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House Passes War Funding Bill that Includes the “Preserve Access to Affordable Generics Act” that Makes Agreements to Settle Hatch-Waxman Patent Infringement Actions Presumptively Anticompetitive.

Last Thursday, the House passed H.R. 4899 –the War Funding Bill– that included the “Preserve Access to Affordable Generics Act” that amended the Federal Trade Commission Act, codified in 15 U.S.C. 44 et seq., to include a new Sec. 28. Under this Act, the FTC would have the authority to initiate a civil action against any party to an agreement settling a pharmaceutical patent case with what is commonly referred to as “reverse payments” or “pay-for-delay agreements.” Fully supporting the passage of this bill, FTC Chairman Jon Leibowitz stated that “Congress has taken a critical step towards ending a practice that is dramatically increasing the cost of prescription drugs.”

[Background on the Increasing Use of Reverse Payment Settlements](#)

The bill proposed by the House of Representatives seeks to resolve a difference of opinion between the federal courts and the Federal Trade Commission (“FTC”) and the United States as to what is the proper standard to assess the lawfulness of reverse payment settlements. Reverse payment settlements are a direct by-product, particularly in the drug-patent context, of the expedited patent infringement suits filed under the Hatch-Waxman Act. Prior to the Hatch-Waxman Act, a generic competitor wanting to enter the drug market had to initiate the costly and tedious FDA approval process itself, incur the costs of bringing the drug to market, then run the additional risk of having to defend off claims of patent infringement, while risking loss of initial upfront costs. This FDA approval process and its inherent risks curtailed bringing generic drugs to market. The purpose of the Hatch-Waxman Act was to offset this risk and “to make available more low cost generic drugs.” H.R. Rep. No. 98-857, pt. 1, at 14 (1984). The reallocation of risks in favor of ANDA filers (generic drug manufacturers) and the requirement that patent holders bring suit within 45 days to defend their patent’s validity, however, created substantial risks for patent holders. For example, if the patent holder loses, it will be stripped of its exclusive market position; where as if the ANDA filers lose, they cannot bring their generic drug to market until the patent expires. As a result of this risk, patent holders began to offer reverse payment settlements. These settlements allowed for patent holders to retain their valid patent and its accompanying profits.

FTC's Perspective on Reverse Exclusionary Agreements

The FTC, the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has long insisted that reverse exclusionary payment settlements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 & n.11 (2d Cir. 2010) (citing statement of FTC Chairman Jon Leibowitz criticizing the “extremely lenient view” taken by some courts towards reverse exclusionary agreements and alleging that such agreements result in massive wealth transfers from consumers to pioneer drug producers). Similarly, the United States Department of Justice (“DOJ”) has also taken the position that federal courts have adopted an improper standard that fails to subject reverse payment settlements to appropriate antitrust scrutiny. *Id.* at 108. Many academic commentators have also taken a similar view arguing that a reverse settlement should be accorded a presumption of illegality if the settlement both restricts the generic firm’s ability to market a competing drug and includes compensation from the innovator to the generic firm. *Id.* at 105 n.11.

Several Circuit Courts' Perspective on the Agreements

By contrast, at least three circuit courts have taken a different view holding that the right to enter into reverse payment agreements falls within the terms of the grant conferred by the branded manufacturer’s patent. *See Carpenters Health* at 105; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 216 (2d. Cir. 2006) (finding a patent holder is entitled to protect its “lawful monopoly over the manufacture and distribution of the patented product”). If competition is restrained only within the scope of the patent, the Second Circuit, bound by earlier precedent, has even taken the view that unless the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under the existing antitrust law. *See Carpenters Health* at 106. In other words, reverse settlement agreements are within the purview of the rights Congress bestowed upon patent holders.

The Preserve Access to Affordable Generics Act

H.R. 4899 mirrors provisions that were considered by Congress, supported by the FTC, and promoted by President Obama, himself, for inclusion into the health care reform legislation passed earlier this year. Under the Act, the FTC may initiate a civil action against “the parties to any agreement resolving or settling ... a patent infringement claim, in connection with the sale of a drug product.” Preserve Access to Affordable Generics Act, H.R. 4899, 111th Cong., at 74 (2010). Most notably, in this civil action, “an agreement shall be presumed to have anticompetitive effects” and be unlawful if the ANDA filer “receives anything of value” and it agrees “to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product [generic drug] for any period of time.” *Id.* at 74-75. To rebut this presumption, a party would need to “demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects.” *Id.* at 75. The Act provides a list of factors that the court *must* consider such as, the time remaining on the life of the relevant patent, the value to consumers; the form and amount of consideration received in settlement; the foregone potential revenue of ANDA filer (generic); the potential reduction of NDA filer’s (Brand Name) revenue; and any other factor in the fact finder’s discretion. *Id.* at 75-76 (emphasis added). Penalties under the Act include forfeiture of up to 3 times (a) the value received in the settlement agreement or (b) the value reasonably attributable to the violation. *Id.* at 79. For a settlement to be excluded from the penalties of the act, the settlement agreement must allow for at least one of the following: (1) right to market generic drug in the U.S. market; (2) payment for litigation expenses not to exceed \$7,500,000, or (3) covenant not to sue generic drug manufacturer for infringement of the patent. *Id.* at 77. Notably, this Act would “apply to all agreements ... entered into after November 15, 2009, *Id.* at 85, and the FTC would have 3 years after Notice of Agreement was filed pursuant to section 1112(c) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 to bring a civil action against a party. *Id.* at 87.

“This bipartisan legislation would save American consumers and taxpayers billions of dollars by stopping sweetheart deals that delay the entry of low-cost generics, while at the same time allowing settlements that benefit consumers.”

–FTC Chairman Jon Leibowitz

What Does It All Mean

Although Senator Kohl and others have proposed a similar bill, the Senate has yet to pass such legislation. If approved by the Senate, this Act would amend the Federal Trade Commission Act and bestow upon the FTC the authority to effectively curtail the use of reverse payment settlements as the FTC could initiate an action against any party involved in such an agreement. The clear and convincing burden that would be placed on the party to prove the procompetitive benefits of the agreement would be significant. In addition, the bill if passed into law would abrogate the majority of federal courts decisions that have found reverse exclusionary payment settlements to be permissible under U.S. patent laws.

This publication is intended only as a general discussion of these issues. It should not be regarded as legal advice. We would be pleased to provide additional details or advice about specific situations if desired.

If you wish to receive more information on the topics covered in this publication, you may contact your regular Shearman & Sterling contact person or any of the following:

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