

Whistling Past the Graveyard: The Problem with *Per Se* Legality Treatment of Pay-for- Delay Settlements

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Arguably, the most important debate in antitrust jurisprudence involves pay-for-delay patent settlements in which the brand company pays the generic to stay out of the market. As a matter of economics, it will generally be most profitable if the brand and the generic firm avoid the possibility of competition and share the resulting monopoly profits; however, such settlements will reduce competition and increase the costs of drugs. If pay-for-delay settlements are legal, parties will enter them to the detriment of consumers. Current cases, in particular the *Tamoxifen* and *Ciprofloxacin* decisions, however, have gone a long way towards adopting just such a standard, a standard that is already having an effect. By adopting an approach without regard to its implications or erroneously suggesting that pay for delay settlements are an ineffective way to delay competition, courts are essentially whistling past the graveyard. In addition, economics and empirical evidences explain why eliminating the 180-day exclusivity will not solve this problem. Unless changed the legal rule articulated in the *Tamoxifen* and *Ciprofloxacin* decisions will costs consumers billions of dollars.

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I. Introduction

The phrase “Whistling Past the Graveyard” has many related meanings and appears in sources as varied as Robert Blair’s *The Grave* and a Don Henley rock song. In Blair’s poem, a school boy whistles “aloud to bear his courage up” as he passes by the graveyard, a scary and dangerous place. Rather than avoiding the danger (using a different route) or finding protection (walking with the group), the boy whistles, which, although it might make him feel better, does nothing to eliminate any real danger of the moment. In Don Henley’s song *If Dirt Were Dollars*, the lines are an indictment of those who blithely ignore the problems surrounding them:

“Gods finest little creatures
 Looking brave and strong
 Whistling past the graveyard
 Nothing can go wrong
 Quoting from the scriptures
 With patriotic tears. . .
 These days the buck stops nowhere
 No one takes the blame”¹

Ignoring the implications of their antitrust analysis is precisely how courts have approached the issue of pay-for-delay patent settlements, also known as reverse-payment settlements or exclusion-payment settlements. Although these agreements occur only within the narrow range of pharmaceutical patent litigation, their growing prevalence makes them the subject of arguably the most important debate in antitrust jurisprudence.

The danger, or the graveyard, is that recent decisions have gone a long way towards adopting a rule of *per se* legality with respect to these settlements which, in turn, will dramatically increase prescription drug prices. Under the developing rule, a patent settlement is almost always legal if it allows the alleged infringer to enter the market at patent expiration or earlier. Such a settlement violates the antitrust laws only if the patent was obtained by fraud, the litigation is a sham, or the settlement blocks entry of a totally unrelated product. In other words, in virtually all pharmaceutical patent litigation, the brand may pay the generic to stay off the market until the expiration of the last patent. Under such a rule, payments to delay entry should occur in virtually every case because such settlements will be profitable for both parties. These settlements will delay generic entry, forcing consumers to pay substantially higher prices for prescription drugs. Already these deals are having an impact. A recent analysis by

Federal Trade Commission (“FTC”) economists estimates that these types of deals cost consumers \$3.5 billion per year.² That number will only increase if the courts settle on a rule of *per se* legality.

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Courts are whistling past this disastrous result; brusquely dismissing it, or offering solutions that are ineffective. Decisions enunciating broad principles of legality generally ignore the implications of this rule. When they do consider it, they comfort themselves with the hypothesis that branded drug manufacturers cannot afford to pay off enough generic competitors to truly delay competition. Although there are many reasons to see this as little better than whistling, the most obvious is the specific regulatory framework under the Hatch-Waxman Act, the law controlling pharmaceutical approvals. In particular, the first company to file for generic approval generally receives 180 days of market exclusivity, meaning that the FDA will not approve a second generic filer during that time. Delaying the first-filer’s entry, then, delays everyone else’s. Although there are ways for subsequent filers to eliminate the first-filer’s exclusivity, the first filer’s exclusivity still creates a heightened barrier. Further, the parties to the settlement can structure it in such a way as to limit the subsequent filer’s incentives to pursue a patent challenge.

In a variation on this theme, others have suggested that the problem is not the reverse payments, but is instead the 180-day exclusivity. In their view, we can avoid the ill effects of delayed entry if we eliminate the 180-day exclusivity for first filers who settle. Although there may be policy reasons for eliminating the 180-day exclusivity or creating incentives for subsequent challengers to eliminate that exclusivity, it will neither end the practice nor solve the problems created by pay-for-delay settlements. Even if there was no 180-day exclusivity, pay-for-delay settlements would still be profitable and delay generic entry for three reasons. First, the number of potential generic competitors may be low. Second, the transaction costs of the payments will be low. Third, it may be less expensive for a branded firm to pay off multiple generics rather than just one.

A fuller understanding of the pay-for-delay problem begins with a background of the regulatory and legal context of brand-generic patent settlements. Recent cases articulate a rule of *per se* legality for settlements in which entry occurs no later than patent expiration. This article does not explore the legal flaws in that proposed rule of *per se* legality; rather, the point is that no one should be fooled about the cost of such a rule. Both the brand and the generic will always earn more if the brand pays the generic to stay out of the market until patent expiration; therefore, these types of deals will only become more prevalent and delay generic entry longer. Finally, economics and empirical evidences explain why eliminating the 180-day exclusivity will not solve this problem.

II. Background on Patent Pharmaceutical Litigation

There are two basic ways to obtain approval for a prescription medication. First, a company can file a New Drug Application (“NDA”) in which it demonstrates the safety and efficacy of its product, among other things.³ Satisfying these standards requires costly clinical trials. It also provides a list of patents which cover the product, which the FDA makes public.⁴ Most branded drugs receive approval through the NDA process.

Companies seeking to sell a generic version of a drug can follow a second path, called an Abbreviated New Drug Application (“ANDA”). Instead of repeating the expensive safety and efficacy testing of the brand product, they can establish that their product is bioequivalent to the brand product.⁵ In addition, when the generic files its application, it must provide a certification as to each patent the brand has listed as covering its product. It can certify that there are no patents listed for the branded drug; that the listed patents have expired; that the generic will not sell the product until the listed products expire; or that the listed patents are invalid or not infringed by the generic’s product.⁶

If the generic makes the last certification (that the patent is not infringed or is invalid), known as a paragraph IV certification, it must give notice to the brand company. In turn, if the brand company sues the generic within 45 days, the Food and Drug Administration may not approve the generic company’s ANDA for thirty months.⁷ In effect, just by filing suit the brand gets the equivalent of a thirty-month preliminary injunction⁸—without any showing on the merits.

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At the same time, the Hatch-Waxman Act gives the first generic applicant to make a paragraph IV certification (the “first filer”) a valuable advantage. The FDA may not approve a second generic filer until 180 days after the first filer begins marketing its product.⁹ Under current law, there are various ways a first filer can forfeit its exclusivity, but it generally requires a second filer either to prevail in a patent infringement action brought by the brand company or to win a declaratory judgment action that the patent is invalid or not infringed.¹⁰ The first filer does not lose its exclusivity by settling the patent litigation. In other words, if the first filer agrees, as part of a patent settlement, not to enter until a year before patent expiration, the 180-day exclusivity period would prevent the FDA from approving any other generic until six months before patent expiration.

III. The Economics of Patent Settlements

Brand companies frequently sue generic companies for patent infringement. Generally hundreds of millions and, not infrequently, billions of dollars are at stake for the brand company. If the generic company successfully defends against the infringement claim, competition occurs. The generic will quickly take as much as 80 percent of the brand’s prescriptions in a matter of months.¹¹ Although initially priced at roughly a twenty percent discount of the brand price, the generic price can fall to as little as twenty percent or less of the brand price when multiple generics enter.¹² In turn, consumers save billions of dollars from generic entry. Conversely, if the brand triumphs, it preserves hundreds of millions or even billions of dollars of additional revenue.

Weeding out weak patents or designing around narrow ones has helped control prescription drug costs. Many patents protecting brand products are weak or sufficiently narrow that they do not block generic entry. In those cases, successful generic challenges ensure that the patent does not deprive consumers of the benefits of generic competition. In the period 1992 to 2000, of those cases that went to trial, brand companies successfully protected their monopoly from all competition less than 30 percent of the time.¹³

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Another study showed that in the pharmaceutical industry, the alleged infringer won roughly two-thirds of the decisions in the Federal Circuit.¹⁴

The savings to consumers are substantial. On four blockbusters alone, consumers are expected to save over 16 billion dollars because of generic entry prior to patent expiration. See Table 1.¹⁵ In each of those cases, the patent was no bar to competition. The generics’ victory in the patent litigation ensured that consumers received the benefits of competition earlier rather than later.

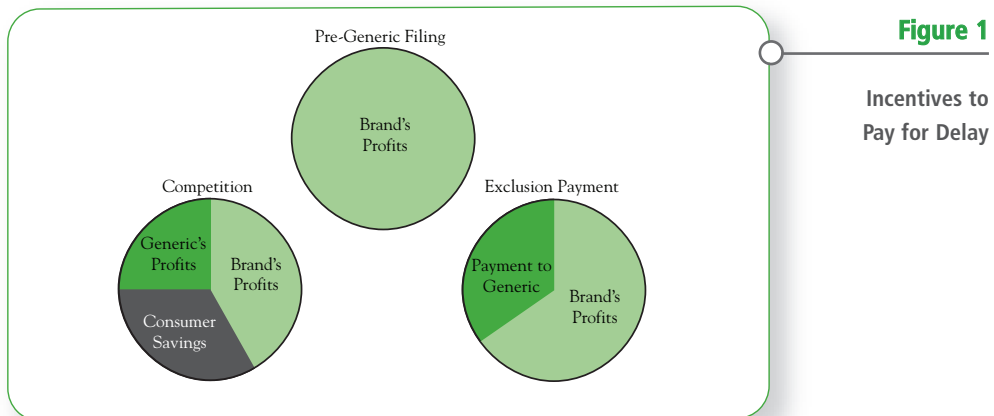
Table 1

Examples of Generic Entry Prior to Patent Expiration from Successful Patent Challenges

Drug	Generic Entry Date	Years Prior to Patent Expiration	Brand Sales Prior to Generic Entry	Consumers Savings
Zantac	1997	5	\$1.6 billion	\$2.45 Billion
Taxol	2000	11	\$1.6 billion	\$3.5 Billion
Prozac	2001	2.5	\$2.5 billion	\$2.5 Billion
Buspar	2001	17	\$600 million	\$8.8 Billion

Of course, not every case goes to trial; many cases settle. As a matter of basic negotiation theory, parties should settle cases when the value of the settlement is greater than the perceived or expected value of pursuing the case to judgment.¹⁶ When combined with the underlying economics of the pharmaceutical industry, this is a recipe for anticompetitive settlements.

Because generic entry causes total profits to fall, it is profitable for the parties to avoid entry if the branded company can compensate the generic company. The generic competes at a lower price, so the profits it makes by competing are lower than the amount the brand loses by facing competition. A simple pie chart, depicted in Figure 1, helps illustrate this point. In the top pie (“Monopoly”), the brand has all of the profit without generic competition. Once generic entry occurs (in the “Competition” pie), the brand loses substantial profits. Although the generic company earns profits, depicted by the dark green-shaded segment, consumers save money by buying the lower-priced generic, represented by the gray-shaded slice. In technical terms, the joint profits of the duopoly are less than the monopolist’s profits.¹⁷



Left to their own devices, both the incumbent monopolist and the entrant are better off if they eliminate competition and share the monopoly profits. As shown in the “Exclusion Payment” pie, the generic earns more from taking a payment not to compete than by entering the market. The dark green-shaded slice in the Exclusion Payment pie is larger than the green slice in the Competition pie; the brand is sharing a portion of its monopoly profits with the generic. Similarly, the light green-shaded slice of the Exclusion Payment pie, representing the branded company’s profits, is larger than the light green-shaded slice of the Competition pie because the brand—despite paying the generic—earns more than if it faces competition.

During a patent litigation, there is obviously uncertainty about whether there will be a monopoly or competition after the court’s decision. While that uncer-

tainty affects what the parties expect to earn from pursuing litigation, it still does not change the fact that, for the vast majority of situations, the brand and the generic can each earn more if the generic agrees not to compete and the brand pays the generic more than the generic values the litigation. The weaker the patent, the more willing the brand is to pay the generic. Graphically, the pie charts of Figure 1 need only a slight modification to account for the uncertainty of the litigation. As Figures 2 and 3 show, we start with the same pre-generic-filing pie, with the brand earning its monopoly profits.

The “Expected Competition” pie replaces the Competition pie. Compared to the Competition pie in figure 1, the slices of the generic’s profits and the consumer savings are all discounted by the chance that the patent will block competition while the brand’s expected profits are larger to account for the possibility that it may win the patent suit. In Figure 2, the patent is weak, so the expected profits of the brand and the generic are similar to what would happen if there is competition. In contrast, in Figure 3, the patent is strong; both the generic’s expected profits and the expected consumer savings are small, but the brand’s expected profits are much larger than what it would earn if there is competition.

Figure 2

Incentives to Pay for Delay (Weak Patent)

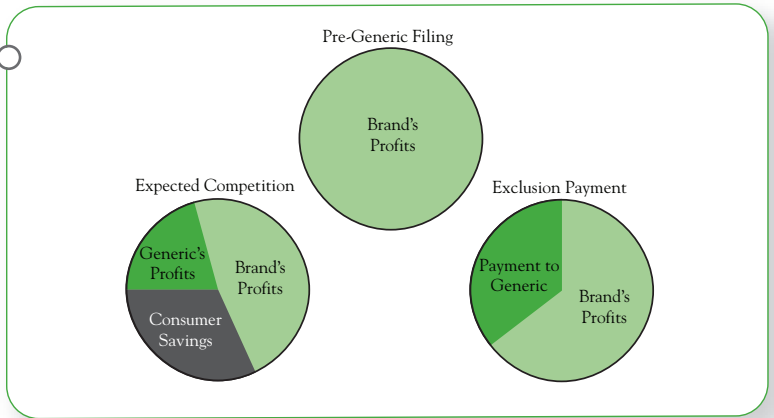
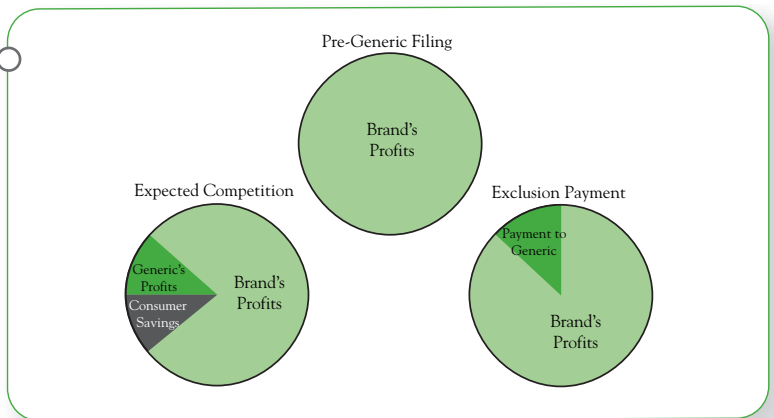


Figure 3

Incentives to Pay for Delay (Strong Patent)



The important point is that, whether competition is certain (Figure 1), the patent is weak (Figure 2), or the patent is strong (Figure 3), the brand and the generic are better off preserving the monopoly by having the branded firm pay the generic company not to enter. Left to their own devices—in a world where they face no antitrust constraints—most brand-generic patent cases should settle with the brand paying the generic not to compete during some portion of the remaining patent term, making what have become known as reverse payments, exclusion payments, or pay-for-delay settlements. The strength of the patent—how likely it is to block competition—would not determine when there is competition; rather, the profits the branded firm earns by eliminating the threat of generic competition and the brand's willingness to share those profits determines when competition would occur.

Not surprisingly, payments are more likely to protect weak patents than strong ones. The brand has more to lose from litigation and is willing to pay more to avoid that possibility than if the patent is strong. Because the payment involves dividing up the gray slice—the avoided consumer savings—and because the value of eliminating those consumers' savings is greatest when the patent is weak, payment becomes an especially attractive method for holders of weak patents to prevent competition.

At the same time, and this is the point of Figure 3, allowing branded firms with strong patents to pay off their generic competitors still harms competition. As Hovenkamp, Janis, & Lemley have explained, even where the patentee has a 75 percent chance of winning, the reason it “is willing to make this payment is precisely because there is a 25 percent chance that the patent would be held invalid or not infringed and the market would become competitive.”¹⁸

The proposition that brands and generics can earn more from the brand paying the generic not to enter than they can from litigating or settling without a payment is uncontroversial. In the 1980s, Michael Meurer identified the general result that allowing a monopolist patent holder to make a lump sum payment to the alleged infringer would eliminate litigation and preserve monopoly profits.¹⁹ More recently, Carl Shapiro explained this result specifically in the context of brand-generic patent settlements: “For this reason, the FTC has a sound basis for its skepticism about ‘reverse cash payments’ from the patent holder to the challenger.”²⁰ Even those who try to justify these agreements grudgingly acknowledge that brands and generics can earn more by eliminating potential competition and sharing the resulting profits.²¹

IV. Current Case Law

Herein is the danger, or the graveyard, so to speak. Allowing brands to settle patent litigation by paying generics will eliminate competition and cost consumers billions of dollars a year, but that is precisely the legal rule the courts are moving toward.

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The *Tamoxifen* decision in the Second Circuit and the *Ciprofloxacin* decision in the Federal Circuit were not subtle in their analysis and approach. Both set out a fairly straightforward rule: Unless the patent was obtained by fraud or the litigation is a sham, a settlement in which the brand pays the generic not to enter the market with an allegedly infringing product until patent expiration is legal.

The *Tamoxifen* decision was the first clear articulation of this broad rule of legality, granting a motion to dismiss a pay-for-delay challenge. Tamoxifen is an anticancer drug.²² The brand, AstraZeneca, sued the first generic, Barr, but Barr won before the trial court.²³ While the case was on appeal, the parties settled. Barr agreed to stay out of the market until six months before patent expiration, and AstraZeneca paid Barr 21 million dollars.²⁴ After settling with Barr, AstraZeneca won three patent cases against successive generic filers.²⁵ Private plaintiffs challenged the Barr agreement as an unreasonable restraint of trade.²⁶ The trial court in the antitrust case dismissed the action, holding that the plaintiffs failed to state a claim upon which relief could be granted.²⁷ In affirming the lower court, the Second Circuit explained:

“Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”²⁸

In the Second Circuit’s view, absent those exceptions, a settlement could restrain competition beyond the scope of the patent only if the generic agreed to stay out of the market beyond the patent’s expiration or the agreement covered unrelated products.²⁹ Because the patent *might* block competition, the brand could pay to ensure that result:

“So long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”³⁰

Therefore, the Second Circuit concluded that “We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.”³¹

In *Ciprofloxacin*, the Federal Circuit adopted the Second Circuit’s holding that there could be no antitrust liability for any exclusion unless it was greater than what the patent might prevent.³² Ciprofloxacin is an antibiotic. The brand, Bayer, sued Barr, the first generic.³³ Before reaching trial, the parties settled. Bayer paid Barr close to \$400 million, and Barr agreed to stay off the market until six months before patent expiration.³⁴ The Federal Circuit upheld the lower court’s decision to grant summary judgment in favor of the defendants.³⁵ Because the patent might block entry, the Federal Circuit reasoned that the means the brand chooses to achieve that result, whether litigation or payment, made no difference:

“[T]here is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements.”³⁶

One could ask why the legal right to exclude embodied in the patent includes the right to use one’s economic power—the sharing of monopoly profits—to eliminate competition. Or, put another way, if the patent’s ability to block competition is uncertain, why should the patent-holder be able to guarantee its monopoly by paying its potential competitor to stay out of the market? In essence, the Second Circuit and the Federal Circuit believe that the patent-holder can buy off its potential competitor so long as the patent infringement claim is not a sham.

V. Implications of the Developing Rule

What happens if the rules of the Second and Federal Circuit become the law of the land? If it is legal to pay for delay, it will certainly be in most parties’ interest. The effect of such a rule is obvious—it will reduce pharmaceutical competition and increase the cost of prescription drugs.

As to the first point, it is a matter of simple logic easily illustrated by probability charts. Suppose that there are six branded products. Suppose further that they are distinct. They contain different active ingredients; employ different methods of actions; are sold in different markets; and are produced by different companies. In each case, a generic has filed an application to sell its product before the expiration of the respective brand firm’s patent, and each brand has a one in three

chance of winning. If all six cases go to judgment, as Figure 4 shows, on average two of the brand companies will win their suits, and there will be a monopoly until patent expiration (represented by green on the timeline). At the same time, on average, four generic firms will win, and there will be competition (represented by gray on the timeline). Of course, not all cases go to trial; some settle. While many factors affect the terms of the settlement, one would expect—if there are no payments to the generic—that the results would roughly correlate with the probable outcome of the patent litigation. So, if three cases settled without payments, as Figure 5 shows, the settlements might roughly prevent entry for one-third of the remaining patent life and allow competition for the remaining two-thirds of the patent life.

Figure 4

Results of Litigation

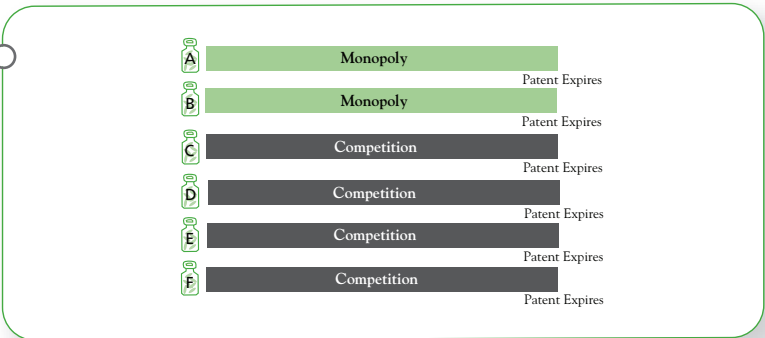
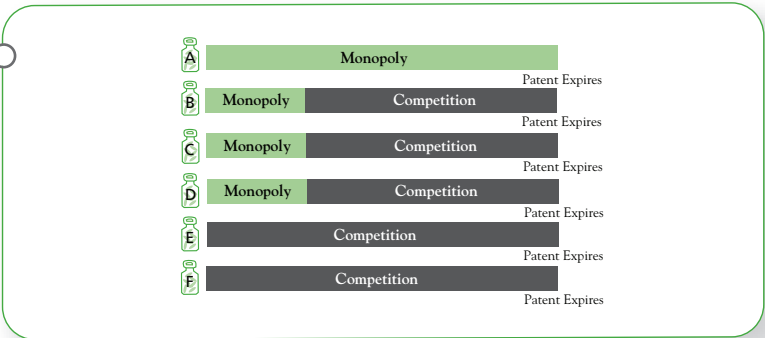


Figure 5

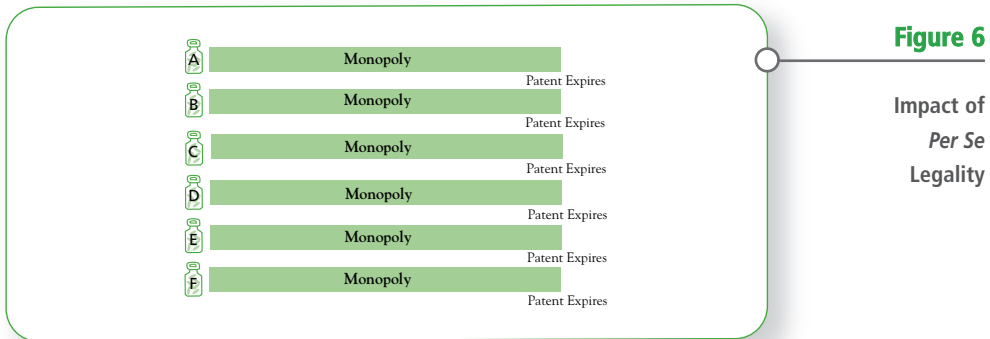
Settlements Without Payments



If, however, the brand may pay the generic, then, as depicted in Figure 6 below, the brand should simply pay the generic to stay out of the market until patent expiration.

Even if the brand has a relatively strong chance of winning, the payment eliminates “the incremental chance that the market would be competitive.”³⁷ For example, if each brand had a two-thirds chance of winning its patent litigation,

then the amount of green and gray would roughly reverse in Figures 4 and 5. If they litigate, the brand on average wins four cases, and the generic wins two. A settlement with just a date would roughly protect two-thirds of the patent life. But, if payments are legal, one would still expect that the vast majority of settlements would reflect Figure 6. Overall, allowing payments will eliminate competition that would otherwise occur.



As a practical matter, the *Tamoxifen* and *Ciprofloxacin* decisions are already having a substantial effect. Based on the analysis of economists at the Federal Trade Commission, settlements with payments delay entry 17 months longer than settlements without payments.³⁸ Virtually all of the settlements with a payment to the generic occurred after the *Tamoxifen* decision.

Going forward, the impact could be staggering. Economists at the Federal Trade Commission estimate that, if nothing changes, settlements with payments for delay will cost consumers \$3.5 billion dollars per year.³⁹ At the end of 2008, brands were attempting to block generic entry on products with roughly \$90 billion in sales.⁴⁰ This is the current universe that the *Tamoxifen* and *Ciprofloxacin* rules could affect. On average, 15 percent of cases settle each year, and 24 percent of those settlements involve a payment. In turn, the delay of 17 months means consumers will lose 17 months of mature generic competition in the life of the product.⁴¹ For a mature market, the average consumer savings is roughly 77 percent.⁴² One can take the consumer savings, the length of delay, likelihood of settlement, and the pool of drugs for which settlements can be reached and calculate the harm to consumers.⁴³ Applying a different methodology and looking at the cost already incurred by consumers, Professor Hemphill estimated that settlements involving payments have already cost consumers 12 billion dollars.⁴⁴

ECONOMISTS AT THE FEDERAL TRADE COMMISSION ESTIMATE THAT, IF NOTHING CHANGES, SETTLEMENTS WITH PAYMENTS FOR DELAY WILL COST CONSUMERS \$3.5 BILLION DOLLARS PER YEAR.

While the description of any methodology may be dry, the implication is not. Under the *Tamoxifen* and *Ciprofloxacin* rule, uninsured patients will pay more for their drugs, insured patients will face higher copayments and premiums, and employers and the government will see their prescription drug costs rise.

Moreover, the FTC economists' estimate is almost certainly low if the *per se* rule of legality becomes the law of the land. Despite its setbacks, the FTC currently remains active in investigating and challenging patent settlements it considers to be anticompetitive, having attacked settlements on two separate products in the last two years. The FTC's enforcement may lead companies to be more cautious. For example, it is much easier to defend a particular settlement if, despite compensation to the generic, it allows for entry before patent expiration.⁴⁵ If the law definitively legalized these settlements, one would expect the companies to pursue more profitable settlements. There would be more pay-for-delay settlements, and in each settlement, the generic—in exchange for a larger payment—would agree to a longer delay.

Such concerns are far more like Cassandra's warnings than Chicken Little's predictions because brand and generic companies have already shown their willingness, in the absence of legal constraints, to push settlements out to patent expiration. In the 1990s, there was a period when drug companies entered pay-for-delay deals before the FTC, state attorneys general, or private plaintiffs were aware of the practice.⁴⁶ Based on the most comprehensive available statistics,

SUCH CONCERNS ARE FAR MORE LIKE CASSANDRA'S WARNINGS THAN CHICKEN LITTLE'S PREDICTIONS BECAUSE BRAND AND GENERIC COMPANIES HAVE ALREADY SHOWN THEIR WILLINGNESS, IN ABSENCE OF LEGAL CONSTRAINT, TO PUSH SETTLEMENTS OUT TO PATENT EXPIRATION.

between 1992 and 1999, there were eight final settlements in which the brand paid the generic, and the generic agree to stay off the market for some period of time.⁴⁷ In six of those eight settlements, the generic agreed to stay out of the market until patent expiration.⁴⁸ Those numbers suggest that if pharmaceutical companies could enter such deals with abandon, consumers would have to pay for higher-priced branded drugs for a much longer period of time.

An example sheds light on the implications of a *per se* legality rule. In 1999, in the middle of the Prozac litigation between Lilly (the brand firm) and Barr (the generic company), Barr offered to settle and walk away from the litigation if Lilly would just pay Barr \$200 million.⁴⁹ Lilly refused because it believed such payments were illegal.⁵⁰ Barr won the case, launched two-and-a-half years before the patent expired, and consumers saved roughly \$2.5 billion.⁵¹ If *Tamoxifen* and *Ciprofloxacin* were law, Lilly would never have taken the risk of losing the profit stream for its blockbuster.

VI. Whistling Toward *Per Se* Legality

The courts have adopted this rule with no concern for its impact—indeed, with barely any recognition of it. At best, they have offered dismissive explanations that are no better than whistling by the graveyard. The *Ciprofloxacin* court was largely silent on the economic implications of its rule. The *Tamoxifen* court assured its readers that payments were not a way to prevent competition because there were simply too many generics to pay off. That assurance, however, should provide little comfort because the economic and regulatory structure of the pharmaceutical industry makes pay-for-delay settlements quite an effective strategy.

The *Tamoxifen* court understood the incentives. The court recognized that the brand earns more profit when it pays for delay than the brand and generic earn if there is competition.⁵² The *Tamoxifen* court further recognized the brand's incentive to pay to protect those profits.⁵³ And, it acknowledged the natural result: “it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered.”⁵⁴ The court acknowledged “a troubling dynamic”: “the less sound the patent or less clear the infringement and, therefore, the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.”⁵⁵

This “troubling dynamic” gave the court little pause because it believed that a patent holder cannot realistically pay off every generic competitor:

“But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.”⁵⁶

In the *Tamoxifen* court's view, then, there could be a problem only if the brand paid off all the generics, an event the court discounted: “We doubt, however, that this scenario is realistic.”⁵⁷

As a matter of economic theory, this tune has some attraction: Paying entrants to stay out of the market will be ineffective if there are too many and the costs of finding and negotiating with them are too high. This perspective ignores the reality of the pharmaceutical market. Even if the brand could only pay one generic and not block anyone else, the delay before a second entered (depending

on the circumstance, the second generic may have to develop the product, get approval, and win its law suit) would still harm consumers significantly.

A. THE 180-DAY EXCLUSIVITY MAKES PAYING THE FIRST FILER AN EFFECTIVE STRATEGY

More specifically, the *Tamoxifen* court ignored the biggest obstacle to taking comfort in the market. Under the Hatch-Waxman Act, the first ANDA filer has an exclusivity that makes it much more difficult for subsequent filers to enter, so the brand may not need to pay multiple filers. Moreover, later filers typically have less incentive to vigorously contest the brand-name firm's patents, because they do not receive the bounty of the 180-day exclusivity.

The 180-day exclusivity is the most obvious reason why the *Tamoxifen* court's assessment is misplaced. The first generic filer to certify that the patent covering the brand product is invalid or not infringed by the generic's product is the first applicant and has 180 days of market exclusivity, meaning the FDA will not approve a second generic until 180 days after the first filer markets its product.⁵⁸ If the first filer accepts a settlement in which it agrees to delay entry for five years, then the FDA may not approve a second filer for 5.5 years. This problem is often referred to as the bottleneck problem because the first filer's delay blocks additional entry.

In principle, the law provides a solution. If the second filer wins its patent case in a non-appealable decision and if the first filer does not launch within 75 days of that decision, the first filer loses its exclusivity.⁵⁹ The FDA may then approve the second or any other filer.

IN PRACTICE, HOWEVER, BRANDS HAVE FOUND WAYS TO LIMIT THE INCENTIVES OF THE SUBSEQUENT GENERIC TO PURSUE ITS CHALLENGE THROUGH A GENERIC ACCELERATION CLAUSE.

In practice, however, brands have found ways to limit the incentives of the subsequent generic to pursue its challenge through a generic acceleration clause. The first filer settles with an agreed entry date. The settlement also provides that the first filer may enter earlier if another generic wins (the entry date is accelerated to the date of the subsequent filer's victory).⁶⁰ As long as the first filer launches within 75 days of the subsequent filer's victory, the first filer does not forfeit its exclusivity, and the second filer must still wait another 180 days before receiving approval. Even if it wins, the subsequent filer still must likely wait for the expiration of the 180-day exclusivity period.

A forerunner of this dynamic occurred in the *Altace* litigation. The first filer (Cobalt) settled. Then, the second filer (Lupin) litigated and won. Under the legal scheme in place, a final appellate court decision triggered the exclusivity. Lupin, however, still had to wait 180 days before it could receive final approval.⁶¹ Lupin would have been in a worse position under the current law because it might have had to wait as long as 255 days after its victory for final approval

because only commercial marketing will trigger the 180 day exclusivity. And, as long as the first filer launches within 75 days of the subsequent generic's victory, the first filer will not lose its exclusivity.

The subsequent filer faces reduced incentives to pursue its litigation. The brand pays the first filer and agrees that the first filer can accelerate its entry if another generic wins its patent litigation. Then, the brand offers the subsequent filer a settlement without a payment and entry 180 days after the first-filer enters. Even if it wins the litigation, the subsequent filer will still enter 180 days after the first filer. The value of winning then is in expediting the process, but this may not justify the cost of going forward. In many cases, a payment to the first filer and an acceleration clause may eliminate the incentive to subsequent generics to vigorously pursue their cases.

B. EVEN WITHOUT THE 180-DAY EXCLUSIVITY, PAYMENTS ARE LIKELY TO BE A SUCCESSFUL STRATEGY

It might be tempting to think that eliminating the 180 day exclusivity for settling first filers will fix the problem of payments,⁶² but it will still be relatively easy for brands to pay generics. Without a broader prohibition on compensation, eliminating the exclusivity is likely to lead to bigger payments to the first filer because the branded company would have to compensate the first generic for the loss of exclusivity, but the payments will still occur. First, there will never be hundreds of companies waiting to enter the generic market. In most cases, the number of entrants—especially those willing to fight patent litigation—will likely be in the single digits.⁶³ Further, if the settlement allowed the first filer to enter as soon as anyone else, that clause would continue to dampen the subsequent filer's incentive to pursue its patent challenge.⁶⁴

Second, the transaction costs in reaching such a deal are relatively low. Because any generic seeking approval to sell its product has to give notice to the brand, the brand always knows who is trying to enter. Because the parties are in litigation, the transaction costs of negotiating the payment are less than the alternative of litigating.

Third, paying-off multiple generics may not substantially increase the overall cost of the strategy; it may cost a brand less to pay two generics to delay entry than one, and it may cost even less to pay three. Additional generics, all of whom are essentially producing an identical branded product, will drive down the price.⁶⁵ At the same time, additional generic entry does not increase generic output.⁶⁶ If prices fall and output is constant, then overall revenues will fall. In turn, with multiple generics, each company expects to earn less. Because the first generic takes such a large portion of the branded company's sales, subsequent generic entry has little additional effect on the branded product's sales. So, the brand receives roughly the same benefit from paying off multiple generics as it does with one. Looking back to Figure 1, the dark green slice for generic profits

shrinks with more generics, but the light green slice (the branded company's expected profits) remains the same.⁶⁷ Therefore, the brand may need to pay less to eliminate the potential competition than if there were only one generic.

Assume that the brand product has yearly sales of one billion dollars. A single generic, assuming it takes 80 percent of the brand's sales and prices at a 30 percent discount, will earn roughly 560 million dollars in revenue. In contrast, if five generics enter, they drive the price down to 33 percent of the brand price. The total generic revenue will fall to 267 million dollars. In other words, if the brand has to pay the full revenue of the generics, it would actually cost more than twice as much to buy off one generic than five generics. Although these numbers may overstate the disparity between revenue in a sole generic market and a multiple generic market,⁶⁸ they clearly illustrate that eliminating the 180-day exclusivity outright may have the unintended consequence of making pay-for-delay settlements more common. On a blockbuster product with 11 or more filers, it may cost very little to pay all the subsequent filers.

VII. Conclusion

This then is what we can conclude about the *per se* legality rule for pay-for-delay settlements. If these settlements are legal, they will occur more frequently, reduce generic entry, and raise the costs of prescription drugs by billions of dollars a year. Furthermore, we should take no comfort in the idea that there are too many generics to pay or that a simple change to the 180 day exclusivity will solve the problem.

ARGUABLY, COURTS DECIDE CASES, NOT PUBLIC POLICY; THEREFORE, THEY NEED NOT CONSIDER THE IMPLICATIONS OF THE RULES THEY DEVELOP. THAT IS AN ESPECIALLY ODD CLAIM IN ANTITRUST LAW.

Arguably, courts decide cases, not public policy; therefore, they need not consider the implications of the rules they develop. That is an especially odd claim in antitrust law, which over the last thirty years has imported ever more sophisticated economic reasoning and

policy into its legal rules. If one believes *Tamoxifen* and *Ciprofloxacin* correctly state the law, it is hard to imagine how the results of the *per se* rule of legality represent sound public policy: the rule protects weak and narrow patents, prevents competition, and raises drug costs.

If the courts are whistling towards *per se* legality, Congress has shown a much deeper and more sophisticated appreciation for the problem. In the House, the Energy and Commerce Committee voted out a bill to eliminate the practice and incorporated it into health care reform. The Senate Judiciary Committee favorably reported a bill that would apply a much more stringent standard. The danger of pay-for-delay settlements is as real as its cost to consumers; the cost of whistling towards *per se* legality is far greater than whistling by the graveyard. ▼

- 1 DON HENLEY, *If Dirt Were Dollars*, on THE END OF INNOCENCE (Geffen Records 1989).
- 2 See, *infra* notes 28-37
- 3 21 U.S.C. § 355(d).
- 4 21 U.S.C. § 355(b)(1).
- 5 21 U.S.C. § 355(j).
- 6 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
- 7 21 U.S.C. § 355(j)(5)(B)(iii).
- 8 The stay will also expire if the district court rules in favor of the generic firm in the rare event that this happens sooner.
- 9 *Id.* § 355(j)(5)(B)(iv).
- 10 *Id.* § 355(j)(5)(D). Under current law, this generally requires a victory at the court of appeals.
- 11 Studies relying on data from the 1980s and early 1990s found generics taking 38-50 percent of the brand's sales within the first year. *How increased Competition from Generic Drugs has Affected Prices and returns in the Pharmaceutical Industry*, A CBO Report (July 1998) (collecting studies), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (last visited September 23, 2009). More recently, generic substitution rates have accelerated. Within the first week of generic Prozac's launch, Merk-Medco achieved an 80 percent substitution rate for mail order customers. See *Merck-Medco Achieves 80 Percent Generic Substitution Rate in First Week*, BW HealthWire (August 20, 2001), available at <http://www.allbusiness.com/health-care/health-care-regulation-policy-health/6112721-1.html> (last visited September 24, 2009).
- 12 David Reiffen & Michael R. Ward, *Generic Drug industry Dynamics*, 87 REV. ECON. & STATS. 37, 38 (2007); Seven N. Wiggins & Robert Maness, *Price Competition in Pharmaceuticals: The Case of Anti-infectives*, 42 ECON. INQUIRY 247, 247.
- 13 Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (last visited September 19, 2009).
- 14 Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006), also John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998) (study of all patent validity litigation from 1989-1996 found 46 percent of all patents litigated to judgment held invalid).
- 15 Written Statement of GPHA (Kathleen Jaeger), *Closing the Gaps in Hatch-Waxman: Assuring Greater Access to Affordable Pharmaceuticals*, Senate Committee on Health, Education, Labor and Pensions, at 60-61, 107th Congress, May 8 2002, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:79636.pdf; *FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition*, available at <http://www.ftc.gov/opal2003/03/bms.shtm>. Some of these products have a checkered past. For example, in both BuSpar and Zantac, there were payments to generic competitors to stay out of the market until an earlier patent expired. See Cmpl. ¶¶ 25-31, In re Bristol-Meyers, Docket C-4076, March 7, 2003, available at <http://www.ftc.gov/os/2003/03/bristolmyerscmp.pdf> (last visited September 19, 2009) (BuSpar) and C. Scott Hempill, *An Aggregate Approach to Antitrust: Using New Data and*

Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 649 (2009). It is unclear whether these figures are discounted for inflation.

- 16 See generally, Robert D. Cooter & Daniel Rubinfeld, *Economic Analysis of Legal Disputes and Their Resolution*, 26 J. ECON. LIT., 1067 (1989).
- 17 See e.g., DENIS CARLTON & JEFFREY PERLOFF, *MODERN INDUSTRIAL ORGANIZATION*, 4th edition, 8, (2005).
- 18 Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV., 1719, 1759 (2003). For an explanation of how payments in cases with relatively strong patents harm competition as a matter of policy, see discussion *infra* at note 31.
- 19 Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. ECON. 77, 78 (1989).
- 20 Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003).
- 21 Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements that Settle Litigation*, ANTITRUST BULL. 655, 659 (2004) "Second, in contrast to the socially beneficial settlements with intermediate dates of entry, the agreements that are the most profitable for the firms (without consideration of legality) might entail the payment of a substantial sum by the patent holder to the entrant in exchange for the promise that the entrant will not actually come into the market, or at least not until the patent has lost its impact and financial value."
- 22 *In re Tamoxifen*, 466 F.3d 187, 193 (2nd Cir. 2005).
- 23 *Id.*
- 24 *Id.*
- 25 *Id.* at 195.
- 26 *Id.* at 196.
- 27 *Id.* at 197.
- 28 *Id.* at 213.
- 29 "Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products. *Id.* at 214.
- 30 *Id.* at 208-209.
- 31 *Id.* at 206.
- 32 *In re Ciprofloxacin*, 544 f.2d 1323, 1336. "The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below, and we find it to be completely consistent with Supreme Court precedent."
- 33 *Id.* at 1328.
- 34 *Id.* at 1328-39 and *supra* note 5.

- 35 *Id.* at 1327.
- 36 *Id.* at 1323, 1337.
- 37 Hovenkamp *et. al.*, *supra* note 18, at 1759 n. 176.
- 38 This estimate does not assume that every settlement with a payment would settle without a payment: "This does not mean that we are assuming that all settlements with payments would 'become' settlements without payments if the former were banned. Some would: others might involve litigation of the patent. But since settlements without payments will tend to reflect patent strength, they can provide a benchmark for the consumer impact of either alternative." Jon Leibowitz, *Pay-for-Delay Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution)*, Speech to the Center for American Progress, Appendix at 14, available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf> (last visited September 13, 2009).
- 39 *Id.*
- 40 *Id.* Appendix at 13.
- 41 *Id.* at 12, note 7.
- 42 *Id.* at 12.
- 43 *Id.*
- 44 Hemphill *supra* note 15 at 650. Professor Hemphill assumed deals on average delayed entry one year, and looked only at deals where there was sufficient public information available.
- 45 See e.g. in re Tamoxifen, 466 F.3d at 216.
- 46 In 2000, the Commission brought the first of its actions in this area. See *Cmpl. In the Matter of Hoescht-Marion-Roussel, Carderm Capital, and Andrx Corp.*, FTC Docket No. 9293 (March 16, 2000).
- 47 *Generic Entry Prior to Patent Expiration, An FTC Study*, p. 31 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (last visited September 19, 2009).
- 48 *Generic Entry Prior to Patent Expiration, An FTC Study*, at Table 3-3, p. 32 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (last visited September 19, 2009).
- 49 David J. Morrow, *Trial is Getting Underway in Prozac Lawsuit*, N.Y. TIMES, (January 25, 1999), available at <http://www.nytimes.com/1999/01/25/business/trial-is-getting-under-way-today-in-prozac-patent-lawsuit.html>
- 50 *Id.*
- 51 See Table 1, *supra* note 17.
- 52 In re Tamoxifen, 466 F.3d at 209 (quoting In re Schering-Plough Corp., slip op. at 27, 2003 WL 22989651 (Fed. Trade Comm'n Dec. 8, 2003), 2003 FTC LEXIS 187, vacated, 402 F.3d 1056 (11th Cir. 2005)).
- 53 *Id.*

- 54 *Id.*
- 55 *Id.*
- 56 *Id.* 466 F3d. at 211 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d at 514, 534 (E.D.N.Y. 2005).
- 57 *Id.* at 212.
- 58 21 U.S.C. 355(j)(2)(B)(iv).
- 59 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(BB).
- 60 *E.g.* First Amended Complaint at 15-16, *Federal Trade Commission v. Cephalon, Inc.*, No. 2:08-cv-02141-MSG (filed August 12, 2009); *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection, 111th Congress* (statement of Barry Sherman, CEO of Apotex Inc., at 3-4).
- 61 See *generally*, Letter from Gary Buehler to Carmen M. Shepherd and Kate C. Beardsley, No. 2007N-0382 (January 29, 2009) Denial of Citizen Petition, *Rampiril Capsules and the 180-day exclusivity*.
- 62 For this view, see Testimony of Barry Sherman, *supra* note 59. Others have argued that a settlement with a delayed entry date and retain its exclusivity may function just like a payment. See Hemphill, *supra* note 15, at 651-653. Obviously eliminating the 180-day exclusivity for such settling first filers would eliminate that form of compensation.
- 63 See Reiffen & Ward, *supra* note 1124, at 48, Table 4. Of the 31 products they examined, 20 had less than 10 approved ANDAs. Even for the former blockbuster Zocor, only 11 companies have received ANDAs. See *Approved Drug Products with Therapeutic Equivalence Evaluations*, <http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm>.
- 64 See *supra* notes 59-63.
- 65 Richard G. Frank & David Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. AND MGMT. STR. 75, 89 (1997).
- 66 *Id.*
- 67 Revenues are not the same as profits, but here they work as a reasonable estimate as to the overall impact of entry on generic profits. See *Authorized Generics: An Interim Report, An FTC Study* at 11 n. 14 (2009).
- 68 The numbers are illustrative only. The price discounts are consistent with Frank & Salkever's findings but not Reiffen's. Compare Frank and Salkever, *supra* note 64, at 84 (Figure 2) with Reiffen & Ward, *supra* note 12, at 44. In most cases, even a first filer will only face competition 180 days after it launches.