

Testimony of C. Scott Hemphill
Associate Professor, Columbia Law School

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

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Chairman Rush, Ranking Member Radanovich, and Members of the Subcommittee, I am Scott Hemphill, an Associate Professor at Columbia Law School. My research and teaching focus upon the balance between innovation and competition established by antitrust law, intellectual property, and sector-specific regulation. I welcome the opportunity to testify today about certain anticompetitive, “pay-for-delay” agreements between brand-name drug makers and their generic rivals. These remarks draw upon my ongoing academic research into the economic effects of these settlements and their appropriate legal treatment.¹ I have advised the Federal Trade Commission on the antitrust issues raised by pay-for-delay settlements, but the views I express today are mine alone.

I wish to make three points. First, the pay-for-delay settlement problem is large and longstanding. Second, the problem is becoming more difficult, as the forms of settlement continue to evolve. And third, Congress can play a useful

¹ C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 *Columbia Law Review* (forthcoming 2009), available at <http://ssrn.com/abstract=1356530> [hereinafter *New Data*], undertakes an empirical examination of settlements, with a view toward identifying a workable policy rule. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 *New York University Law Review* 1553 (2006) [hereinafter *Paying for Delay*], analyzes the competitive effects of certain settlements and their proper treatment under antitrust law.

role in this area by passing legislation that prohibits settlements that combine payment with delay.

The pay-for-delay settlement problem

For more than twenty years, the Hatch-Waxman Act has provided a mechanism by which generic drug makers may introduce a competing version of a brand-name drug.² Frequently, the generic firm seeks to market a product prior to the expiration of a patent (or patents) claimed by the brand-name firm to cover the product. Under the Act, the generic drug maker first asserts that the brand-name firm's patent is invalid or not infringed by the generic product;³ often, the brand-name firm then files a suit in response alleging patent infringement. This form of litigation has become the norm with respect to the most important brand-name drugs. Moreover, these challenges often succeed in securing early entry by generic rivals. For example, of the ten best-selling drugs of 2000, nine attracted challenges, of which at least four led to entry prior to patent expiration.⁴

In some cases the brand-name firm, rather than take a chance that the generic firm might win the patent suit, settles the litigation. The parties dismiss the suit and agree to a particular date when the generic firm may enter the

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtit. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355 (Supp. III 2003)).

³ Technically, the pre-expiration challenge takes the form of an Abbreviated New Drug Application ("ANDA") with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000) (also known as "Paragraph IV") that relevant patents are invalid or not infringed.

⁴ In 2000, the ten best sellers were Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zoloft. See Robert Pear, Spending on Prescription Drugs Increases by Almost 19 Percent, N.Y. Times, May 8, 2001, at A1. Of these, all but Glucophage attracted a pre-expiration challenge. Ctr. for Drug Evaluation & Research, FDA, Paragraph IV Patent Certifications as of April 23, 2007, <http://www.fda.gov/cder/OGD/ppiv.htm>. Of the nine challenges, those targeting Paxil, Prilosec, Prozac, and Zocor resulted in pre-expiration entry. See Paying for Delay, *supra* note 1, at 1567 n.57.

market. The entry date is the result of a hard-fought bargain between rivals. The brand-name firm pushes for a later entry date by arguing that, if the litigation proceeds to judgment, a court is likely to hold that the patent is valid and infringed. The likelier that judgment is, the later the entry date.

A settlement that relies solely upon the inherent strength of the patent is properly permitted. Such a settlement delays entry, to be sure, but the brand-name firm is simply using its patent protection as leverage. The brand-name firm's success in achieving a later date in this fashion defines the maximum extent of the patent right.

The situation is different when a brand name firm's makes a payment to its rival, rather than relying solely upon its prospects at trial. In that case the payment secures a later entry date than is warranted by the likely validity of the patent alone. That payment to a rival, made to secure additional delay, is a privately-arranged patent term extension that should be understood to violate antitrust law.⁵

Early generic competition benefits consumers by lowering drug prices sooner. A pay-for-delay settlement transfers wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm. The higher price also alters the purchase decisions of consumers and insurance providers, introducing an additional welfare loss. 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.

A payment to secure delayed entry undermines the existing balance between innovation and competition set by the Hatch-Waxman Act. The Act as

⁵ For further discussion, see *Paying for Delay*, supra note 1.

written provides brand-name firms with important special protection for their innovative efforts, including patent term extension and a variety of nonpatent regulatory delays to generic entry. For example, if the brand-name firm's approved drug contains a novel active ingredient, the Food and Drug Administration (FDA) may not accept any application to market a generic version for four years.⁶ Once the generic firm's application is accepted, and assuming that the brand-name firm files a patent suit in response, the Act blocks FDA approval of the generic firm's application for the first several years of the suit's pendency.⁷ These provisions, taken together, can provide more than seven years of protected profits even if the patent protection is very weak.⁸ A privately arranged term extension, then, is in addition to extensive protections already granted by Congress.

Pay-for-delay settlements are a frequently employed tactic for brand-name and generic firms. To examine the frequency and evolution of brand-generic settlements since 1984, I collected a novel dataset.⁹ The object was to identify and synthesize all public information about the frequency and terms of settlement. The effort drew upon press releases, trade publications, financial analyst reports and analyst calls with management, court filings of patent and antitrust litigation, SEC filings, FDA dockets, and Federal Trade Commission (FTC) reports. The search period extended from 1984, when the Hatch-Waxman

⁶ See § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs that do not contain a Paragraph IV certification. *Id.*

⁷ § 355(j)(5)(B)(iii) (2000 & Supp. III 2003). The stay goes into effect provided that the brand-name firm files suit within forty-five days of receiving notice of the certification. *Id.* The "thirty-month" stay can persist for more than three years. See *Paying for Delay*, *supra* note 1, at 1566 n.50. The stay resembles a preliminary injunction, but is superior from the brand-name firm's standpoint, as there is no requirement that the brand-name firm show a likelihood of success on the merits, and no obligation to pay damages if the brand-name firm subsequently loses the patent case.

⁸ If the patent case is decided before the expiration of the automatic stay, the period is shorter.

⁹ The full results are reported in *New Data*, *supra* note 1.

Act was passed, through August 2008, and therefore ignores significant settlement activity since then.

This work yielded information for 143 settlements involving 101 brand-name drugs. Of the 143 settlements, 60 settlements include both delayed generic entry and possible contemporaneous provision of value by the brand-name firm. The 60 settlements involve 51 drugs. (For some drugs, the brand-name drug maker settled with multiple generic firms.) Most of the 51 drugs fall into two categories: monetary settlements and retained exclusivity settlements.

Monetary settlements. For 21 of the 51 drugs, the compensation was wholly or partly monetary. Sometimes the payment was an open conferral of cash. For other drugs, the possible payment was embedded within a more complicated transaction, as discussed in more detail below. The caveat “possible” is used because in some cases public information leaves it unclear whether the settlement included compensation. These 21 drugs are listed in Table 1. On average, they had annual U.S. sales, measured in the year of settlement and adjusted for inflation, of \$1.3 billion.

The 21 drugs include blockbusters such as Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). More than half are new versions of existing therapeutic agents, whose patents are generally thought to be weaker because they tend to be obvious (and hence invalid) and are easily worked around. Some of these settlements have eventually given way to generic entry, due to scheduled entry or patent expiration, while others continue to block generic competition today. Ten drugs in the latter category account for annual sales of about \$17 billion.¹⁰

¹⁰ Measured in the year of settlement and adjusted for inflation.

Table 1: Settlements with Monetary Payment

Year	Drug	Sales	Entry
1993	Nolvadex	400	9
1995	BuSpar	400	5
	Zantac	2950	2
	Sinemet CR	150	11
1997	Cipro	900	7
	K-Dur*	250	4
1999	Naprelan	50	3
2005	Lamictal	1100	3
	Niaspan	450	8
	Effexor XR	2750	5
2006	Provigil*	700	6
	Altace	700	2
	Plavix	3400	5
	Propecia	150	7
	Adderall XR*	900	3
	AndroGel*	350	9
2007	Wellbutrin XL (150 mg)	850	1
2008	Nexium	3400	6
	Lipitor and Caduet	7600	3
	Aggrenox	300	7

Drug: * indicates monetary settlements with multiple generic firms. *Sales:* Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or twelve months preceding settlement, adjusted to constant 2008 dollars using the monthly Consumer Price Index prepared by U.S. Bureau of Labor Statistics, and rounded to the nearest \$50 million increment. *Entry:* Time between settlement and scheduled entry, rounded to the nearest year, except for Altace, where no date appears to have been disclosed. Does not include immediate authorized generic sales in Nolvadex, or unexpected six-month pediatric extensions for Nolvadex and Cipro. For further details, see New Data, supra note 1.

The effect of delayed entry can be enormous. For the settlements in Table 1, a one year delay in generic entry represents, under conservative assumptions, a transfer from consumers to producers of about \$12 billion.¹¹ Whether the one-year benchmark is an overestimate or an underestimate is often difficult to assess in a particular case using public information. Part of the delay is attributable to the strength of the patent itself, rather than payment. Since the pre-expiration period covered by settlement is several years—the average period, weighted by sales, is four years—the benchmark is likely conservative.

For some drugs, public statements by management or the expectations of financial analysts help to provide a specific measure of delay. For example, in the case of Provigil, a wakefulness drug, the drug maker's CEO said that due to settlements, "We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected."¹² The CEO's statement reflects the firm's pre-settlement expectation of entry in 2006,¹³ and settlements delaying entry until 2012.¹⁴ In the case of Lipitor, a blockbuster cholesterol drug, the settlement delayed anticipated entry by nearly two years.¹⁵ Overall, the \$12 billion benchmark estimate is likely to be conservative.

¹¹ Suppose generic entry achieves 75% penetration and that the generic product is priced at a two-thirds discount, relative to the brand-name drug. These figures are a simplification, because in reality, penetration and the discount (particularly during the 180-day period) are smaller at first, but quickly increase. Under these assumptions, the avoided transfer is one-half of annual sales; across 20 drugs, the total is about \$12 billion. This calculation does not include Plavix, a settlement that never took full effect because it was rejected under the terms of an earlier consent decree between Bristol-Myers Squibb and regulators, or welfare losses caused by pricing distortions.

¹² John George, *Hurdles Ahead for Cephalon*, *Phila. Bus. J.*, Mar. 20, 2006, at 1.

¹³ See, e.g., Q3 2005 Cephalon, Inc. Earnings Conference Call Transcript (Nov. 1, 2005), available at Factiva (statement of Frank Baldino, Chairman and CEO, Cephalon, Inc.) (providing earnings guidance for 2006, and assuming "generic versions of modafinil enter the market midyear").

¹⁴ See *Complaint, FTC v. Cephalon, Inc.*, No. 08-0244 (D.D.C. Feb. 13, 2008).

¹⁵ See, e.g., Merrill Lynch, Pfizer Inc.: Settlement Good News, June 18, 2008 ("We now expect an extra 20 months of U.S. Lipitor exclusivity (we had assumed U.S. generic competition in March 2010 and the Ranbaxy settlement delays generic launch until November 2011).").

Retained exclusivity. Money is not the only way to compensate the generic firm. For settlements involving 25 drugs, compensation took the form of retained exclusivity.¹⁶ The 180-day period is valuable to the generic firm. One hundred eighty days of duopoly is worth hundreds of millions of dollars in the case of a blockbuster. The value of this opportunity, however, is discounted by the uncertainty that the generic firm might lose the litigation, and thus never enjoy the exclusivity period. A brand-name firm's agreement to drop the patent fight—an arrangement that, under current law, does not forfeit eligibility—is valuable to the generic firm because it raises the probability of enjoying the exclusivity. In addition to the 25 drugs for which the only form of compensation is retained exclusivity, most of the settlements in Table 1 include an assured 180 days of generic sales.

Other pay-for-delay settlements. Five pay-for-delay settlements involving four drugs fit neither of these categories. Three are “interim” agreements, which restrict entry while the patent infringement suit is pending but do not resolve the suit. After such agreements were targeted for antitrust enforcement in the late 1990s,¹⁷ parties turned to the monetary and retained exclusivity settlements discussed above. The remaining two settlements are supply agreements in which the generic firm did not retain exclusivity eligibility.

The Evolution in Settlement

The settlements have occurred in two distinct waves. The first wave began in 1993 and ended in 2000 after the FTC made clear its opposition to pay-

¹⁶ For a list of these drugs, see New Data, *supra* note 1.

¹⁷ Interim settlements were reached for Cardizem CD and Hytrin (tablets and capsules), which led to FTC consent decrees.

for-delay settlements. The second wave began in 2005, after two appeals courts rejected antitrust liability for the settlements.¹⁸

The new wave of settlements is a direct response to the failure of federal courts to recognize and resolve the pay-for-delay issue.¹⁹ When private parties and the FTC have challenged the settlements on antitrust grounds, courts have failed to recognize the illegality of the settlements. That failure is likely to be compounded, moreover, by an evolution in the means by which brand name firms now pay for delay.

In the earliest settlements, such as the first five settlements in Table 1, payment was a relatively straightforward affair. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. The largest naked cash payment was nearly \$400 million, which Bayer agreed to pay Barr in settling litigation over Cipro, a major antibiotic.

In the wake of increased antitrust scrutiny, naked payments have given way to more complex "side deal" arrangements. In the most common type of side deal, the generic firm contributes—in addition to delayed entry—some further value, such as an unrelated product license. The additional term provides an opportunity to overstate the value contributed by the generic firm and claim that the cash is consideration for the contributed value, rather than for delayed entry.

Side deals are now a frequent feature of entry-delaying settlements. The contributed value can include a wide range of product development,

¹⁸ In *re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005). The Second Circuit's ruling in *Tamoxifen* was handed down in 2005 but revised in 2006.

¹⁹ The failure has not been uniform. One appeals court recognized liability on the somewhat unusual facts of the case. In *re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003). A second appeals court considering the same facts reached a similar conclusion in *dicta*. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001).

manufacturing, and promotion services. In some of the deals listed in Table 1, the generic firm offers a product or patent license, or agrees to develop a new product.²⁰ In one variant, the generic firm develops a new formulation of the brand-name drug.²¹ In other deals, it agrees to furnish manufacturing services to the brand-name producer,²² or to provide inventory,²³ or even to provide “backup” manufacturing services.²⁴ In some cases, the generic firm provides promotional services as to the product at issue, related drugs, or unrelated products.²⁵ For some drugs, the brand-name firm reaches entry-delaying settlements with multiple generic firms, each with side deals.²⁶

Some of these arrangements are suspect on their face. It may seem clear that the brand-name firm does not need a patent license that does not clearly cover its product, new drug development that is unrelated to its current core business, a new source of raw material supply, backup manufacturing, or additional promotion. Moreover, the “value” contributed by the generic firm is often far from the firm’s actual expertise. But not all such settlements are facially absurd. In some cases, the generic firm has plausible expertise in the subject of the side deal. It can be difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers. However, outside of settlement, brand-name firms seldom contract with generic

²⁰ For example, K-Dur (two settlements), Naprelan, Provigil (four settlements), and Adderall XR (two settlements) all involved a license or product development agreement. For further details about these and other settlements discussed in this section, see New Data, supra note 1.

²¹ The Altace settlement had this feature.

²² The Nexium settlement and two of the Provigil settlements include such a term. In one of the Adderall XR settlements, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. The Altace settlement included manufacturing of a new formulation by the generic firm.

²³ See, for example, Cephalon’s agreement with Barr over Provigil.

²⁴ AndroGel’s settlement as to Par has this feature, as does the Niaspan agreement.

²⁵ Examples include Niaspan, Adderall XR (one settlement), both AndroGel settlements, and Aggrenox.

²⁶ This is the case for Provigil (as to multiple first filers), Adderall XR (as to both a first filer and a later filer), AndroGel (same), and K-Dur (same).

firms for help with the activities that form the basis of side deals. That rarity provides a basis for inferring that the side deal provides a disguised means to pay for delay.

H.R. 1706

The current approach to pay-for-delay settlement is not working. Case-by-case judicial evaluation of individual settlements has failed to identify and remedy the consumer harm. And the inadequacy of judicial resolution is likely to worsen, as payment increasingly takes alternative forms.

H.R. 1706 takes an important step toward identifying and deterring pay-for-delay settlement. In particular, Section 2(a) of the bill prohibits settlements that combine a delay in generic entry with a brand name firm's provision to the generic firm of "anything of value" beyond a negotiated entry date. In defining the forms of compensation, it is crucial that this Subcommittee recognize the broad range of forms that payment can take. As noted above, generic firms are compensated not only with cash, but also with the exclusivity period itself. "Anything of value," properly understood, includes *all* forms of compensation that induce delay, including effective guarantees of exclusivity. The Subcommittee may wish to consider making this point explicit in its bill.

An alternative method to prevent pay-for-delay settlements that rely upon exclusivity is to amend the Hatch-Waxman Act, by ending eligibility for the exclusivity period for a settling generic firm. Currently, a first-filing generic firm can expect to enjoy exclusivity provided it does not lose the patent suit, even if it settles.²⁷ Ending exclusivity for settling generic firms would reduce both the

²⁷ See *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation.").

amount of payment conferred in a settlement, and the extent to which a settlement delays entry.

* * *

The pay-for-delay settlement problem is getting worse. Congress has a vital role to play in establishing a broad prohibition of anticompetitive settlements, whether the brand-name firm pays with cash or with some other form of compensation. Thank you for the opportunity to discuss this important issue with the Subcommittee.