

Congressional Efforts to Mend the Hatch-Waxman Act: H.R. 1706 and S. 369

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Rapidly escalating health care costs have become a major issue for Congress, which spent a significant portion of its time in 2009 debating a mammoth health care reform bill. While continuing to grapple with the complicated issue of health care reform, the U.S. Senate and House of Representatives are also considering legislation aimed at anticompetitive behavior in pharmaceutical patent settlements. Specifically, H.R. 1706 and S. 369 both seek to end the use of exclusion payments, also known as pay-for-delay or reverse payment settlements, to settle pharmaceutical patent infringement litigation. If passed, the legislation promises to significantly increase the number of generic drugs that enter the market each year, potentially saving billions of dollars for both consumers and the federal government.

The Hatch-Waxman Act of 1984 was designed to make low-cost generic drugs available while protecting the legitimate patent rights of pharmaceutical companies. Under the Hatch Waxman Act, a company that wishes to manufacture a generic version of a patented drug may file an Abbreviated New Drug Application (ANDA) with the FDA. The manufacturer of the brand-name drug usually then sues the generic company for patent infringement based on the ANDA. The companies usually settle the litigation by negotiating an entry date for the generic based on the strength of the branded company's patent.¹ The weaker the patent, the earlier the entry date for the generic. These settlements often allow generic drugs to enter the market years earlier than they would if the patent were allowed to naturally expire. Because 73 percent of

¹ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection, 111th Cong., 19 (2009) (statement of the FTC).*

drug product patents are invalidated if litigated to a decision on the merits, the savings to consumers that result from early entry by a generic can be dramatic.²

In recent years, exclusion payments have changed the way in which litigation under the Hatch-Waxman Act is settled. Instead of negotiating an early entry date based solely or primarily on the strength of the branded company's patent, the two companies negotiate a later entry date for the generic drug in exchange for compensation paid to the generic company. Effectively, the companies agree that the patent-holder will pay the infringer to keep the infringing drug off the market. This type of seemingly counter-intuitive settlement is unique to pharmaceutical patent litigation.³ However, the result is profitable to both companies, as the payments exceed the amount the generic would be estimated to make if it brought its generic to market, but fall far short of the additional monopoly profits generated by the branded drug during the remainder of the patent term. The branded company may receive an additional benefit, as some have used the additional period of exclusivity to switch patients to related drugs that have a longer patent life and have not yet been challenged.⁴ This tactic virtually ensures a minimal market share for generics when they finally are able to enter the market.⁵

The Circuit Courts of Appeal have reached opposite conclusions about the validity of exclusion payments, creating a circuit split that has yet to be resolved. In 2003, consistent with the FTC's position on the issue, the Sixth Circuit Court of Appeals held that exclusion payments were per se illegal.⁶ Until 2005, drug companies settled infringement litigation without any money changing hands, usually by negotiating an entry date for the challenger. Exclusion

² *Id.* at 14.

³ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong., 2 (2009) (statement by Bobby L. Rush, Chairman, H. Subcomm. on Commerce, Trade, and Consumer Protection).

⁴ FTC, *supra* note 1, at 18-19.

⁵ *Id.*

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

payments arose as a common component in pharmaceutical patent infringement cases following the Eleventh Circuit's decision in *Schering-Plough*⁷ and the Second Circuit's decision in *Tamoxifen*,⁸ both of which upheld the legality of settlements involving exclusion payments. So far, the Supreme Court has declined to review a case involving exclusion payments.

Despite recent decisions in the above noted cases, there seems to be little doubt that the use of exclusion payments to settle litigation under the Hatch-Waxman Act violates the spirit of the Act. Congressman Waxman, one of the sponsors of the Act, co-sponsored H.R. 1706 because "the law has been turned on its head" by permissive views toward exclusion payments.⁹ Senator Hatch, the Act's other main sponsor, has stated that he "finds these types of reverse payment collusive agreements appalling" because Congress "did not wish to encourage situations where payments were made to generic firms not to sell generic drugs."¹⁰

The stakes in the debate over exclusion payments are significant: The estimated cost savings to consumers and the federal government by eliminating them is a staggering \$12 billion per year.¹¹ Generic drugs typically cost up to 80 percent less than branded drugs and have a tendency to decrease in price over time. Where branded drug prices have had a cumulative average increase of more than 50 percent since 2002, generic drug prices have, on average, decreased nearly 10 percent over the same period.¹² Meanwhile, the costs to consumers of just one settlement suing exclusion payments is equally alarming: When branded drug company Cephalon, holder of a particularly weak patent for a wakefulness drug called Provigil, succeeded

⁷ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁸ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

⁹ FTC, *supra* note 1, at 15.

¹⁰ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong., 6 (2009) (statement by Joanna Handy, Board Member, AARP).

¹¹ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong., 7 (2009) (statement of C. Scott Hemphill, Assoc. Prof., Columbia Law School).

¹² Handy, *supra* note 9, at 2-3.

in paying four generic challenger companies to stay off the market its CEO announced “We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.”¹³

Pharmaceutical companies generally oppose H.R. 1706 and S. 369 on the grounds that the legislation will unreasonably chill patent settlement negotiations. These companies argue that the extremely high costs of research and development and the uncertainty of litigation require flexibility in patent settlements so companies can “get on with the business of developing new medicines for patients.”¹⁴ Although the average branded drug spends 11.5 years on the market before a generic drug enters, the pharmaceutical companies maintain that this time period is insufficient to cover costs related to research on other potential drugs that did not make it to market.¹⁵

Pharmaceutical companies have expressed particular concern over the legislation’s requirement that the companies refrain from exchanging “anything of value” when settling patent infringement litigation. Citing Judge Richard Posner of the Seventh Circuit, one pharmaceutical company spokesperson notes that “this broad description could almost over any settlement agreement because a generic challenger logically would only settle in exchange for something of value.”¹⁶ Pharmaceutical companies point to the inclusion of side deals, such as licenses for unrelated products, as useful tools for settling patent litigation that would be banned by the legislation. Proponents of the legislation argue that such broad language is necessary to prevent creative side deals involving disguised payments that would further exploit the loophole that

¹³ FTC, *supra* note 1, at 8.

¹⁴ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong., 10 (2009) (statement by Diane E. Bieri, Exec. V. Pres. & Gen’l Counsel, Pharm. Research & Manuf. of Am.).

¹⁵ *Id.* at 5, 7.

¹⁶ *Id.* at 10.

currently exists in the Hatch-Waxman Act.¹⁷ Although the “anything of value” language is a legitimate point of contention in the legislation, neither the House subcommittee handling H.R. 1706 nor the Senate committee that looked at S. 369 have entertained the idea of amending the bills to provide clearer guidance on this issue.

H.R. 1706 and S. 369 also seek to remedy what some generic manufacturers point to as other key barriers that also prevent generic drugs from entering the market in a timely fashion. For example, the first company to challenge a branded company’s patent by filing an ANDA for a given generic drug is entitled to a 180-day period of exclusivity when marketing that generic. Because the 180-days begins to run when the first challenger’s generic enters the market, as part of a settlement under the Hatch-Waxman Act, generic companies may agree to refrain from entering the market and “park” their exclusivity in exchange for monetary consideration.¹⁸ This prevents any other generic from entering the market. Some generic companies have supported the proposed changes in the Act to allow a shared exclusivity period for the first to file an ANDA and the first to successfully challenge the patent.¹⁹ The companies agree that such an amendment is consistent with the intent of the Act, which was, in the words of Senator Hatch, “to award the 180-day head start to the first *successful challenger* of the innovator firm’s patents.”²⁰

With health care reform currently at a standstill, the fate of H.R. 1706 and S. 369 is unclear. Despite unanimous, bipartisan support by FTC Commissioners,²¹ previous votes on the legislation, including in the House Subcommittee on Commerce, Trade, and Consumer

¹⁷ Hemphill, *supra* note 10, at 11.

¹⁸ *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong., 2 (2009) (statement by Dr. Bernard C. Sherman, CEO, Apotex, Inc.).

¹⁹ *Id.* at 13.

²⁰ *Id.* at 8. Emphasis added.

²¹ FTC, *supra* note 1, at 1. Every FTC Commissioner since 1998, regardless of political party affiliation, has supported a ban on exclusion payments in pharmaceutical patent litigation. *Id.*

Protection in June 2009, have largely followed party lines. In a climate of increasing concern over federal budget expenditures, the savings the federal government is expected to realize by passing the legislation may become a more prominent factor in the bills' passage. Even if unsuccessful in this session of Congress, enthusiastic sponsors, including Senator Herb Kohl and Congressman Bobby Rush, are likely to continue to reintroduce the legislation in subsequent sessions of Congress with the hope of finally obtaining a favorable result.