

Pay-for-Monopoly? An Assessment of Reverse Payment Deals by Pharmaceutical Companies

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Abstract

Over the past eighteen years, pharmaceutical firms have developed a blueprint to impede competition in order to maintain their monopoly profits. This scheme, termed pay-for-delay, involves direct or indirect payment of money from a branded-drug manufacturer to a generic-drug producer to stay out of market. In most cases, the payment is shrouded as a side deal, where the generic-drug entrant agrees to stay out of the market in return for overpayment on some unrelated agreement from the branded drug company. These agreements are signed at the same time, or even within the same legal agreement. While the Federal Trade Commission has often asserted that these agreements restrict trade by keeping the generic off the market at the expense of consumers, traditional expert economists have developed a number of defenses for such practices. Drawing on insights from behavioral economics, we argue that these agreements are very unlikely to be pro-competitive. We suggest solutions, both judicial and legislative, that would lead generic drugs to the market faster, providing more medicine to those that need it at a more affordable price.

Keywords

Pay-for-delay — anti-trust — reverse payments

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Introduction

One of the most important economic concerns facing society today is the increasing cost of health care. The United States spends more on healthcare per capital than any other country (Peterson Institute, 2017). Rising drug costs make up a significant percentage of these costs and occur in large part when pharmaceutical firms have monopolies over a particular drug. Traditionally, generic drugs have helped minimize consumer costs by breaking these monopolies. However, by offering generic manufacturers large indirect payments to forgo or delay market entry, brand-name manufacturers have succeeded at keeping generics off the market, costing U.S. consumers billions of dollars each year.

One consistent strategy pharmaceutical firms have used to maintain their monopoly profits is by providing payments to generic firms drugs indirectly, namely through “side deals” in which they overpay the producers of generic drugs to stay out of the market for a specific time period. In some cases, these side deals are included in the same contract as the settlement of the patent dispute. In other cases, they are coordinated to be signed at the same time. The Federal Trade Commission (FTC) has argued that these agreements reduce competition by keeping the generic off the market. Current arguments in favor of pay-for-delay practices rely on assumptions that are unlikely to occur in the real world. Once these assumptions are updated from textbook cases to real-world scenarios, the likelihood of a pay-for-delay exchange to be pro-competitive

disappears. Thus, deciding individual disputes on a case-by-case basis is not only an inefficient use of legal resources but also incapable of ending anti-competitive practices. Therefore, we suggest judicial and legislative actions that can be taken to erase the blueprint that pharmaceutical companies have developed to engage in anti-competitive behavior.

Section I of this paper traces the history of pay-for-delay practices and provides a review of relevant legislation. Section II synthesizes arguments provided by expert economists in defense of pay-for-delay as a pro-competitive practice. Section III presents our counter-arguments that in real-world settings the likelihood of these pay-for-delay cases being pro-competitive is very low. Finally, Section IV provides some specific recommendations to improve consumer welfare.

Background

According to rules set forth in the Hatch-Waxman Act of 1984, the U.S. regulatory framework for approval of generic drugs aims to balance the ease of generic entry with protection for branded manufacturers. The Food and Drug Administration (FDA) grants generic drug approval. Paragraph IV of Hatch-Waxman outlines the path for generic entry before the patents on branded drugs have expired. This regulation aims to lower the cost of entry for generic manufacturers, which can file for an Abbreviated New Drug Application (ANDA)—a streamlined process that requires them to show bioequivalence of

the generic drug rather than perform costly clinical trials.¹

Before FDA approval of an ANDA can take effect, however, a generic manufacturer must assert that its product does not infringe on existing patents held by the brand-name manufacturer. The brand-name manufacturer can counter such a claim by alleging patent infringement, which results in FDA suspension of the approval process for 30 months. To incentivize generics to file for ANDAs, the first generic manufacturer to successfully challenge the patent is given exclusivity for 180 days to bring the product to market and compete solely with the brand-name company. The first pay-for-delay case was in 2001 when the Federal Trade Commission brought a lawsuit against Schering-Plough and Upsher-Smith.² Upsher-Smith was preparing to introduce a generic version of K-Dur, a Schering-Plough drug that had a near-monopoly. As a result, Schering-Plough sued Upsher-Smith for patent infringement. Eventually, the two companies reached a settlement in which Upsher-Smith agreed to wait for the majority of the remaining life of Schering-Plough's patent before entering market, and Schering-Plough agreed to pay Upsher-Smith \$60 million for five unrelated products.

Since then, many manufacturers with brand-name drugs have repeatedly exploited this strategy to extend their monopoly. Their strategy is simple: sue the manufacturer of an impending generic for patent violation, then settle the case to delay the entry of the generic and vastly overpay the manufacturer of the generic drug for some unrelated side deal.³ The next major case to follow *Schering-Plough* was *Cipro* in 2011.⁴ In this case, Barr Pharmaceuticals' tried to enter the market with a generic version of Cipro, an antibiotic produced by Bayer. Bayer sued, and the case settled with Bayer paying \$398 million to Barr Pharmaceuticals.

Court decisions regarding the legality of these agreements have been mixed. In *Cipro*, the U.S. Court of Appeals for the Federal Circuit followed the precedent set by *Schering-Plough*, holding that reverse payments are within the exclusionary "scope of the patent."⁵ This scope-of-the-patent test essentially prioritizes patent law over antitrust law, holding that any injury to the market automatically falls within the patent, which by nature is anti-competitive. Thus, patent holders are entitled to reach settlements that protect their patents,

even if such agreements look questionable from an antitrust perspective.

However, in 2012, the Third Circuit Court of Appeals adopted the "quick look rule of reason" test. Under this rule, once plaintiffs establish a prima facie case, the burden of proof shifts to the defendant. Any payment from a patent holder to a generic challenger that delayed entry was considered *de facto* evidence of an unreasonable restraint on trade.⁶ The court argued that the goal of the Hatch-Waxman Act was to increase the availability of low-cost generic drugs. The scope-of-the-patent test frustrates this intention by benefiting those with weak patents and harming the consumers whom Congress originally intended to protect. The court agreed that while encouraging settlement is a favored judicial principle, it is outweighed in some cases by public policy considerations.

In 2013, the Supreme Court reviewed a pay-for-delay settlement in *FTC v. Actavis*.⁷ The case involved two generic firms, Actavis and Paddock, that had filed ANDAs to market the generic equivalents of a drug called AndroGel. Solvay, AndroGel's manufacturer, sued Actavis and Paddock for patent infringement. Because the dispute lasted beyond the 30-month stay set by the Hatch-Waxman Act, Actavis obtained permission to enter the market. However, instead of launching its generic equivalent, Actavis reached a settlement with Solvay that prohibited Actavis from entering the market for a number of years and instead promoted AndroGel to a subgroup of doctors in exchange for a large lump of money.

The Supreme Court declined to endorse either the quick-look rule of reason or the scope-of-the-patent approach. Instead, it ruled that pay-for-delay cases must be analyzed under the rule of reason. This meant that for a pay-for-delay settlement to be anticompetitive, its anticompetitive harms must outweigh its pro-competitive benefits. While the court acknowledged these settlements had the potential for "genuine adverse effects on competition", it did not deem monetary reverse payments as per se illegal.⁸ Rather, it held that the illegality of the reverse payments depended on many factors, including "the size of the payment, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."⁹ Lower courts were left to flesh out more details.

In 2010, the FTC estimated that such deals cost consumers \$3.5 billion annually in higher drug costs.¹⁰ The 10 highest-revenue drugs implicated in reverse-payment deals cost, on average, 10 times more than their generic equivalents and as much as 33 times more.¹¹ During the years in which generic versions of these drugs were delayed, brand-name manufacturers earned an estimated \$98 billion dollars in total

¹21 U.S.C. §355(j))

²The FTC filed a parallel lawsuit against Schering-Plough and ESI Lederle.

³*Anticompetitive Patent Settlements In The Pharmaceutical Industry: The Benefits Of A Legislative Solution*, Committee on the Judiciary of the United States Senate Cong. (2007) (testimony of Jon Leibowitz) available at https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-anticompetitive-patent-settlements_senate.pdf

⁴In re *Cipro* Cases I II, 200 Cal. App. 4th 442, 134 Cal. Rptr. 3d 165 (2011)

⁵The U.S. courts of appeal, also called circuit courts, are the intermediate appellate courts in the United States federal court system. A circuit court makes decisions on appeals from district courts within its jurisdiction. Twelve circuit courts are geographically defined; the 13th is the U.S. Court of Appeals for the Federal Circuit, which has nationwide jurisdiction.

⁶In re *K-Dur* Antitrust Litig., 686 F.3d 197 (3d Cir. 2012)

⁷*FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)

⁸*FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2224 (2013)

⁹*FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013)

¹⁰FTC Staff Study, 2010

¹¹U.S. PIRG Report, 2013

sales.¹² Putting this in perspective, an individual and her health plan pays an additional \$4,590, on average, over 17 months for a drug subject to a pay-for-delay settlement.¹³

Arguments Defending Pay-for-Delay

The pharmaceutical companies have offered a variety of defenses in support of their action when sued by the FTC in pay-for-delay cases. In this section, we highlight the most prevalent arguments.

Incentivize R&D

The pharmaceutical industry is research intensive, with long and uncertain drug approval processes. Thus, to incentivize pharmaceutical companies to invest in RD, the intellectual property underlying these drugs must be protected. By granting patents and allowing them to reap monopoly profits, the government ensures that the pharmaceutical companies continue investing in the RD of new drugs (Dickey and Rubinfeld, 2012). The option to settle with the generic manufacturer reduces the uncertainty associated with investing in new generic drugs.

Encourage settlement

There could be overall benefits to branded-drug manufacturers settling with generic-drug manufacturers rather than pursuing litigation. Under some circumstances, these settlements can be favorable to consumers, as they are often cost-effective and time-efficient. Expert witnesses for pharmaceutical firms often argue that real-world complexities can make these settlements pro-competitive. This argument is presented by Dickey *et al.* (2011), who propose the following scenario:

[Imagine] the parties are considering settlement at the beginning of Year 1. The patent expires at the end of Year 10. The generic manufacturer both believes that it has and in fact has a fifty percent chance of winning the patent case (and the brand name manufacturer also has, and perceives, a fifty percent chance of winning). There are no costs to litigation and litigation is instantaneous. Both parties are risk neutral. Under this condition, no settlement without payment is possible, as illustrated in Figure 1.

However, now consider the following possible scenarios:

- (i) The branded-drug company is risk averse
- (ii) Litigation costs are high
- (iii) The branded-drug company knows its patent is weak, and the generic company has private knowledge of manufacturing delays of the generic's drug
- (iv) The branded-drug firm has a low discount rate
- (v) The branded-drug firm is pessimistic about its prospects of winning the litigation

¹²FTC Staff Study, 2010

¹³U.S. PIRG Report, 2013

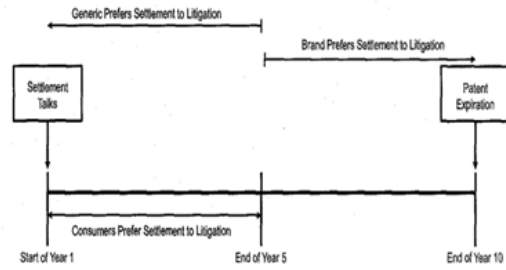


Figure 1. No settlement without payment is possible

Source: Dickey *et al.* (2011).

Defenders of pay-for-delay argue that, under these circumstances, a pro-competitive settlement is possible (Dickey *et al.*, 2011). For instance, let's assume that the branded-drug company is risk-averse. In this case, the firm would concede more than the expected value of pursuing litigation. Thus, a branded-drug firm might agree to an earlier entry date than the expected date from litigation. Therefore, this negotiated agreement could bring the generic to the market faster than an expected court decision. Hence, Dickey *et al.* argue that these settlements could be pro-competitive, as shown in Figure 2.

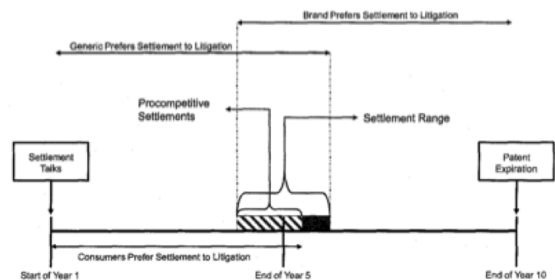


Figure 2. Pro-competitive settlements are possible

Source: Dickey *et al.* (2011).

Similarly, a variety of factors may lead to pro-competitive settlements. For instance, a branded-drug firm with a low discount rate might be willing to accept a settlement for an earlier entry rather than take the chance to litigate. A branded-drug firm with a pessimistic expectation of winning the litigation might be more willing to accept an earlier date for entry. Thus, in these circumstances, pay-for-delay provides a solution that enables a settlement that would not occur without a payment. This benefits consumers by providing an earlier drug entry date.

Create additional value

An expert witness in *Schering Plough* argues that creating joint gains in a settlement negotiation can be a net positive for society.¹⁴ One strategy for creating joint gains is to add issues

¹⁴Testimony of Professor Robert Mnookin, <https://www.ftc.gov/sites/default/files/documents/cases/2002/07/>

to the existing negotiation to create additional value. In other words, looking beyond existing issues (e.g., patent settlement) and expanding interests (e.g., co-branding of another drug) can help create more value from a deal.

Behavioral Economics and the Case Against Pay-for-Delay

Pharmaceutical companies have offered a variety of defenses in support of their actions when sued by the FTC in pay-for-delay cases. While to some economists these defenses are anti-competitive and indicative of collusion, economists serving as expert witnesses for the pharmaceutical firms have testified in support of these defenses, published related papers, and documented their views in *amici curiae*.¹⁵ The dominance of their perspective in this issue has led to a *feasibility* analysis that overlooks the *practical likelihood* of an outcome occurring. We argue that our approach focused on practical likelihood instead of feasibility is rooted in behavioral economics.

Traditional economics assumes that each individual has a stable and coherent set of preferences, and that she rationally maximizes those preferences against a constraint. However, behavioral economics suggests various modifications to this conception of human choice. According to behavioral economics, individuals are subject to biases that impact their decision-making. To give a couple of examples: these biases could take the form of lack of self-control and procrastination - and these might prevent someone from going to the gym; or a tendency to fit with the status quo might make a person resistant to positive changes. Additionally, given decision-making requires cognitive capacity, individuals' use heuristics to make decisions (Kahneman, Slovic and Tversky, 1982). While these heuristics are useful in reducing cognitive burden, they could lead us to make faulty decisions. Therefore, behavioral economists emphasize the role of "choice architecture" and suggest using "nudges" to influence good decision outcomes (Sunstein and Thaler, 2010).

These refinements to the classical model are embedded in empirical evidence, mostly from observations of human behavior in lab and field settings. As an additional knowledge base in litigation, behavioral economics can provide insights about the *practical likelihood* of an action occurring based on realistic assumptions of human behavior. For example, it is *feasible* to imagine that there could be a situation in which a pay-for-delay settlement is pro-competitive. However, the relevant policy questions are: (1) How likely is this situation to occur, and (2) Will the welfare gains from pro-competitive

settlements outweigh the welfare losses from non-competitive settlements?

From the first pay-for-delay case on, defendants in these cases have argued that settlements that occur with side deals, with payments from branded-drug manufacturers to generic ones, are not necessarily anti-competitive. Essentially, they argue that it is feasible to imagine a set of preferences such that even if the side deals pushed back the generic entry, that the entry date was still earlier than the expected value of the entry date through a court settlement (Dickey, Orszag, and Tyson, 2010). These "real-world complexities," such as information asymmetries, different perceptions regarding the likelihood of winning the litigation, discount rates, and risk aversion, create conditions in which reverse payments could feasibly be pro-competitive. In this section, we consider the most common of these feasibility arguments and illustrate that a behaviorally informed lens will uncover that pro-competitive pay-for-delay agreements are unlikely to occur and thus, on aggregate, will not increase consumers' welfare.

"Risk aversion" by the branded firm is the most common argument invoked to defend the possible pro-competitiveness of pay-for-delay agreements and was presented by the defense in the *Schering-Plough* case. Expert economists for the pharmaceutical firms argue that if the branded firm is risk averse, it is feasible to imagine that it will concede more than the expected value of a court decision in the negotiated settlement. Thus, the consumer is getting access to the generic faster than the expected value date provided by a court settlement. However, the policy-relevant question in this case is: Is it likely that the branded-drug firms are risk averse? In fact, the more accurate question is: What is the likelihood of branded-drug manufacturer being more risk averse than the generic-drug producer? The answer to both questions is, not very likely.

First, it is not likely for the branded-drug firm to be extremely risk averse. Shareholders do not want the firms in which they invest to demonstrate extreme risk aversion (Brealey, Myers, and Allen, 2008). This is because shareholders deal with their own risk preferences through alternative investment strategies, such as selecting a diversified portfolio. Moreover, most shareholders disfavor firms that pay a significant premium to avoid risk. While some firms may be extremely risk-averse, the branded-drug manufacturer is unlikely to be so, as large corporations are expected to be more profitable in the long run if they act closer to risk neutrality (Berk and DeMarzo, 2011).

Second, even if the firm was extremely risk averse against all odds, the outcome of the settlement depends on the relative risk aversion of both firms, rather than simply on the risk aversion of one of the parties. Thus, one could argue that the relatively more risk-averse party is predicted to make greater concessions to eliminate the risk of an impasse. In other words, Schering-Plough would have to be relatively more risk averse than Upsher-Smith to justify this settlement being pro-competitive (Raiffa, 1982).

Yet it is unlikely that Schering-Plough will be more risk

scheringinitialdecisionp2.pdf

¹⁵Some of the economists who signed the *amici curiae* include John P. Bigelow (Princeton Economics Group), W. David Bradford (University of Georgia), Margaret E. Guerin-Calvert (Compass Lexecon), Pierre-Yves Cremieux (Analysis Group), Henry G. Grabowski (Duke University), Rahul Guha (Cornerstone Research), R. Glenn Hubbard (Columbia Business School), Daniel P. Kessler (Stanford Law School) and Edward A. Snyder (Yale School of Management).

averse than Upsher-Smith. This assertion is based on one of the most important and powerful results to have emerged from behavioral economics: prospect theory, which stipulates that the frame of the decision systematically affects decision makers' propensity to take risks (Tversky and, Kahneman, 1981). Prospect theory tells us that individuals treat risks differently depending on their perceived frame of reference. Individuals are risk averse when they are operating in a positive frame—viewing a “gain” from the status quo—and risk seeking in a negative frame—viewing “losses” from the status quo. Extending this empirical result to the negotiation context, there is evidence across multiple studies that positively framed negotiators tend to be risk averse and negatively framed negotiators tend to be risk seeking (Neale and Bazerman, 1985; Bottom and Studt, 1993; De Dreu and McCusker, 1997; Olekalns, 1997).

Given the findings of prospect theory, the question then becomes, which party in the Schering-Plough and Upsher-Smith negotiations was operating in the loss frame? Results from behavioral science show that the status quo is an extremely common reference point (Samuelson and Zeckhauser, 1998; Bazerman, Baron, and Shonk, 2001). Because it owns the market prior to the generic's entry, the branded-drug manufacturer is likely to frame any proposed resolution as a loss in market share against the status quo. Meanwhile, the generic defendants are likely to frame any market access as a gain against the status quo of not having any market share. Thus, from this perspective, Schering-Plough was losing market share with the entry of the generic, and Upsher-Smith was gaining market share. If either firm deviated from risk neutrality, findings from behavioral economics would dictate that Upsher-Smith would be more likely to be risk averse since it was operating in the “gains” domain. If Schering-Plough deviated from risk neutrality, it would be much more likely to be comparatively risk seeking.

Another defense provided for the feasibility of a pro-competitive settlement was that if the generic-drug producer was overly optimistic of winning in court and thereby resistant to a settlement, then a payment from the branded-drug firm to the generic-drug firm could lead to generic entry in advance of the expected entry date under a court decision (Willig and Bigelow, 2004). That is, the overly optimistic party (the generic producer) would demand more than the expected value of its entry date under a court decision. But while it is feasible for the generic producer to be overly optimistic, it is unlikely that it would be more optimistic about a court victory than the branded firm. A branded-drug company holds the patent on the production of the drug. Studies from behavioral economics show that owners overly value what they own, a phenomenon termed the “endowment effect.” (Kahneman, Knetsch, and Thaler, 1990). Thus, those endowed with the asset will have a higher propensity to exhibit optimism about their odds of winning in court than those who do not own the asset. Therefore, even if it is conceivable that overoptimism can create a context in which a reverse payment ends up being

beneficial to consumers, it was unlikely in this case because the overly optimistic party, Schering-Plough, was less likely to make concessions in the negotiation unless it was getting additional value from the deal.

This brings us to the question of any additional value created in these side deals. The expert economist for the pharmaceutical firms argued that adding new issues to the discussion (such as a contract to buy a license for another drug) enables parties to make trades across issues, allowing them both to be better off than if they simply compromised on each issue (Malhotra and Bazerman, 2007). That is, creating joint gains in negotiations results in a net positive for both companies and is therefore welfare enhancing. The negotiation literature generally recommends “enlarging the pie” as much as possible by adding issues to the table. The second author of this paper has taught this view to many students over the last three decades. However, this analysis leaves out critical principals involved in antitrust enforcement—namely, consumers—from the discussion. Specifically, while these agreements might be welfare enhancing for the two companies involved, they partially draw that value from consumers and society at large. In fact, we argue that negotiators' “value creation” can sometimes harm rather than benefit society because the value the parties create is taken from parties who are not at the bargaining table—in this case, consumers (Gillespie and Bazerman, 1997). We refer to such arrangements as “parasitic integration” because value is taken from others, often without their knowledge. Because these parasitic agreements create value for the parties involved in the deal, they are often mistakenly labeled as “pie-enlarging”. In fact, the negotiators are increasing the size of their slices of the pie by reducing the slices of other stakeholders who are not at the table.

Moreover, parties are much more likely to create value for themselves in a negotiation when they have a strong relationship, which enhances information sharing (Mnookin, Peppet, and Tulumello, 2004; Malhotra and Bazerman, 2007; Thompson, 2008). In the Schering-Plough case, the parties had very little connection to each other before negotiating the settlements, making this transaction even more unlikely to be one of *pure* value creation. Thus, even if it is feasible for these side deals to create value for the drug manufacturers, it is unlikely that the value creation is for the consumers, who lose out by not being at the negotiation table.

More broadly, by allowing pay-for-delay agreements to continue, society ensures anti-competitive behaviors will continue as well. If drug manufacturers can negotiate both transactions at once, they both increase their profits by agreeing to delay the generic's entrance to market and for the brand-name manufacturer to pay the generic manufacturer more than the unrelated patent is worth. Consumers continue to fund these increased profits because of the failure of our judges and policymakers to block such “parasitic” transactions.

Thus, while it is conceivable that the type of side deal we have described between a branded-drug and generic-drug manufacturer would benefit consumers, it is extremely un-

likely that it will. Moreover, evidence based on broader trends illustrates the anti-competitive nature of these agreements. If these side deals were truly value-creating, then why are so many patent disputes settled near the end of the life of a patent, and why does the cash almost always move from the brand-name manufacturer to the generic manufacturer, and not the reverse?¹⁶ That is, if the added issues beyond the settlement dates were independent of the patent settlement, it would be reasonable to predict that cash would be equally likely to flow from the generic manufacturer to the brand-name manufacturer as from the brand-name manufacturer to the generic manufacturer. Instead, the pattern is always for the cash to move from the brand-name manufacturer to the generic manufacturer. Moreover, if these agreements are truly value creating, then they should be common in the pharmaceutical industry. Yet there is evidence that these types of side deals are uncommon and almost non-existent outside the context of pay-for-delay (Hemphill and Lemley, 2011).

Other pharmaceutical companies have followed the blueprint provided by Schering-Plough, often with greater complexity and deniability. After denying FTC charges that it was paying a generic manufacturer to delay entry, the pharmaceutical firm Cephalon reached a \$1.2 billion settlement with the FTC in 2015. The settlement provides evidence that at least one brand-name manufacturer was following in Schering-Plough's footsteps. Why else would Cephalon agree to a \$1.2 billion penalty? Traditional expert economists for these pharmaceutical firms typically have argued that it is feasible for rational actors to have created pay-for-delay agreements that are good for society. We agree that, given these experts' very restrictive and unrealistic assumptions, this is feasible—but extremely unlikely. By contrast, behavioral economics makes arguments based on empirical data and the likelihood of events occurring. As we have demonstrated, it is extremely likely that most visible pay-for-delay cases to date were anti-competitive.

Conclusion

While multiple approaches can be taken to resolve the antitrust concern posed by pay-for-delay agreements in the pharmaceutical industry, we argue that courts should consider the *likelihood* of such agreements being pro-competitive rather than just *feasible*, since feasibility arguments rely on unrealistic assumptions. Allowing for arguments embedded in behavioral economics, and thus empirical evidence, will create opportunities for better-informed arguments that rely on the *likelihood* of these side deals being pro-competition. Finally, these soft changes should be complemented with *hard* legislative reform to eliminate the perverse incentives for reverse payments in the first place.

We believe such behaviorally informed analyses would lead to very different regulatory outcomes than what we currently have. One approach would be for Congress to amend

¹⁶We do not know of any settlement with net payments going from generic to branded, and have only inserted "almost" into this sentence in case we missed a counter example.

the Hatch-Waxman Act to grant generic manufacturers the 180-day exclusivity period *if and only if* they successfully defeat the patent holder in court (Hemphill and Lemley, 2011). If the generic manufacturer were to settle the lawsuit, then it would lose the 180-day exclusivity period. This solution would reduce the incentives for the generic manufacturer to settle, especially if the brand-name manufacturer's patents are weak. It would also make it less likely that the brand-name manufacturer would settle with the generic, as another generic firm, incentivized to obtain the 180-day exclusivity, may file for an ANDA and thus leave the brand-name firm open to future litigation and settlements.

We also propose prohibiting any linked, unrelated business transactions between two companies that are currently involved in a pay-for-delay lawsuit. As demonstrated earlier, because these "side deals" are most likely disguised payments to delay entry, prohibiting any simultaneous business transaction between the two litigating companies would limit the avenue through which the branded company could ostensibly make large payments to the generic companies for unrelated products. Prohibiting such transactions would prevent brand-name companies from making sham payments. This suggestion is consistent with the court order in the Cephalon case cited earlier:

From the date this Order is signed by Cephalon and Teva, the Cephalon Parties are prohibited from, together or separately, entering into any Brand/ Generic Settlement that includes: (1) Payment by the NDA Holder to the ANDA Filer; and (2) an agreement by the ANDA Filer not to research, develop, manufacture, market or sell the Subject Drug Product for any period of time, provided, however, that any agreement entered into by an entity prior to that entity becoming part of the Cephalon Parties is not subject to the terms of this Order; provided further, however, that the Cephalon Parties may enter into any written agreement that receives the prior approval of the Commission.¹⁷

Unfortunately, this court order only applies to the parties in that case, rather than changing laws regulating other pharmaceutical firms. Even after the most recent Supreme Court decision on *Actavis*, a blueprint remains for pharmaceuticals to parasitically integrate and subvert value from consumers to themselves. Allowing for arguments embedded in behavioral theory in court cases would be a first step toward exposing the anti-competitive nature of these agreements. A sampling of the behavioral arguments presented in this paper would aid in disrupting the corrupt scheme that keeps drug prices artificially high and takes money out of the pockets of consumers.

References

1. Bazerman, M.H., Baron, J. and Shonk, K. (2001). *You Can't Enlarge the Pie: Six Barriers to Effective Government*. New York: Basic Books.

¹⁷<https://www.ftc.gov/system/files/documents/cases/150617cephalonstip.pdf>

2. Berk, J.B. and DeMarzo, P.M. (2011). *Corporate Finance* (Second Edition). New York: Pearson.
3. Bottom, W.P. and Studt, A. (1993). Framing Effects and the Distributive Aspect of Integrative Bargaining, *Organizational Behavior Human Decision Processes*, 56(3):459-474.
4. Brealey, R.A., Myers, S.C. and Allen, F. (2008). Brealey, Myers, and Allen on Real Options, *Journal of Corporate Applied Finance* 20(4):58-71.
5. De Dreu, C.K.W. and McCusker, C. (1997). Gain-loss frames and cooperation in two-person social dilemmas: A transformational analysis, *Journal of Personality and Social Psychology* 72(5):1093-1106.
6. Dickey, B.M., Orszag, J. and Tyson, L. (2010). An Economic Assessment of Patent Settlements in the Pharmaceutical Industry, *Annals Health Law* 19(2):367-401.
7. Dickey, B.M. and Rubinfeld, D.L. (2012). Would the *per se* Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment? *Journal of Competition Law and Economics*, 8(3):615–625.
8. Federal Trade Commission (2010). Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. Washington, D.C. Retrieved from <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>
9. Gillespie, J.J. and Bazerman, M.H. (1997). Parasitic Integration: Win-Win Agreements Containing Losers. *Negotiation Journal* 13:271-282.
10. Hemphill, C.S. and Lemley, M.A. (2011). Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act. *Antitrust Law Journal* 77:972-975.
11. Hemphill, C.S. (2009). An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, *Columbia Law Review*, 109(4):629-688.
12. Kahneman, D. and Tversky, A. (1979). Prospect Theory: An Analysis of Decision Under Risk. *Econometrica*, 47(2):263-291.
13. Kahneman, D. and Tversky, A. (1986). Rational Choice and the Framing of Decisions, *Journal of Business*, 59(4):S251-S278.
14. Kahneman, D., Knetsch, J.L., and Thaler, R.H. (1990). Experimental tests of the endowment effect and the Coase Theorem, *Journal of Political Economy*, 98:1325-1348
15. Kahneman, D., Knetsch, J., and Thaler, R.. (1991). Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias. *Journal of Economic Perspectives*, 5(1):193-206.
16. Kahneman, D., Slovic, P., and Tversky, A. (1982). *Judgment Under Uncertainty: Heuristics and Biases*. New York: Cambridge University Press.
17. Malhotra, D. and Bazerman, M.H. (2007). Investigative Negotiation, *Harvard Business Review* 85(9):72-78.
18. Mnookin, R.H., Peppet, S.R., and Tulumello, A.S. (2000). *Beyond Winning: Negotiating to Create Value in Deals and Dispute*. Cambridge MA: Harvard University Press.
19. Neale, M.A., and Bazerman, M. H. (1985). The effects of framing and negotiator overconfidence on bargaining behaviors and outcomes. *Academy of Management Journal*, 28(1):34-49.
20. Olekalns, M. (1997). Situational Cues as Moderators of the Frame-Outcome Relationship. *British Journal of Social Psychology* 36(2):191-209.
21. Rabin, M. and Thaler, R. (2001). Anomalies: Risk Aversion. *Journal of Economic Perspectives*, 15:219-232
22. Raiffa, H. (1982). *The Art and Science of Negotiation*. Cambridge, MA: Harvard University Press.
23. Samuelson, W. and Zeckhauser, R. (1998). Status Quo Bias in Decision Making. *Journal of Risk and Uncertainty*, 1(1):7-59.
24. Thaler, R. and Sunstein, C. (2009). *Nudge: Improving Decisions about Health, Wealth, and Happiness* (revised edition). New York: Penguin Books.
25. Tversky, A. and Kahneman, D. (1974). Judgment under Uncertainty: Heuristics and Biases, *Science*, 185:1124-1131
26. Tversky, A. and Kahneman, D. (1981). The framing of decisions and the psychology of choice. *Science* 211(4481):453-458.
27. U.S. PIRG. (2013). Top Twenty Pay for Delay Drugs. Retrieved from <http://www.uspirg.org/sites/pirg/files/reports/TopTwentyPayForDelayDrugsUSPIRG.pdf>
28. Willig, R.R. and Bigelow, J.P. (2004). Antitrust Policy toward Agreements that Settle Patent Litigation, *The Antitrust Bulletin* 49(3):655-698.