Bayer	Biovail and Elan	Incumbent	1	Mar-99	Nov-10	140
6	Advil Cold Snius		Wyeth		Incumbent	1	Nov-06	Jun-09	34
7	Alphagan	250	Allergan	Bausch & Lomb	Incumbent	1	Aug-02	Dec-15	160
8	Altace	700	King		Challenger	0			0
9	Augmentin	1,400	GlaxoSmithKleine	Geneva Pharmaceuticals,	Incumbent	1	Jul-02	Jun-02	0
10	Avelox	600	Bayer	Dr Reddy's	Challenger	0			0
11	Axid	202	Eli Lilly	Zenith Goldline Pharm	Challenger	0			0
12	Buspar		Bristol Myers		Incumbent	1	Mar-01	Jul-10	112
13	Celebrex	3,000	Pfizer	Teva	Challenger	0			0
14	Claritin; Claritin Reditabs	2,000	Shering Plough	Mylan Laboratories	Incumbent	1	Aug-02	Oct-04	26
15	DDAVP	191	Sanofi Aventis	Barr	Incumbent	1	Jul-05	Sep-08	43
16	Depakote	600	Abbott	Apotex	Challenger	0			0
17	Diflucan	1,100	Pfizer	Ranbaxy	Challenger	0			0
18	Diprivan	500	AstraZeneca	Amphastar Pharmaceutica	Challenger	0			0
19	Ditropan XL	400	Alza/J&J	Mylan	Incumbent	1	Sep-05	May-15	116
20	Duragesic	900	Alza / J&J	Noven	Challenger	0			0
21	Flexeril		Merck	Aptalis Pharmatech, Celap	Incumbent	1	Aug-88	Apr-94	68
22	Flomax	785	Astellas / Boehringer Ingelheim	Ranbaxy	Challenger	0			0
23	Floxin		Daichii Sankyo	Apotex	Challenger	0			0
24	Fosamax	2,900	Merck	Teva	Challenger	0			0
25	Glucophage XR		Bristol Squibb		Challenger	0			0
26	Hytrin	600	Abbott	Geneva Pharmaceuticals	Incumbent	1	Jan-98	Apr-13	175
27	Levaquin	1,160	Ortho / J&J	Novopharm	Challenger	0			0
28	Lexapro	1,600	Forest	Ivax Pharmaceuticals - Te	Challenger	0			0
29	Lipitor	6,000	Pfizer	Ranbaxy	Challenger	0			0
30	Lovenox	2,500	Sanofi Aventis	Amphastar Pharmaceutica	Incumbent	1	Jun-05	Feb-12	80
31	Micro K; K-Dur		A.H. Robins		Incumbent	1	Apr-91	Jun-00	110
32	Mircette	102	Akzo Nobel	Barr	Incumbent	1	Jun-01	Oct-08	82
33	Monopril	242	Bristol Myers	Andrx	Incumbent	1	Oct-03	Jan-10	75
34	Norvasc	2,100	Pfizer	Mylan	Challenger	0			0
35	Nuerontin	2,000	Pfizer	Ivax	Incumbent	1	Aug-05	Apr-17	140
36	Oxycontin	1,800	Purdue Pharma LP	Endo Pharmaceuticals	Incumbent	1	May-04	Apr-13	107

Table II Continued

Observation	Drug	US sales (million USD)	Incumbent	Challenger	Winner	Numerical Expression of Trial Outcome (0=Challenger; 1=Incumbent)	Date of Decision	Expiration	Months of Additional Competition
37	Paraplatin	900	Bristol-Myers	Teva	Challenger	0			0
38	Paxil	1,400	GlaxoSmithKleine	Apotex	Incumbent	1	Mar-03	Jun-07	51
39	Pepcid	1,100	Merck	Schein Pharmaceuticals	Challenger	0			0
40	Platinol	100	Bristol-Myers Squibb		Incumbent	1	Oct-99	Oct-16	204
41	Plavix	2,500	Bristol-Myers / Sanofi Aventis	Apotex	Incumbent	1	Jun-07	Nov-11	53
42	Plendil ER	151	AstraZeneca	Mutual Pharmaceutical	Challenger	0			0
43	prelan	25	Elan	Andrx	Incumbent	1	Mar-02	Oct-14	151
44	Prilosec	5,400	AstraZeneca	Andrx	Challenger	0			0
45	Protonix	1,910	Wyeth	Teva	Incumbent	1	Jun-07	Jul-10	34
46	Prozac	2,000	Eli Lilly	Barr and Novartis	Challenger	0			0
47	Rebetol	800	Ribapharm	Three Rivers	Incumbent	1	Jul-03	Jul-16	156
48	Relafen	266	GlaxoSmithKleine	Teva	Incumbent	1	Aug-01	Dec-02	16
49	Remeron	700	Akzo Nobel	Teva and Mylan	Incumbent	1	Dec-02	Jun-17	174
50	Retrovir	300	Burroughs Wellcome	Mylan	Challenger	0			0
51	Risperdal	4,000	Johnson & Johnson	Mylan	Challenger	0			0
52	Sarafem		Warner Chilcott	Teva	Challenger	0			0
53	Seldane	200	Hoechst Marrion Roussel	Ivax	Incumbent	1	Dec-96	Apr-99	29
54	Sinemet CR	1,300	Merck	Mylan	Incumbent	1	Aug-98	Oct-06	98
55	Sporandox	161	Janssen / J&J	Eon Labs	Incumbent	1	Jul-04	May-14	118
56	Tambocor	90	3M pharma	Barr	Incumbent	1	Jul-01	Feb-04	34
57	Taxol	1,500	Bristol Myers	Ivax	Incumbent	1	Jan-00	Oct-15	187
58	Tenormin; Tenoretic	600	Imperial Chemical Industries	Danbury Pharmacal	Challenger	0			0
59	Tiazac	`	Biovail	Andrx	Incumbent	1	Jun-00	Jun-13	159
60	Topamax	1,500	Ortho-McNeill / J&J	Mylan	Challenger	0			0
61	Toprol XL	1,700	AstraZeneca	Andrx	Incumbent	1	Jan-06	Sep-07	20
62	Tricor	400	Abbott	Teva	Incumbent	1	Mar-02	Jan-09	82
63	Ultane	300	Abbott	Baxter	Incumbent	1	Sep-05	Jul-17	142
64	Ultracet	322	Ortho-McNeill / J&J	Par Pharmaceutical	Incumbent	1	Oct-05	Aug-11	70
65	Univasc	56	Schwartz	Teva	Incumbent	1	Mar-03	Jul-06	40
66	Vicoprofen	104	Abbott	Teva	Incumbent	1	Dec-02	Dec-04	27
67	Wellbutrin SR; Zyban	1,200	GlaxoSmithKleine	Impax	Incumbent	1	Feb-02	Aug-13	137
68	Wellbutrin XL	1,400	Biovail	Impax	Incumbent	1	Nov-06	Oct-18	143
69	Xalatan	349	Pfizer	Par Pharmaceutical	Challenger	0			0
70	Zantac	2,000	Glaxo Inc	Novopharm	Challenger	0			0
71	Zofran	1,410	GlaxoSmithKleine	Teva	Challenger	0			0
72	Zyprexa	2,400	Eli Lilly	Ivax and Teva	Challenger	0			0
Mean		**1193**				**0.53**			**49.9**
Median		**800**				**1.00**			**18.0**
St dev		**1213**				**0.50**			**62.6**



Correlation Coefficient	**-0.38**



Correlation Coefficient	**-0.28**

Section V: Methodology

The methodology in this study is remarkably simple. I run a difference in means hypothesis test comparing the *months of added competition* for reverse payment settlements, and the *months of added competition* for disputes resolved in trial. Ideally, hypothesis tests are conducted between two means that come from unbiased samples of the populations of interest. And neither of my samples is entirely unbiased. However, the comparison is informative and largely valid, for two key reasons. First, the sources for the two datasets are identical: publically available news archives, corporate and government press releases and annual financial reviews. Relying entirely on these sources definitely makes my observations biased toward the settlements/trials involving drugs with higher revenues and prevalence. But this bias is consistent across both datasets, so it should not render my comparison invalid. What is more, precisely these blockbuster settlements/trials have a disproportionately large impact on consumers. So it is fair to assume that my methodology compares the most relevant data points, for anyone trying to gauge the impact of reverse payment settlements on competition in the market for pharmaceutical drugs.

The figure on the following page depicts the results of the difference in means hypothesis test. The one-tailed test is of interest for this study, since the goal is to test whether reverse payment settlements tend to result in fewer months of competition than disputes resolved in trial. The results of the hypothesis test unequivocally verify this expectation. Indeed, the difference in the mean *months of additional competition* between the two categories of patent disputes is very large and statistically significant at the 1% level. The test statistic is -2.69, and the p-value is 0.005.

t-Test: Two-Sample Assuming Unequal Variances

	Reverse Payment Settlements: Additional Months of Competition	*Trials: Additional Months of Competition*
Mean	23.55555556	49.90277778
Variance	753.9084967	3916.736894
Observations	18	72
Hypothesized Mean Difference	0	
df	64	
t Stat	-2.68509829	
P(T<=t) one-tail	0.004611568	
t Critical one-tail	1.669013025	
P(T<=t) two-tail	0.009223136	
t Critical two-tail	1.997729654	

Section VI: Expanding on this Study

I conducted this investigation under stringent time constraints, and the empirical limitations are evident. But with more time, this basic methodological approach could offer even more insightful and conclusive findings. Indeed, there are several ways in which I would have expanded, or other people could perhaps expand, on this study in order to strengthen the conclusions.

First and foremost, I would have have increased the number of observations in both datasets. Indeed, I have reiterated that my datasets are neither entirely unbiased nor perfectly complete. The observations for both reverse payment settlements and trialed patent challenges disproportionately feature drugs with extremely high revenues. With more time, the datasets could be expanded to include drugs with fewer sales. Even though blockbuster patent disputes dictate the implications of reverse payment settlements on consumers and competition, adding

lower-revenue drugs is worthwhile for two key reasons. First, it would help verify the relationship between the *additional months of competition* and the annual revenues of the drug in question. (Increasing the variance this independent variable would present a more conclusive correlation coefficient). I am confident that this relationship is even stronger than my data suggests, and the best way to demonstrate this idea is by including more lower-revenue drugs. The second reason these lower-revenue drugs are important is because the stakes surrounding their challengers are lower. Indeed, the costs of losing a patent on a drug that offers relatively low revenues is significantly lower than the costs of losing a patent on a billion-dollar blockbuster. In the same vein, reverse payment settlements involving lower-revenue drugs attract far less antitrust scrutiny than the settlements in my dataset have tended to attract. Both of these factors definitely influence the behavior of disputing parties that engage settlements for these drugs, so their terms are likely to look different. And by incorporating these broader differences in settlement outcomes, this study would be much more conclusive.

The second area I would have spent more time examining is reverse payment settlements that did not feature monetary forms of compensation. Indeed, this is becoming one of the most contentious branches of the reverse payment controversy. The reason is that many settling parties have opted not to use reverse payment settlements in their drug patent disputes, because of the intense antitrust scrutiny they tend to invite. So it is definitely important to explore these non-monetary drug patent settlements, because most of them are merely reverse payment settlements in disguise. Unfortunately, I did not have the time nor resources at my disposal to properly account for this category of settlements. But if I had, I would have proceeded in the following ways. First, I would have developed a precise definition of "reverse payment settlements in disguise", in order to avoid including benign settlements that were negotiated entirely via

changing the patent expiration date. Drawing this distinction is tricky, but necessary. One possible way to accomplish this is to consider whether there were any side-deals involved, and account for the magnitude of these deals. Next, I would have attempted to quantify the value of the side deal in question. This would be extremely challenging, but it would not be impossible to compile reasonably accurate estimates. Indeed, numerous investment/financial firms scrutinize every detail of every deal that listed firms engage in. The analysts in these firms definitely hold an opinion regarding the value of these deals, because their professions involve analyzing the financial implications of these types of agreements. And given that almost every pharmaceutical company engaging in reverse payment settlement is publically traded, a series of interviews with different investment analysts could definitely provide a reasonable estimate of the value of some of these opaque side-deals.

On a related note, I also would have liked to have expanded my dataset to include more thorough information on the terms of the reverse payment settlements. Indeed, for many observations, I indicate that the size of the payment is "unknown". And even though I do include a "payment value" for certain observations, the information is often incomplete, and does not account for other side deals that frequently accompany the payments. In order to improve upon these figures, I would have spent more time investigating the precise terms and negotiation processes that led to these settlements. One way to gather this information would be to arrange interviews with representatives from the firms themselves. Admittedly, though, this is unlikely to yield very much, since the firms are secretive and already fear that their settlements will invite antitrust scrutiny. Another way to gather this information would be to interview investment analysts who specialize in pharmaceutical companies; the same ones who can theoretically help quantify the value of the side-deals. Doubtless, these figures would be imperfect. But they would

be an improvement over the payment figures that I currently use, which come entirely from publically available media records.

So there is definitely potential to expand upon this study. I believe that it already offers a noteworthy contribution to the debate on reverse payment settlements, because it draws on real-world data on reverse payment settlements. But its limitations are evident. And this methodological approach could offer an even more conclusive verdict on reverse payment settlements, if it were carefully expanded in a few directions.

Section VII: Conclusion

Reverse payment settlements tend to be anticompetitive. Indeed, my data lucidly reveals that the *months of added competition* are dramatically lower for disputes resolved via reverse payment settlement than for disputes resolved in trial. So lawmakers and courts should definitely approach reverse payment settlements with an understanding of their harmful effects on consumers.

Over the past decade and a half, as reverse payment settlements became more common and more sophisticated, many scholars concluded that these deals had the potential to be welfare-enhancing. And they promoted this theory, and other similar ones, with numerous, compelling models. But there have hardly been any attempts to test these ideas using observable, real-world data. Precisely for this reason, the two sides of the reverse payment settlements debate have remained quite polarized.

My study's methodological approach was simplistic, and came with various shortcomings. But it still allowed us to test some of these common theories on the effects of

reverse payment settlements. And the results unmistakably reveal that drug manufacturers abuse these settlements to divide the market. Indeed, even though my sample sizes were small and not unbiased, the patterns in the data were overwhelming, and there is no alternative way to explain these results. So it is crucial that the courts recognize the pervasive tendency to abuse reverse payment settlements, and account for it as their legal frameworks evolve.

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