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Delaying Generic Drugs: The Legal Landscape Surrounding Reverse Payment Agreements To Protect Patent Holders

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Settlement agreements involving reverse payments by pharmaceutical patent holders to delay the introduction of generic equivalents are receiving increased attention from all three branches of the federal government.

Due in part to persistent judicial and legislative challenges to such agreements by the Federal Trade Commission (FTC), the legality of reverse payment settlements in ANDA-based patent infringement cases remains uncertain. The legal landscape surrounding these agreements ranges from being presumptively unlawful to being legal restrictions within the exclusionary scope of patents.

In the context of the Hatch-Waxman Act, reverse payments are typically payments made by a drug company holding a patent on a brand name drug to a generic drug company to delay, or entirely forego marketing its generic version of the drug during the term of the patent. The Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984) was enacted by Congress in an effort to accelerate the approval process for lower price generic versions of already approved brand name drugs. The Act provides an expedited drug approval process under an Abbreviated New Drug Application (ANDA) procedure to generic drugs that are bioequivalents of drugs already approved by the Food and Drug Administration (FDA) for safety and effectiveness. The FDA maintains a list of such approved drugs in what is commonly known as the "Orange Book."

As an incentive for generic drug manufacturers to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification (that the patent in question is invalid or would not be infringed by the manufacture, use, or sale of the new drug) the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date 1) the first ANDA filer commercially markets the generic drug, or 2) a court concludes that the patent in question is invalid or not infringed. [21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II)] Many times, the patent holder and the ANDA filer will settle a patent infringement suit with an agreement that involves a reverse payment.

The FTC has been very vocal in its disapproval of reverse payment settlement agreements, keeping the issue in the forefront by repeatedly and aggressively challenging such agreements through court actions. Its position is that reverse payment agreements, which it calls "pay-for-delay," are per se violations of the antitrust laws. The FTC argues that the agreements impermissibly delay less expensive generic drugs from reaching consumers until the end of the term of an underlying patent which is likely invalid. Many of the FTC's court challenges, however, have been unsuccessful.

On the other hand, the Department of Justice (DOJ) recently reversed its prior stance and aligned itself with the FTC. In response to an invitation from the Second Circuit in *Arkansas Carpenters Health and Welfare Fund v. Bayer*, 05-2851-cv(L) (2009), the DOJ submitted a brief in which it recommended against the legality of reverse payment settlement agreements under the antitrust laws. In its brief, the DOJ proposed

that an antitrust plaintiff should be able to establish a prima facie case of illegality under the antitrust laws by showing that 1) the generic manufacturer gave up its challenge to the branded patent's validity, 2) the patent holder provided consideration to the generic manufacturer, and 3) the consideration accompanied an agreement to withdraw the validity challenge. However, the DOJ proposed that the antitrust defendant should be given the opportunity to rebut that prima facie case through a rule of reason analysis showing that the reverse payment settlement did not unreasonably restrain competition.

The Circuit Courts are split. While the Sixth Circuit agrees with the FTC that reverse payment settlements are per se violations of the antitrust laws, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the more recent wave of decisions in the Second, Eleventh and Federal Circuit Courts of Appeals have held reverse payments to be acceptable restrictions within the exclusionary scope of patents. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *FTC v. Schering Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); *Valley Drug Co. v Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2828 (2009). In these more recent decisions, the general rule appears to be that a reverse payment agreement will not likely be found to be violative of the antitrust laws so long as the agreement is not found to have anti-competitive effects outside the exclusionary zone of the patent. That is, the underlying patent must not have been procured through fraud, the related patent infringement litigation must not have been objectively baseless, and the anti-competitive effects of the agreements must not be outside of the exclusionary scope of the underlying patent.

To date, the Supreme Court has refused to consider the issue of reverse payment agreements, denying certiorari in the Schering Plough and Ciprofloxacin cases. In *Schering Plough*, the Court allowed the Eleventh Circuit's holding to stand that neither the rule of reason nor per se analysis was appropriate in the context of reverse payment agreements. In *Ciprofloxacin*, the Court allowed the Federal Circuit's holding to stand that reverse payment settlements do not violate antitrust laws, except where the underlying patent was procured through fraud, the related patent infringement litigation was objectively baseless, or the anti-competitive effects of the settlement agreement are outside of the exclusionary scope of the underlying patent.

On February 3, 2009, Senator Herbert Kohl (D-WI) introduced S.369, the Preserve Access to Affordable Generics Act. The Act seeks to prohibit brand name drug companies from compensating generic drug companies to delay entry of a generic drug into the market. The Act would make unlawful any settlement of patent litigation which involves payments by a brand name drug maker to a generic drug maker in exchange for delay to market entry of a generic version. The bill was reported by the Senate Judiciary Committee to the Senate as a whole on October 15, 2009 and has been placed on a calendar of business.

In the House, on March 25, 2009, Representative Bobby Rush (D-IL) introduced a related bill, H.R. 1706, the Protecting Consumer Access to Generic Drugs Act of 2009. Like its Senate counterpart, this Act seeks to eliminate reverse payment settlements in the context of the Hatch-Waxman Act. The bill has been referred to the Energy and Commerce Committee's Subcommittee on Commerce, Trade and Consumer Protection as well as the Judiciary Committee. The Subcommittee forwarded the bill to the Full Committee by a vote of 16 to 10.

In conclusion, the general thrust of judicial precedent, with certain exceptions, is that reverse payment agreements are likely legal, so long as the underlying patent was not procured through fraud, the related patent infringement litigation was not objectively baseless, and the anti-competitive effects of the agreements are not outside of the exclusionary scope of the underlying patent. However, the executive and legislative branches of the government appear to be aligned in seeking to eliminate, or severely restrict, such agreements. It is presently unclear whether the House and Senate bills will build up enough momentum to make it into law.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.