

FTC Says A Legislative Solution Is Needed To Curb Pay-for-Delay Agreements

By Craig A. Conway, J.D., LL.M. (Health Law)
caconway@central.uh.edu

Last month, the Federal Trade Commission (FTC) and a group of United States House lawmakers went on the offensive against big pharmaceutical companies in an effort to block business deals in which they say makers of brand-name drugs directly or indirectly pay generic makers to delay release of cheaper generic alternatives.¹ During a press conference held by the federal agency, officials released a report² which analyzed the effects of “pay-for-delay” deals in the drug industry over the past six years. The FTC estimates that such deals have delayed the introduction of a range of generics including cancer drugs, antidepressants, and others, and cost American consumers an estimated \$3.5 billion annually.

Background

In 1984, the Drug Price Competition and Patent Term Restoration Act,³ known more commonly as the Hatch-Waxman Act, was signed into law and currently serves as the regulatory framework for generic drugs. The Act was designed to promote generics while leaving in tact a financial incentive for research and development.⁴ To make up for the time a patented drug remains in development, the Act grants a period of marketing exclusivity for up to five years; this is in addition to the 20 years granted by the issuance of the drug patent. It additionally allows generics to win FDA marketing approval by submitting bioequivalence studies instead of the costlier and more time consuming clinical studies. A generic competitor may seek entry prior to expiration of the patents on a brand-name drug; the first to file can obtain 180 days of marketing exclusivity during which it is the only generic on the market.⁵

In recent years, pharmaceutical companies making brand-name drugs have utilized provisions of the Act to their benefit by filing lawsuits against generic makers to keep them from entering the marketplace or entering into financial settlements with them to

¹ See Natasha Singer, *Deals to Restrain Generic Drugs Face a Ban*, N.Y. TIMES, Jan. 13, 2010, <http://www.nytimes.com/2010/01/13/business/13generic.html>; Matthew Perrone, *FTC Wants a Ban on “Pay-to-Delay” Drug Settlements*, ASSOC. PRESS, (Jan. 13, 2010), available at http://www.usatoday.com/money/industries/health/2010-01-13-pay-to-delay-drug-settlements_N.htm.

² Fed. Trade Comm’n, Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, (Jan. 2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

³ Pub. L. No. 98-417, 98th Cong. (1984).

⁴ See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD AND DRUG L. J. 187 (1999); J. Thomas Rosch, Comm. Fed. Trade Comm’n, Oral Stmt. Before the Subcomm. on Commerce, Trade, and Consumer Protection Committee on Energy and Commerce, U.S. House of Rep., *How Pay-For-Delay Settlements Make Consumers and the Federal Government Pay More For Much Needed Drugs*, (Mar. 31, 2009), available at <http://www.ftc.gov/speeches/rosch/090331payfordelay.pdf>.

⁵ *Pay-for-Delay*, *supra* note 2, at p. 3.

delay entry of cheaper generic alternatives – thus allowing for a longer period of market exclusivity for brand-name drugs.

In his statement before a subcommittee in the United States House of Representatives last May, FTC Commissioner J. Thomas Rosch explained how pay-for-delay agreements frustrate the purpose of the Hatch-Waxman Act. He said:

...first, these settlements incentivize the generic to abandon the patent challenge, leaving a suspect patent intact for the entire extended patent period; second, they may incentivize the generic to challenge patents that shouldn't be challenged (in hopes of getting paid off for settlement). In other words, these anticompetitive agreements have ended up vitiating the incentives for generics to protect consumers and instead can result in generics feathering their own nests: by virtue of the reverse payment settlement agreement the brand can stop the generic's challenge and thus doesn't lose its patent monopoly even if its patent is invalid or not infringed. The generic meanwhile can get a share of the brand's monopoly profit in the form of the reverse payment. But the consumer (including the federal government) ends up being a huge loser since consumers continue to pay monopoly prices until the generic starts to compete.⁶

In its report issued last month, the FTC noted that pay-for-delay arrangements declined between 1999 and 2004 due, in large part, to the agency's investigations and enforcement actions. The agency was helped during part of that time by a federal appellate court ruling that such pay-for-delay arrangements were *per se* illegal in 2003. However, since 2005, subsequent appellate court decisions reversed that posture leading to a resurgence in pay-for-delay deals. Currently, pay-for-delay agreements protect nearly \$20 billion in sales of brand-name pharmaceuticals from generic competition and will cost American consumers nearly \$35 billion over the next 10 years.⁷

FTC Report: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions

For a generic to win FDA approval prior to a brand-name drug's patent expiration, it must first declare that its product does not infringe on the relevant patents or that the patents are invalid. Often, manufacturers of brand-name drugs challenge the generic maker's declaration ultimately leading to costly and lengthy litigation. For the brand-name maker to prevail, it must successfully defend the validity of its patents and demonstrate that the generic's product would infringe those patents.⁸

A 2002 FTC study concluded that generics prevailed in 73 percent of the patent litigation resolved by court decision between 1992 and June 2002.⁹ These court decisions acted as

⁶ Rosch, *supra* note 4, at p. 2.

⁷ See *Pay-for-Delay*, *supra* note 2, at p. 2.

⁸ *Id.* at p. 3.

⁹ *Id.* (citing *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>).

an incentive for brand-name pharmaceutical companies to settle future litigation. Often, such settlements involved compensating generic manufacturers for substantial entry delays. At that time, the FTC urged Congress to pass legislation that would require pharmaceutical companies to file certain agreements with the FTC. In 2003, Congress did so through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).¹⁰ Under the MMA, drug makers are required to file pay-for-delay settlement agreements with the FTC and Department of Justice within 10 days of their execution.

Pay-for-delay settlements have not been widespread, however. From 2004 to 2009, only 66 agreements involved some form of compensation from the brand-name manufacturer to the generic maker for delay into the marketplace.¹¹ In fact, settlements that involved no compensation were more common – 152 between 2004 and 2009.¹² However, those settlement agreements that do involve compensation prohibit generic entry, on average, for nearly 17 months longer than those without.¹³ Additionally, out of the 66 agreements involving compensation to the generic manufacturer, 77 percent were between the brand-name manufacturer and the first generic company to seek entry prior to patent expiration.¹⁴ That means that those agreements with first-to-file generic companies can prevent any subsequent generic maker from entering the market. Pursuant to the Hatch-Waxman Act, every subsequent generic entrant must wait until the first generic has been marketed for 180 days.¹⁵

The FTC is looking to Congress to enact legislation to prevent pay-for-delay settlement agreements because, in recent years, court decisions not agreed on the validity of such deals.

Legal Decisions

a. In re Cardizem CD Antitrust Litigation

In 2003, the United States Court of Appeals for the Sixth Circuit decided *In re Cardizem CD Antitrust Litigation*¹⁶ which held that a pay-for-delay agreement was a *per se* illegal restraint of trade in violation of the Sherman Act.

The agreement provided that the manufacturer of the brand-name drug would pay the generic maker \$40 million per year, in quarterly payments, beginning the year the generic make gained FDA approval.¹⁷ Additionally, the generic maker was to receive \$100 million per year, less whatever interim payments had been made, once “(1) there was a final and unappealable determination that the patent was not infringed; (2) [the brand-name manufacturer] dismissed the patent infringement case; or (3) there was a final and

¹⁰ Pub. L. No. 108-173, 117 Stat. 2066, 108th Cong. (2003).

¹¹ See *Pay-for-Delay*, *supra* note 2, at p. 4.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at p. 5.

¹⁵ 21 U.S.C. § 355(j)(5)(D) (2009).

¹⁶ 332 F.3d 896 (6th Cir.2003).

¹⁷ *Id.* at 903.

unappealable determination that did not determine the issues of the patent’s validity, enforcement, or infringement...”¹⁸

In making its decision, the Court methodically analyzed relevant antitrust law and noted that Section 1 of the Sherman Act, “[r]ead literally, ... ‘prohibits every agreement in restraint of trade.’”¹⁹ However, instead of applying the often-used “rule of reason”²⁰ test to determine whether the alleged restraint of trade was “unreasonable,” the Court utilized the *per se* illegal test. A *per se* rule is applied when “the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.”²¹ The *per se* illegal restraints are struck down because they “have such predictable and pernicious anticompetitive effect, and such limited potential for precompetitive benefit.”²² After applying the *per se* illegal test to the facts of the case, the Court concluded:

[t]here is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.²³

However, just two years later, other federal appellate courts would disagree with the determination made by the Sixth Circuit and hold that pay-for-delay agreements did not constitute unreasonable restraints of trade.

b. *Schering-Plough Corp. v. Federal Trade Commission*

In 2005, the United States Court of Appeals for the Eleventh Circuit decided *Schering-Plough Corporation v. FTC*²⁴ involving a pay-for-delay agreement between the brand-name manufacturer of K-Dur 20, a supplement generally taken in conjunction with other prescription medications for the treatment of high blood pressure. Upsher-Smith Laboratories, a competitor of Schering, sought FDA approval to market a generic of the drug. Prior to trial, the two companies entered into an agreement where Upsher agreed to sell Schering an exclusive license to one of its patented drugs in order to create a revenue stream and also agreed to stay out of the market for several years in marketing a K-Dur 20 generic.

¹⁸ *Id.*

¹⁹ *Id.* (citing *Arizona v. Maricopa Cty. Medical Soc.*, 457 U.S. 332, 342, 102 S.Ct. 2466 (1982)).

²⁰ Under the rule of reason, the “finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” See *State Oil v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275 (1997) (citing *Maricopa Cty.*, 457 U.S. at 343 & n. 13).

²¹ *In re Cardizem CD Antitrust Litigation*, 332 F.3d at 906 (citing *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20, 99 S.Ct. 1551 (1979)).

²² *Id.*; see also *State Oil*, 522 U.S. at 3 (citing *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5, 78 S.Ct. 514 (1958)).

²³ *Id.* at 908.

²⁴ 402 F.3d 1056 (11th Cir.2005).

The Court declined to agree with the FTC that the arrangement was an “unreasonable” restraint of trade. In making that determination, the Court did not use a rule of reason nor *per se* analysis. Instead, the Court used prior case law to fashion an opinion. It relied on *Valley Drug Company v. Geneva Pharmaceuticals, Inc.*²⁵ where the Eleventh Circuit “held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market.”²⁶ What was need in this case, the Court noted, was an “analysis of the extent to which antitrust liability might undermine encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.”²⁷ Thus, the Court utilized a three-part test pulled from *Valley Drug*, namely conducting an examination of:

- (1) the scope of the exclusionary potential of the patent;
- (2) the extent to which the agreements exceed that scope; and
- (3) the resulting anticompetitive effects.²⁸

After conducting its analysis using the three parts, the Court concluded that if settlement negotiations were to fail between the brand-name maker and the generic, and the “patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent.”²⁹ Thus, the Court went on, “settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.”³⁰

In concluding that a settlement cannot be more anticompetitive than litigation, the Court said:

[o]ur conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles...³¹

Conclusion

The same year that the Eleventh Circuit decided *Schering*, the United States Court of Appeals for the Second Circuit decided *In re Tamoxifen Citrate Antitrust Litigation*³² holding that a pay-for-delay settlement did not rise to be a cause of action under the

²⁵ 344 F.3d 1294 (11th Cir.2003).

²⁶ *Schering-Plough Corp.*, 402 F.3d at 1065 (citing *Valley Drug Corp.*, 344 F.3d at 1311, n. 27).

²⁷ *Id.* at 1066.

²⁸ *Id.* (citing *Valley Drug Corp.*, 344 F.3d at 1312).

²⁹ *Id.* at 1075.

³⁰ *Id.*

³¹ *Id.* at 1076.

³² 466 F.3d 187 (2nd Cir.2005).

Sherman Act and thus was not a restraint on trade. Thus a split in the courts has emerged regarding the legality of pay-for-delay arrangements.

In his statement before the House subcommittee, FTC Commissioner Rousch said it was Congress that had the power and responsibility to set patent policy, not the courts (no doubt referring to the decision made in *Schering*).³³ He said “Congress should correct that imbalance...and shouldn’t wait for the Supreme Court to review these erroneous judicial decisions either. There’s no reason to think the Court will set things right anytime soon.”³⁴

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³³ Rosch, *supra* note 4, at p. 3.

³⁴ *Id.*