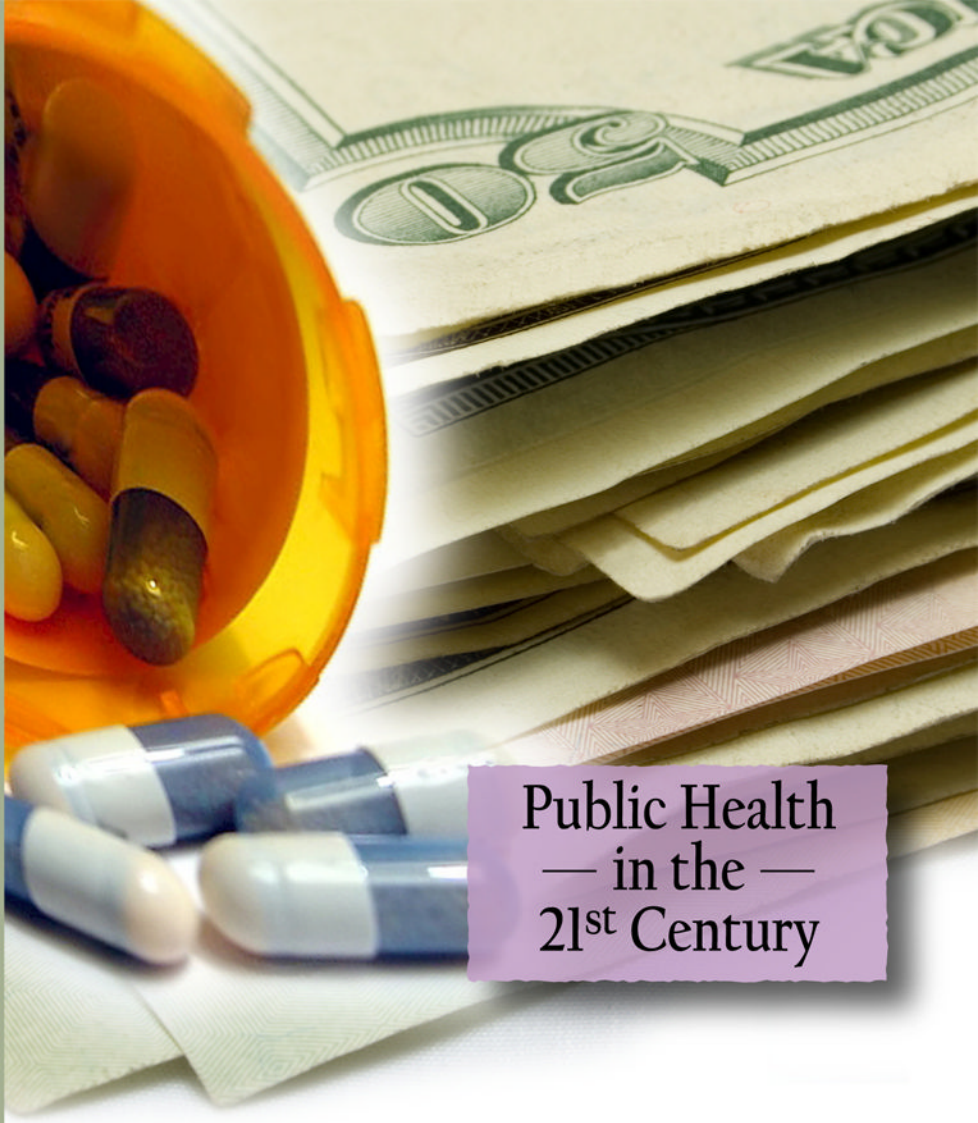

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21st Century

Generic Drugs

The Pay-for-Delay Problem

Christina M. Curtin
Editor

NOVA

PUBLIC HEALTH IN THE 21ST CENTURY

GENERIC DRUGS: THE PAY-FOR-DELAY PROBLEM

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PREFACE

Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time. These so-called "pay-for-delay" agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies. "Pay-for-delay" agreements are "win-win" for the companies: brand name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month, might be sold as a generic for as little as $30 per month. This book examines the "pay-for-delay' program and how drug company pay-offs cost consumers billions.

Chapter 1- Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time. These so-called “pay-for-delay” agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies.

“Pay-for-delay” agreements are “win-win” for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand’s monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month might be sold as a generic for as little as $30 per month.

Chapter 2- Many thanks to the Center for American Progress for hosting this exceedingly timely event. Your outstanding work has helped focus

attention and inform public policy on a number of critical issues facing our nation, including health care reform. Ensuring access to affordable medicines is an essential part of this debate—so I appreciate the opportunity to be here today.

Getting health care costs under control is a daunting challenge. But one simple step could save consumers and the federal government billions of dollars annually: stopping pharmaceutical companies from colluding with their competitors to keep low-cost generic drugs off the market. At the FTC, we call these deals "pay-for-delay" settlements. (You may also hear them referred to as "exclusion payments" or "reverse payments.")

Chapter 3- Chairman Johnson, Ranking Member Coble, and members of the Subcommittee, I am Richard A. Feinstein, Director of the Federal Trade Commission's Bureau of Competition. I appreciate the opportunity to appear before you today to testify on behalf of the Commission about the need for legislation to prevent anticompetitive agreements between branded and generic drug firms that delay consumer access to generic drugs.[1] And the Commission appreciates the Subcommittee's attention to this issue of great importance not only to consumers but also to the federal and state governments, which spend substantial sums on prescription drugs. Since this issue first arose in 1998, every single member of the Commission, past and present, – whether Democrat, Republican, or Independent – has supported the Commission's challenges to anticompetitive "pay-for-delay" deals.

Chapter 4- Thank you Chairman Johnson, ranking Member Coble, and members of the Judiciary Subcommittee on Courts and Competition Policy. In particular, thank you Chairman Conyers for inviting us to attend today. My name is Heather Bresch, and I am the Chief Operating Officer of Mylan Inc. For nearly 50 years, Mylan has built a legacy of manufacturing high quality, affordable pharmaceuticals. We are the largest U.S.-based generic pharmaceutical manufacturer and the third largest generics and specialty pharmaceutical company in the world. One out of every 13 prescriptions dispensed in the U.S. – brand name or generic – is a Mylan product. Additionally, Mylan has consistently been recognized by the FDA and by the pharmacy community for excellence in quality and service.

Chapter 5- Chairman Johnson, Ranking Member Coble, and Members of the Subcommittee, good morning. My name is Bret Dickey and I am a Senior Vice President with Compass Lexecon, an economic consulting firm specializing in competition policy. I appreciate the opportunity to testify today.

Since receiving my Ph.D. in Economics from Stanford University, I have spent the last 10 years analyzing the economics of competition policy, with a

particular focus on the pharmaceutical industry. During that period I have analyzed the competitive effects of several patent settlement agreements between branded and generic manufacturers.[1] Recently, I co-authored a paper with Laura Tyson, the former chair of President Clinton's National Economic Counsel, and Jonathan Orszag, a colleague at Compass Lexecon and a former advisor to President Clinton, that presents an economic framework for evaluating such settlements.[2] Our paper demonstrates that patent settlements between branded and generic manufacturers, even settlements involving "reverse payments," can be procompetitive.

Chapter 6- Mr. Chairman and Members of the Subcommittee, my name is Guy Donatiello and I am the Vice President for Intellectual Property for Endo Pharmaceuticals Inc. I am a patent attorney and have worked exclusively in the intellectual property field for more than twenty years.

Endo is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of branded and generic prescription medicines in pain management, urology, endocrinology, and oncology. Endo is based in Chadds Ford, Pennsylvania and employs nearly 1,500 people throughout the United States.

Endo is a mid-sized company with $1.2 billion in sales in 2008. We are a member of PhRMA, our trade group that represents the country's leading research-based pharmaceutical and biotechnology companies which as an industry invested over $50 billion in research and development in 2008. In addition, Endo is a member of America's Specialty Medicines Companies, an informal working group of mid-sized pharmaceutical companies.

Chapter 7- Nephron Pharmaceuticals Corporation ("Nephron"), a family owned pharmaceutical manufacturing and sales company, has grown rapidly since it was purchased in 1991. Nephron utilizes state of the art Blow-Fill-Seal technology to manufacture sterile generic respiratory medications. Only four such facilities currently exist in the US. In spite of today's volatile economic times, Nephron is undergoing a 35 million dollar expansion to upgrade automation and technology at its Orlando, Florida manufacturing facility. Already a large employer, the company is adding specialized engineers and scientists to support its efforts to double manufacturing capacity of their life saving generic respiratory medications.

Chapter 8- Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of *Consumer Reports*.[1] Consumers Union investigates and reports extensively on the issues surrounding the costs, safety,

and effectiveness of prescription drugs and other health products so that we can provide physicians and consumers with expert, non-biased information.

Attachment #1 describes our Best Buy Drugs program. This is a major campaign by Consumers Union to use comparative effectiveness research to provide free, unbiased information to doctors and patients on the safest, most effective *brand and generic drugs*, and then to make a best buy recommendation. These recommendations can save consumers thousands of dollars a year.

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Chapter 1

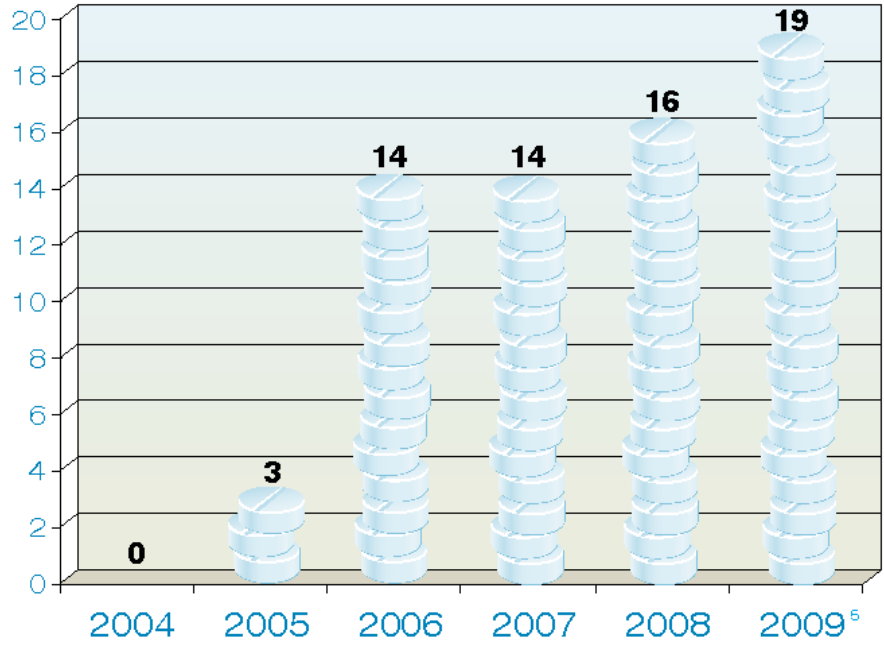
PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS

Federal Trade Commission

SUMMARY

- Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time. These so-called "pay-for-delay" agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies.
- "Pay-for-delay" agreements are "win-win" for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month might be sold as a generic for as little as $30 per month.
- The Federal Trade Commission's (FTC) investigations and enforcement actions against pay-for-delay agreements deterred their use from April 1999 through 2004.[1] In 2003, an appellate court held that such agreements were automatically (or *per se*) illegal.[2]

- Since 2005, however, a few appellate courts have misapplied the antitrust law to uphold these agreements.[3] Following those court decisions, patent settlements that combine restrictions on generic entry with compensation from the brand to the generic have re-emerged.
- Agreements with compensation from the brand to the generic on average prohibit generic entry for nearly 17 months longer than agreements without payments, where the average is calculated using a weighted average based on sales of the drugs.[6] Most of these agreements are still in effect. They currently protect at least $20 billion in sales of brand-name pharmaceuticals from generic competition.[7]
- Pay-for-delay agreements are estimated to cost American consumers $3.5 billion per year – $35 billion over the next 10 years.[8]



Agreements with Delay and Compensation[4]

RECOMMENDATION

Pay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices. The Commission has recommended that Congress should pass legislation to protect consumers from such anticompetitive agreements.

BACKGROUND

Pay-for-delay agreements appear in some settlements of patent litigation between brand-name and generic pharmaceutical companies. That patent litigation usually takes place within the framework for generic entry established by the Hatch-Waxman Act.[9] Under that Act, a generic competitor may seek entry prior to expiration of the patents on a brand-name drug. Generic drug entry before patent expiration can save consumers billions of dollars. Generics have an incentive to challenge brand patents because the first generic to file its application can obtain 180 days of marketing exclusivity during which it is the only generic on the market. To seek FDA approval for entry before patent expiration, a generic must declare that its product does not infringe the relevant patents or that the relevant patents are invalid.

Typically, brand-name pharmaceutical companies challenge the generic's declaration, and litigation ensues between the brand-name and generic pharmaceutical manufacturers to determine whether the relevant patents are valid and infringed. For the brand to prevail and block entry, it must successfully defend the validity of its patents and demonstrate that the generic's product would infringe those patents. In 2002, the FTC issued a study showing that generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002.[10]

Given the costs and potential uncertainty of patent litigation, brand-name and generic pharmaceutical companies sometimes settle their patent litigation before a final court decision. For example, the parties may agree that the generic can enter at some time before the patent's expiration date, but not as soon as the generic seeks through its litigation. Absent compensation to the generic for the delay in its entry, such settlement agreements are unlikely to raise antitrust issues.

The FTC's 2002 study determined, however, that some brand-name and generic pharmaceutical companies had settled their patent litigation through

agreements that compensated generics for substantial delays in generic entry. The FTC recommended that Congress pass legislation to require pharmaceutical companies to file certain agreements with the FTC. The intent of the legislation was "to put an end to this exploitation of the provision in Hatch-Waxman that grants a short-term protection from competition to the first manufacturer to bring a generic version of a brand name drug to market."[11]

Congress acted on the FTC's recommendation. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), pharmaceutical companies must file certain agreements with the FTC and the Department of Justice within ten days of their execution.[12]

FINDINGS FROM PHARMACEUTICAL AGREEMENT FILINGS FROM FY2004 THROUGH FY2009

- **How Many Final Agreements Have Involved Compensation from the Brand to the Generic Combined with Restrictions on Generic Entry?**
  From FY2004-FY2009, 66 final agreements involved some form of compensation from the brand to the generic combined with a delay in generic entry.
- **Can Pharmaceutical Companies Settle Patent Litigation without Pay-for-Delay Agreements?**
  Yes. From FY2004-FY2009, pharmaceutical companies filed a total of **218 final settlement agreements** involving brand and generic companies. **Seventy percent of those patent settlements – 152 – did not involve compensation from the brand to the generic combined with a delay in generic entry**. This large number of settlements not involving compensation from the brand to the generic undermines brand and generic firms' arguments that compensation is the only way to settle patent litigation. In fact, there are a variety of ways to settle litigation that do not involve these payments.
- **Do Agreements with Compensation from the Brand to the Generic Postpone Generic Entry Significantly Longer than Other Patent Settlement Agreements?**
  Yes. Staff analysis of patent settlements restricting generic entry finds that agreements with compensation on average prohibit generic entry

for nearly **17 months** longer than agreements without payments, where the average is calculated using a weighted average based on sales of the drugs.[13] This difference in time to entry is very unlikely to be caused by random variation in the agreements. In fact, there is less than a 1% chance that this large a difference in average time to entry would be observed if the amount of delay from the two types of agreements were drawn from the same statistical distribution.

A hypothetical consumer paying $300 per month for a brand-name drug, instead of a generic price as low as $30 per month, could pay as much as $270 per month more for prescription drugs. Over a 17-month period, this could total additional expenses of $4,590 resulting from the extra delay that occurs, on average and weighted for sales.

- **Is the First Generic to Seek Entry Prior to Patent Expiration Involved in Most of the Potential Pay-for-Delay Settlements?**

  Yes. Out of the 66 agreements that combined compensation from the brand to the generic with deferred generic entry**, 51 agreements** (77%) were between the brand pharmaceutical company and the generic company that was the first to seek entry prior to patent expiration for the relevant brand-name drug.

  Settlements with first-filer generics can prevent *all* generic entry. Those agreements place a "cork in the bottle" that typically ensures the brand-name drug's lock on the market. This cork-in-the-bottle effect occurs because every subsequent generic entrant has to wait until the first generic has been marketed for 180 days. [14]

- **Do All Pay-for-Delay Agreements Involve Dollar Payments from the Brand to the Generic?**

  No. Brand-name pharmaceutical companies have found a wide variety of techniques through which to compensate generic companies for delaying their entry.

  Recently, brand-name pharmaceutical companies have sometimes compensated generics by agreeing not to compete through a so-called "authorized generic." Under the Hatch-Waxman Act, the generic that is first to file its approval application can be entitled to market its generic product for 180 days with no competition from other generics.[15] This rule, however, does not protect the first-filer generic from competition from an "authorized generic" or "AG" during those 180 days.

AGs are brand-name pharmaceutical products marketed as generics. AG competition can substantially reduce the revenues a first-filer generic earns during its 180 days of marketing exclusivity.[16]

About 25% of patent settlement agreements from FY2004-FY2008 that were with first-filer generics involved an explicit agreement by the brand not to launch an AG to compete against the first filer, combined with an agreement by the first-filer generic to defer entry past the date of the agreement.[17] In effect, by agreeing not to launch an AG, the brand agrees not to subtract from the generic's profits during the 180-day period.

- **Has the FTC Given Up Litigating Pay-for-Delay Cases under the Antitrust Laws?**

  No. The FTC has multiple investigations underway and currently is litigating two cases in the trial courts.[18] Over the past nine years, the FTC has invested substantial resources in investigating and, when necessary, litigating cases involving patent settlements in which brand-name pharmaceutical companies allegedly paid generic companies to stay off the market, thus depriving consumers of millions of dollars in cost savings that would otherwise have been available.[19]

  Given the magnitude of consumer harm from pay-for-delay settlements – an estimated $35 billion over the next ten years – a legislative solution offers the quickest and clearest way to deter these agreements and obtain the benefits of generic competition for consumers.

STUDY METHODOLOGY

This study was prepared by staff from the FTC's Bureau of Competition, Bureau of Economics, and Office of Policy Planning.

This study is based on patent settlement agreements filed with the FTC between January 1, 2004 and September 30, 2009 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, codified in relevant part at 42 U.S.C. § 1395w-101 note (section 110), 21 U.S.C. § 355 note (sections 1111-1118), 21 U.S.C. § 355(j)(5) (section 1102).

Staff identified agreements in which restrictions on generic entry were combined with compensation from the brand to the generic. The FTC has challenged some of these agreements as violating the antitrust laws, but the agency lacks sufficient resources to investigate and litigate the legality of all of these agreements.

How Staff Calculated the Additional Delay in Generic Entry Associated with Agreements that Involved Compensation from the Brand to the Generic

To calculate how long (on average and weighted for sales) generic entry was delayed as a result of compensation from brand-name pharmaceutical companies to generic drug companies, staff compared agreements with and without compensation to the generic in terms of the sales-weighted average time between the date of the agreement's execution and the date of generic entry.

To avoid double counting multiple settlements on the same drug, only the settlement that establishes the earliest date for generic entry was used in this calculation.

To better reflect the amount of consumer savings held up by the delay, staff used weighted averages of sales.

This calculation established that, on average and weighted for sales, agreements with compensation from the brand to the generic delayed generic entry for nearly 17 months longer than agreements without compensation. Staff determined that the 17 month difference in time until generic entry was statistically significant at the 99% confidence level. Thus, this difference in time to entry is very unlikely to be caused by random variation in the agreements. In fact, there is less than a 1% chance that this large a difference in average time to entry would be observed if the amount of delay from the two types of agreements were drawn from the same statistical distribution.

How Staff Calculated the Estimate of $3.5 Billion Annually that Consumers Lose due to Pay-For-Delay Agreements

The calculation below is a method of estimating the likely harm to consumers from the loss of competition when patent settlements delay generic

entry.[20] The analysis estimates that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from eliminating "reverse-payment" settlements would be approximately $3.5 billion.

This calculation requires four factors:

1. the consumer savings that result from generic competition in any given month,
2. the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation,
3. the length of entry delay resulting from such settlement, and
4. the combined sales volume of drugs for which settlements are likely.

(1) Consumer savings from generic competition

When generic entry occurs, purchasers immediately begin to benefit from the savings associated with lower generic drug prices. Following an initial entry period, the generic market matures and consumers receive the full savings from generic competition. Thus, any delay in entry results in a longer period of purchases at the full brand price and correspondingly fewer purchases at the mature competitive prices.[21] This means that the costs to consumers (or what they would have saved but for the entry delay) are equal to the monthly savings from the mature generic market multiplied by the number of months of delay.

Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant comes on the market. The generic penetration rate at that point is about 90% on average, i.e. pharmacists fill 90 of every 100 prescriptions for the molecule with an AB-rated (or bioequivalent) generic. Recent information also shows that in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price.[22]

Using the above figures and assumptions, the average consumer savings from a mature generic market relative to pre-generic levels are approximately 77% (85% savings multiplied by 90% of market demand). If purchasers discount future savings at the same rate as they expect drug prices and quantities to increase, then all future savings can be expressed in terms of today's dollars without complicated net present value calculations. Thus, the costs of delay are the average discount (77%) times the length of the delay times the pre-generic entry revenues of the branded drugs that will reach a settlement with delay.

(2) Likelihood of Settlements with Payment to Delay, and the Length of Delay

It is more difficult accurately to estimate how much delay is likely to result from settlements that have not yet been reached, especially because future legislative or judicial actions could alter the types of settlements that are likely. Therefore, the calculation assumes that recent settlements provide the best information about what may happen in the future. Data on settlements reported to the FTC from FY2004 to FY2008 show that of all patent settlements resulting from a Paragraph IV (invalidity or non-infringement) challenge, approximately 24% included both restrictions on timing of generic entry and a payment to the generic firm.

The additional length of the delay that is attributed to the payments in these settlements can be calculated by taking the universe of Paragraph IV settlements that have restrictions on entry, then comparing the average number of months between the execution of the agreement and the date of generic entry in agreements with and without payments to the generic entrant. Agreements with payments on average allow entry nearly 17 months (1.42 years) later than agreements without payments.

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.

(3) Sales Volume of Drugs for which Settlements are Likely

Staff relied on recent history as a guide to the settlements likely to be seen in the future. The analysis starts with the FDA's list of all drugs that have received a Paragraph IV filing.[23] It then uses information from the FDA's Orange Book, IMS NPA retail sales data, and the settlement filings to determine whether there had been a generic version of a challenged drug launched before 2004. If a generic had entered, it was removed from the list of drugs that could have settled between FY2004 and FY2008. The analysis next uses the IMS data to determine the total dollar sales associated with those drugs remaining in the sample for each year. It adjusts these annual totals by removing drugs that reached a settlement or experienced generic entry due to a non- settlement event such as a court victory or patent expiration.

By the end of FY2008, the above method estimates that there were $90 billion of branded drug sales still facing a Paragraph IV challenge. Since the IMS data used does not cover all purchasing channels and excludes injectable

drugs, $90 billion is a conservative estimate of the total branded dollars affected by possible settlements.

The next step is to look at the number of settlements per year as a percentage of all Paragraph IV-challenged drugs that could possibly settle. Over the FY2004 to FY2008 time period, the percentage of drugs that settled per year (not including injectables) increased from 7 percent to 18 percent, with most of the increase following the Eleventh Circuit's *Schering* decision. Since this post-*Schering* era is probably a better reflection of likely future settlement patterns, it seems appropriate and conservative to use the 15 percent per year average from this period in the estimate calculations.

Multiplying $90 billion by 15 percent yields $13.5 billion in drug purchases that are predicted to be affected by settlements each year. Multiplying this $13.5 billion total by 24 percent (an assumption based on the percentage of past settlements with payment and delayed entry), leads to a prediction of $3.2 billion in drug sales that will be affected by reverse payment settlements in a given year.

(4) Final Estimate Calculation

The final steps in calculating the savings to be gained by eliminating pay-for-delay settlements are to factor in the discount consumers would receive from matured generic entry and the length of delay. From the 77 percent savings and 1.42 year delay figures above, the calculation is therefore:

77% savings
x $3.2 billion (15% per year settling)
x 1.42 years (median delay)
$3.5 billion of annual purchaser savings

In sum, the calculation yields a conservative estimate of $3.5 billion per year of potential savings from eliminating pay-for-delay settlements.

Results with Varied Assumptions

The $3.5 billion figure represents staff's best estimate of the effect based on what staff believes to be the most reasonable assumptions. Nonetheless, this estimate is sensitive to changes in the assumptions.[24] Reasonable estimates about the length of delay and the sales of drugs likely to be affected by the legislation can vary. The calculations below present high and low estimates of savings derived from the data ranges.

77% savings
x $3.9 billion (18% per year settling)
x 2.5 years (high of interquartile distribution of delay)
$7.5 billion of annual purchaser savings

77% savings
x $1.5 billion (7% per year settling)
x 0.5 years (low of interquartile distribution of delay)
$0.6 billion of annual purchaser savings

End Notes

[1] *See Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Exec. Summary at viii (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. This study covered the period through June 2002. The FTC began receiving patent settlement agreements in January 2004 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Although there is a gap between July 2002 and December 2003, we are unaware that brand and generic firms entered into any pay-for-delay settlement agreements during this time period.

[2] *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[3] *See Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005); *see also In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008). But *see Brief For the United States In Response To the Court's Invitation*, In re Ciprofloxacin Hydrochloride Antitrust Litigation, No. 05-cv-2851(L) (2d Cir. July 6, 2009), available at http://www.justice.gov/atr/cases/f247700/247708.htm.

[4] These agreements were filed with the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part 42 U.S.C. § 1395w-101 (2009) note (section 110), 21 U.S.C. § 355 (2009) note (sections 1111-1118), 21 U.S.C. § 355(j)(5) (2009) (section 1102)). All of these agreements involved patent settlements that combined restrictions on generic entry with compensation from the brand to the generic. The FTC has challenged some of these agreements as violating the antitrust laws, but the agency lacks sufficient resources to investigate and litigate the legality of all of the agreements represented in this chart.

[5] These years represent fiscal years.

[6] The 17-month delay attributed to payments was calculated by comparing the sales-weighted average time between the date of the agreement's execution and the date of generic entry for agreements with and without compensation to the generic.

[7] This dollar amount represents the prior-year total sales of the brand-name pharmaceuticals that are currently covered by agreements with delay and compensation and thus indicates the order of magnitude of brand-name pharmaceutical sales for which generic competition (with lower prices) has likely been delayed.

[8] See Jon Leibowitz, Chairman, Fed. Trade Comm'n, "*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) at 8

(June 23, 2009), available at *http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.*

[9] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (2009)) governs how generics may enter the marketplace to compete with brand-name pharmaceuticals.

[10] See *supra note* 1.

[11] See S. Rep. No. 107-147 at 4 (2002).

[12] See Pharmaceutical Agreement Filing Requirements, available athttp://www.ftc.gov/os/2004/01/04106pharmrules.pdf.

[13] The delay attributed to payments was calculated by comparing the sales-weighted average time between the date of the agreement's execution and the date of generic entry for agreements with and without compensation to the generic. The distribution of annual sales figures for drugs covered by these pay-for-delay agreements is not discernibly different from the distribution of annual sales figures for drugs covered by agreements that restrict generic entry with no payment to the generic.

[14] Later-filing generics cannot enter the market until they win their own patent litigation at the court of appeals level and the first filer generic either markets its product for 180 days or forfeits its right to do so. 21 U.S.C. § 355(j)(5)(D) (2009) (forfeiture provisions).

[15] There may be more than one "first-filer" if more than one generic firm files its application on the same, "first" day.

[16] *Authorized Generics: An Interim Report*, Fed. Trade Comm'n at 3 (June 2009); available at http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[17] *Id*.

[18] *See Fed. Trade Comm'n v. Cephalon*, No. 08-cv-2141-RBS (E.D. Pa. May 8, 2008) (transfer order); *Fed. Trade Comm'n v. Watson*, No. 09-cv-00598 (N.D. GA Feb. 9, 2009) (transfer order).

[19] *See In re Hoechst Marion Roussel Inc., Carderm Capital L.P. and Andrx Corp.*; 131 F.T.C. 927 (2001) (consent order); *In re Abbott Laboratories and Geneva Pharmaceuticals*, Inc., C-3945, C-3946 (consent orders issued May 22, 2000); In re Schering-Plough Corp., et al, D. 9297, *Initial Decision issued June 27, 2003; rev'd by Commission Decision and Order*, December 8, 2003(136. F.T.C. 956 (2003)); rev'd 402 F.3d 1056 (11th Cir. 2005); *In re Bristol-Myers Squibb*, 135 F.T.C. 444 (2003) (consent order); *Fed. Trade Comm'n v. Cephalon*, No. 08-cv-2141-RBS (E.D. Pa. May 8, 2008) (transfer order); Fed. Trade Comm'n v. Watson, No. 09-cv-00598 (N.D. GA Feb. 9 2009) (transfer order).

[20] This calculation first appeared as an Appendix to Chairman Leibowitz's speech. *See supra note* 8.

[21] If one assumes some future end-point in the drug's life on the market, delayed entry means that, by that end-point, consumers will have had less time buying in the mature competitive market.

[22] The calculation assumes that the total demand for the drug/molecule (market size in unit sales) remains the same after generic entry occurs. It also assumes that the brand's price stays the same after generic entry occurs. Data show that branded prices often rise following generic entry, but there are also instances when brand price declines. Assuming the price stays the same simplifies the analysis.

[23] This is based on a version downloaded from the FDA's website on May 19, 2009.

[24] In addition, a possible effect in the other direction could arise if a future legislative or judicial action made pay-for-delay agreements illegal. To the extent that such an action would reduce generic firms' incentives to file Paragraph IV challenges, it could reduce the sales volume of drugs facing such challenges. Any such deterrent effect would likely be very low, however. As noted above, only 24% of all cases settled with both payment and delay, so presumably generic drug firms do not assume that they will be able to settle their patent litigation through compensation for deferred generic entry. Moreover, a generic would still have a strong incentive to challenge a weak patent in a large market.

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Chapter 2

"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)

Jon Leibowitz

Many thanks to the Center for American Progress for hosting this exceedingly timely event. Your outstanding work has helped focus attention and inform public policy on a number of critical issues facing our nation, including health care reform. Ensuring access to affordable medicines is an essential part of this debate—so I appreciate the opportunity to be here today.

Getting health care costs under control is a daunting challenge. But one simple step could save consumers and the federal government billions of dollars annually: stopping pharmaceutical companies from colluding with their competitors to keep low-cost generic drugs off the market. At the FTC, we call these deals "pay-for-delay" settlements. (You may also hear them referred to as "exclusion payments" or "reverse payments.")

No matter what you call them, eliminating these deals is one of the Federal Trade Commission's highest priorities. And as Congress moves

forward on health care reform, momentum to prohibit these agreements appears to be growing: just recently a House bill was passed out of subcommittee; its bipartisan Senate version is poised to be marked up as early as Thursday.

This morning I want to discuss how the Hatch-Waxman Act has been distorted to spawn these anticompetitive arrangements. Then I'll talk about the FTC's new empirical study (the first of its type) which shows that American consumers would save $35 billion dollars over the next decade if these deals were banned. Because the federal government pays for about a third of the nation's prescription drug bill, this means about $12 billion in savings to federal programs. (Even in 2009, that is real money.)

But let me begin with a story recently in the news. Some of you may have read about U.S. District Judge Ricardo Urbina handing down an unusual sentence - ordering former Bristol-Myers Squibb senior vice-president Andrew Bodner to write a book about how he came to be convicted of lying to the FTC. Bristol-Myers was the subject of an FTC order stemming from charges that, among other things, it had paid a competitor to drop a patent challenge. So when it decided to settle a patent case with a company planning to sell a generic version of Plavix—no, that's not a Roman general, it's a blockbuster blood thinner used to prevent heart attacks and strokes, with annual U.S. sales of more than $6 billion—Bristol Myers had a problem. Based on the earlier decree, it had to submit its proposed settlement to the FTC for approval. In an attempt to evade FTC review, Bristol-Myers lied about a secret deal, in which it agreed to provide substantial payments to a generic competitor to stay out of the market.

Both Dr. Bodner and his former employer subsequently pleaded guilty to criminal charges of making false statements. The company paid the maximum fine. Dr. Bodner was also fined and was ordered to write a book about the case, presumably to discourage other drug company executives from lying to the federal government.

The sad truth is, however, that if Bristol-Myers weren't under a previous order it probably could have gotten away with it. The cost of doing business this way would have been passed along to American consumers.

How did we get to this point?

A BRIEF HISTORY

Let me start with a brief history.

More than two decades ago, Congress passed a landmark law, the Hatch-Waxman Act, to make it easier for generic drugs to enter the market, while giving brand-name manufacturers the patent protection they needed to encourage the lifesaving research that is the hallmark of America's pharmaceutical industry. One of the critical steps was to set up a process that encourages generic drug firms to challenge weak branded drug patents—those that are likely invalid or not infringed.

For a time the legislation worked. Generic manufacturers brought patent challenges and, when the parties did not reach a settlement based on the strength of their claims, generic firms won often—getting victories for over two-thirds of the challenged branded drugs, according to a 2002 FTC study. The result was significantly lower prices for patients. The law truly spurred competition.

Now, as most of you already know, when multiple generics are on the market, the price for the generic version can drop more than 90 percent below the price of the branded product, which means enormous savings for Americans. For example, you can go to the pharmacy and get a month's supply of the generic version of the anti-ulcer drug Zantac for $3, instead of paying $111 for the brand-name product. You can spend $12 a month to lower your cholesterol with generic Zocor, instead of $164 for the brand-name version.

Those of us with the good fortune to have health insurance don't see these cost differences directly because we only pay the difference between the brand and the generic copay -- the rest of the additional cost is hidden in our health insurance premium. But if you are one of the 46 million uninsured in this country with high cholesterol and need Zocor, it's an entirely different story—this can mean saving more than $1800 a year. And it's not just a matter of economics: high prescription drug prices often cause patients to cut their pills in half or skip needed medications altogether.

So we had a good policy, and a law that implemented that policy effectively. But, unfortunately, drug companies have derailed that law by entering pay-for-delay deals.

The vastly cheaper prices and lower profit margins of generics create powerful incentives for both the brand and generic manufacturers to agree to avoid competition. So if it is legal for a brand to pay the generic to "sit it out," why wouldn't it? And if a generic drug company is allowed to make more

money by not competing than by going to market, isn't that a good business deal for the company and its shareholders?

Of course it is. Clearly, these are win-win deals for both companies. But they leave American consumers footing the bill.

That is why the Commission has made stopping these deals a top priority. Initially, under the leadership of both Democrat Bob Pitofsky and Republican Tim Muris, when the Commission found drug companies engaging in pay-for-delay settlements, we stopped them cold.

But unfortunately, since 2005, several circuit courts have mistakenly blessed these anticompetitive settlements. Essentially, these decisions conclude that because the brand's patent might block the generic's product, a brand can pay to eliminate the possibility of competition until its patent expires. This approach is at odds with both market realities and established antitrust principles.

An industry investment analyst got it right when he said that these court decisions "opened a Pandora's box of settlements." Instead of competing to be first to come to market, generic companies compete to be first to get paid off.

Some in the industry are quite candid - at least privately - about the overriding financial incentives that drive these deals. Some are even candid in public. Take the CEO of Cephalon, a company that is the subject of a current FTC action. When announcing settlements with four generic drug makers that kept the generic versions of Provigil off the market until 2012 (in return for compensation of roughly $200 million collectively to the generics), he stated: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected*."[1]

The FTC is continuing to bring cases to protect consumers from these anticompetitive settlements, and we hope the trend in courts will change. But waiting for a potential judicial solution is a time consuming and expensive prescription, so the agency strongly supports legislation to eliminate pay-for-delay deals.

Now, the lobbying strength of the pharmaceutical industry is legendary; according to the Center for Responsive Politics, the industry has 1325 registered lobbyists, and that is only in D.C. The industry is busy defending these arrangements but, to be blunt, their claims don't hold up.

To begin with, they claim Hatch-Waxman patent cases cannot be settled without paying a generic to delay entry. But that is contradicted by actual market experience: from 2000 through 2004, when the prospect of antitrust enforcement was deterring such settlements, companies continued to settle.

They simply picked a date based on the strength of their case without any exclusion payments.

Brand companies also claim that barring pay-for-delay settlements would mean less innovation. If anything, however, brand companies are most likely to pay-off a generic competitor when they have *not* innovated. As defenders of these settlements have conceded, the incentive to pay a generic to abandon its patent challenge is *greatest* for the *weakest* patents. As all of us know, competition rather than collusion fosters creativity. The Supreme Court has repeatedly observed that protecting weak patents slows rather than promotes innovation.[2]

For their part, some generic firms—and not all by the way —are saying that banning payfor-delay settlements will mean fewer patent challenges. I have seen no evidence to support that argument. In any event, if generics are filing patent challenges only to get a payoff, then those patent challenges are no longer serving consumers.

NEW FTC ANALYSIS OF EMPIRICAL DATA

Now, everyone knows what lobbyists say in the Halls of Congress sometimes has only a distant relationship with the reality of a situation. So let me share with you what these settlements are actually costing consumers and how much consumers and the federal government could save if Congress stopped them.

Savings to Consumers and the Federal Government

For years, a lot of us at the Commission have been frustrated by the lack of empirical studies on the effect of pay-for-delay settlements. We could point to the Generic Pharmaceutical Association's own estimate that early generic competition following successful challenges to just four products— Prozac, Zantac, Taxol, and Platinol—saved consumers more than $9 billion dollars. But the cost and growing prevalence of these deals call for more than anecdotes and back-of-the-envelope calculations.

More recently, Columbia University Professor Scott Hemphill analyzed 21 drug settlements involving reverse payments and estimated that, if entry was delayed just one year, the cost to consumers would be in the billions.[3] His

analysis was necessarily limited, however, because he did not have access to the entire universe of brand-generic settlements, the terms of which are often confidential. On the other hand, thanks to a law Congress enacted in 2003 that requires drug companies to file their Hatch-Waxman patent settlements with the FTC, *we do*.

Because the FTC is uniquely positioned to analyze these deals, it was the first thing I asked our new Bureau of Economics team to do. Not surprisingly, the dedicated economists at the FTC accepted the challenge.

Let me try to translate their methodology into layman's terms. Initially, they determined that currently 90 billion dollars of brand drug sales may face pre-patent expiration generic competition, depending on the outcome of current patent litigation. Based on the history of settlements from as early as 2004, *i.e.*, before the courts began to hand down decisions sanctioning these payments, the staff calculated that roughly 3.4 percent of cases settle each year with payments. On average, those settlements delay generic entry by 17 months more than settlements without payments. Based on a review of the economic literature and information obtained in FTC investigations, consumers save an estimated 85 percent compared to when only a brand is available. So the cost to consumers is 17 months savings.

These assumptions are quite conservative. For example, the estimate projects that the rate of settlements with payments as well as the average length of delay will remain the same. If the lenient court decisions stand, however, more and more companies will likely make these deals and agree to longer postponements. Moreover, we excluded injectable drugs—about a quarter of the market—because we did not have reliable sales data and because the post generic entry savings may be different for injectables than for tablets or capsules.

Even with conservative assumptions and limitations, eliminating these pay-for-delay settlements would still save consumers $35 billion over ten years—or about $3.5 billion per year. Conversely, that is the cost of failing to eliminate pay-for-delay patent settlements.

We know that the federal government alone pays about one third of the nation's $235 billion annual prescription drug bill. Based on that, savings to federal programs would be about $12 billion over 10 years. That is another conservative estimate because the government’s share of drug expenditures is projected to rise to 40 percent within a decade.

These numbers were based on pretty conservative assumptions. Perfectly reasonable alternative assumptions would lead you to $75 billion in savings

for American consumers, which would work out to $25 billion for federal programs over the next decade.

Naturally, these are estimates and the analytical work is ongoing.

ENCOURAGING SIGNS

So where are we now?

I see encouraging signs in the Administration, in the courts, and in Congress. As the evidence mounts, there appears to be growing recognition that pay-for-delay deals should be stopped.

The New Administration: The arrival of a new Administration determined to make health care more available and affordable to all Americans has created momentum for a national solution to stop reverse payments.

Don't take my word for it; ask President Obama. As a Senator he co-sponsored the KohlGrassley bill to ban these anticompetitive settlements, and his February 2009 budget statement says barring "collusion between brand-name and generic drug manufacturers intended to keep generic drugs off the market" is one of the ways to achieve savings to help pay for health care reform.[4] The new Assistant Attorney General for Antitrust, Christine Varney, has testified that she supports efforts to stop these anticompetitive deals.[5]

The Courts: In the courts, as many of you know, there has been a dramatic split. The Sixth Circuit says these deals are *per se* illegal, while other appellate courts have come close to rules of *per se* legality. Even with the decision by the Supreme Court yesterday not to take *cert.* in *Cipro*, the good news is that things may be changing. The Court of Appeals for the Second Circuit originally issued a 2-1 decision in the *Tamoxifen* case with a very permissive standard— one that essentially says you can pay your competitor to stay out of the market until your patent expires. Now, however, it has done something extremely rare. It has questioned one of its own precedents, recently asking the new Solicitor General to propose a new standard. I am cautiously optimistic that the court's invitation may foreshadow a shift in the law.

The Congress: Perhaps most importantly, support is building in Congress for a solution. Earlier this month, in a critical vote, a House Energy and Commerce subcommittee by a vote of 16 to 10 approved legislation that would

establish a clear, bright-line standard to prohibit payfor-delay patent settlements.[6] Just as important, the Subcommittee rejected a variety of industry- supported amendments that would have weakened the bill to such an extent that the only "protection" for consumers left would have been in the bill's title: the Protecting Consumer Access to Generic Drugs Act of 2009.

The Senate Judiciary Committee is poised to report out similar legislation as early as Thursday.

LOOKING FORWARD

As all of you recognize, fixing our broken health care system is an enormously complicated task. Should we have a government plan? How should we finance the program? Who should be insured? Each decision has complex ramifications.

From my perspective, though, the decision about whether to restrict pay-for-delay settlements should be simple. On the one hand, you have savings to American consumers of $35 billion or more over ten years— about $12 billion of which would be savings to the federal government—and the prospect of helping to pay for health care reform as well as the ability to set a clear national standard to stop anticompetitive conduct. On the other hand, you have a permissive legal regime that allows competitors to make collusive deals on the backs of consumers.

Enacting legislation is always an uphill battle, but under these circumstances, I like our odds.

Thank you.

APPENDIX: CALCULATION OF CONSUMER SAVINGS

This appendix describes a calculation of the potential savings from a prohibition on exclusion payments. The calculation below is a method of estimating the likely harm to consumers from the loss of competition when patent settlements delay generic entry. This calculation requires four factors: (1) the consumer savings that result from generic competition in any given month, (2) the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation, (3) the length of entry delay resulting from such settlement, and

(4) the combined sales volume of drugs for which settlements are likely. The analysis estimates that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from a ban on "reverse-payment" settlements would be approximately $3.5 billion.

Consumer Savings from Generic Competition

When generic entry occurs, purchasers immediately begin to benefit from the savings associated with lower generic drug prices. Following an initial entry period, the generic market matures and consumers receive the full savings from generic competition. Thus, any delay in entry results in a longer period of purchases at the full brand price and correspondingly fewer purchases at the mature competitive prices.[7] This means that the costs to consumers (or what they would have saved but for the entry delay) are equal to the monthly savings from the mature generic market multiplied by the number of months of delay.

Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant comes on the market. The generic penetration rate at that point is recently about 90% on average, i.e. pharmacists fill 90 of every 100 prescriptions for the molecule with an AB rated generic. The data show that generics are heavily discounted: on average the mature generic price is 85% lower than the pre-entry branded drug price was.[8]

Using the above figures and assumptions, the average consumer savings from a mature generic market relative to pre-generic levels are approximately 77% (85% savings multiplied by 90% of market demand). If purchasers discount future savings at the same rate as they expect drug prices …… increase, then all future savings can be expressed in terms of today's dollars without complicated net present value calculations. Thus, the costs of delay are the average discount (77%) times the length of the delay times the pre-generic entry revenues of the branded drugs that will reach a settlement with delay.

Likelihood of Settlements with Payment to Delay, and the Length of Delay

It is more difficult accurately to estimate how much delay is likely to result from settlements that have not yet been reached, especially because future legislative or judicial decisions could alter the types of settlements that are likely. Therefore, the calculation assumes that recent settlements provide the best information about what may happen in the future. Data on settlements reported to the FTC from 2004 to 2008 show that of all patent settlements resulting from a Paragraph IV challenge, approximately 24% included both restrictions on timing of generic entry and a payment to the generic firm.

The …… length of the delay that s attributed to the payments n these settlements can be …….. taking the universe of Paragraph IV settlements that have restrictions on entry, then comparing the average number of months between the execution of the agreement and generic entry in agreements with and without payments to the generic entrant. Agreements with payments on average allow entry 17 months (1.42 years) later than agreements without payments.

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.

Sales Volume of Drugs for which Settlements are Likely

Determining the set of drugs for which pay-for-delay settlements are likely is also a challenge. Once again, one can rely on recent history as a guide to the settlements likely to be seen in the future. The analysis starts with the FDA's list of all drugs which have received a paragraph IV filing.[9] It then uses information from the FDA's Orange Book, IMS NPA retail sales data, and the settlement filings to determine whether there had been a generic version of a challenged drug launched before 2004. If a generic had entered, it was removed from the list of drugs that could have settled between 2004 and 2008. The analysis next uses the IMS data to determine the total dollar sales associated with those drugs remaining in the sample for each year. It adjusts these annual totals by removing drugs that reached a settlement or experienced

generic entry due to a non-settlement event such as a court victory or patent expiration.

By the end of 2008, the above method estimates that there were $90 billion of branded drug sales still facing a paragraph IV challenge. Since the IMS data used does not cover all purchasing channels and excludes injectable drugs, $90 billion is a conservative estimate of the total branded dollars affected by possible settlements.[10]

The next step is to look at the number of settlements per year as a percentage of all paragraph IV challenged drugs that could possibly settle. Over the 2004 to 2008 time period, the percentage of drugs that settled per year (not including injectables) increased from 7% to 18%, with most of the increase following the Eleventh Circuit's *Schering* decision. Since this post *Schering* era is probably is a better reflection of likely future settlement patterns, it seems appropriate and conservative to use the 15% per year average from this period in the estimate calculations.

Multiplying $90 billion by 15% yields $13.5 billion in drug purchases that are predicted to be affected by settlements each year. Multiplying this $13.5 billion total by 24% (an assumption based on the percentage of past settlements with payment and delayed entry), leads to a prediction of $3.2 billion in drug sales that will be affected by a ban on reverse payments in a given year.

Final Estimate Calculation

The final steps in calculating the savings to be gained by avoiding pay-for-delay settlements are to factor in the discount consumers would receive from matured generic entry and the length of delay. From the 77% savings and 1.42 year delay figures above, the calculation is therefore:

($3.2 billion) x (0.77) x (1.42) = $3.5 billion.

In sum, the calculation yields a conservative estimate of potential savings from a ban on pay for delay settlements of $3.5 billion per year.

Results with Varied Assumptions

The estimate above is sensitive to changes in the model's assumptions. Reasonable estimates about the length of delay and the sales of drugs likely to be affected by the legislation can vary. The table below presents high and low estimates of savings derived from the data ranges.

77% savings x **$1.5** billion (7% per year settling) x 0.5 years (low of interquartile distribution of delay) = **$0.6 billion of annual purchaser savings**	**77%** savings x **$3.9** billion (18% per year settling) x **2.5 years** (high of interquartile distribution of delay) = **$7.5 billion of annual purchaser savings**

End Notes

[1] John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

[2] *See, e.g., KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007) ("Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress.").

[3] Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, Hearing on H.R. 1706, "Protecting Consumer Access to Generic Drugs Act of 2009" (March 31, 2009) at 7, available at http://energycommerce.house.gov/Press 111/20090331/testimony hemphill.pdf.

[4] OMB, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010 (2009) (proposed), at 28, *available at http://www.whitehouse.gov /omb/assets/fy2010* new era/A New Era of Responsibility2.pdf.

[5] In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supports efforts to stop "reverse payments" and would work to "align" the positions of the Department of Justice and the FTC. *Executive Nominations: Hearing Before the S. Judiciary Comm.*, 111th Cong. 3 8-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

[6] Representatives Rush, Waxman, Dingell, Schakowsky, and others introduced the bill, titled "Protecting Consumer Access to Generic Drugs Act of 2009" (H.R. 1706).

[7] If one assumes some future end-point in the drug's life on the market, delayed entry means that by that end-point consumers will have had less time buying in the mature competitive market.

[8] The calculation assumes that the total demand for the drug/molecule (market size in unit sales) remains the same after generic entry occurs. It also assumes that the brand's price stays the same after generic entry occurs. Data show that branded prices often rise following generic

entry, but there are also instances when brand price declines. Assuming the price stays the same simplifies the analysis.

[9] This is based on a version downloaded from the FDA's website on May 19, 2009.

[10] While these effects understate the sales volume at issue, a possible effect in the other direction could arise if a future legislative or judicial action made reverse payments illegal. To the extent that such an action would reduce generic firms' incentives to file Paragraph IV challenges, it could reduce the sales volume of drugs facing such challenges. Any such deterrent effect would likely be very low, however. As noted above, only 24% of all cases settled with both payment and delay, and presumably there would be no effect outside those 24% of cases. Even within the 24%, it would be extreme to assume that the underlying Paragraph IV filing would not have occurred without the prospect of a settlement payment: those filings might well still have occurred and either not settled or settled without payment. In particular, a generic would still have a strong incentive to challenge a weak patent in a large market, so any deterred filings will tend to be in respect of stronger patents (where generic entry is unlikely or will be long delayed even at best) and/or in smaller markets, where all these effects are less important in dollar terms.

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Chapter 3

STATEMENT OF THE FEDERAL TRADE COMMISSION, BEFORE THE SUBCOMMITTEE ON COURTS AND COMPETITION POLICY, HEARING ON "ANTICOMPETITIVE PAY-FOR-DELAY SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: WHY CONSUMERS AND THE FEDERAL GOVERNMENT ARE PAYING TOO MUCH FOR PRESCRIPTION DRUGS"

Chairman Johnson, Ranking Member Coble, and members of the Subcommittee, I am Richard A. Feinstein, Director of the Federal Trade Commission's Bureau of Competition. I appreciate the opportunity to appear before you today to testify on behalf of the Commission about the need for legislation to prevent anticompetitive agreements between branded and generic drug firms that delay consumer access to generic drugs.[1] And the Commission appreciates the Subcommittee's attention to this issue of great importance not only to consumers but also to the federal and state governments, which spend substantial sums on prescription drugs. Since this issue first arose in 1998, every single member of the Commission, past and present, – whether Democrat, Republican, or Independent – has supported the Commission's challenges to anticompetitive "pay-for-delay" deals.

The threat that these agreements pose to our nation's health care system is a matter of pressing national concern. The enormous costs that result from unwarranted delays in generic entry burden consumers, employers, state and local governments, and federal programs already struggling to contain spiraling costs. Furthermore, these deals to delay generic entry will increase the cost of health care reform proposals that seek to extend coverage to the uninsured. Over twenty years ago, Congress passed the Hatch-Waxman Act,[2] which was designed to prevent weak patents from obstructing lower-cost, generic competition and has helped control the costs of prescription drugs. But pay-for-delay settlements of patent cases, which are unique to the Hatch-Waxman setting, threaten to extinguish that benefit. Therefore, congressional action to prohibit these costly and anticompetitive settlements is both appropriate and timely.

The FTC has sought to use antitrust enforcement to stop "pay-for-delay settlements" (also known as "exclusion payment" or "reverse payment" settlements). These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower- priced, generic drugs is delayed, sometimes for many years.

Agreements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason these pay-for-delay settlements should be prohibited under the antitrust laws. But since 2005, court decisions have taken a lenient approach to such agreements in drug patent settlements. As a result, it has become increasingly difficult to bring antitrust cases to stop pay-for-delay settlements, and such settlements have become a common industry strategy. As one investment analyst report put it, the courts' permissive approach to exclusion payments has "opened a Pandora's box of settlements."[3]

The implications of these developments are extremely troubling. The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers, the federal government, state governments trying to provide access to health care with limited public funds, and American businesses striving to compete in a global economy. The federal government is particularly affected: Federal dollars accounted for an estimated 31 percent of the $235 billion spent

on prescription drugs in 2008, and that share is expected to rise to 40 percent by 2018.[4]

To be sure, the development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Hatch-Waxman Act's framework. But the court decisions allowing pay-for-delay settlements grant holders of drug patents the ability to buy protection from competition based only on an allegation of infringement – more protection than congressionally-granted patent rights afford. These rulings disrupt the careful balance between patent protections and encouraging generic drug entry that Congress sought to achieve in the Hatch-Waxman Act.

For these reasons, the Commission strongly supports H.R. 1706, which would prohibit these anticompetitive settlements.[5] And we are encouraged that the list of those speaking out against pay-for-delay settlements is growing. President Obama's budget proposal expresses the Administration's opposition to these anticompetitive deals,[6] and Assistant Attorney General Christine Varney has testified that she supports stopping them.[7] In addition, this past summer the American Medical Association House of Delegates adopted a resolution announcing its opposition to pay-for-delay settlements.[8]

As is discussed below, the Commission is continuing to bring cases challenging pay-fordelay settlements despite the difficulties created by several recent court decisions. But we believe there are compelling reasons for Congress to act to stop such anticompetitive agreements and that the approach taken in H.R. 1706 is sound.

I. THE NEED FOR A LEGISLATIVE SOLUTION

Legislation can provide a comprehensive solution to a problem that is prevalent, extremely costly, and subverts the goals of the Hatch-Waxman Act.

A. Permissive Court Decisions have Made Pay-for-Delay Settlements Commonplace in Hatch-Waxman Patent Cases

The Sixth Circuit Court of Appeals held in 2003 that a branded drug firm's exclusion payments to a generic firm that had filed a patent challenge were per se unlawful, noting:

> it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.[9]

But in 2005, two appellate courts adopted a more permissive – and, respectfully, in our view, incorrect – position on pay-for-delay settlements.[10] The Eleventh Circuit reversed the Commission's decision in the *Schering* case that a substantial exclusion payment, made to induce the generic to abandon its efforts to enter the market before expiration of the branded drug's patent, was illegal.[11] In doing so, the Eleventh Circuit not only rejected the Sixth Circuit's approach to pay-for-delay settlements, it refused to apply any antitrust analysis, either the per se rule or the rule of reason.[12] The Second Circuit in the *Tamoxifen* case likewise upheld the legality of a pay-for-delay settlement.[13] In 2008, a third appellate court adopted a similarly lenient view of pay-for-delay settlements.[14] In that case, *Cipro*, the Federal Circuit Court of Appeals held that "absent fraud before the [Patent and Trademark Office] or sham litigation," the mere presence of a patent entitles the patent holder to purchase protection from competition until patent expiration.[15] Plaintiffs have asked the Supreme Court to review the *Cipro* decision, and we believe the Court should do so.[16]

The Commission believes that the courts' permissive approaches in *Cipro*, *Tamoxifen*, and *Schering* are misguided and not supported by the law. These holdings disrupt the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws. The Commission is not the only advocate to voice concern about the harmful effects of these decisions. Former Solicitor General Paul Clement criticized the standard set forth in *Tamoxifen* as "erroneous" and "insufficiently stringent . . . for scrutinizing patent settlements."[17] The Solicitor General observed that "[t]he interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a weak patent by dividing its monopoly profits with an alleged infringer."[18] Forty-one legal scholars, economics professors, and other academics likewise deemed the *Tamoxifen* standard to be "far outside the mainstream of judicial and academic analysis."[19] Indeed, the Second Circuit, which decided *Tamoxifen* and now has another exclusion payment case before it, has asked the Department of Justice to submit a brief addressing the legality of a branded drug manufacturer's

paying its potential generic rival to abandon its patent challenge and refrain from competing.

Because this is such an important issue for consumers, the Commission continues to bring antitrust challenges to pay-for-delay settlements in other circuits despite the permissive legal treatment afforded these settlements by three of the four circuits that have considered the issue. The Commission currently has two pending cases challenging pay-for-delay settlements.[20] We also have a number of ongoing non-public investigations of such settlements.

The first case, filed in February 2008, challenges a course of anticompetitive conduct by Cephalon, Inc. to prevent generic competition to its leading product, Provigil, a drug used to treat excessive sleepiness caused by narcolepsy and sleep apnea, with annual sales of more than $800 million.[21] The complaint charges that Cephalon agreed to pay in excess of $200 million collectively to settle patent litigation with four manufacturers of generic versions of Provigil to induce them to abandon their plans to sell generic Provigil for six years, until 2012. Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected*."[22] Cephalon has asked the court to dismiss the case based on the permissive standard adopted by appellate decisions in other circuits. There has been no action on the motion to dismiss, which was fully briefed in June 2008. In the meantime, Cephalon has instituted two price increases on Provigil since the Commission filed its complaint.

In the second case, the Commission has challenged patent settlement agreements in which Solvay Pharmaceuticals, Inc. agreed to pay generic drug makers Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., to delay generic competition to Solvay's branded drug AndroGel.[23] According to the February 2009 complaint, Solvay promised payments of hundreds of millions of dollars collectively to induce the generic companies to abandon their patent challenges and agree to forbear bringing a generic AndroGel product to market for nine years, until 2015. Although the case was filed in California, where one of the four defendants is headquartered, at the request of the defendants the California court transferred the case to the Northern District of Georgia. As a result, the law of the Eleventh Circuit, which issued the *Schering* decision, will govern the case.

Despite the Commission's ongoing antitrust enforcement efforts to stop pay-for-delay settlements, the appellate court decisions upholding their legality have prompted a resurgence in settlements in which the parties settle with a payment to the generic company and an agreement by the generic

company not to market its product. Settlements with payments to the generic patent challenger had essentially stopped in the wake of antitrust enforcement by the FTC, state attorneys general, and private parties during 2000 through 2004. But the recent appellate court decisions have triggered a disturbing new trend.

After a five-year hiatus in payments to generics following the initiation of Commission enforcement actions aimed at pay-for-delay settlements, they have become commonplace.[24] By the end of fiscal year 2005, the year of the Eleventh Circuit's decision in *Schering*, there were three such settlements. In the years after the *Schering* and *Tamoxifen* rulings came out, there were significantly more. The staff's analysis of settlements filed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 during the fiscal year ending in September 2007 found that almost half of all of the final patent settlements (14 of 33) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time.

Moreover, the findings concerning settlements with first generic filers – that is, settlements that can serve to block FDA approval of later applicants[25] – are even more striking. Since 2005, 69 percent (22 of 32) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.[26]

B. The Profitability of Delaying Generic Entry Means that these Agreements will become More Prevalent

In the current legal climate, there is every reason to expect the upsurge in such settlements to continue, and early entry of generics under Hatch-Waxman to decline. Why? Because pay-for-delay settlements are highly profitable for both brand-name and generic firms. If such payments are permissible, companies have compelling incentives to use them.

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. The reason is simple: in nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand-name

product. The difference between the brand's loss and the generic's gain is the money consumers save.

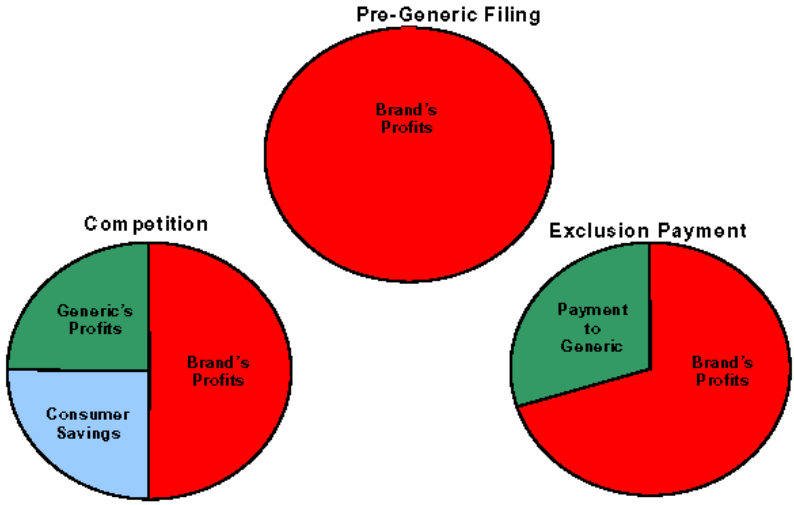
Consequently, it will typically be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer – an amount less than the brand-name manufacturer would have lost and more than the generic would have gained – to settle the patent dispute and the latter agrees to defer entry. As is illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because (1) the generic company would have prevailed in the lawsuit (as noted in Section I.C., *infra*, the FTC's Generic Drug Study found generic challengers enjoyed a success rate in excess of 70 percent), or (2) because the parties would have negotiated a settlement with an earlier entry date absent the payment (i.e., the payment induced the generic to delay entry longer than it otherwise would have). Instead, consumers pay higher prices because such early generic entry is delayed. By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete.

C. Pay-For-Delay Settlements Impose Enormous Costs on Consumers and the Health Care System

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced cost. Although it is well known that the use of generic drugs – which are priced 20 to 80 percent or more below the price of the branded drug[27] – provides substantial savings, what is not so well known is the important role that generic drug firms' patent challenges play in delivering savings to consumers.

One of the key steps Congress took in the Hatch-Waxman Act to promote more rapid introduction of generics was establishing special rules and procedures to encourage firms seeking approval of generic drugs to challenge invalid or narrow patents on branded drugs. Experience has borne out the premise of the Hatch-Waxman patent challenge framework: that many patents, if challenged, will not stand in the way of generic entry,[28] and that successful

challenges can yield enormous benefits to consumers. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the generic challengers had a success rate of 70 percent.[29] The FTC's study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and generic applicants found that when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.[30] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration.[31] Indeed, generic competition following successful patent challenges involving just four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) is estimated to have saved consumers more than $9 billion.[32]



Incentives to Pay for Delay

These cost savings are lost, however, if branded drug firms are permitted to pay a generic applicant to abandon challenging the brand, thereby deferring entry. So are the savings to the federal government, which accounted for an estimated 31 percent of the $235 billion spent on prescription drugs in 2008, a share that is expected to rise to 40 percent by 2018.[33] Many of the top-selling prescription drugs in the United States – including such blockbusters as the asthma/allergy drug Singulair, the deep vein thrombosis (blood clot) and pulmonary embolism treatment Lovenox, and the schizophrenia, bipolar, and

depression drug Abilify – are currently the subject of patent challenges by generic firms seeking to enter the market under the provisions of the Hatch-Waxman Act. The prospective cost savings to consumers and taxpayers from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. But given the lenient case law in some circuits, the parties have a strong economic incentive to enter into highly profitable anticompetitive settlements that deprive consumers of the benefit of low-cost, non-infringing generic drugs.

Prozac provides a telling example of what will be lost if brand and generic companies can enter pay-for-delay settlements. In the course of the Prozac patent litigation, the generic challenger reportedly asked to be paid $200 million to drop its patent challenge. The brand company rejected the idea, stating that such a settlement would violate the antitrust laws.[34] The generic ultimately won that patent litigation, and consumers – as well as federal and state governments – saved over two billion dollars.[35] Under the legal standard articulated in the *Schering*, *Tamoxifen*, and *Cipro* cases, however, the proposed settlement would have been legal and profitable for both parties. The parties would have had every reason to enter the agreement, generic Prozac entry would not have occurred until much later, and consumers and others would have paid the price.

D. Permissive Legal Treatment of Pay-for-Delay Settlements Undermines the Hatch-Waxman Act

The problem of pay-for-delay patent settlements has arisen in – and, to the FTC's knowledge, only in – the context of the special statutory framework that Congress created with the Hatch-Waxman Act. Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[36] The special rules that apply in this area were designed to balance the two policy goals that are of critical significance in the pharmaceutical industry: speeding generic drugs to market and maintaining incentives for new drug development. Legislative action concerning pay-for-delay settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Hatch-Waxman was designed to give generic companies an incentive to challenge weak patents and to compete, not to take money in exchange for sitting on the sidelines. But as one of the authors of the Act, Congressman

Henry Waxman, has observed, because of pay-for-delay settlements, the law "has been turned on its head."[37]

The reasoning underlying these permissive appellate court rulings underscores the need for action by Congress. These decisions reflect judicial judgments about the policy choice that Congress made in Hatch-Waxman. For example, the Eleventh Circuit's *Schering* decision – which opined that the Hatch-Waxman framework Congress created gave generic firms "considerable leverage in patent litigation," and could therefore "cost Schering its patent"[38] – emphasized that its decision was based on "policy."[39] Congress, however, is the body with the responsibility to set patent policy. Striking the balance so as to promote innovation while also promoting generic entry is fundamentally a legislative choice. Accordingly, it is fitting that if courts have disturbed the balance Congress struck in Hatch-Waxman between patents and competition, Congress should address the use of exclusion payments in drug patent settlements to correct that balance.

E. Legislation is Likely to be Swifter and More Comprehensive than Litigation

While the Commission's enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. The Commission's *Provigil* case has been stalled at the district court level for over a year without progress, thus illustrating the delay that can arise in litigation. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years, and the outcome of such litigation is uncertain given the *Schering*, *Tamoxifen*, and *Cipro* decisions. In any event, such litigation will provide little relief for those harmed in the interim by not being afforded the option of a generic alternative. The cost to consumers, employers, and government programs will be substantial. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

II. THE ARGUMENTS AGAINST BARRING EXCLUSION PAYMENTS ARE CONTRADICTED BY EXPERIENCE IN THE MARKET

In the debate over legislation to ban pay-for-delay settlements, certain arguments are routinely offered by supporters of these settlements: (1) such settlements typically allow generic entry before patent expiration and therefore benefit rather than harm consumers; (2) it is virtually impossible to settle Hatch-Waxman patent cases without payments to the generic challenger; and (3) barring such payment to generic firms will mean that fewer generic firms will undertake patent challenges. In the Commission's view, these arguments overlook market realities.

First, the suggestion that pay-for-delay patent settlements are procompetitive – by guaranteeing generic entry prior to the expiration of the disputed patent – is contrary to the Commission's experience. The *Provigil* case is a good example. The branded drug company, Cephalon, touted the "obvious benefits and efficiencies" of its settlement to the court on the ground that the settlement "permitted the [g]enerics to enter the market three years prior to the expiration of the [] patent."[40] But Cephalon has told a very different story to its investors. Discussing its plan to switch sales from Provigil to a follow-on product, Cephalon's CEO stated, "if we do our job right . . . the Provigil number in 2012 [the date the settlement agreement permit the generics to enter the market] that will be genericized will be very, very small."[41] As this example reveals, that a settlement permits generic entry before patent expiration in no way ensures that consumers will benefit from the settlement.

Second, experience does not support the contention that Hatch-Waxman cases can typically only be settled by the transfer of value from the patent holder to the generic challenger. On the contrary, the settlement data that the FTC has for the period from 2000 through 2004 indicate that parties can and do find other ways to settle cases. During that period of successful Commission enforcement, pay-for-delay settlements essentially stopped. But patent settlements – using means other than exclusion payments – continued to occur. In less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.[42] Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases. And patent settlements will continue if

Congress enacts legislation that prohibits anticompetitive payments in settlements of Hatch-Waxman patent cases.

Third, the argument that banning pay-for-delay settlements will discourage generic drug companies from mounting patent challenges overlooks one of the fundamental premises of the Hatch-Waxman Act: the Congressional judgment that weak patents should not create unwarranted barriers to competition from generic drugs. The Hatch-Waxman Act implements that judgment by establishing special rules and procedures when a generic firm seeks approval to market its product before all relevant patents have expired. Congress designed the regulatory framework to facilitate generic entry; patent challenges are not an end in themselves. The measure of success of the framework Congress devised is not the number of patent challenges filed, but the extent to which such challenges actually deliver savings to consumers. Permitting patent settlements in which the parties share monopoly profits preserved by delaying generic competition may increase the number of patent challenges that are filed, but it does not promote consumer access to generic drugs or cost savings.

III. THE LEGISLATIVE REMEDY

The Commission believes that certain principles are important in crafting the precise form and scope of a legislative remedy to the pay-for-delay settlements. The fundamental antitrust concern underlying such settlements is the sharing of monopoly profits that are preserved by an agreement not to compete, whatever form the compensation to the generic takes. Thus, legislation must be sufficiently broad to encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future. At the same time, legislation should be designed to avoid unwarranted deterrence of settlements that present no competitive problem.

H.R. 1706 embodies these principles. It broadly proscribes settlements in which a generic firm receives “anything of value” and agrees to refrain from selling the product, while also providing two mechanisms to prevent settlement avenues from being unduly limited and avoid chilling procompetitive settlements. First, section 2(b) contains express exclusions from the general prohibition on settlements in which the generic firm receives something of value and agrees to refrain from selling its product. Second,

section 3 provides flexibility by authorizing the FTC to adopt rules to exempt other agreements from the general prohibition.

In sum, H.R. 1706 offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements.

CONCLUSION

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Subcommittee to protect consumers from anticompetitive pay-for-delay settlements that cost consumers and the federal government billions of dollars.

End Notes

[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)). For a discussion of the Act's statutory background, see "Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Settlements in the Pharmaceutical Industry," FTC Testimony before the Subcommittee on Trade, Commerce, and Consumer Protection, Committee on Energy and Commerce (May 2, 2007) at 8-9, available at http://ftc.gov/os/testimony/P859910%20Protecting Consume %20Access testimony.pdf.

[3] Stephanie Kirchgaessner & Patti Waldmeir, *Drug Patent Payoffs Bring a Scrutiny of Side-Effects*, FINANCIAL TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S.G. Cowen & Co. analyst's report describing the Eleventh Circuit's opinion in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006)).

[4] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

[5] Similar legislation has been introduced in the Senate. *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

[6] President Obama explained in his recent budget that "The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market." OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010 (2009) (proposed), at 28, *available at* http://www.whitehouse.gov/omb/assets/fy2010 new era/A New Era of Responsibility2.pdf.

[7] In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supported opposition to "reverse payments" and

would work to "align" the positions of the Department of Justice and the FTC. *Executive Nominations: Hearing Before the S. Judiciary Comm.*, 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

[8] At its 2008 annual meeting, the House of Delegates of the American Medical Association adopted Resolution 520 concerning '"Pay for Delay' Arrangements by Pharmaceutical Companies" and resolved "that our American Medical Association support the Federal Trade Commission in its efforts to stop 'pay for delay' arrangements by pharmaceutical companies," *available at http://www.ama-assn.org/ama1/pub/upload/mm/38/a08resolutions.pdf.*

[9] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

[10] *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S.Ct. 3001 (2007). For further discussion of the *Schering* and *Tamoxifen* cases, see the FTC's May 2, 2007 testimony, "Protecting Consumer Access to Generic Drugs," *supra* note 2, at 14-19, *available at* http://www.ftc.gov/os/testimony/P859910%20Protecting Consume %20Access testimony.pdf.

[11] *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Federal Trade Commission, 2003 FTC LEXIS 187, Dec. 8, 2003; *vacated, Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

[12] 402 F.3d at 1065.

[13] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006).

[14] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *petition for cert. filed*, __ U.S.L.W. __ (U.S. Mar. 23, 2009) (No. 08-1194).

[15] *Id.* at 1336. Bayer had settled patent litigation with the manufacturer of a generic counterpart, Barr, by making periodic payments to Barr ultimately totaling almost $400 million in exchange for Barr's agreement to delay marketing its generic version of Cipro for almost seven years. The Commission filed an amicus brief in *Cipro* that urged the Federal Circuit to allow an antitrust challenge to the patent settlement to proceed to trial, *available at* http://www.ftc.gov/os/2008/01/ciprobrief.pdf.

[16] *See Ark. Carpenters Health & Welfare Fund, et al., v. Bayer AG, et al.*, __ U.S.L.W. __ (U.S. Mar. 23, 2009) (No. 08-1194).

[17] Brief for the United States as Amicus Curiae at 17, *Joblove v. Barr Labs., Inc.*, 127 U.S. 3001 (2007) (No. 06-830) ("U.S. Tamoxifen Br."), *available at http://www.usdoj.gov/osg/briefs/2006/2pet/6invit/2006-*0830.pet.ami.inv.pdf .

[18] *Id.* at 11.

[19] Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition at 2, *Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007) (No. 06-830), *available at* http://www.orangebookblog.com/Tamoxifen 20_cert_ 20final _20brief.pdf.

[20] At the time the agency testified before you on May 2, 2007, the Commission had already challenged the following patent settlements: *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at http://www.ftc.gov/os/2000/05/c3945complaint.htm; Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at http://www.ftc.gov/os/2000/05/c3946complaint.htm; Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm*; Bristol-Myers Squibb Co.*, Dkt. No. C-4076, (April 18, 2003), complaint *available at http://www.ftc.gov/os/caselist/c4076.htm*. The consent order in *Abbott Laboratories* is *available at* http://www.ftc.gov/os/2000/03/abbot.do.htm. The consent order in *Geneva Pharmaceuticals* is *available at* http://www.ftc.gov/os/2000/03/genevad&o.htm. The consent order in *Hoechst/Andrx* is *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm. The consent

order in *Bristol-Myers Squibb* is *available at http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf. See also Schering-Plough Corp.*, 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11 Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 2, 2002) (consent order as to American Home Products).

[21] *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), *available at* http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf.

[22] John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

[23] *FTC v. Watson Pharmaceuticals, Inc.*, No. 09-00598 (C.D. Cal. first amended complaint filed Jan. 12, 2009), *available at http://www2.ftc.gov/os/caselist/0710060/090212amendedcmpt.pdf.*

[24] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.*

[25] Further discussed, *infra*, Section IV.

[26] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition* (May 2008), *available at http://www.ftc.gov/os/2008/05/mmaact.pdf;* Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition* (Apr. 2007), *available at http://www.ftc.gov/reports/mmact/MMAreport2006.pdf;* Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

[27] *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0 (hereinafter "CBO Study").

[28] *See, e.g., Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, 2008 WL 2039065 (Fed. Cir. May 14, 2008) (patents covering blood-clotting drug Lovenox held unenforceable), *petition for cert. filed*, 77 U.S.L.W. 3441 (U.S. Jan. 23, 2009) (No. 08-937); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent covering hypertension drug Norvasc held invalid); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006) (product-by-process patent covering anti-depressant drug Paxil was invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

[29] Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006). *See 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).

[30] 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.

[31] *SmithKline Beecham Corp. v. Apotex Corp*., 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom*. *In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. 2003) (noninfringement of patents claiming Prilosec); *American Biosciences, Inc. v. Baker Norton Pharms. Inc.*, 2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming Taxol held invalid); *Eli Lilly & Co. v. Barr Labs., Inc*., 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

[32] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm*., 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107*senate hearings&docid=f:901 55.pdf.

[33] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

[34] Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 5, *available at* http://money.cnn.com/magazines/fortune/fortune archive/2001/08/13/308077/index.htm.

[35] Kirchgaessner & Waldmeir, *supra* note 3.

[36] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

[37] Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES , July 23, 2000, at A11 (quoting Rep. Waxman), *available at* http://www.nytimes.com/2000/07/23/us/keeping-down-competition-companies-stall-generics-keep-themselves-healt hy.html?sec=&spon=&pagewanted=all.

[38] 402 F.3d at 1074.

[39] *Id.* at 1076.

[40] Ceph. Mem. in Support of its Mtn. to Dismiss at 1, *FTC v. Cephalon, Inc*., No. 08-2141 (E.D. Pa. Mem. filed May 5, 2008).

[41] Cephalon Q4 2008 Earnings Call Transcript at 9 (Feb. 13, 2009), *available at* http://seekingalpha.com/article/87859-cephalon-inc-q2-2008-earnings-call.

[42] The agency lacks data for the approximately three year period between the end of the Generic Drug Study in 2000 and the beginning of the MMA reporting period in 2003. It is likely that there are additional settlements that occurred during this period for which the agency does not have information.

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Chapter 4

TESTIMONY OF HEATHER BRESCH, CHIEF OPERATING OFFICER, MYLAN, INC., BEFORE THE SUBCOMMITTEE ON COURTS AND COMPETITION POLICY, HEARING ON "PAY TO DELAY: ARE PATENT SETTLEMENTS THAT DELAY GENERIC DRUG MARKET ENTRY ANTICOMPETITIVE"

Thank you Chairman Johnson, ranking Member Coble, and members of the Judiciary Subcommittee on Courts and Competition Policy. In particular, thank you Chairman Conyers for inviting us to attend today. My name is Heather Bresch, and I am the Chief Operating Officer of Mylan Inc. For nearly 50 years, Mylan has built a legacy of manufacturing high quality, affordable pharmaceuticals. We are the largest U.S.-based generic pharmaceutical manufacturer and the third largest generics and specialty pharmaceutical company in the world. One out of every 13 prescriptions dispensed in the U.S. – brand name or generic – is a Mylan product. Additionally, Mylan has consistently been recognized by the FDA and by the pharmacy community for excellence in quality and service.

In addition to my 17 years with Mylan, I have served as both Chairman and Vice Chairman of the Generic Pharmaceutical Association (GPhA), and I am currently a member of the association's Executive Committee. GPhA represents more than 100 generic manufacturers and distributors of finished

generic products as well as manufacturers and distributors of bulk active pharmaceutical chemicals.

Generic products are now used to fill nearly 70 percent of all prescriptions dispensed across the country but account for only 16 percent of all dollars spent on prescription medicines. A recent study conducted by IMS Health revealed that using generic pharmaceuticals saved the American health care system more than $734 billion in the last decade (1999-2008), with approximately $121 billion in savings in 2008 alone. These savings directly benefit consumers, businesses, and state and federal government agencies.

Mr. Chairman, our country is facing a crisis in rising healthcare costs and the generic pharmaceutical industry represents one of the few proven and successful solutions to contain those costs. President Obama, in his remarks on reforming the health care system stated:

> When it comes to health care spending, we are on an unsustainable course that threatens the financial stability of families, businesses and government itself...
>
> Over the last decade, Americans have seen their out-of-pocket expenses soar, while health care premiums doubled at a rate four times faster than wages. Today, half of all personal bankruptcies currently stem from medical expenses.

In 2007, Obama emphasized the importance generics would have in his future administration when he said:

> My administration will look carefully at key industries to ensure that the benefits of competition are fully realized by consumers. Americans, for example, spend billions of dollars each year on drugs. Competition from generic manufacturers has the potential to reduce these costs significantly, or at least prevent these costs from ballooning further.

The generic drug industry plays a key role in reducing health care costs. The entry of safe and effective generic medicines adds competition to the marketplace and reduces the costs of medicines dramatically. In this current economic environment it is therefore even more critical to ensure timely access to generic pharmaceuticals. I am pleased to be here today to discuss critical issues that relate to timely access to affordable generic medicines and how these issues relate to patent settlements.

A BRIEF HISTORY OF HATCH-WAXMAN

By way of background, *Hatch-Waxman* – officially "The Drug Price Competition and Patent Term Restoration Act of 1984" – reflected an attempt by Congress to strike a balance between two policy objectives: to incentivize name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products and to enable competitors to bring lower- cost, bioequivalent and therapeutically equivalent generic versions of those drugs to market. *Hatch-Waxman* is designed to both reward innovation and encourage the development of affordable health care. When the balance is disturbed, the system is jeopardized, and consumers, the government and taxpayers suffer financially.

On the branded pharmaceutical side of the scale, *Hatch-Waxman* protects intellectual property in a variety of ways. It provides the means for innovators to restore up to five years of patent life to compensate for time the product underwent regulatory review at the FDA. Congress has provided branded pharmaceutical companies an additional five years of data exclusivity for new chemical entities; a supplement of three years of data exclusivity for clinical trials; six months marketing exclusivity for pediatric studies; and, an automatic 30-month stay of generic approvals to resolve patent disputes.

On the generic pharmaceutical side of the scale, *Hatch-Waxman* streamlined the generic drug approval process and provided 180 days of market exclusivity to incentivize generic manufacturers to challenge questionable or frivolous patents held by brand manufacturers that essentially protect monopolies and prevent affordable medications from reaching the market. The marketing exclusivity period allowed generic companies to gain financial resources necessary to reinvest and continue to develop additional affordable and high quality generic products.

In the early 2000s, branded pharmaceutical companies began to exploit certain legislative loopholes in *Hatch-Waxman*. One such loophole was a practice known as 'evergreening,' a tactic which is aptly demonstrated by a brand company's gaming of the system with tactics relating to the depression/anxiety product Paxil®.

The FDA lists drug products approved on the basis of safety and effectiveness in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book." If another pharmaceutical company believes a patent listed in the Orange Book is invalid or not infringed by its product, the patent must be challenged by the generic company by filing a Paragraph IV certification. If the brand company

sues the generic applicant for infringement, an automatic 30-month preliminary injunction or stay is triggered.

In the case of Paxil, the brand company successfully timed the issuance of multiple patents that resulted in successive 30-month stays that significantly delayed the introduction of a bioequivalent generic version of the product and kept it from reaching patients who suffer from anxiety and/or depression. The first stay of FDA approval expired in November 2000, but the FDA was not able to approve a generic version of Paxil until September 2003 due to four successive and overlapping statutory stays of approval. The brand company had annual sales in excess of $2 billion and these successive and overlapping stays resulted in an almost three-year delay before a more affordable generic product could be offered to consumers.

While Congress put an end to the evergreeni ng practice in 2003 with the passage of the *Medicare Modernization Act* (MMA), brand companies had moved on to new tactics to extend their monopolies. The most notorious of these tactics is the use of so-called authorized generics. The practice has become so prevalent that authorized generics are factored in at every step of a company's decisions regarding each product that could potentially find its way or does find its way into a company's pipeline. Authorized generics affect decision making and the availability of capital needed for research and development and litigation costs required to bring a new generic product to the American market. Since the presence of an authorized generic is assumed on the launch of every product, a company must carefully consider the impact of an authorized generic when it determines what products to develop, how to pursue litigation and when it evaluates a potential litigation settlement.

AUTHORIZED GENERICS

Authorized generics are, in fact, the same exact products as their branded counterparts made on the same production lines with the exact same ingredients, but before packaging, they are given a different label. Same product, same bottle, different label. Brand companies do not release authorized generics until the first true generic begins its 180 days of statutory exclusivity. This practice can all but eliminate the incentive for a generic filer to identify frivolous or invalid patents, invest in the research and development necessary to produce a bioequivalent and affordable generic product and accept the risk of expensive patent litigation. As generic companies, we simply

assume that an authorized generic will be launched by the brand company upon release of our true generic, and we assume that our earned 180 days of marketing exclusivity will be significantly diminished.

Let me be very clear: Mylan is not opposed to authorized generics in and of themselves. Our issue lies only in the marketing of authorized generics during the 180 days of exclusivity as provided under *Hatch-Waxman*. Following the 180 days granted to the first generic filer, we recognize and respect the right of any company with an FDA-approved product, including the brand company, to compete in the generic marketplace. The issue is *when* the authorized generic is brought to market.

I might add that it is the timing of the introduction of the authorized generic that has caught the attention of the Federal Trade Commission (FTC) and is being examined in their pending study.

The words of several brand pharmaceutical CEOs best demonstrate their motives.

> In an April 2003 press release, GlaxoSmithKline announced an authorized generic agreement for Paxil®. The agreement prevented the authorized generic from becoming available until "another generic version fully substitutable for Paxil becomes available." In other words, the more affordable authorized generic was prohibited from launching until the product of a generic filer with 180 days of exclusivity was launched.
>
> In December 2003 in a Pink Sheet article, Eli Lilly CEO Sidney Laurel was quoted saying that systematically launching authorized generics each time a patent expires would mean the brand industry could "truly eliminate the incentive in the calculation that generic companies would make."
>
> In a February 2004 earnings conference call, GlaxoSmithKline CEO J.P. Garner said, *"The idea was somebody has a six-month exclusivity, but we are a king maker; we can make a generic company compete during [the 180-day exclusivity]."*

"King maker" doesn't sound like the competitive balance intended by Congress when it enacted *Hatch-Waxman.*

Professors Aidan Hollis and Bryan Liang prepared a study in 2006 on the effects of authorized generics, "An Assessment of Authorized Generics: Consumer Effects and Policy Issues." [*http://www.gphaonline.org/sites /default/files/GPhA*_AG Study.pdf] They assessed claims that authorized generics have positive effects on consumers by allegedly reducing prices on drug products immediately after generic entry during the 180-day exclusivity period. Professors Hollis and Liang found that in fact authorized generics had

a negligible effect on prices during this period. More importantly, they determined that the use of authorized generics diminishes the incentive for generic companies during the 180-day exclusivity period which in turn reduces the incentives generic companies have to challenge invalid patents and develop non-infringing products. They found that authorized generics will lead generic firms to be less aggressive in competing against brand companies and the ultimate losers will be consumers and taxpayers who bear the burden of healthcare costs.

For the past three years, the FTC has been studying the effect of authorized generics in the marketplace. No study has been more anxiously awaited by the generic industry, which has endured enormous detrimental effects from the practice of authorized generics being released during the 180-day exclusivity period. We understand this study will be released in June, and we expect the results to address the immediate negative impact of authorized generics during the 180 days on consumers and the long–term detrimental effects of authorized generics on patent settlements.

In fact, Members of Congress have recognized the detrimental effects of authorized generics during the 180-day exclusivity period and in January House Representative Emerson (R-MO) together with Representatives Berry (D-AR), Moore (D-KS), and Wamp (R-TN) reintroduced bipartisan legislation to prohibit the marketing of authorized generics (H.R. 573). A similar bill has been introduced in the Senate (S. 501) by Senator Rockefeller (D-WV) along with Senators Brown (D-OH), Inouye (D-HI), Kohl (D-WI), Leahy (D-VT), Schumer (D-NY), Shaheen (D- NH) and Stabenow (D-MI). Mylan applauds these Members for recognizing that prohibiting authorized generics is an important part of the solution to the problem of rising health care costs in America.

When crafted, *Hatch-Waxman* offered a careful and thoughtful balance. It promoted innovation and provided an incentive to companies that expend significant resources to bring generic drugs to market, ensuring that Americans have timely access to affordable medicines. When a brand company exploits a loophole in *Hatch-Waxman*, as they certainly do with authorized generics, they artificially extend a patented monopoly. Everyone suffers and the carefully crafted balance disintegrates. Had authorized generics been addressed by Congress in MMA in 2003, it is unlikely we would be here today discussing patent settlements.

PATENT SETTLEMENTS

Drug patent settlements have recently come under increased scrutiny by the FTC and Congress. The FTC appears to be concerned with settlements that involve a payment of money in exchange for a generic company accepting a fixed date of entry to the market. However, it is important to remember that patent settlements, in and of themselves, do not have a negative impact on competition. In fact, a settlement involving the breast cancer treatment Tamoxifen® allowed a generic version to enter the market nine years before the date the relevant patent expired.

In almost every other type of litigation, settlement is encouraged. It is an efficient way to resolve disputes and not impact court resources. The settlement option is particularly important to generic companies attempting to challenge brand patents. The development of a product including the submission of an abbreviated new drug application is expensive. Patent litigation results in additional costs, which can escalate depending on the complexity of the product and patents at issue. Since these challenges are extremely costly and the outcomes of even the best cases are uncertain, companies need the ability to settle cases.

The process for bringing a generic product to market is not as simple as some may think. In fact, the process starts many years before the affordable generic medication becomes available to a patient. There are many market factors that a company considers before deciding to invest in the necessary research and development for a particular product. These factors include the impact of delay tactics and manipulated loopholes that brand companies employ. These tactics are introduced throughout the entire generic development process, including during patent settlement discussions. The fact that a brand company is almost certain to launch an authorized generic, or at the very least threaten to launch one, means that the incentive to continue litigation is significantly weakened for the generic company.

As a result, brand companies have a much stronger bargaining position during patent settlement negotiations. Brand companies use authorized generics as a "trump card" to reduce generic returns, even if the generic company believes it can invalidate the brand's patents. This leaves the generic company with limited bargaining power and little choice but to settle. This situation takes the power away from the generic company, the party that is best suited to determine how to get a generic product to the market.

In 2008, the FTC found that 78% of the reported patent settlements involved a restriction on the launch of an authorized generic during the period

of the generic company's exclusivity. In essence, generic companies must settle in order to safeguard the exclusivity promised by Congress in 1984 by *Hatch-Waxman*.

The FTC has recognized the crucial role authorized generics play in settlement negotiations. FTC Commissioner Jon Leibowitz noted in a 2006 speech that:

> The profits to be made in the 180-day exclusivity period are reduced substantially [by authorized generics], perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice.

Some might suggest that a bright-line ban on patent settlements involving the receipt of anything of value apart from generic entry pre-patent expiry is required to protect consumers. However, this approach would eliminate many pro-competitive settlements and more specifically would make it illegal for a generic to secure what was intended by Congress in *Hatch-Waxman* – 180 days of *exclusive* market presence. Such a result is inconsistent with the purposes and intent of Congress in enacting the *Hatch-Waxman Act* in the first place. We urge Members of Congress to address all the considerations of patent settlements and to support legislation that would eliminate authorized generics during the 180-day exclusivity period.

In summary, we believe that Congress must ensure the timely access of affordable generic medications is offered to patients when patents are either invalid or not infringed. This requires the restoration of the incentive of the 180-day exclusivity period which will enable generic companies to challenge patents and appropriately pursue worthy patent cases. A prohibition on authorized generics during the 180-day exclusivity period will also re-establish a level playing field for generic companies as they contemplate settlement with a brand company in patent litigation, thereby allowing the generic company to view settlement options without the threat of an authorized generic looming overhead. Taking away the ability for generic companies to settle expensive litigation without also providing a ban on authorized generics will be sure to result in further delays of affordable generic products for Americans.

I want to thank the subcommittee again for its time and interest in making sure all Americans have access to affordable, safe generic pharmaceuticals. As always, Mylan is willing to work with Congress and the FTC on these issues. I am happy to answer any questions you might have.

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Chapter 5

TESTIMONY OF BRET M. DICKEY, SENIOR VICE PRESIDENT, COMPASS LEXECON, BEFORE THE SUBCOMMITTEE ON COURTS AND COMPETITION POLICY, HEARING ON "PAY TO DELAY: ARE PATENT SETTLEMENTS THAT DELAY GENERIC DRUG MARKET ENTRY ANTICOMPETITIVE"

Chairman Johnson, Ranking Member Coble, and Members of the Subcommittee, good morning. My name is Bret Dickey and I am a Senior Vice President with Compass Lexecon, an economic consulting firm specializing in competition policy. I appreciate the opportunity to testify today.

Since receiving my Ph.D. in Economics from Stanford University, I have spent the last 10 years analyzing the economics of competition policy, with a particular focus on the pharmaceutical industry. During that period I have analyzed the competitive effects of several patent settlement agreements between branded and generic manufacturers.[1] Recently, I co-authored a paper with Laura Tyson, the former chair of President Clinton's National Economic Counsel, and Jonathan Orszag, a colleague at Compass Lexecon and a former advisor to President Clinton, that presents an economic framework for evaluating such settlements.[2] Our paper demonstrates that patent settlements between branded and generic manufacturers, even settlements involving "reverse payments," can be procompetitive.

Consumers benefit from the availability of innovative new products and from lower prices. In the pharmaceutical industry, both the development of new medicines and price competition from manufacturers of generic drugs provide substantial consumer benefits. Competition policy towards the pharmaceutical industry must therefore represent a balance between protecting incentives for manufacturers of branded drugs to innovate and facilitating entry by manufacturers of lower-priced generic drugs.

The current framework for patent litigation between branded and generic pharmaceutical manufacturers, established by the Hatch-Waxman Amendments in 1984, is an important component of this balance. Generic manufacturers must notify branded manufacturers before launching a potentially infringing generic product, providing branded manufacturers an opportunity to sue for patent infringement before the generic enters the market. In many cases, litigation is resolved with a settlement between the parties. These settlements may include a wide variety of provisions, such as:

- A negotiated date upon which the generic manufacturer will enter the market (with or without royalty payments to the branded manufacturer);
- Cash payments from the branded manufacturer to the generic;
- Business transactions between the branded and generic manufacturer such as cross-licensing or supply agreements; and
- Agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry.

In recent years, patent settlements involving “reverse payments” from branded manufacturers to generic manufacturers have received close antitrust scrutiny, driven by concerns that such settlements harm consumers by delaying the entry of lower-priced generic drugs. Yet economic models demonstrate that when the real-world complexities of litigation are accounted for such settlements can in fact benefit consumers. My paper with Dr. Tyson and Mr. Orszag presents a broad analytical framework for evaluating the competitive effects of these settlements.

On the one hand, settlements of litigation – including patent settlements – can provide clear competitive benefits. Litigation imposes substantial costs upon the litigating parties and on society as a whole, costs which can be mitigated through settlement. Settlements also reduce risk associated with litigation. Because settlements can lower costs and uncertainty, economists agree that settlements can be procompetitive.

On the other hand, under certain conditions, patent settlements between branded and generic manufacturers can be anticompetitive. Ultimately, the competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent. If the patent is strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future but before patent expiration may bring generic drugs to market sooner than continued litigation and generate lower prices for consumers. In contrast, if the patent is weak, and likely to be found invalid and/or non- infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers. Assessing the strength or weakness of a patent in real-world patent litigation is complex – indeed, the precise strength of a patent is subject to the uncertainties of the litigation system and is ultimately unknowable even to the parties themselves. Nevertheless, such an assessment is necessary at some level in determining whether a patent settlement is pro- or anticompetitive.

While the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so called "reverse payment" settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash or through some other business transaction (*e.g.*, a cross-licensing agreement) which provides a conduit through which the branded manufacturer might allegedly "overpay" the generic manufacturer.

Some analysts contend that such "reverse payments" are on their face evidence that the settlements are nothing more than a payment by the brand manufacturer to delay generic entry. They argue that in what one might think of as the "typical" patent settlement case, the defendant (an alleged patent infringer) makes a payment to the plaintiff (the holder of the patent). But in "reverse payment" settlements, they argue that the payment flows the "wrong" way, from the patent holder (the branded manufacturer and plaintiff) to the defendant (the generic manufacturer and alleged infringer).

"Reverse payment" is a misnomer based on flawed logic. In contrast to a "typical" patent case, where the alleged infringer is already selling a product and the patent holder is suing for damages, in patent suits between branded and generic pharmaceutical manufacturers, the generic has typically not entered the market and the branded manufacturer is suing for a remedy akin to

injunctive relief. In this case, there is no *a priori* expectation that a payment should flow from the generic manufacturer to the branded manufacturer.

The use of overly simple economic models can inappropriately lead to the conclusion that "reverse payment" settlements will always reduce competition. But these economic models ignore important economic realities that can make "reverse payment" settlements procompetitive. Such realities include, but are not limited to:

(a) risk aversion, that is, concern by one or both of the parties over the uncertainty of the litigation process,
(b) information asymmetries, that is, information that is available to one of the parties but not to the other,
(c) differences in expectations, such as the parties' beliefs about their chances of winning the patent litigation, and
(d) differences in discount rates, that is, the relative value of future income relative to present income.

More realistic economic models that consider these factors demonstrate that patent settlements involving "reverse payments" can be procompetitive. In fact, under certain conditions, without a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers. A ban on all patent settlements where some compensation is provided to the generic manufacturer would deprive consumers the benefits of such settlements.

Moreover, competition policy towards patent settlements can have important effects both on the incentives of branded manufacturers to innovate and on the incentives of generic manufacturers to challenge branded patents. A broad ban on "reverse payment" settlements would narrow the patent protection provided to branded manufacturers and, on the margin, lower incentives to invest in new medicines in the future. Importantly, such a ban would also reduce the ability of generic manufacturers to settle such cases and increase the cost and risk of litigation – and therefore the cost and risk of bringing a generic drug to market prior to patent expiration. On the margin, this will lower the incentives of generic pharmaceutical manufacturers to challenge branded patents in the first place. Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition could be substantial.

Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core it depends upon the validity of the patent claims. What is clear is that under many circumstances, patent settlements between branded and generic manufacturers – even those involving "reverse payments" – can benefit competition and consumers. An outright prohibition of "reverse payment" settlements would harm consumer welfare in a range of circumstances.

"Reverse payment" settlements can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any patent settlement agreement between a branded pharmaceutical company and a generic applicant be provided to the Federal Trade Commission and the Department of Justice. But a law that would paint all such settlements with the same brush is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework to the facts specific to that settlement.

Thank you again for the opportunity to discuss this issue with the Subcommittee.

APPENDIX. AN ECONOMIC ASSESSMENT OF PATENT SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY

– by –
Bret Dickey[3], Jonathan Orszag[4], Laura Tyson[5],
March 2009[6]

Executive Summary

- Consumers benefit from the availability of innovative new products and from lower prices. In the pharmaceutical industry, both the development of new medicines and price competition from manufacturers of generic drugs provide substantial consumer benefits. Competition policy towards the pharmaceutical industry must therefore represent a balance between protecting incentives for manufacturers of branded drugs to innovate and facilitating entry by manufacturers of lower-priced generic drugs.

- The current framework for patent litigation between branded and generic pharmaceutical manufacturers, established by the Hatch-Waxman Amendments in 1984, is an important component of this balance. Generic manufacturers must notify branded manufacturers before launching a potentially infringing generic product, providing branded manufacturers an opportunity to sue for patent infringement before the generic enters the market. In many cases, litigation is resolved with a settlement between the parties. These settlements may include the following types of provisions:
  - A negotiated date upon which the generic manufacturer will enter the market (with or without royalty payments to the branded manufacturer);
  - Cash payments from the branded manufacturer to the generic;
  - Business transactions between the branded and generic manufacturer such as cross-licensing or supply agreements; and
  - Agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry.
- In recent years, patent settlements between branded and generic manufacturers involving "reverse payments" from branded manufacturers to generic manufacturers have received close antitrust scrutiny, driven by concerns that such settlements harm consumers by delaying the entry of lower-priced generic drugs. It appears that such settlements will be a focus of the Obama Administration's antitrust enforcement policy. Yet there is a growing consensus among the courts that such settlements are anticompetitive only under narrow sets of circumstances. This paper presents an analytical framework for evaluating the competitive effects of these settlements.
- On the one hand, settlements of litigation – including patent settlements – can provide clear competitive benefits. Litigation imposes substantial costs upon the litigating parties and on society as a whole. Settlements also reduce risk associated with litigation. Because settlements can lower costs and uncertainty, economists agree that settlements can be procompetitive.
- On the other hand, under certain conditions, patent settlements between branded and generic manufacturers can be anticompetitive. Ultimately, the competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent. If the patent is strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future but

before patent expiration may bring generic drugs to market sooner than continued litigation and generate lower prices for consumers. In contrast, if the patent is weak, and likely to be found invalid and/or non-infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers. Assessing the strength or weakness of a patent in real-world patent litigation is complex – indeed, the precise strength of a patent is subject to the vagaries of the litigation system and is ultimately unknowable even to the parties themselves. Nevertheless, such an assessment is necessary at some level in assessing whether a patent settlement is pro- or anticompetitive.

- While the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so called "reverse payment" settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash or through some other business transaction (*e.g.*, a cross-licensing agreement) which provides a conduit through which the branded manufacturer might allegedly "overpay" the generic manufacturer.
- The FTC and some antitrust scholars contend that such "reverse payments" are on their face evidence that the settlements are nothing more than a payment by the brand manufacturer to delay generic entry. They argue that in what one might think of as the "typical" patent settlement case, the defendant (an alleged patent infringer) makes a payment to the plaintiff (the holder of the patent). But in "reverse payment" settlements, they argue that the payment flows the "wrong" way, from the patent holder (branded manufacturer/plaintiff) to the defendant (the generic manufacturer and alleged infringers).
- A "reverse payment" is a misnomer based on flawed logic. In contrast to a "typical" patent case, where the alleged infringer is already selling a product and the patent holder is suing for damages, in patent suits between branded and generic pharmaceutical manufacturers, the generic has typically not entered the market and the branded manufacturer is suing for a remedy akin to injunctive relief. In this

case, there is no *a priori* expectation that a payment should flow from the generic manufacturer to the branded manufacturer.

- The use of highly simplified economic models can inappropriately lead to the conclusion that "reverse payment" settlements will always reduce competition. But overly simple economic models ignore important economic realities that can make reverse payment settlements procompetitive. Such realities include, but are not limited to, (a) risk aversion, (b) information asymmetries, (c) differences in expectations, and (d) differences in discount rates. In fact, under certain conditions, without a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers.
    - For example, suppose that both the branded and generic manufacturers are overly optimistic about their chances of success in the patent litigation – say the branded manufacturer believes that there is a 75-percent chance that it will win the litigation and the generic manufacturer believes that there is a 75-percent chance that it will win. In this case, the parties will be unable to reach a settlement based upon entry date alone. A reverse payment, however, can facilitate a settlement that is agreeable to both parties and, given the actual chance of success in the patent litigation based on the strength of the underlying patent, provide benefits to consumers relative to continued litigation.
    - Other examples of circumstances in which settlement is not possible without compensation between the parties will be discussed in more detail in the report.
- Moreover, competition policy towards patent settlements can have important effects both on the incentives of branded manufacturers to innovate and on the incentives of generic manufacturers to challenge branded patents. Taking some potentially procompetitive settlement options off the table would narrow the patent protection provided to branded manufacturers and, on the margin, lower incentives to invest in new medicines in the future. This would also reduce the ability of generic manufacturers to settle such cases and increase the cost and risk of bringing a generic drug to market. On the margin, this will lower the incentives of generic pharmaceutical manufacturers to challenge branded patents in the first place. Even if the effect on a

particular generic manufacturer's decision is relatively small, the collective impact on future generic competition can be substantial.

- Despite the contention by some that reverse payment settlements should be treated as *per se* illegal, courts, the Department of Justice (DOJ), and many economists have concluded that patent settlements between pharmaceutical manufacturers can be procompetitive and should be given considerable latitude.
    - Decisions by the Second, Eleventh, and most recently the *Cipro* decision by the Federal Circuit Court of Appeals have all concluded that patent settlement agreements between branded and generic pharmaceutical manufacturers – even agreements involving reverse payments – are appropriately treated under a rule of reason standard and are not anticompetitive as long as the agreement is not beyond the exclusionary scope of the patent and the litigation is not objectively baseless.
    - The DOJ has stated that "...settlements between an ANDA filer and the patent holder [even those with a reverse payment] also can benefit consumer welfare. Accordingly, the Department of Justice does not believe per se liability under the antitrust laws is the appropriate standard." Economists have reached similar conclusions.
- Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core it depends upon the validity of the patent claims. What is clear is that under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and consumers. An outright prohibition of reverse payment settlements would harm consumer welfare in a range of circumstances. Patent settlements between branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any patent settlement agreement between a branded pharmaceutical company and a generic applicant be provided to the FTC and the DOJ. But painting all settlements with the same brush is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework, such as that presented here, to the facts specific to that settlement.

Introduction

In recent years, the Federal Trade Commission ("FTC") has been closely scrutinizing patent settlements between branded and generic manufacturers involving "reverse payments" from branded manufacturers to generic manufacturers. The FTC has been concerned that such settlements harm consumers by delaying the entry of lower- priced generic drugs.

Despite what appears to be a growing consensus among the courts that such settlements are anticompetitive only under narrow sets of circumstances, it is likely that antitrust scrutiny will only increase in the next several years. In 2007, then-Candidate Obama specifically pointed to concerns over such settlements in laying out his views on antitrust enforcement policy.[7] Jon Leibowitz, the current Chairman of the Federal Trade Commission, recently called eliminating anticompetitive patent settlements "one of the most important objectives for antitrust enforcement in America today."[8] Bills that would outlaw settlements involving payments from branded to generic manufacturers were introduced in the U.S. Senate and House of Representatives in recent months.[9]

In this paper, we present an analytical framework for evaluating the competitive effects of patent settlements, including those involving reverse payments, and demonstrate that these settlements can benefit consumers. Thus, we conclude that while continued scrutiny of such settlements is important, broad brush treatments are inappropriate and only a more individualized evaluation can correctly determine the competitive effects of a particular settlement agreement.

I. Competition in the Pharmaceutical Industry

Innovative branded pharmaceutical firms can benefit consumers by developing new drugs. Generic pharmaceutical firms can benefit consumers by offering competition that drives down prices. Thus, the challenge of competition policy in this area (as in all highly innovative industries) is to benefit consumers by striking the appropriate balance between providing sufficient rewards to encourage innovation, followed after a time by a transition to a more competitive market with lower prices.

A. Innovation and Patent Protection

Innovation is the lifeblood of the pharmaceutical industry. In 2007, the pharmaceutical and biotechnology industries invested nearly $60 billion in

research and development ("R&D").[10] As described by the Congressional Budget Office ("CBO"):

> The pharmaceutical industry is one of the most research- intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.[11]

Since 1990, R&D by pharmaceutical manufacturers has led to the approval of an average of roughly 30 new drugs (molecular entities) and dozens of newly approved formulations or other modifications of existing drugs each year.[12]

Protection of the intellectual property underlying these innovations is critical to providing incentives for pharmaceutical manufacturers to continue to invest in, and develop, new drugs. The research and development process is lengthy, costly, and uncertain. Only a tiny fraction of medicines tested are eventually approved for patient use,[13] and only 20 to 30 percent of those approved eventually recoup their R&D investment.[14] Development of a new drug entails considerable time and expense. These development costs have been rising significantly. Recent studies estimate that the average new drug took 10 to 15 years[15] and cost over $1.3 billion (including both direct costs and opportunity costs) to develop.[16] Strong protection of intellectual property, and the potential rewards that come with it, provide incentives for pharmaceutical companies to undertake such large development costs.

B. Generic Competition

After a branded drug loses patent protection (or a generic manufacturer is able to produce a non-infringing generic version), generic manufacturers often bring bioequivalent versions of branded drugs to market. Numerous economic studies have consistently found that entry of a competing generic manufacturer typically leads to lower average prices, and that this price competition typically intensifies with the entry of additional manufacturers.[17] For example, the CBO concluded in a review of the evidence that:

> The dramatic rise in generic sales since 1984 has held down average prices for drugs that are no longer protected by a patent. ...[A]verage prices fall primarily because consumers switch from the higher-priced innovator drug to the lower-priced generics. To be on the receiving end of that switch, generic manufacturers compete with each other intensely in the area of price, partly because they sell identical products. The increased use of

> generic drugs has kept total spending on prescription drugs below what it might otherwise have been.[18]

As the next section discusses, given the significant consumer benefits that result from both innovation and lower prices, policy-makers have sought to facilitate generic competition within a framework intended to provide branded manufacturers sufficient incentives to innovate.

C. The Hatch-Waxman Amendments

1. Introduction

In 1984, the U.S. Congress passed the Hatch-Waxman Amendments ("HatchWaxman")[19] to the Federal Food, Drug, and Cosmetic Act of 1938, which sought to balance the importance of innovation and generic entry. Hatch-Waxman established the current framework for patent litigation in the pharmaceutical industry, and although this framework has been modified since 1984, it largely remains intact. Any analysis of the economics of patent settlements must begin with an understanding of this framework.

2. FDA approval prior to Hatch-Waxman

Since 1962, the Food and Drug Administration ("FDA") has required pharmaceutical companies to prove that new branded drugs are "safe and effective" prior to approval. Branded drug manufacturers provide such evidence by conducting costly and lengthy clinical trials. The process of conducting clinical trials and obtaining FDA approval decreases the effective life of pharmaceutical patents substantially, because approval is typically received many years after a patent is granted.[20] Before Hatch- Waxman, the FDA also required generic manufacturers to conduct their own safety and efficacy studies. Generic manufacturers could not begin their safety and efficacy studies until patents on the brand-name drug had expired.

3. Overview of Hatch-Waxman

The intent of Hatch-Waxman was to alter the FDA approval process in two important ways:

On the one hand, Hatch-Waxman sought to increase patent protection and to strengthen the incentives of branded manufacturers to innovate. Recognizing that the lengthy FDA approval process often substantially reduced the effective life of pharmaceutical patents, Hatch-Waxman allowed

branded manufacturers to apply to extend the life of these patents to regain some of the patent life lost by clinical trials and the FDA approval process.[21]

On the other hand, Hatch-Waxman attempted to encourage generic competition. It streamlined the approval process for generic manufacturers, thereby reducing the costs of obtaining FDA approval and speeding their time to market. More specifically, Hatch- Waxman allowed generic pharmaceutical companies to submit an Abbreviated New Drug Application (ANDA), simply referencing the safety and efficacy results submitted by the branded company rather than conducting new clinical trials, so long as the generic drug could demonstrate "bioequivalence," which means that the rate and extent of absorption of the generic drug is not significantly different from that of the brand-name drug when administered with the same dosage. Branded manufacturers were required to file information about any relevant patents with the FDA. In addition, the ANDA filer must certify one of the following:

(1) the required patent information has not been filed by the branded manufacturer
(2) the patent has expired;
(3) the patent will expire, identifying the expiration date; or
(4) the patent is invalid and/or not infringed.

The latter representation is known as a Paragraph IV certification.

Since Hatch-Waxman, competition from generic drugs has grown significantly. The generic share of prescriptions has grown from 19 percent in 1984 to nearly 67 percent today.[22]

4. Patent litigation under Hatch-Waxman

Hatch-Waxman established several important aspects of patent litigation between branded and generic manufacturers. First, an ANDA filer who makes a Paragraph IV certification that the existing patent is invalid or not infringed must notify the patent holder (and the branded manufacturer) of the basis for its assertion. Under Hatch- Waxman, if a branded manufacturer files suit within 45 days of receiving notice of a Paragraph IV certification, the branded company is granted an automatic stay of FDA final approval of the generic company's ANDA until the earliest of: (1) 30 months from the notification date; (2) the district court decides the patent is invalid or not infringed; or (3) the patent expires. This is commonly known as a "30-month stay." If the patent holder does not file suit within the 45-day window, then the FDA may approve the ANDA immediately, provided all other requirements are met.

Second, the earliest generic pharmaceutical company to file an ANDA with a Paragraph IV certification for a particular drug is awarded a "180-day exclusivity period," during which time the FDA may not approve any Paragraph IV ANDAs filed subsequently for the same drug.[23] The start of the 180-day exclusivity period is triggered by commercial marketing of the first filer's product.[24] If the first filer does not exercise its exclusivity in a timely fashion, a variety of circumstances can lead to the forfeiture of its eligibility for exclusivity.[25] The substantial profits available during the 180-day period of exclusive marketing (in which the exclusive generic can charge a higher price than it could in the face of competition from other generic manufacturers and capture a larger share of sales) provide generic firms with an additional incentive to be first to challenge potentially invalid patents or to invent around the patented technology by developing a non-infringing alternative.

D. Patent Litigation and Settlement Agreements

ANDA filings frequently result in patent litigation. From 1998 to 2000, roughly 20 percent of filed ANDAs contained Paragraph IV certifications, where the generic manufacturer claimed that the branded manufacturers' patent(s) were invalid or not infringed.[26] A study by the FTC of ANDA filings between 1992 and 2000 found that a Paragraph IV certification resulted in patent litigation nearly 75 percent of the time.[27]

In general, the vast majority of patent litigation is resolved through a settlement between the parties.[28] Settlements between branded and generic pharmaceutical manufacturers are common. From 1992 to 2000, nearly 40 percent of litigations against the first ANDA filer resulted in settlement.[29] Similarly, Barr, one of the largest generic manufacturers, has settled nearly half of the 30 patent cases that it has been involved with (and the vast majority of cases that are not still pending) in the last 15 years.[30]

These settlements take many forms and can include the following types of provisions:

- An agreed-upon date upon which the generic manufacturer will enter the market (with or without royalty payments to the branded manufacturer);
- Cash payments from the branded manufacturer to the generic;
- Ancillary business transactions such as cross-licensing or supply agreements; and
- Agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry.

Pharmaceutical manufacturers settling patent litigation are required to report information on those settlements to the FTC and DOJ, and the FTC publishes annual reports summarizing those settlements.[31] The following table provides a summary of the FTC's classification of settlements that have been entered into over the last several years between branded and generic pharmaceutical manufacturers.[32]

	Total Settlements	Settlements Allowing Immediate Generic Entry	Settlements Not Allowing Immediate Generic Entry	
			With No Compensation to Generic	With Compensation to the Generic[33]
FY 2004	14	9	5	0
FY 2005	11	7	1	3
FY 2006	28	8	6	14
FY 2007	33	8	11	14

II. Competitive Effects of Patent Settlements: Short-Run

A. Overview

1. Patent settlements reduce the direct and indirect costs of litigation

Settlements of litigation provide clear potential benefits. After all, litigation imposes substantial costs. Costs to litigating parties include (1) direct litigation costs such as legal fees, (2) indirect costs such as requiring attention of company executives and distracting them from their responsibilities of running the business, and (3) indirect costs due to uncertainty.[34] Additional costs to society as a whole include increased congestion of the court system and corporate resources focused on private dispute resolution as opposed to innovation and production activities. Moreover, as firms generally pass on at least some portion of costs incurred, consumers ultimately bear some of these costs.

2. Patent settlements have the potential to be anticompetitive

While patent settlements between branded and generic manufacturers have clear potential benefits, they also can harm competition and consumers under certain conditions. The potential for anticompetitive effects is increased when the settlement is with the first generic filer, rather than a subsequent generic

filer, and the first filer does not relinquish its exclusivity. As described above, under Hatch-Waxman, the first generic filer receives 180 days of marketing exclusivity. This creates the potential for anticompetitive effect to the extent that delaying entry by the first filer could delay entry by all other generics as well. Prior to 2003, when much of the concern over patent settlements in the pharmaceutical industry originated, a settlement agreement did not affect 180-day exclusivity. Thus, a settlement with a first filer specifying an entry date well into the future could also prevent other generics from entering before that date (unless a subsequent-filing generic obtained a court decision that its product did not infringe or that the patent was invalid. Recognizing the potential anticompetitive effects of such a situation, a 2003 law introduced additional restrictions on "parking" the 180- day exclusivity. Importantly, the law was changed such that if the branded and generic manufacturers reach a settlement agreement, the settlement is challenged by the FTC or DOJ, and the agreement is determined to violate the antitrust laws, then the generic manufacturer forfeits its exclusivity.[35] This change substantially lessens the antitrust concerns with such settlements.

Ultimately, the competitive effects of a particular settlement will depend importantly upon the strength of the underlying patent.[36] A patent gives the branded manufacturer the right, within certain boundaries, to exclude competition.[37] If the patent is quite strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future but before patent expiration may bring generic drugs to market sooner than the expected outcome from continued litigation and generate lower prices for consumers. Moreover, there are frequently several generic manufacturers challenging a brand-name patent at any given time. Where this is the case, a settlement agreement with the first-filing generic has even less potential for anticompetitive effect where the brand-name patent is weak. While the incentive may not be as strong as that of the first filer (due to the 180-day exclusivity), other generic manufacturers continue to have an incentive to continue their challenge of patents they believe are invalid or that they do not infringe.[38]

In contrast, if the patent is quite weak, and likely to be found invalid and/or non- infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers. Considering the strength of a patent in real-world patent litigation, at least to some extent, is complex, but necessary. The next section presents an economic framework for this evaluation.

B. Economic Framework

1. Basic Model

Determining the scope of patent settlements that could raise antitrust concerns amounts to evaluating the following question: Which settlements would be in the economic interest of both the branded and generic manufacturer, but would harm consumers, relative to continuing litigation? Answering this question requires modeling the settlement decisions of both the branded and generic manufacturers, as well as evaluating the benefit to consumers from generic entry.

The standard economic model of settlements compares each settling party's economic gains from settling to its economic gains from continuing the litigation.[39] One then compares these two sets of settlement terms to determine the range of settlement terms that both parties would find preferable to continued litigation – in other words, those settlement terms that would feasibly lead to the end of the litigation.

Once the range of feasible settlements is established, one needs to determine which of these settlements, if any, would benefit consumers.[40] After all, consumers are not a party to the settlements, and so one might imagine that there could be settlements which benefit branded and generic manufacturer that do not benefit consumers.

For expositional purposes, we start with a highly simplified model of a patent settlement between branded and generic manufacturer. Assume:

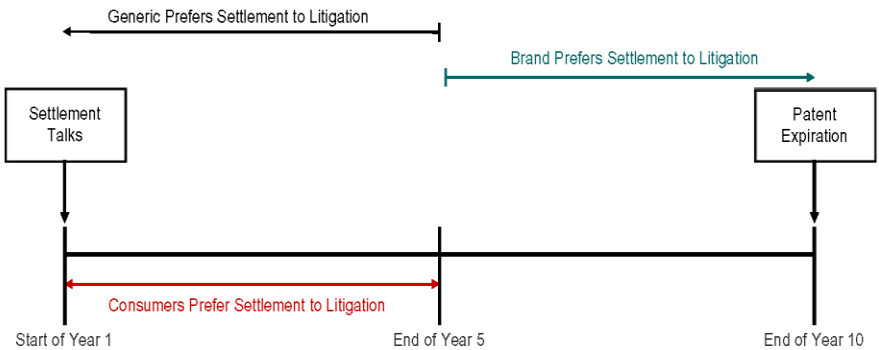
- The parties are considering settlement at the beginning of Year 1
- The patent expires at the end of Year 10
- The generic manufacturer both believes that it has and in fact has a 50 percent chance of winning the patent case (and the branded manufacturer also has, and perceives, a 50 percent chance)
- There are no costs to litigation
- The only settlement tool available is the date of generic entry (*i.e.*, lump sum payments, royalty payments, and other business transactions are not allowed).[41]

As we describe below, many of these assumptions do not affect the conclusions, but rather allow for an easier grasp of the intuition underlying the economic model. Other assumptions will have important effects on the conclusions. In the sections that follow, we will introduce real-world complexities and examine the implications of enriching the model.

Under these original assumptions, the expected or average outcome from litigation is generic entry at the end of Year 5. There is a 50 percent chance of immediate entry if the generic wins and a 50 percent chance of entry at the end of Year 10 if the brand wins. The settlement decision amounts to a comparison of the profits from settling to a simple average of the profits assuming immediate generic entry (50 percent chance the generic wins) and the profits assuming generic entry in Year 10 (50 percent chance the generic loses). Under the assumptions provided above, the simple average of profits from litigation is equivalent to the profits from entry at the end of Year 5.

In this simple framework, the only tool the parties can use in settlement negotiations is the date of entry of the generic. As shown in Figure 1, the branded manufacturer would agree to a settlement with generic entry at any point after the end of Year 5, whereas the generic manufacturer would agree to a settlement with generic entry at any point up until the end of Year 5. Thus, no settlement can be mutually agreeable to the two parties. The settlement ranges of the two parties are contiguous, but do not overlap.

Of course, this simple model assumes away many complexities present in the real world – indeed, some of the very complexities that provide important incentives for litigating parties to settle. In the next section, we relax some of these assumptions and demonstrate that doing so leads to a range of reasonable conditions under which patent settlements can benefit consumers.



Note: There are no settlements that both the Brand and Generic prefer to Litigation

Figure 1. Settlement with Generic Entry Date

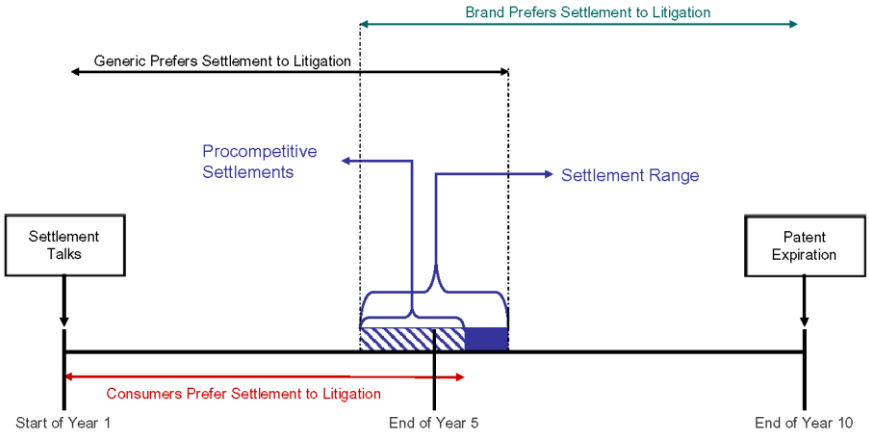


Figure 2. Settlement with Generic Entry Date Litigation Costs

2. Litigation costs

A primary motivation for parties to settle litigation is that it is costly. The oversimplified model presented above ignores this motivation. We now introduce litigation costs into the model and show that it leads to a range of settlements that would be agreeable to both the branded and generic manufacturers and could also make consumers better off.

Figure 2 shows that, because litigation is costly, the brand-name manufacturer would be willing to accept settlements where the generic enters before the end of Year 5 (i.e., earlier than it would be willing to accept based only on the profits from winning or losing the litigation), because the brand-name manufacturer would avoid these costs. Similarly, the generic would be willing to accept settlements which would have it entering after the end of Year 5 (i.e., later than it would be willing to accept based only on the chance of winning or losing the litigation). These litigation costs enlarge the range of settlements that would be agreeable to both parties.[42] In this way, litigation costs create the possibility of some settlements those that would lead the generic to enter before the end of Year 5 – that would benefit consumers. Accounting for the fact that part of litigation costs are ultimately borne by consumers broadens the range of procompetitive settlements.

Of course, the particular size of settlement ranges shown in these figures is not meant to convey the relative likelihood of any particular type of settlement, but simply to demonstrate the economic logic that certain kinds of settlements exist. Indeed, what seems to be a clear distinction between

procompetitive and anticompetitive in these diagrams is in fact quite difficult to distinguish in the real world. Recall that our example assumes a 50 percent chance that the generic manufacturer will win the patent litigation – and that everyone knows that probability. But the precise strength of the patent is not knowable to the antitrust analyst or even the parties themselves. It will depend on a wide range of factors that affect the outcome of litigation, including the documentary evidence, the quality of presentations by counsel, the testimony of company witnesses, the testimony of expert witnesses, and the particular judge and jury assigned to the case. Whereas settlements with entry after Year 5 could harm consumers under the assumptions we have presented, such settlements could in fact be procompetitive if the generic manufacturer's chance of winning the patent litigation was only, say, 30 percent.

3. Risk aversion

Another cost of litigation is the substantial uncertainty that it creates. Economists model the cost of uncertainty using the concepts of "risk aversion" and "risk premiums."[43] For example, a risk-averse economic actor will prefer to receive $2 with certainty, rather than a 50 percent chance at $1 and a 50 percent chance at $3. That is, risk-averse individuals prefer a certain outcome to uncertain outcomes with the same average or expected value but some degree of variance. A risk premium is the amount of money that a party would pay to avoid taking a risk. In the example above, the risk premium is the amount the individual would pay in order to receive the $2 with certainty rather than the option with 50-50 odds. The concept of a risk premium allows us to model uncertainty in the same way we do other litigation costs – where the risk premium is the additional cost to the parties created by the uncertainty. Thus, just as in the discussion of litigation costs above, both branded and generic manufacturers would accept lower expected profits under a settlement relative to continued litigation to avoid heightened uncertainty. As shown in Figure 3, the effects are similar to those with litigation costs.[44]

Is it reasonable to assume that large pharmaceutical companies are risk averse? After all, a basic tenet of financial economics holds that a large firm and/or a firm owned by (and effectively managed for) well-diversified shareholders should be risk neutral. The risk from a particular litigation can be effectively eliminated through diversification—in this case, by investing in many projects or holding many stocks. However, this argument ignores two important realities. First, it ignores the so-called principal-agent problem that can exist between the managers of the firm (in this case, the executives with decision-making power over the decision to settle or continue litigating) and

the shareholders of the firm.[45] While the firm's shareholders may be risk neutral, because they can diversify their risks over many investments, managers whose jobs and salaries depend to some extent on their current employer may be risk averse, instead. Second, not all pharmaceutical companies – not even all branded manufacturers – are large firms owned by diversified shareholders. For some branded manufacturers, the financial health of the company may depend importantly on the success of a single drug line.

4. Information asymmetries

Information asymmetries are another important component of settlement decisions. Both the branded and the generic manufacturer are likely to have information that the other party does not possess. The generic manufacturer, for example, may have better information about its ability to manufacture a generic version of the branded product. For example, a generic manufacturer may have manufacturing problems that delay its entry beyond the point at which it receives FDA approval (or that make such entry less effective). The branded manufacturer would be unlikely to know of such problems at the time of the settlement discussions.

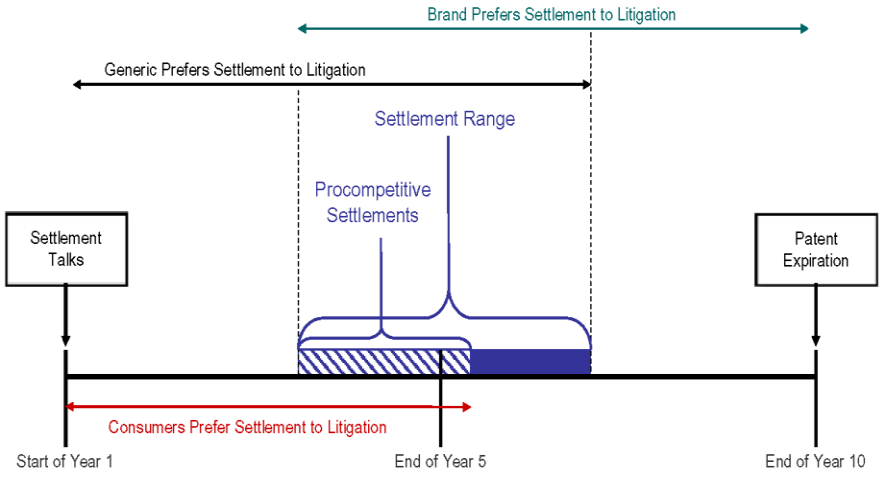


Figure 3. Settlement with Generic Entry Date Risk Aversion and Litigation Costs

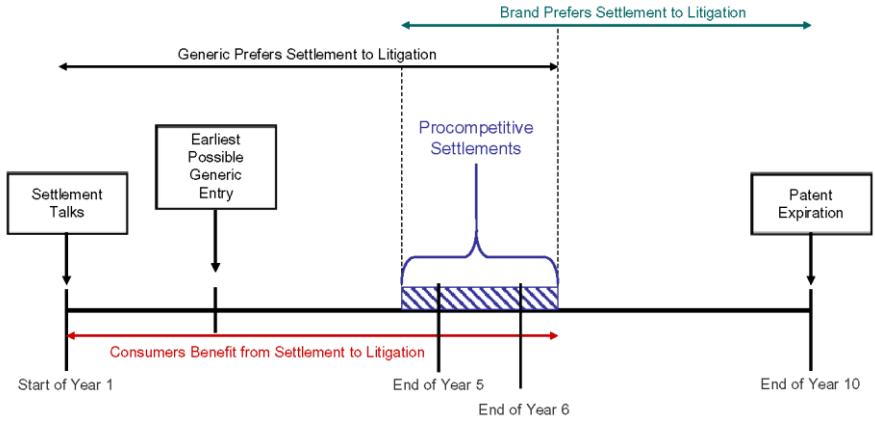


Figure 4. Settlement with Generic Entry Date Information Asymmetry and Litigation Costs

The branded manufacturer, on the other hand, may have better information about the expected size of the market for the product in the future. Branded pharmaceuticals generally have a limited life cycle; a branded drug often faces increasing competition from newer and often more effective branded products. The branded manufacturer may, for example, have specific knowledge of a next-generation product in its development pipeline which could substantially reduce the potential market for the litigated drug in the future.

These are just two examples of information asymmetries; there are many dimensions on which such asymmetries can exist. The parties may have private information that alters their probabilities of winning the patent litigation, about the competitive strategies (*e.g.*, pricing) they plan to employ after generic entry, or other factors.

We now introduce a specific example of information asymmetry to our model. Assume that the generic manufacturer knows that, even if it wins the patent litigation, manufacturing issues will prevent it from launching until the beginning of Year 3 (two years from now). Assume also that the branded manufacturer is unaware of this.

In this case, as shown in Figure 4, the generic manufacturer would be willing to agree to a settlement with entry as late as Year 6 (even later factoring in litigation costs), which would give it an additional four years of generic profits relative to the scenario when it litigates and loses. This outcome splits the difference between the eight years of additional profits (Year 3 through Year 10) it would receive if it won the litigation, and the zero

years if it lost. Similarly, consumers would be better off under a settlement with a date up to and including Year 6. The branded manufacturer, unaware that the generic has any production issues, has the same preferences it did in the initial example: It would agree to any settlement with generic entry as early as Year 5. Thus, as shown in Figure 4, procompetitive settlements with an entry date between Year 5 and Year 6 are feasible (and adding litigation costs or risk aversion to the model would only expand the range of procompetitive settlements).

Litigation costs, risk aversion, and information asymmetries are only three of the potential real-world complexities that can give rise to procompetitive patent settlements between the branded and generic manufacturer. For example, the preceding section has assumed that both parties have identical expectations as to the outcome of the litigation. It is highly likely, however, that the parties' expectations will differ at least to some extent – and perhaps greatly – and these differences can have important effects on the ability of the parties to reach settlement and the effects of those settlements on consumers. In the next section, we explore these and other issues in the specific context of reverse payment settlements.

III. Competitive Effects of Reverse Payment Settlements: Short-Run

A. Overview

While the possibility of the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so-called "reverse payment" settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash payments or through a payment associated with some other business transaction (*e.g.*, a cross- licensing agreement) where the branded manufacturer might allegedly "overpay" the generic manufacturer or the generic manufacturer might allegedly "underpay" the branded manufacturer.

The FTC and some antitrust scholars contend that these "reverse payments" are on their face evidence that the settlements are nothing more than a payment by the brand manufacturer to delay generic entry. In this section, we show that such a perspective is flawed because reverse payment settlements can serve to increase or decrease competition and consumer

welfare, depending upon the facts and circumstances surrounding the settlement. Thus, a *per se* rule against such settlements would be misguided. Indeed, a view allowing the possibility of reverse payments, with appropriate scrutiny in specific cases (as is available to the FTC under current law), has been adopted by most courts, the DOJ, and many scholars that have addressed this issue.

B. Regulatory and Judicial Enforcement

1. History

The FTC began scrutinizing reverse payment settlements in the late 1990s. Its initial challenges were directed at settlements where the brand-name manufacturer paid cash to the generic manufacturer to settle patent litigation. These challenges resulted in several consent decrees.[46]

The FTC's most prominent challenge was against Schering-Plough ("Schering") and two generic manufacturers relating to Schering's K-Dur (potassium chloride). Schering settled patent litigation with both Upsher-Smith ("Upsher") and ESI Lederle ("ESI") in 1997. The settlement agreement with Upsher included a related licensing agreement where Schering paid Upsher a $60 million royalty for five Upsher drugs and provided a royalty-free license for Upsher to launch a generic potassium chloride product in 2001 (Schering's patent expired in 2006). The settlement agreement with ESI included a cash payment, as well as a $15 million royalty payment for two ESI products, and provided a royalty-free license for ESI to launch a generic potassium chloride product in 2004.

The case has a long legal history, in which the disagreements over this issue are on full display. The FTC brought suit against the three companies, alleging that the royalty payments were simply disguised payments to delay generic entry and that the patent settlement agreements were anticompetitive. In 2002, the FTC's Administrative Law Judge ruled that the appropriate legal standard was a "rule of reason" analysis, and that under such an analysis the patent settlement agreements at issue were not anticompetitive.[47] The FTC appealed this decision to the full Commission, which reversed the decision and concluded that the payments were indeed anticompetitive.[48] Schering and Upsher then appealed the Commission's opinion to the Eleventh Circuit Court of Appeals. The Eleventh Circuit reversed the Commission's decision, finding that ultimately the determination of competitive effects depends upon the strength of the patent.[49] The FTC appealed to the Supreme Court, which declined to hear the case.

2. Current status

After these developments, reverse payment settlements are now treated quite differently by the various regulatory agencies and Courts. The FTC has clearly expressed that it views reverse payment settlements as essentially *per se* illegal.[50] Despite the adverse ruling by the Eleventh Circuit in *Schering*, the FTC has continued to demonstrate an interest in challenging reverse payment settlements.[51] The DOJ submitted a brief urging the Supreme Court *not* to hear the *Schering* case – a position at odds with the FTC's view.[52] Elsewhere, the DOJ has explained that "...settlements between an ANDA filer and the patent holder [even those with a reverse payment] also can benefit consumer welfare. Accordingly, the Department of Justice does not believe per se liability under the antitrust laws is the appropriate standard."[53]

Courts that have evaluated these reverse payment settlements have also reached varying conclusions. In the *Cardizem* case, the Sixth Circuit embraced a standard of *per se* illegality.[54] In stark contrast, the other three circuit courts to address this issue have given reverse payment settlements significant latitude. In both the *Schering* (described above) and *Valley Drug* cases, the Eleventh Circuit relied on a standard that acknowledges the potentially procompetitive nature of these settlements and would give significant latitude as long as the branded patent litigation was not objectively baseless.[55] Similarly, the Second Circuit applied a rule of reason standard in the *Tamoxifen* case when affirming the trial court opinion that the settlements were not anticompetitive.[56]

Recently, the Federal Circuit applied a similar standard in the *Cipro* case.[57] In 1991, Bayer entered into an agreement with generic manufacturers Barr Labs, Hoechst Marion Roussel, and The Rugby Group settling patent litigation over Cipro. Under the settlement agreement, Barr certified that it would not market its generic version prior to the expiration of Bayer's patent. Bayer paid Barr a lump sum payment and agreed to either supply Barr with Cipro for resale, or make payments to Barr through December 2003. Consistent with the decisions by the Second and Eleventh Circuits, the Federal Circuit concluded that a rule of reason approach was appropriate and that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." The appellate court affirmed the trial court's conclusion after a similar inquiry, that the plaintiffs had not shown that the agreement was anticompetitive.

C. "Reverse Payment" and "Exclusion Payments" Are Misnomers

Before presenting our economic analysis of reverse payment settlements, it is useful to examine the "reverse payment" moniker itself. Such settlements were baptized by commentators who believe that a payment from the branded manufacturer to the generic manufacturer flows the "wrong" way. In a typical settlement of a patent lawsuit, this argument points out, the alleged infringer pays the patent holder (a lump-sum payment and/or a license fee), while in a reverse payment settlement the patent holder (branded manufacturer) pays the alleged infringer (generic manufacturer).

But this label is based on flawed logic. Hatch-Waxman creates an unusual circumstance in the pharmaceutical industry where the patent holder (branded manufacturer) can sue the alleged infringer (generic manufacturer) before the alleged infringer markets a product.[58]

In the typical patent case – indeed, in any patent case – the alleged infringer is going to require some compensation for abandoning the litigation.[59] In a typical case where the patent infringer has been on the market for a significant period of time and would owe significant damages if found liable, the parties may agree to a settlement where the infringer pays damages to the patent holder, but those damages are far less than the damages the patent holder is seeking. In this case, the patent holder pays the infringer to settle the lawsuit by accepting lower damages – this payment is just obscured by the fact that on net some cash flows from the infringer to the patent holder. Reverse payment settlements can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the branded manufacturer to the generic manufacturer. Since nothing nefarious can be gleaned from the simple fact that the payment flows in a particular direction, one must examine the underlying economics of these settlement agreements.

Similarly, the term "exclusion payments" does not accurately reflect the nature of many of these deals. If the branded manufacturer holds an ultimately valid patent, and the parties settlement allows the generic manufacturer to enter the market prior to patent expiration (but after the generic manufacturer preferred to enter), then the generic was not "excluded" in any meaningful way. The patent itself provided the ability to exclude, not the payment.

D. Basic Economic Model

The framework presented above for an analysis of patent settlements can be used to evaluate reverse payment settlements as well. We start with the

highly simplified case outlined in Figure 1 – no litigation costs, full information, and risk neutrality – and relax only the assumption requiring the only term of settlement to be the date of generic entry and allow settlements to include cash payments. How will this affect the range of settlements?

Monopoly profits (profits when only the brand is in the market), will typically be larger than profits when the brand and the generic are both in the market. Of course, branded pharmaceuticals are not necessarily monopolies before the entry of generics, because patents give only a limited right to exclude identical competition and because they may compete with other branded or generic manufacturers. Nonetheless, thinking about analogy to monopoly profits can provide intuition as to why the parties may have an incentive to agree to delay generic entry. A year of delay will be worth more to the branded manufacturer (because it gains a year of "monopoly" profits) than it costs the generic manufacturer (because it loses a year of contested profits), so there will be settlements that delay entry beyond Year 5 that both parties prefer to litigation. As shown in Figure 5, this expands the range of settlements that the brand and generic manufacturers could potentially agree to, but only to include generic entry dates later than Year 5. Consumers will be clearly worse off under these settlements. Of course, without knowing the precise strength of the patent, observed terms of a particular settlement agreement could be consistent with delayed generic entry, as shown in Figure 5, or with a procompetitive settlement where generic entry occurs sooner than would be expected with litigation.

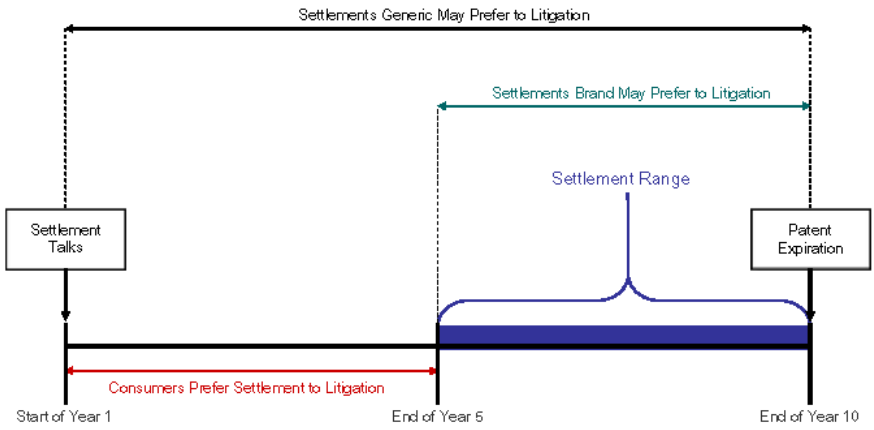


Figure 5. Settlement with Generic Entry Date and Cash Payment

Thus, a model that ignores real-world complexities can lead to the conclusion that a settlement with cash payments from the brand to the generic can harm consumers. In the next section, we extend the basic model – as we did in the earlier section – to account for the additional complexities that drive real-world settlements. This analysis demonstrates that relying on the overly simplistic framework discussed above can frequently lead one to draw incorrect conclusions as to the competitive effects of a patent settlement.

E. Introducing Real-World Complexities to the Basic Model[60]

1. Overview

Expanding the model to account for other real-world factors demonstrates that settlements with reverse payments can be procompetitive. In fact, under certain conditions, without the bargaining tool of a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers.

Many economists that have written on this subject agree that when real-world complexities are taken into account, reverse payment settlements can be procompetitive.

Shapiro (2003) explained:

> This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement.[61]

Bigelow and Willig (2009) share a similar view:

> It also follows from economic logic that the opportunity to employ reverse payments may be necessary for socially beneficial and procompetitive settlements to be reached, due to such common situations as asymmetric information, excess optimism, and differential cash needs between the parties to the patent dispute.[62]

Executives in the pharmaceutical industry have expressed similar views. For example, Bruce Downey, the CEO of generic manufacturer Barr Pharmaceuticals, testified to Congress that if a law were passed prohibiting reverse payments "there would be very, very few settlements."[63]

2. Cash payments with litigation costs and/or risk aversion

As described above, litigation costs and risk aversion can be important real-world factors to consider in evaluating patent settlements. Accounting for litigation costs and/or risk aversion expands the range of settlement agreements that each party is willing to accept. As shown in Figure 6, these factors expand the range of potential settlements that branded manufacturers will accept (relative to Figure 5), and by creating incentives for branded manufacturers to settle on terms more favorable to consumers it becomes clear that settlements with reverse payments can be procompetitive.

3. Cash payments with a cash-strapped generic

Some observers have argued that, while reverse payment settlements can leave consumers better off than continued litigation, there is always a feasible alternative settlement without a payment (where the parties simply agree on an entry date) that will leave consumers better off than either litigation or a reverse payment settlement. Under this argument, a prohibition on reverse payment settlements would unambiguously leave consumers better off while still allowing the parties to reap the benefits of settlement. This argument ignores the complexities of settlement negotiations.[64] In the presence of such complexities, additional flexibility in negotiations may be *essential* to enabling a pro-consumer settlement between the parties. That is, under these circumstances, without a reverse payment the parties would be unable to reach a settlement at all.

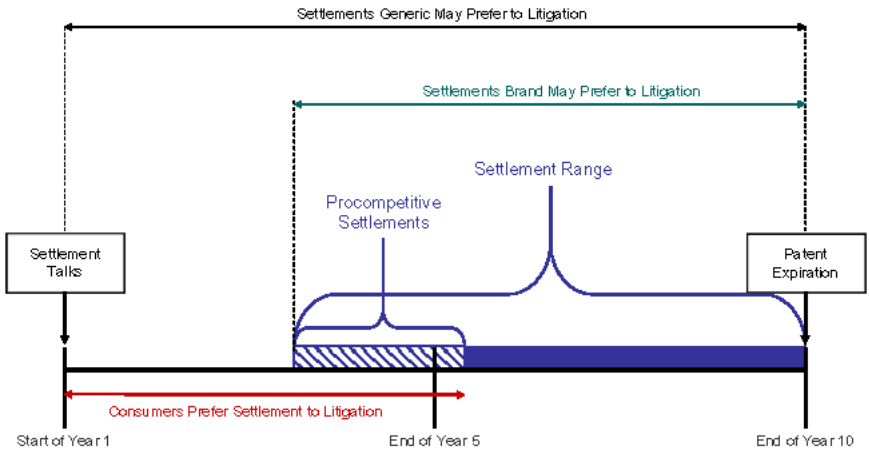


Figure 6. Settlement with Generic Entry Date and Cash Payment Litigation Costs

Two real-world complexities ignored by the basic model are the time value of money and the possibility of liquidity constraints. The time value of money refers to the fact that individuals prefer a dollar received today to dollar received in the future; thus they discount the value of future cash flows. Imagine a small, cash-strapped generic entrant that is having a difficult time raising needed capital from the financial markets. As a result, the entrant discounts future profits very heavily; in other words, since it needs cash, it values near-term profits very highly. This generic manufacturer will only accept settlements that allow for relatively early entry, which under the conditions of the example illustrated in Figure 7a would not be acceptable to the branded manufacturer.

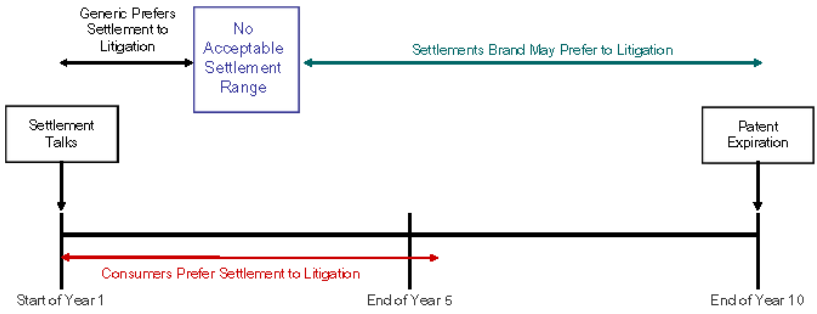


Figure 7a. Settlement with Generic Entry Date and No Cash Payment Cash-Strapped Generic and Litigation Costs/Risk Aversion

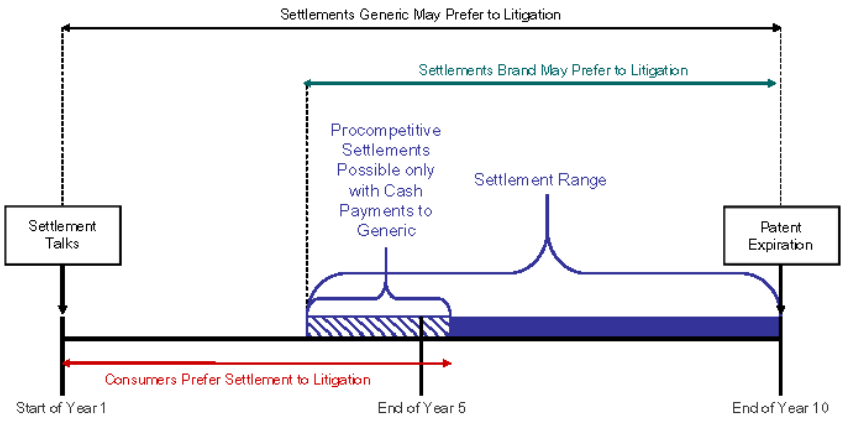


Figure 7b. Settlement with Generic Entry Date and Cash Payment Cash-Strapped Generic and Litigation Costs/Risk Aversion

The latest entry date to which the cash-strapped generic would be willing to agree is earlier than the earliest date to which the branded manufacturer would be willing to agree. As a result, settlement talks would break down.

A cash payment by the branded manufacturer may allow the branded and generic manufacturers to bridge the settlement gap shown in Figure 7a. The branded manufacturer would be willing to include a cash payment in the settlement in exchange for a later generic entry date. The generic manufacturer would be willing to accept later entry in exchange for a cash payment. As described above, the incremental profits that a branded manufacturer would receive because of postponed generic entry would be higher than the incremental profits that the generic manufacturer would lose from delaying its entry to a more competitive market. Thus, a given cash payment will move the range of entry dates that the branded manufacturer is willing to accept later in time, but it will move the dates the generic is willing to accept by an even greater amount. Such a payment will bring the parties closer together and could bridge the settlement gap between the two parties. As shown in Figure 7b, under these circumstances, reverse payments can lead to a range of settlements that would not have been otherwise feasible.

Importantly, many of these newly conceivable settlements would benefit consumers by resulting in a generic entry date earlier than that expected with continued litigation.

4. Cash payments with an optimistic generic

Cash payments can also help bridge settlement gaps arising under other circumstances. For example, imagine a generic manufacturer that, despite actual odds of winning the patent suit of only 50 percent, believes that it in fact has a 75 percent chance of winning. This mismatch of beliefs and actual probabilities could create a situation similar to that depicted in 7a, where (absent a reverse payment) the generic manufacturer would not be willing to accept any settlement terms the branded manufacturer would be willing to offer because the generic manufacturer has an unrealistic belief about its chance of winning if it holds out and continues to litigate. Just as with a cash-strapped generic, a reverse payment can potentially bridge the settlement gap and lead to a settlement that benefits consumers. Of course, it is possible that the branded manufacturer is also overly optimistic about its odds of success in the litigation, which would reduce the range of procompetitive settlements that a cash payment could generate. Our point here is not that these are the only scenarios that could play out, but rather that there are reasonable scenarios

under which a patent settlement with a reverse payment can benefit consumers.

5. Cash payments with information asymmetries

The sets of information known by the brand and the generic manufacturer almost certainly differ significantly, and often in important ways. Willig and Bigelow (2004) describe how this information asymmetry can create another circumstance where cash payments can facilitate a procompetitive settlement agreement that would not otherwise be feasible.

Imagine that the branded manufacturer has private information about the effective life of the patent – for example, about the prospects of future competition from other branded products that would reduce or eliminate demand for the product at issue in the patent litigation. The generic entrant knows that the branded manufacturer is better informed about future competition, and therefore will interpret settlement offers from the branded manufacturer with this in mind.

Suppose there are two types of patents: "high-value" patents, where there is no chance that other branded competitors enter before the patent expires, and "low-value" patents, where there is a decent chance that such brand-name entry happens, significantly reducing the effective life, and the value, of the current patent. The branded manufacturer knows which type of patent it holds, but the generic manufacturer does not.[65] In the case of a low-value patent, agreeing to a compromise entry date may have little benefit to the generic because the market may be eliminated by future competition. So a generic may be wary of accepting a reasonable settlement offer because it worries that that settlement may indicate that in fact the patent is low value – and the generic would be better off continuing to litigate.

The problems created by information asymmetries can be overcome if the branded manufacturer is allowed to provide a cash payment to the generic manufacturer. In our example, only branded manufacturers with high-value patents would find it profitable to offer an up-front payment to the generic. Thus, the generic can interpret the reverse payment as a signal that the patent is high value, and have strong reason to believe that the settlement offer is in fact a good offer from a branded manufacturer with a high-value patent, rather than a poor offer from a branded manufacturer with a low- value patent. Here again, cash payments can facilitate settlements – including procompetitive settlements – that would not be reached if such payments were not allowed.

6. Collateral business agreements

Many settlements between branded and generic manufacturers involve collateral business agreements. These agreements may take a variety of forms, including:

- Branded manufacturer licenses products from the generic manufacturer;
- Generic manufacturer licenses products from the branded manufacturer;
- Generic manufacturer agrees to co-promote one or more of the branded manufacturer's products; and/or
- Generic manufacturer agrees to serve as supplier for the branded manufacturer.

Such collateral agreements can be helpful in facilitating settlements by allowing the parties to get around some of the complexities discussed above that may otherwise pose obstacles to successful settlements like information asymmetries and differences in expectations. Unlike cash, the parties' valuations of the components of a collateral business arrangement may be quite different. This difference in valuation could be used to offset different expectations in the patent litigation to arrive at a settlement. In addition, these collateral agreements could in and of themselves benefit consumers, bringing together business partnerships that would not be possible with continued litigation. But while these collateral agreements can serve to facilitate settlements, they could also, in theory, contain "effective" payments that are designed to delay entry of the generic, if the generic manufacturer is over-compensated for what it is providing or the branded manufacturer is under-compensated for what it is providing.

In recent years, patent settlements with collateral business agreements have received significant regulatory and legal scrutiny. For example, as described above, the agreement between Schering and Upsher that was challenged by the FTC did not involve an isolated cash payment to the generic. Rather, in settling the patent dispute, Schering also licensed five different products from Upsher, including Upsher's Niacor SR, in exchange for royalty payments of $60 million.[66] The FTC argued that the $60 million royalty payments were well above the value of the licensed products, and that the payments were just another means to delay generic entry.[67]

Evaluating the competitive implications of settlements with collateral business arrangements is even more complicated than those with cash

payments. Such an analysis first requires an evaluation of the collateral business transaction to determine a reasonable assessment of the market value of the transaction. To the extent that it is clear from the evidence that the generic was over-compensated or the brand was under-compensated, then the difference between the payment and the arms-length value of the transaction can be thought of in the same way as a "reverse payment." Collateral business transactions, just like reverse payments, therefore can be anticompetitive, but they can also serve to produce procompetitive outcomes, some of which may not have been otherwise feasible.

IV. Long-Run Competitive Effects

The discussion to this point has focused on the short-run competitive effects of patent settlements. Clearly, patent settlements can be procompetitive, even when focusing on short-run competition. Patent settlements can also have important long-run competitive effects. First, the scope of patent protection can affect future incentives for branded manufacturers to invest in additional R&D. Patents give patent holders, such as branded pharmaceutical manufacturers, the right to litigate claims against alleged infringers, and the right to settle such litigation – at least as long as such a settlement does not exclude competition beyond that allowed by the patent. Broad-brush limits on the types of patent settlements that are allowed by pharmaceutical manufacturers would likely result in a narrowing of the patent protection currently provided to patent holders. As described above, such patent protection is an important component of pharmaceutical manufacturers' incentives to invest substantial sums in R&D and to introduce new medications. To the extent that limits on patent settlements reduce incentives to invest in pharmaceutical R&D, consumers may suffer significant adverse effects in the long-run, in the form of a smaller number of new medicines that become available.[68]

Second, the availability of procompetitive settlements can provide further incentives to generic manufacturers to challenge branded patents and bring lower-priced generic drugs to market. Patent litigation can be expensive and risky, particularly for small firms. Restricting the range of settlement options will reduce the ability of generic manufacturers to settle these cases and increase the cost and risk of bringing a generic drug to market. On the margin, this will lower the incentives of generic pharmaceutical manufacturers to challenge branded patents in the first place.[69] Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition can be substantial.

V. Policy Implications and Conclusions

Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core this depends upon the validity of the patent claims. A settlement agreement whereby the generic manufacturer agrees to enter in, say, five years – but five years before patent expiration – might be anticompetitive if the patent was weak (*i.e.*, if the generic had a high probability of winning at trial). But the same settlement terms might be procompetitive if the patent was strong (*i.e.*, if the generic had a low probability of winning at trial). Ultimately, an evaluation of the competitive effects of a patent settlement cannot avoid at least some investigation into the merits of the patent litigation.

While antitrust economists generally agree with this line of argument, some analysts have suggested prohibiting settlements with "reverse payments." Several bills have been introduced in Congress that would do just that.[70]

However, as we explain above, under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and consumers. An outright prohibition of reverse payment settlements would harm consumer welfare in a range of circumstances. Indeed, prohibiting settlements with cash payments could simply lead to a shift to settlements with other business arrangements which are even more complicated to evaluate, which makes enforcement of potentially anticompetitive arrangements even more difficult to assess. Efforts to prevent settlements with any compensation (whether in the form of cash or compensation from other business arrangements) flowing from the branded manufacturer to the generic would similarly block many pro-consumer settlements. Of course, an outright prohibition on such settlements would reduce the uncertainty and litigation costs that may follow from antitrust challenges to such settlements. But it is not at all clear that these savings would outweigh the harm created by eliminating potentially procompetitive settlements. "Quick look" or "safe harbor" approaches (whereby settlements with certain characteristics are presumptively anticompetitive or procompetitive, while leaving open the opportunity to rebut this presumption) could reduce these costs while still allowing procompetitive settlements.

Moreover, a restrictive policy approach that sought to bar reverse payment settlements would not only have short-term impacts by preventing procompetitive settlements, but may harm consumers in the long-run by reducing the incentives of branded manufacturers to continue to develop

innovative new drugs, and reducing the incentives of generic manufacturers to challenge weak patents and bring generic drugs to market sooner.

Patent settlements between branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any relevant patent settlement agreement be provided to the FTC and the DOJ. But painting all settlements with the same brush is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework, such as that presented here, to the facts specific to that settlement.

End Notes

[1] I have consulted with both brand and generic pharmaceutical manufacturers on cases regarding the competitive effects of patent settlements. The views I express here are solely mine and do not necessarily represent the views and opinions of Compass Lexecon or its clients.

[2] Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry," March 2009. This testimony draws substantially from that paper, which I include as an Appendix.

[3] Bret Dickey is a Senior Vice President with Compass Lexecon, an economic consulting firm.

[4] Jonathan Orszag is a Senior Managing Director and member of the Executive Committee of Compass Lexecon. He is also a Fellow at the University of Southern California's Center for Communication Law & Policy. Previously, he served on President Clinton's National Economic Council and as the Assistant to the Secretary of Commerce and Director of the Office of Policy and Strategic Planning.

[5] Laura D'Andrea Tyson is Professor of Business Administration and Economics at the Haas School of Business at the University of California, Berkeley. Dr. Tyson served with cabinet rank in the first Clinton Administration, first as chair of the White House Council of Economic Advisers, then as National Economic Adviser to the President and chair of the National Economic Council. She is the former dean of the London Business School and the Haas School of Business.

[6] The authors thank Jamie Mullins of Compass Lexecon for his excellent research assistance. This study was supported by funding from the Pharmaceutical Research and Manufacturers of America (PhRMA). The views and opinions expressed in this study are solely those of the authors and do not necessarily reflect the views and opinions of PhRMA or any of the organizations with which the authors are or have previously been associated. Compass Lexecon has served as economic consultants to branded and generic manufacturers regarding the competitive effects of patent settlements.

[7] Statement of Senator Barack Obama for the American Antitrust Institute, September 2007, p. 2 (available at *http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209- 07*_092720071759.pdf).

[8] Concurring Statement of Commissioner Jon Leibowitz re: *Federal Trade Commission v. Watson Pharmaceuticals et. al.*, February 2, 2009 (available at *http://www.ftc.gov/speeches/leibowitz/090202watsonpharm.pdf).*

[9] The Preserve Access to Affordable Generics Act was introduced by Senators Kohl and Grassley in February 2009 (see http://kohl.senate.gov/newsroom/pressrelease.cfm?customel_dataPageID_1464=2126), and the Protecting Consumer Access to Generic Drugs Act of 2009 was introduced by Representative Rush in March 2009 (see *http://thomas.loc.gov/home/gpoxmlc111/h1706_ih.xml).*

[10] Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2008*, March 2008, pp. 2-3. See also Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006, pp. 7-9 ("CBO 2006").

[11] CBO 2006, p. 9.

[12] U.S. Food and Drug Administration, "CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type" (http://www.fda.gov/cder/rdmt/pstable.htm); U.S. Food and Drug Administration, "CDER Drug and Biologic Approvals for Calendar Year 2005" (http://www.fda.gov/cder/rdmt/InternetNDA05.htm); U.S. Food and Drug Administration, "CDER Drug and Biologic Approvals for Calendar Year 2006" (http://www.fda.gov/cder/rdmt/InternetNDA06.htm); U.S. Food and Drug Administration, "CDER Drug and Biologic Approvals for Calendar Year 2007" (*http://www.fda.gov/cder/rdmt/InternetNDA07.htm).*

[13] For example, one report indicates that only 1 of every 5,000 medicines tested is eventually approved (Tufts Center for the Study of Drug Development, "Backgrounder: How New Drugs Move Throughout the Development and Approval Process," November 1, 2001).

[14] Vernon, John M., Golec, Joseph H., and DiMasi, Joseph A., "Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model," *Tufts Center for the Study of Drug Development Working Paper*, 2008, p. 3 (concluding that 20 percent cover their R&D expenses); Grabowski, Henry G., Vernon, John M., and DiMasi, Joseph A., "Returns on Research and Development for 1990s New Drug Introductions," *PharmacoEconomics*, 20(3), March 2002, p. 17 (concluding that 30 percent do).

[15] CBO 2006, p. 20. See also DiMasi, Joseph A., Hansen, Ronald W., and Grabowski, Henry G., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 22(2), March 2003, pp. 164-165,.

[16] DiMasi, Joseph A. and Grabowski, Henry G., "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics*, 28, 2007, pp. 469-79. See also CBO 2006, and Adams, Christopher P. and Brantner, Van V., "Estimating the Cost of New Drug Development: Is It Really $802 Million?" *Health Affairs*, 25(2), 2006, pp. 420-428.

[17] See, for example, Grabowski, Henry G. and Vernon, John M., "Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, 35, October 1992, pp. 331-350. Other articles reaching similar findings include: Frank, R. G. and Salkever, D. S., "Pricing, Patent Loss and the Market for Pharmaceuticals," *Southern Economic Journal*, 59(2), 1992, pp. 165-179; Caves, Richard E., Whinston, Michael D., and Hurwitz, Mark A., "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*, 1991, pp. 1-48; Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, pp. 28-33 ("CBO 1998"). As Grabowski and Vernon (1992) and others have found, branded manufacturers may increase their prices in response to generic entry, but the net effect of lower generic prices and higher branded prices is generally to lower average prices for the molecule.

[18] CBO 1998, p. 13.

[19] More formally, the law was known as the Drug Price Competition and Patent Term Restoration Act of 1984.

[20] CBO 1998, p. 39.

[21] Specifically, the branded manufacturer could apply for an extension on one patent equal to half of the time spent on clinical trials plus all of the time spent in FDA review, subject to a maximum extension of five years and a maximum effective patent life of 14 years. *See*

Grabowski, Henry G. and Kyle, Margaret, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* 28, 2007, p. 492. Additionally, regardless of whether a new drug has patent protection, upon approval of an NDA for a New Chemical Entity, a drug will receive a 5-year term of exclusivity from the FDA. During this exclusivity period an ANDA that references the brand manufacturer's NDA cannot be submitted (except after four years if there is a patent challenge). See: U.S. Food and Drug Administration, "Frequently Asked Questions on Patents and Exclusivity" (http://www.fda.gov/cder/ob/faqs.htm#How).

[22] See, for example, Generic Pharmaceutical Association (GPhA), "Annual Report 2008: Generics: The Right Choice for Better Health," 2008, p. 6; GPhA, "Industry History" (available at http://www.gphaonline.org/Content/NavigationMenu/AboutUS/History.htm).

[23] Under certain circumstances (e.g., two generic manufacturers file ANDAs containing a Paragraph IV certification for the same branded drug on the same day) the FDA may grant "shared exclusivity" in which both generic manufacturers can receive final approval simultaneously and potentially share the 180-day exclusivity period.

[24] For products subject to the prior law before 2003, the 180 days would also be triggered by a court decision of invalidity or noninfringement of the relevant patent.

[25] "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," §1102 (a)(2)(D)(i)(I)(aa)(AA) ("2003 MMA").

[26] Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," (2002), p. 10 ("FTC 2002").

[27] FTC 2002, pp. 13-15.

[28] See, for example, Shapiro, Carl, "Antitrust Limits to Patent Settlements." *RAND Journal of Economics*, 43(2), 2003, pp. 391-411 ("Shapiro (2003)").

[29] FTC 2002, pp. 15-16.

[30] Testimony of Bruce Downey, "Paying Off Generics to Prevent Competition With Brand Name Drugs: Should It Be Prohibited?" *Hearing Before the Committee on the Judiciary, United States Senate, Serial No.* J-1 10-4, 2007, p. 23. ("Testimony of Bruce Downey") Specifically, Mr. Downey testified that this has been true during his tenure as CEO, which began in 1993.

[31] This requirement was created by the 2003 MMA and effective in FY 2004.

[32] Federal Trade Commission, "Summary of Agreements Filed in FY 2004," Figure II; Federal Trade Commission, "Summary of Agreements Filed in FY 2005," p. 3; Federal Trade Commission, "Summary of Agreements Filed in FY 2006," pp. 3-4; Federal Trade Commission, "Summary of Agreements Filed in FY 2007," p. 3 and Figure III.

[33] As defined by the FTC, compensation may be in the form of cash, an ancillary business transaction, or an agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry. According to the FTC reports, many of these settlements also include compensation to the branded manufacturer – the reports do not provide sufficient information to determine whether there was a net payment to the generic.

[34] See, for example, Shapiro (2003), p. 394; Bessen, James E. and Meurer, Michael J., "The Private Costs of Patent Litigation," *2nd Annual Conference on Empirical Legal Studies Paper*, February 1, 2008, p. 2.

[35] 2003 MMA.

[36] Some courts have considered not the subjective assessments of the parties but what a "reasonable person" would think. *See, e.g., Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 992-993.

[37] See Shapiro (2003) for a discussion of patents as probabilistic property rights.

[38] The 180-day exclusivity provides a motivation for generic manufacturers to bear the cost and risk associated with developing generic versions of branded drugs and challenging branded patents. But at the time of a settlement with the first-filing generic, many subsequent generic entrants may have already incurred many of these costs. Thus, even relatively small

profits expected by a subsequent filer could provide the incentive to continue to challenge the branded patent.

[39] For a general discussion of the settlement decision, see Cooter, Robert and Rubinfeld, Daniel L., "Economic Analysis of Legal Disputes and their Resolution," *Journal of Economic Literature*, September 1989, pp. 1067-1097.

[40] In this paper, the term "consumers" is used to represent those that ultimately pay for prescription drugs. In reality, this is a combination of patients, private insurers, and government.

[41] Other assumptions include: (1) Total prescriptions are constant in each year, as is the share of prescriptions by the branded and generic manufacturers after generic entry. (2) There is perfect information, so both parties know the ultimate chance of winning. (3) Both parties are risk neutral. (4) There is no time value of money for either party. (5) After entry, there will be only one generic competitor.

[42] Because annual profits for the generic are lower than annual pre-generic entry profits for the branded manufacturer, the generic would be willing to give up more time in the market to avoid those costs, assuming litigation costs for the brand and the generic are similar.

[43] See Pindyck, Robert S. and Rubzinfeld, Daniel L., *Microeconomics*, 7th Edition, 2009, Section 5.2.

[44] Similarly, if consumers are risk averse, accounting for this would broaden the range of procompetitive settlements.

[45] For a general discussion of the principal-agent problem see, for example, Pindyck, Robert S. and Rubinfeld, Daniel L., *Microeconomics*, 7th Edition, 2009, Section 17.4.

[46] FTC Decision and Order, *In the Matter of Abbott Laboratories*, No. C-3945 (May 22, 2000); FTC Decision and Order, *In the Matter of Hoeschst, Carderm, and Andrx*, No. 9293 (May 8, 2001). Many of these cases were followed by private suits by direct and indirect purchasers.

[47] Initial Decision, *In the Matter of Schering-Plough Corp*., et al, 136 F.T.C. 956, 1092 (2002) (No. 9297).

[48] Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957.

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

[50] See, for example, Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957, prohibiting settlements "under which the generic receives 'anything of value'" (carving out an exception for payments up to $2 million linked to litigation costs).

[51] *See, e.g.*, Oral Statement of FTC Commissioner Jon Leibowitz, Hearing of the House Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, May 2, 2007.

[52] On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit, Brief For The United States As Amicus Curiae, *FTC v. Schering-Plough Corp. et al*, 548 U.S. 919 (2006) (No. 05-273).

[53] U.S. Department of Justice, Office of the Assistant Attorney General, Letter to the Honorable Jon Kyl. February 12, 2008.

[54] *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (In re Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. Mich. 2003).

[55] The *Valley Drug* case involved an "interim settlement" of a patent suit between Abbott and Geneva over generic Hytrin. See *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (11th Cir. Fla. 2003). Whereasthe focus of our paper is on final settlements – where the settlement resolved the litigation – in an interim or "partial" settlement, the litigation continues but the generic manufacturer agrees not to launch "at risk" while the litigation is ongoing. For a more complete discussion of the competitive implications of interim settlements, see Langenfeld, James and Li, Wenqing, "Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers," *Antitrust Law Journal*, 70, 2003, pp. 777-818.

[56] *In Re: Tamoxifen Citrate Antitrust Litigation, 29 F.3d 370* (2d Cir. 2005).

[57] *In Re: Ciproflaxin Hydrochloride Antitrust Litigation* (Fed Cir. 2008).

[58] Generic manufacturers can "enter at risk" – that is enter before final judgment in the patent litigation – but this is the exception rather than the rule. For example, Mr. Downey testified that Barr never enters at risk (Testimony of Bruce Downey, p. 24).

[59] Crane, Daniel A., "Correspondence: Ease Over Accuracy in Assessing Patent Settlements," *Minnesota Law Review*, 88, 2004, pp. 698-711; Schildkraut, Marc G., "Patent-Splitting Settlements and the Reverse Payment Fallacy," *Antitrust Law Journal*, 71(3), 2004, pp. 1033-1068.

[60] This section draws on the work of Robert Willig and John Bigelow. See Willig, Robert D. and Bigelow, John P., "Antitrust Policy Toward Agreements that Settle Patent Litigation," *The Antitrust Bulletin*, pp. 655-698, (Fall 2004),; Bigelow, John P. and Willig, Robert D., "'Reverse Payments' in Settlements of Patent Litigation: Schering Plough, K-Dur and the FTC," *The Antitrust Revolution: Economics, Competition, and Policy*, 5th Edition (2008) ("Bigelow and Willig (2008)").

[61] Shapiro (2003), p. 408.

[62] Bigelow and Willig (2008), p. 35.

[63] Testimony of Bruce Downey, p. 28.

[64] A related argument is that an alternative settlement with a different payment and a different entry date may be better for consumers. However, this argument ignores the fact that antitrust regulators consider the implications to competition of an agreement among competitors (such as a reverse payment settlement) versus a but-for world without the agreement, not against an optimal agreement. See Department of Justice and Federal Trade Commission, "Antitrust Guidelines for Collaborations Among Competitors," April 2000, p. 4, 7, and 10.

[65] Economic models on this point often assume that the branded manufacturer knows the type of patent it holds with certainty. However, the results depend not upon this assumption (as there may be some uncertainty even on the part of the branded manufacturer) but only that the branded manufacturer will have better information on the type of the patent than the generic manufacturer.

[66] *Schering-Plough v. FTC*, 402 F.3d, at 1060.

[67] Ultimately, the Appeals Court concluded that the FTC did not convincingly demonstrate that the $60 million was not simply a royalty payment within the range of fair market value for the licensed products. See *Schering-Plough v. FTC*, 402 F.3d, at 1068.

[68] For a more extensive discussion of these effects, see Langenfeld, James and Li, Wenqing, "Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers," *Antitrust Law Journal*, 70, 2003, pp. 777-818.

[69] See, for example, Judge Posner's opinion in *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994.

[70] See, most recently, the Preserve Access to Affordable Generics Act, S.3 69, 111th Cong. (2009) and the Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

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Chapter 6

STATEMENT OF GUY DONATIELLO, ENDO PHARMACEUTICALS INC., BEFORE THE SUBCOMMITTEE ON COURTS AND COMPETITION POLICY, HEARING ON "PAY TO DELAY: ARE PATENT SETTLEMENTS THAT DELAY GENERIC DRUG MARKET ENTRY ANTICOMPETITIVE"

Mr. Chairman and Members of the Subcommittee, my name is Guy Donatiello and I am the Vice President for Intellectual Property for Endo Pharmaceuticals Inc. I am a patent attorney and have worked exclusively in the intellectual property field for more than twenty years.

Endo is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of branded and generic prescription medicines in pain management, urology, endocrinology, and oncology. Endo is based in Chadds Ford, Pennsylvania and employs nearly 1,500 people throughout the United States.

Endo is a mid-sized company with $1.2 billion in sales in 2008. We are a member of PhRMA, our trade group that represents the country's leading research-based pharmaceutical and biotechnology companies which as an industry invested over $50 billion in research and development in 2008. In addition, Endo is a member of America's Specialty Medicines Companies, an informal working group of mid-sized pharmaceutical companies.

Thank you for the opportunity to testify on behalf of the biopharmaceutical industry regarding an issue of great importance to future medical innovation and patient care: patent settlements and competition in the marketplace. I hope I can provide you with a unique perspective on this issue as a representative of a mid-sized pharmaceutical company that participates in both the branded and generic markets.

Before I respond directly to the issue we are here to discuss, I would like to point out that pharmaceutical products effectively have a shorter period of useful patent life than other types of products. Pharmaceutical companies must obtain FDA approval before marketing their products, and by the time the medicine comes to the market, there is usually far less time before patent expiration than with other products. Hatch-Waxman attempted to balance the interests of both branded and generic companies by recognizing these patent life challenges. The law made it easier for generics to come to market but also restored to branded companies some of the patent time lost during clinical research and the FDA regulatory review process.

As a *mid-sized* pharmaceutical company that brings to market *both branded and generic medicines*, patents are critical to our success in both commercial areas. On the branded side, strong patents permit Endo to innovate and bring new medicines to market to treat unmet medical needs and to compete, **on price**, with other branded products in the same therapeutic class to the benefit of patients. On the generic side, patent expirations of branded medicines permit us to bring to market medicines that will compete with generic and branded counterparts, **also on price**, to the benefit of patients.

Our ability to defend, and to challenge, patents underpins our continued success and fosters future medical innovation for tomorrow's cures. Legislation banning certain patent settlements is unnecessary and harmful. It would halt pro-consumer settlements, erode the value of patents, chill incentives for medical innovation, and reduce patient access to generic drugs.

There are current mechanisms in place to handle truly anti-competitive settlements. To be clear, current law dictates that every settlement between a brand and generic must be submitted to the FTC for review, and any settlement that is judged to be anti-competitive can be invalidated.

This judgment is a result of fact-sensitive litigation that recognizes that every case is different and every case might result in a unique compromise in settlement. Under the proposed legislation, generic companies may bring fewer patent challenges if they have fewer options to resolve litigation without the cost and risk of going to trial. The rapid increase in generic utilization has been fueled in part by the fact that branded and generic manufacturers have

been able to settle some patent suits in appropriate ways without taking every case through trial and appeal.

Banning certain types of patent settlements would restrict the ability of both branded and generic companies to settle ANDA patent cases logically. As a result, it would force companies to engage in patent disputes that might otherwise be settled reasonably, quickly, and in the public interest. The parties involved could be forced to spend significant resources on litigation, diverting those resources from valuable investment in future innovation. In addition, statistics show that innovators are likely to win the majority of patent cases litigated through appeal, and these patents would bar generic entry until they expire. In contrast, a settlement might include a provision allowing the generic to come to market well before the patent expires, getting a low-cost generic into patients' hands sooner.

Under certain circumstances, the impact of banning certain patent settlements could result in companies being forced out of business. Small to mid-sized companies like Endo are particularly vulnerable because they often rely on just one or two branded products to generate revenue. These revenue-generating products are often medicines with revenues too small or markets too specialized to be profitable for larger companies to bring to market. It is the smaller companies that bring these medicines to the patients who need them. When generic competition threatens these patented products through an ANDA filing, a patent dispute often results. Because the small branded company is so dependent on the product being disputed, losing the patent case threatens the company's very existence. Furthermore, if a generic company launches its generic product during a long and expensive litigation, it may ruin a small branded company; even though the branded company may ultimately win the litigation and compel the generic product off the market, the harm has already been done – the genie cannot be put back in the bottle.

I would like to turn to the generic drug development process to highlight another point. The development of generic drugs is not always a smooth pathway with success as a given. Despite excellent scientists, a generic company may work on a project for years and never duplicate the brand to FDA's satisfaction. By the time an ANDA is filed, significant resources are committed to the project based on an anticipated return on investment. Allowing settlements where we recoup some of our investment allows us to develop more low-cost generics for patients. Conversely, adding new barriers to settlements will increase uncertainty, sap resources, and chill investment in new generic medicines.

In short, when a small company, whether a branded manufacturer or a generic challenger, becomes involved in complex, lengthy, expensive litigation with an uncertain outcome, the continued existence of that company is threatened. Resources for future R&D are inevitably squeezed and channeled into legal fees. Patients are the real losers because access to future branded and generic medicines will be delayed or denied.

In conclusion, H.R. 1706 would add cost and uncertainty to bringing new branded and generic medicines to patients. Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis, examining all relevant facts including the strength of the patent and whether the settlements benefit consumers.

While it is a delicate balance, the current system works – innovation is rewarded and competition is robust. Without the ability to make full legitimate use of intellectual property rights, the innovative process that results in intense competition between and among branded and generic manufacturers will suffer, and patients will ultimately suffer. There will be fewer medicines to treat diseases. And with fewer medicines there is also less price competition.

Thank you. I would be happy to answer any questions.

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Chapter 7

STATEMENT OF WILLIAM P. (BILL) KENNEDY, CO-OWNER, NEPHRON PHARMACEUTICALS CORPORATION, BEFORE THE U.S. HOUSE OF REPRESENTATIVES, HEARING ON "H.R. 1706, THE PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2009"

COMPANY PROFILE

Nephron Pharmaceuticals Corporation ("Nephron"), a family owned pharmaceutical manufacturing and sales company, has grown rapidly since it was purchased in 1991. Nephron utilizes state of the art Blow-Fill-Seal technology to manufacture sterile generic respiratory medications. Only four such facilities currently exist in the US. In spite of today's volatile economic times, Nephron is undergoing a 35 million dollar expansion to upgrade automation and technology at its Orlando, Florida manufacturing facility. Already a large employer, the company is adding specialized engineers and scientists to support its efforts to double manufacturing capacity of their life saving generic respiratory medications.

INTRODUCTION

Chairman Conyers, Ranking Member Smith and Members of the Committee, thank you for allowing me to testify before you today. My remarks are in support of H.R. 1706. I am here to show you how the American consumer can save 60% of the cost of their prescribed medications, if Congress will adopt my suggestions.

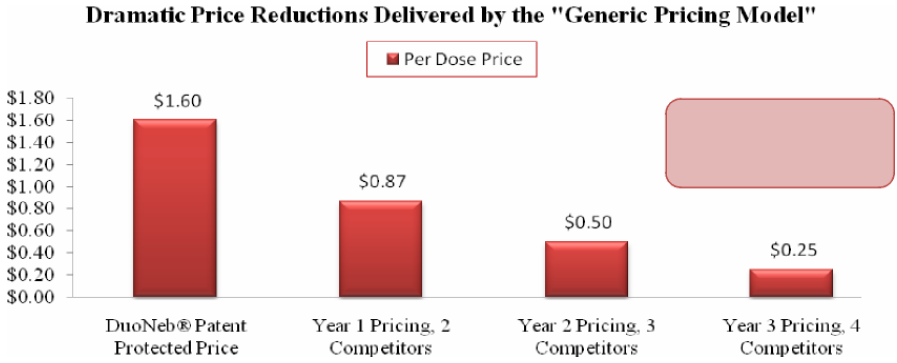
My name is Bill Kennedy and I purchased Nephron in the early nineties. I am a pharmacist by trade, and have 42 years of experience in healthcare. I have personally witnessed the struggles of the elderly and poor to afford their medications. I also remember the introduction of generic drugs, offering patients affordable therapeutic equivalents. As a generic drug manufacturer, it is my business practice to deliver low cost, high quality generic drugs to our customers. In fact, it is the hallmark of our company.

Multi-source generic drugs operate in a highly price competitive arena, while single source generic drugs or "authorized generics", rarely deliver significant price savings over their branded rivals. I propose that this committee supports H.R. 1706 to restore the incentives to generic drug makers in their challenge of patents with little or no legal basis, or medical benefit to consumers. Drugs with weak patents serve only to maintain artificially high prices for the American consumer. If Congress adopts H. R. 1706, competition and government savings that benefit all constituents and tax payers will prevail, restoring the public policy rationale originally envisioned by Hatch-Waxman.

THE CHALLENGE

A product pricing example from Nephron's recent history shows how the price of a generic drug rapidly drops in a competitive drug market. Nephron manufactures and sells a generic version of DuoNeb®, a widely used respiratory solution. As shown in the following diagram, this product was originally priced at approximately $1.60 per dose as a single source, brand name drug. When the first authorized generic entered the market, the price dropped to approximately 0.87 cents. After the entrance of the third, fourth and fifth generic competitor, prices eroded to the current 0.25 cents range. In this case, consumers and the U.S. Government realized a cost reduction of more than 80% within three years after generic price competition began. Even

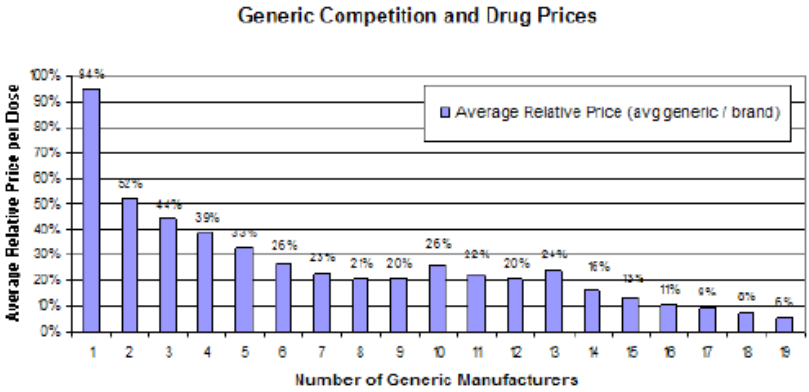
though this price drop was steep and fairly rapid, this three year window could have been shortened, given the weak patent at introduction. By adopting H. R. 1706 Members of the Committee have the power to **accelerate that price drop by 2 or more years;** thus, saving billions of federal dollars and providing great benefit to the patient.



The Hatch-Waxman amendments to FDCA, include a feature called the "paragraph IV certification" filing. The filing offers generic drug manufacturers who challenge and successfully win a patent litigation case, a 180 day period to exclusively market a new generic drug before a brand drug is openly exposed to further generic competition. Filing a paragraph IV certification typically involves litigation between a patent holder and generic challenger. The 180 day exclusivity window serves as an incentive to the generic challenger to dispute a weak patent. This allows the potential winner of the challenge to recover the costs of litigation. Originally, the Hatch-Waxman amendments were intended to create additional access to generic drugs for the American consumer. In recent years, "patent settlement" agreements (sometimes referred to as "reverse settlement agreements"), between the patent holder of a drug and the first and second to file generic competitors have stifled competition. These agreements allow the brand manufacturer to continue selling its drug, at or near, the original branded price, while paying the first to file generic drug manufacturer not to distribute its product, or to offer its "authorized generic product", priced just beneath the branded drug. As a result, greatest consumer savings are delayed, and the American healthcare system, including Medicaid and Medicare, are forced to spend millions more on drugs.

If a prior party has filed a Hatch-Waxman paragraph IV certification application with the FDA, and entered into a corresponding patent settlement

agreement with the patent owner, then Nephron, as a third or fourth filer is unwilling to commit precious capital to the highly litigious process of weak patent challenges. As the law is currently written, Nephron would not receive the financial benefit of the 180 day exclusivity window, even if Nephron prevails in the weak patent challenge case. This is a disincentive for companies like Nephron to challenge weak patents and restricts price competition in the drug market. It is crucial to understand that the generic drug pricing model will not deliver significant cost savings to the consumer, until the 3rd and 4th competitor has entered the market. The FDA research presented below notes the average price drop of a dose of product from the 1st generic manufacturer to the 4th generic manufacturer is 61%.



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

THE POSITION OF NEPHRON PHARMACEUTICALS CORPORATION ON H.R. 1706

On March 31, 2009, testimony to the Subcommittee on Commerce Trade and Consumer Protection Energy and Commerce Committee, US House Of Representatives was given regarding H.R. 1706 by some of the largest generic drug manufacturers in the world. Those large companies explained their positions eloquently, and testified drug prices fall as much as 20% when they enter the market. I am here to offer the perspective of a manufacturer that may file third or fourth. With our entrance into the market…..**prices fall 60% and more!** In fact, our very existence has been charted by the ability to compete

behind the first and second filers. For this reason, my recommendations to the committee, as a family owned manufacturer, differ from a large scale publicly owned one. Drug companies are engaging in a business practice using "patent settlement agreements", and Hatch-Waxman Act paragraph IV certifications, to create disincentives to generic drug manufacturers from challenging weak patents in the courts. Nephron is in opposition to collusive business practices known as "patent settlement agreements" between generic and branded drug companies and **strongly** supports H. R. 1706.

For the generic and branded pharmaceutical companies that have aligned themselves through patent settlement agreements, there is tremendous incentive to maintain the status quo due to the enormous profits generated for each day a product remains protected by a weak patent. My competitors, large generic manufacturers, often refer to their settlement agreements as "pro-consumer". This is only slightly true, because with a third or fourth competitor in the market, the generic drug pricing model takes over, allowing for pricing to reach truly "pro-consumer" levels. Weak drug patents should receive adequate review in a court venue. In court, it is the burden of potential competitors to fund the analysis and arguments, while generating new and novel approaches to the drugs they can produce. By supporting H. R. 1706, the committee will restore the original vision of Hatch-Waxman, which is to allow generic drug companies to rationally invest in challenging weak patents. Increasing the availability of generic drugs is vital to lowering costs within the U.S. healthcare system.

NEPHRON'S RECOMMENDATION FOR H.R. 1706

1. Nephron recommends that the committee adopt H.R. 1706 and eliminate the practice of patent settlement agreements.
2. Nephron urges the committee to consider a major change in Hatch-Waxman, by changing the "first to file" approach to a "first to win the patent case without settlement" approach. If Nephron were to win in court challenging a weak patent, Nephron would expect to be the sole beneficiary of the exclusivity period starting when the weak patent is knocked out, regardless of its position among other "paragraph IV" filers.
3. The "first to win" approach is likely to be time consuming, expensive and an all-or-nothing proposition. Therefore, Nephron proposes to the

> Committee to consider expanding the exclusivity period from 180 days to one year. A company investing in a successful challenge to a weak patent deserves to achieve a reasonable rate of return on its investment, and the expanded exclusivity period would provide more incentive and protection to the challenger. After the expiration of the one year exclusivity period, the market for the new generic drug would be open to all respective abbreviated new drug application ("ANDA") holders. Nephron believes that four to five competitors would readily enter and compete in the market place for the new generic drug one day after the expiration of the exclusivity period.

We feel the implementation of our recommendations would create an extremely competitive marketplace, and it is only with greater competition that lower prices will reach the American consumer.

Thank You, Mr. Chairman, my family and I are extremely grateful for the opportunity to speak to the committee in support of H.R. 1706, which we feel is critical in lowering costs to the American consumer. I am happy to answer any questions you may have.

End Notes

[1] FDA. (2005, February1). *Generic Competition and Drug Prices.* Retrieved May 1, 2009, from www.fda.gov: http://www.fda.gov/cder/ogd/generic_competition.htm

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Chapter 8

TESTIMONY OF WILLIAM VAUGHAN, SENIOR HEALTH ANALYST, CONSUMERS UNION, NON-PROFIT PUBLISHER OF CONSUMER REPORTS, BEFORE THE SUBCOMMITTEE ON COURTS AND COMPETITION POLICY, HEARING ON "PAY TO DELAY: ARE PATENT SETTLEMENTS THAT DELAY GENERIC DRUG MARKET ENTRY ANTICOMPETITIVE"

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of *Consumer Reports*.[1] Consumers Union investigates and reports extensively on the issues surrounding the costs, safety, and effectiveness of prescription drugs and other health products so that we can provide physicians and consumers with expert, non-biased information.

Attachment #1 describes our Best Buy Drugs program. This is a major campaign by Consumers Union to use comparative effectiveness research to provide free, unbiased information to doctors and patients on the safest, most effective *brand and generic drugs*, and then to make a best buy recommendation. These recommendations can save consumers thousands of dollars a year.

To answer the hearing question: Absolutely!

Consumers Union absolutely believes that payments between brand and generic drug companies that delay the entry of generic drugs are bad for consumers and are the very definition of anticompetitive behavior. We support legislation to ban these payments—bills such as HR 1706 by Representatives Rush, Waxman, and others, and S.369 by Senators Kohl, Grassley, and others. That bill clarifies the law to make these agreements illegal and is a necessary step to give the enforcers and the courts the ability to stop this egregious conduct which costs consumers over $12 billion annually in excessive drug prices.

Almost all of these settlements restrict generic competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years. These settlements also jeopardize the health of millions of Americans who have difficulty obtaining safe and effective medicines at affordable prices. In light of the recent increased use of these agreements, we hope that you will quickly pass legislation like HR 1706. There is an excellent chance that CBO will score it with savings, perhaps substantial savings, and we hope you will consider adding it to any Health Reform legislation Congress considers this year, as a partial pay-for.

This testimony

- discusses why generic drugs are critical to affordable health care today and how Consumers Union is educating its readers and the public about the substantial benefits of using the most effective drugs, whether brand or generic;
- explains how the dynamics of generic drug competition create powerful incentives for brand-name and generic companies to settle patent litigation in a way that harms consumers;
- urges that other anti-competitive practices, such as abuse of the generic 6-month exclusivity provision and ‘authorized generics’ be addressed.

The testimony also describes Consumers Union's support of several other legislative changes to help consumers, speed generic entry *and* improve pharmaceutical research and consumer information, including: (a) creating an incentive for other “later filer” generic firms to successfully challenge patents by permitting them to secure exclusivity, (b) eliminating the abuse of ‘authorized generics‘, (c) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines (biosimilars), (d)

clearing the backlog of generic applications at the FDA, (e) eliminating the abuse of citizen petitions in the generic drug approval process, (f) using Medicare to control costs while encouraging innovation, and (g) advancing the pace of drug R& D and consumer safety.

RAPID ENTRY OF GENERIC DRUGS CAN HELP DAMPEN HIGH HEALTH CARE COSTS NOW, ASSISTING FAMILIES AND GOVERNMENTS IN A DIFFICULT TIME

Health care costs continue to surge at double or more the rate of general inflation. While drug inflation has moderated in recent years—in large part due to the increased use of generics—it is still a serious burden to consumers and government and private insurers, and the higher rate of inflation is expected to resume in a few years.[2]

High Costs Impact Familie

We all know how badly the high cost of health care is hurting America‘s families, especially now in this time of recession and high unemployment. Because generics are substantially cheaper than brand name drugs, it is more important than ever that we ensure that generics come to market without collusive, anti-competitive delays.

In a poll of over 2000 households this spring, Consumers Union found 28 percent of the public has tried to reduce health care costs by not filling prescriptions, skipping doses or cutting dosage in half without their doctor‘s approval—all potentially dangerous actions and bad for the longterm health of those who need drugs like statins, diabetes medicines, etc.[3] In particular, seniors and people with disabilities on Medicare will need extra help in the next several years dealing with high drug prices, because Social Security COLAs are estimated to remain at zero or close to zero, yet Part D premiums are likely to increase, cutting into the net Social Security check.

Costs of Drugs Impact Governments and Taxpayers

In 2008, the federal government was projected to have accounted for 31 percent of the $235 billion spent on prescription drugs, and the Federal government's share is expected to rise to 40 percent by 2018.[4] The new Part D program added a tremendous future obligation onto the government: $9.4 trillion in present value costs to Medicare over the next 75 years, with Part D outlays estimated to increase from 0.4 percent of GDP to 1.8 percent by 2083. In the short-run, the Part D average annual increase in expenditures is estimated to be 11.1 percent through 2018, while the US economy is projected to grow by only 4.5 percent.[5]

Generics Dramatically Lower Costs

The rapid entry of generic drugs into the market can help dampen health inflation by providing equally safe and effective medicine at a far lower price— often prices up to 80 percent or less of the brand name drug and capturing 44 to 80 percent of sales in the first year of generic launch[6]. In 2007, the average retail price of a generic prescription drug was $34.34, while the average retail price of a brand-name prescription was $119.51 and almost 70 percent of all prescriptions are now for generics.[7] It has been estimated that generic drugs save consumers between $8 and $10 billion each year.

Generics also inflate substantially less than brand name drugs:

> "Prices for generic drugs increase more slowly than prices for brand-name drugs. In 2008, the average price inflation for generic drugs used by M edco members was only 0.5%, and unit costs for many generic drugs actually declined as market competition expanded. In contrast, the average price inflation for brand-name drugs was 8.4%.[8]
>
> "In 2008, the average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for brand name prescription drugs widely used by Medicare Part D beneficiaries was 8.7 percent, or about 2.3 [times] the general inflation rate of 3.8 percent. The 2008 average rate of increase in manufacturer prices of specialty drugs (brand and generic) was even greater—9.3 percent. By contrast manufacturer prices of (non-specialty) generic drugs widely used by Medicare beneficiaries *decreased* by an average of 10.6% in 2008."[9]

Many Generics about to Enter Market

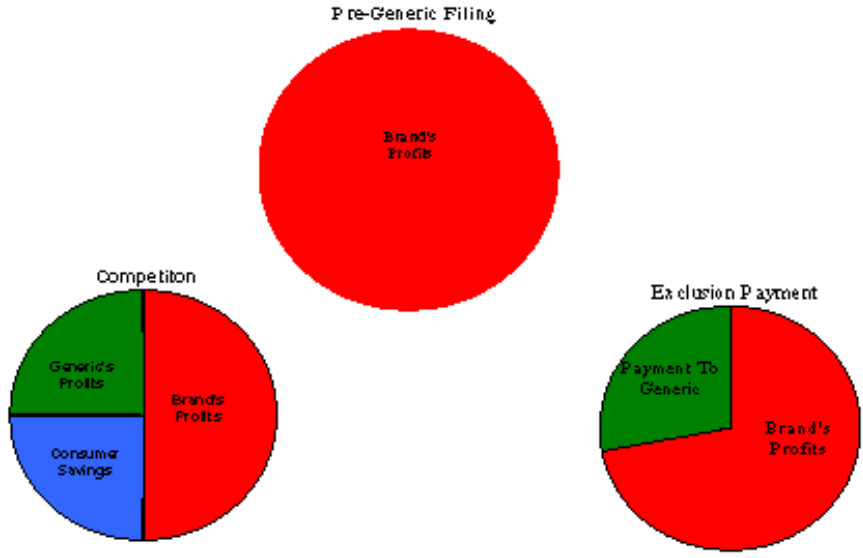
What is exciting for consumers is that there are major brand-name medicines about to be available in generic form—if anti-competitive and collusive practices do not block their timely entry. As of the fall of 2007, Hatch-Waxman challenges were pending for over 120 brand name prescription drugs with combined annual sales of over $90 billion, and it is estimated that between now and 2012, about $139 billion in international annual sales of brand-name drugs will face generic competition.[10]

Clearly, it will be a major help to America's consumes and taxpayers if the expected flow of generics to market is not thwarted by anti-competitive, collusive payments between brand and generic drug manufacturers.

THE DYNAMICS OF GENERIC DRUG COMPETITION CREATE POWERFUL INCENTIVES FOR BRAND-NAME AND GENERIC COMPANIES TO SETTLE PATENT LITIGATION IN A WAY THAT THWARTS THE OBJECTIVES OF THE HATCH-WAXMAN ACT

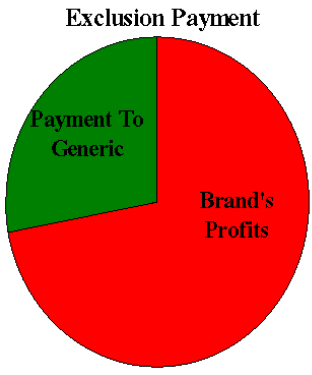
The economics surrounding generic entry create powerful incentives for brand-name and generic companies to enter into these types of patent settlements. These incentives are created because the total profits available to the brand-name company prior to generic entry exceed the total profits of both the brand-name and generic applicant after generic entry. As a result, the brand- name company has a powerful economic incentive to pay the generic applicant something more than it would earn by entry with its generic product, because the sum the brand-name company pays will still be less than it would lose if the generic applicant did enter the market. Likewise, the generic applicant who is sued for patent infringement can earn more by entering into a settlement in which it agrees to defer market entry—do nothing--than it could earn by winning its patent challenge and competing in the market. In short, when these payments are allowed, the generic company may obtain more by settlement than it could have obtained by outright victory in the patent case.

The following pie charts from FTC Commissioner Rosch before a House Energy and Commerce Subcommittee this March 31st clearly makes the point:

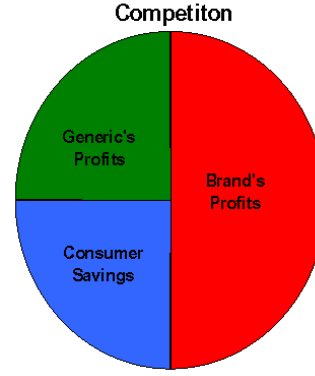


Incentives to Pay for Delay

#1



#2



Let me see if I understand the argument of the brand and generic industries? They say we should allow their for-profit brand members (whose fiduciary duty is to their stockholders to make profits) to pay the for-profit generic companies (whose fiduciary duty is to their stockholders to make profits)—diagram #1. They then say that we should permit this because it will encourage both industries to more quickly bring generics to market--diagram

#2—where both for-profit parties will make less money and less profit. The industries say that prohibiting these payments will delay the day that they both voluntarily act together to help the consumer with lower drug prices while reducing their own profits.

That is their argument. Said with a straight face.

As Columbia University Law Professor C. Scott Hemphill testified before the Energy and Commerce Committee March 31st, "If the brand-name firm paid a rival after patent expiration to abandon its effort to market a competing drug, that transaction would clearly be inappropriate. The same is true when the privately arranged extension postpones an entry date that is prior to patent expiration."

The argument is made that some of these reverse payment settlements have led to bringing more quickly a generic to market. Like a Blue Moon, it is possible. And HR 1706/S. 369 allow the FTC to recognize and accept such settlements in the rare cases they occur.

But in the great majority of cases, it would be extremely naïve to assume that the Diagram #1 above is being done to help speed up the results in Diagram #2. The FTC has provided massive documentation that in most cases, these payments cost the consumer—and the cumulative cost is running in the billions.

As this Committee knows, the courts have not grasped the reality of the anticompetitive effects of these settlements. Absent Congressional action the substantial harm to consumers will continue. If the law is not clarified pharmaceutical patentees will continue to pay off generic firms to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. The costs are substantial: a recent study by Professor C. Scott Hemphill of Columbia Law School found that consumers are paying over $12 billion more annually because of these exclusion payments.2

Attachment #2 is a discussion of how and why these problems arose and why legislative action is needed as soon as possible.

OTHER LEGISLATIVE SUGGESTIONS TO HELP SPEED GENERIC ENTRY

Congress should also consider several other alternatives to support the effort to assure consumers receive access to safe and low cost generic drugs as quickly as possible.

First, the Hatch Waxman Act should be amended to give "**later filers**" – generic firms that are not the first to file a patent challenge, the opportunity to secure exclusivity if they successfully challenge a patent. Preventing exclusion payments is a necessary, but not sufficient step to preventing the gaming of the regulatory system to delay generic entry. A subsequent generic patent challenger often is well positioned to successfully challenge and invalidate a patent. Unfortunately, under the current system, there is little incentive for the subsequent filer to take on the burden of expensive patent litigation, since it cannot secure any exclusivity if it succeeds. Congress should address this issue by giving a subsequent filer who successfully challenges a patent a period of exclusivity.

Second, we hope that you can address the problem of 'authorized generics.' The very phrase should raise red flags about the level of competition from an 'authorized' generic. It is just another way to avoid rigorous, meaningful competition. An authorized generic is a generic which enters under a licensing arrangement from the branded firm. These authorized generics occur at the end of patent life and seem intended to undermine the reward system established under the Hatch-Waxman Act which gives the first generic filer a six-month period of exclusivity. Without the rewards of exclusivity the incentive to challenge pharmaceutical patents is diminished. Moreover, branded firms often use the threat of an authorized generic to force generic firms to enter into these anticompetitive settlements.

Third, we urge Congress to stop the use of phony citizens petitions to delay generic entry. According to the FDA, only 3 of 42 petitions answered between 2001 and 2005 raised issues that merited changes in the agency's policies about a drug. For example, Flonase, a commonly used prescription allergy medication, went off-patent in May 2004. But GlaxoSmithKline stretched its monopoly window by almost two years with citizen petitions and a legal challenge to the use of generics. We recommend Congress end this abuse.

Fourth, there is no clear pathway, in law or FDA regulation, providing for FDA approval of generic versions of complex molecular biologic medicines which are so important in modern medicine (although the Europeans are moving ahead in this area). To date, the developers of biologics have a de facto monopoly market stretching as far as the eye can see. One such drug on the market for the past twenty years has probably earned its company $20 billion from Medicare alone, and there is still no generic in the US. These new biologic products are the most expensive medicines on the market—some costing as much as $100,000 to $250,000 for a course of treatment. Consumers

Union and the Congressional Budget Office believe that biogenerics could provide billions in savings and can be provided safely, thus helping some of our most severely ill patients. The CBO estimate on Chairman Kennedy's S. 1695 from the 110th Congress (with a 12 year exclusivity compared to Chairman Waxman's proposal of 5 year exclusivity) showed total savings to the economy of $25 billion between 2009-2018 or about 0.5 percent of national spending on prescription drugs at wholesale prices.[11] (Presumably, a 5-year exclusivity bill will show even larger savings.) Existing FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers. Therefore, we hope that as part of health reform, Congress will enact legislation like Chairman Waxman's bill, HR 1427.

Fifth, we urge Congress to provide the FDA with sufficient resources to eliminate the backlogs in the approval of generics. The President's new FY 2010 budget request asks for $36 million to "provide greater access to affordable generic drugs and improve the productivity of generic drug review through a new user fee program." As the FDA testified last month:

> In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. It is imperative that FDA have the resources to ensure the safety, quality, and therapeutic equivalence of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs[12]

We urge Congress to approve this request—consumers must have confidence in generics, and the faster we can move these safe drugs to market, the faster we can help families meet their medical costs.

FINDING OTHER WAYS TO HELP CONSUMERS HOLD DOWN DRUG COSTS WHILE PROMOTING DRUG INNOVATION

Whenever consumers question a pharmaceutical industry policy, no matter how anti-consumer, the industry says that if there is any reduction whatsoever in their profit margins, they won't be able to invent the cures to the diseases we all dread. Even though about 85 percent of new drug approvals are just for me-too drugs and bring little new to the medical world, this threat is always

troubling. We believe that there many policies that Congress should consider to encourage the industry to spend more on true R& D while helping consumers obtain access to more generics, faster. We hope that you will join us in considering some of the following types of policies:

- require drug rebates to Medicare for drug inflation in excess of population and CPI growth, except no rebates would be required on new breakthrough drugs (as defined in the FDA approval process), thus controlling costs while encouraging drug innovation;
- amend the FDA laws to require that new drugs be tested against the best practice in the field, not just against a placebo;
- increase the world's medical scientific base by eventually making Phase I trial results, both the successful and the unsuccessful, public;
- after ensuring safety, permit the importation of drugs (Berry et al, HR 1298), including biosimilars;
- prohibit drug, device, and other vendor gifts to providers (Physician Payments Sunshine Act by Kohl, Grassly, Stark, DeFazio);
- provide additional rebates from the 20 percent of Part D plans that have the lowest generic drug substitutions rates in cases where a generic is exchangeable with a brand;
- permit Medicare to negotiate on drug prices (Berry et al., HR 684)[13]; special attention should be given to negotiating prices on selected biologics;
- enact a two or three year moratorium on the direct-to-consumer advertising of newly approved prescription drugs, for safety reasons (proposals by DeLauro and others); require rebates for the increased high-cost drug utilization caused by such advertising.

Our Hope that the Judiciary Committee will Examine the Growing Concentration in the Health Insurance Industry, and Why Insurers have been Unable to Control Costs Better. Is it an Argument for a Public Plan Option in Health Care Reform?

Finally, switching topics, in this year of health care reform debate, we urge the Subcommittee and Committee to consider an investigation into why the health insurance industry has failed so badly to control health care costs, and whether our experience with this increasingly-concentrated industry doesn't argue for a public plan option as part of health care reform.

For decades, the health delivery marketplace has been inflating roughly twice as fast as the rest of the economy, creating special burdens for American businesses and taxpayers, and raising rates of un-insurance, under-insurance, personal bankruptcy and increased morbidity and even mortality for uninsured consumers.

Recently, there have been rumors of possible further mergers among some of the nation's largest health insurers.

We believe it would be useful for Congress to investigate the level of market concentration in the health insurance versus health provider sectors to determine if there are steps that should be taken in health reform to bring us a system which is better at reducing the cost of health insurance for employers, employees and their families.

A Congressional investigation could address the following kinds of questions:

It is often thought that a large buyer can demand discounts and be able to control costs better than many small purchasers. At the same time, it is usually feared that a monopolist will collect excessive profits from their market dominance. There are reports that in a sixth of our large metropolitan areas, a single insurer/purchaser has enrolled 70 percent or more of the local consumer-patient population. It would seem that in such a situation, the insurer could both control costs and reap windfall or oligopolistic profits. Obviously the insurers are not doing a good job controlling costs, but are they collecting higher than expected profits? That is, do we have the worst of both worlds: higher profits being added to failure to control costs?

But at the same time that insurers have been consolidating, there are reports that in many markets, hospital and physician practices have been merging and have formed a dominant countervailing force. Has the consolidation of providers been a contributing factor in the crippling rate of health inflation? Yet while oligopolistic or even monopolistic behavior among providers is a source of concern, so is quality of care. And there is strong data that smaller hospitals, which do limited numbers of procedures, often have a difficult time delivering quality outcomes. In general, consumers needing complex treatments are well-advised to seek out hospitals and practices which do large volumes of such treatments (centers of excellence) and which coordinate care. From a quality, medical education, and research point of view, a larger health care provider can often be a good thing.

The March 2009 Medicare Payment Advisory Commission report to Congress provides a remarkable chart showing that an eighth of the nation's larger hospitals which deliver the highest quality care have, on average,

positive Medicare margins and are below average cost hospitals. The other seven-eighths of the hospitals have poorer quality and higher costs. It is MedPAC's thesis that while Medicare is paying approximately 100% of the costs of an efficient provider, the private insurers (who have become relatively consolidated and may be planning further consolidation) are paying about 132 percent of cost at most hospitals. Basically, MedPAC is saying that the private insurers, despite their growing consolidation, have become toothless buyers, and are often turning a blind eye to the unacceptable rate of medical inflation.

This raises a fundamental question: if large private buyers, who for marketing reasons feel a need to maintain a broad network of health care providers, cannot control costs, what is the alternative? As we consider health care reform, doesn't this argue for a public plan option (like Medicare) that can set rates at the approximate level of cost that an efficient provider can deliver quality care?

If the current situation does not argue for a public plan option, then why are these large insurers not doing a better job in controlling health care inflation, and what hope is there that they will do a better job in the future? What kinds of amendments would Congress need to make to ensure that the private payers can hold inflation down to at least Medicare's past rates of growth?

APPENDIX #1

Best Buy Drug Campaign

Consumer Reports strongly encourages consumers to talk to their doctor about the use of generics as a way to save money while obtaining quality health care. We have made a major organizational commitment to educate consumers about generic drugs and to help consumers obtain reliable, easy-to-understand advice about the safest, *most effective brand or generic*, and lowest cost prescription drugs available. In December 2004, Consumers Union launched Consumer Reports Best Buy Drugs , a free public education project. Attached is a sample Best Buy Drugs summary report on prescription drugs to relieve heartburn. We currently provide information for 40 different medical conditions, and we plan to expand to additional classes in the near future.

The goals of Best Buy Drugs are to:

- improve the quality of care by ensuring people get the safest, *most effective* drugs—*brand* or generic--with the least side effects;
- improve access by helping consumers choose drugs that are most affordable (taking into account effectiveness, side effects, safety, and price); and
- help consumers and taxpayers by reducing the cost of health insurance, consumers' out-of- pocket expenses, and Medicare and Medicaid costs.

We estimate that a consumer who switches from a highly advertised, high-priced brand name drug to a Best Buy Drug can often save between $1,000 and $2,000 a year—or even as much as $3,000 a year. If all Americans took advantage of the best buy generics, the economy would save billions of dollars. Approximately 100,000 Consumer Reports Best Buy Drugs reports are downloaded each month, including about 20,000 in Spanish. In addition to our Web site, *www.CRBestBuyDrugs.org*, we distribute print versions of our reports in five states with the help of pharmacists, senior organizations, doctors, and libraries. The Best Buy Drugs website also provides additional information describing how Best Buy Drugs operates and the rigorous evidence-based review that is used to derive the "Best Buy Drug" in each class of medicine.

Consumer Reports also has been active in reporting on the consumer benefits of generic drugs. Most recent, *Consumer Reports* published a report in its November 2006 issue that explained how cash prices for generic drugs vary widely at different types of pharmacies. The report concluded that for five highly prescribed generic drugs (fluoxetine, lisinopril, lovastatin, metformi n, and warfarin), median prices at mass merchant and online pharmacies were approximately 20 to 50 percent less expensive than prices at supermarket and drug chain pharmacies. We urged our readers to shop around for the best deals.

APPENDIX #2

The Hatch-Waxman Act Exacerbates the Incentive to Settle Patent Litigation with Compensation Paid to the Generic Applicant

When Congress enacted the Hatch-Waxman Act, it represented a compromise between making available more low-cost generic drugs, while at the same time restoring patent life lost due to the length of FDA brand-name drug approval process. To accomplish this goal, Congress created a number of industry-specific incentives to speed generic entry. In order to see how these incentives work, and their effects on the dynamic of patent settlements, it is necessary to understand three unique features of the Act: a paragraph IV certification, the 30-month stay period, and the 180-day marketing exclusivity provision.

The Act establishes a procedure for accelerated FDA approval of generic drugs through the use of an "Abbreviated New Drug Application" (ANDA). The Act requires a generic applicant to show that its generic drug is "bioequivalent" to the brand-name drug. The generic drug manufacturer does not have to replicate the costly safety and efficacy tests for its drug; rather, the Act permits the generic company to rely on the safety and efficacy tests of the brand-name drug product.

One of the most important features of this application process is if the generic applicant seeks prompt approval of its generic drug, it must certify that its generic drug product does not infringe on the patents claimed by the brand-name drug product, or that patents claimed by the brand- name drug product are invalid. The Act names this a "paragraph IV" certification.

A generic applicant that makes a paragraph IV certification must notify the patent holder. If the patent holder does not bring an infringement action against the generic applicant within 45 days, the FDA may approve the A N DA, assuming the other regulatory requirements are met. Alternatively, if the brand-name company brings an infringement action during the 45-day period after notification, the patent owner is entitled to an automatic stay of FDA approval of the A N DA for 30 months (the 30-month stay). This process provides the brand-name company and the generic applicant an opportunity to litigate patent issues before the generic drug has entered the market and incurred any damage exposure.

The Act provides that the generic applicant to file the *first* ANDA containing a paragraph IV certification (the "first filer") for a particular brand-name drug is entitled to 180-days of marketing exclusivity. During this period, the Food and Drug Administration may not approve a subsequently filed A N DA for the same brand-name drug product. The 180-day period starts once the first filed generic applicant begins commercial marketing of its generic drug product. The real effect of this exclusivity period is that the FDA is prohibited from approving any subsequently filed A N DA for the same brand-drug product until the first filer's 180-day period of marketing exclusivity expires. The 180-day exclusivity period is an important incentive Congress provided to would-be generic entrants to encourage them to challenge weak or questionable patents claiming brand-name drug products or to design around a brand-name drug's patent.

It is important to note that the first generic competitor usually shadows prices the brand. Consumers usually do not really see sharp, dramatic drops in price until there are several generic competitors.

This regulatory structure exacerbates the economic incentives underlying patent settlements between brand-name companies and generic applicants discussed above. A settlement between the brand-name company and the first filer will avoid the brand-name company's lost profit potential. In addition, the 180-day marketing exclusivity provision blocks entry by subsequently filed generics until 180 days after the first filer actually begins commercial marketing. Unfortunately for consumers, the first filer has a powerful incentive to accept a settlement because it will not only get the brand name company's compensation, but it retains its 180-day marketing exclusivity when it does enter at a later date. Although both the brand-name company and the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment.

THESE SETTLEMENTS ARE CONTRARY TO THE PURPOSE OF THE HATCH-WAXMAN ACT

The irony, of course, is that the purpose of the ANDA application process was to speed the entry of generic drugs. This policy was reaffirmed in 2003 when Congress amended the Hatch- Waxman Act in the Medicare

Modernization Act. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of Hatch-Waxman Act resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market." Indeed, Senator Hatch, one of the Act's coauthors, stated during the debate over these amendments that

> "[a]s a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these types of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition."

EXPERIENCE SHOWS THAT BRAND-NAME COMPANIES AND GENERIC APPLICANTS DO NOT NEED TO USE PAYMENTS FOR DELAY TO SETTLE PATENT LITIGATION

As noted above, the FTC has reported that these types of patent settlements reappeared in 2005, after a six year hiatus. Two observations can be made from this fact. First, the FTC reported that in 1999 its investigations into the legality of these types of settlement agreements became public. The result of this public knowledge was that brand-name and generic companies stopped entering into patent settlement agreements with these terms. Second, brand-name and generic companies continued to settle patent disputes during this period (roughly from 1999 to 2005), when many industry participants believed it to be anticompetitive to enter into these types of patents settlements. This fact undermines any contention now that these payments are necessary to settle patent litigation.

THE COURTS ARE UNLIKELY TO PROVIDE TIMELY RELIEF TO CONSUMERS

We encourage Congress to act now to end the use of these types of settlement agreements because it is unlikely the federal courts will provide consumers relief in a timely manner. At least two recent appellate court

decisions have taken a lenient view of these types of patent settlements, with one of the courts rejecting the reasoned antitrust analysis of these settlements put forth by the FTC. Both courts have, in essence, held that these settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham. These courts relied on the presumptive validity of a patent to support the conclusion that any settlement which does not exceed the exclusionary scope of a patent also must be valid. The upshot of these court rulings is that a patent holder can pay whatever it takes to buy off a potential challenger during the life of the patent. In one sense, court approval of these types of payments will convert Hatch- Waxman into a vehicle for facilitating the collection of "greenmail" by generic applicants.

These rulings are based on two faulty premises. First these courts seem to require that unless the patent can be proved to be invalid or not infringed, a court cannot declare a settlement illegal. This test, as the FTC discussed in its *Schering* opinion, may be good in theory but, it is nearly impossible to make work from a practical point of view.

The second faulty premise is that these courts have elevated the generally held principle that public policy favors settlements above the statutory mechanisms that Congress put in place to encourage generic applicants to challenge weak patents and, hence, speed generic entry. This reasoning also lacks an appreciation of the view, as recently articulated by the U.S. Department of Justice Antitrust Division, that public policy also strongly favors ridding the economy of invalid patents, which impede efficient licensing, hinder competition, and undermine incentives for innovation.

Indeed, the industry experience under Hatch-Waxman between 1992 and 2000 shows that Congress struck the right balance when it established these incentives. During this period, generic challengers that had used paragraph IV certifications won their patent challenges in 73% of the cases. Indeed, these challenges have resulted in generic entry earlier than what otherwise would have occurred absent the generic challenge. These patent challenges and subsequent generic entry have yielded enormous benefits to consumers.

Although the FTC remains vigilant in searching for appropriate ways to take enforcement action against these types of patent settlements, administrative law enforcement actions and appeals take several years to complete. During this time, consumers will be denied access to affordable drugs.

End Notes

[1] Consumers Union, the nonprofit publisher of *Consumer Reports*, is an expert, independent organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

[2] From AARP's "Rx Watchdog Report," April, 2009: "In 2007, US health care spending growth slowed to its lowest rate since 1998. A majority of this change was due to retail prescription drug spending, which grew 4.9 percent in 2007, the slowest rate of growth since 1963. The deceleration in prescription drug spending, in turn, was largely attributed to generic drugs, including a further increase in the generic dispensing rate and slower growth in prescription drug prices due to the introduction of generic equivalents for several blockbuster drugs."

[3] CU March 17, 2009 Poll, In addition, CMS "posits that the slowdown for prescription spending is likely due to the effects of the recession, which may be causing consumers to shift from more expensive brand-name drugs to lower-cost generics and to fill fewer prescriptions." Quote from 2009 Drug Trend Report, Medco, p. 6. The importance of affordable maintenance medicines can be seen in the fact that a person starting on a generic maintenance drug has a 62 percent better chance of staying on it, than a person started on a non-preferred brand drug, according to ARRP testimony before the Energy and Commerce Committee, 3/31/09.

[4] CMS National Health Expenditures, 2008.

[5] Medicare Trustees Report, pp. 2, 3, and 127.

[6] Testimony of FTC Commissioner Jon Leibowitz, before Senate Judiciary Committee, January 17, 2007.

[7] GPhA Website, Facts at a Glance.

[8] Medco, Drug Trend Report, 2009, p. 22.

[9] AARP Rx Watchdog Report, April, 2009.

[10] Ibid.

[11] Letter of CBO of June 25, 2008 on S. 1695

[12] Statement of Joshua Sharfstein, MD., Principal Deputy Commissioner, FDA, before Senate Appropriations Committee, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, May 21, 2009.

[13] This provision receives an amazing 86 percent support in the Kaiser Family Foundation Health Tracking Poll of April, 2009.

CHAPTER SOURCES

The following chapters have been previously published:

Chapter 1 – This is an edited, excerpted and augmented edition of a United States Federal Trade Commission publication, Report Order Code RL30113, dated January 2010.

Chapter 2 – These remarks were delivered as Statement of Chairman John Leibowitz, before the Center for American Progress, given June 23, 2009.

Chapter 3 – These remarks were delivered as Statement of the Federal Trade Commission before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

Chapter 4 – These remarks were delivered as Statement Heather Bresch before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

Chapter 5 – These remarks were delivered as Statement of Bret M. Dickey, Ph.D., before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

Chapter 6 – These remarks were delivered as Statement of Guy Donatiello before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

Chapter 7 – These remarks were delivered as Statement of William P. (Bill) Kennedy before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

Chapter 8 – These remarks were delivered as Statement of William Vaughan, before the U.S. House of Representatives Subcommittee on Courts and Competition Policy, given June 3, 2009.

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