

THE PATENT PAY-FOR-DELAY SCAM

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In recent years, branded drug manufacturers have engaged in a tactic designed to stifle competition from lower-cost generic medicines. In what are known as ‘pay-for-delay’ patent settlements, generic drug competition is effectively blocked. A US Federal Trade Commission (FTC) study estimates that these anti-competitive arrangements result in \$3.5 billion of higher annual drug costs.

The FTC has filed lawsuits and supported anti-pay-for-delay legislation in an effort to stop this practice. Whether pay-for-delay tactics violate US antitrust laws is a matter currently before the courts. If there is an ultimate court finding that these tactics constitute an antitrust violation, those who engage in this practice may find themselves the targets of criminal prosecutions.

An excellent consideration of whether pay-for-delay is illegal was written by Lyle Denniston in his blog *Argument preview: Is “pay for delay” of drugs illegal?* at www.scotusblog.com/2013/03/argument-preview-is-pay-for-delay-of-drugs-illegal/

Denniston reminds us that Congress “... in 1984 made a major change in federal drug law in order to encourage the earlier marketing of generic substitutes ... It did so mainly to give consumers the benefit of lower prices for generics ... Because marketing a substitute for a patented drug might infringe on the patent, the generic maker is obligated to make a claim that its version either won’t infringe on the patent, or that the patent is invalid and cannot be enforced.

“In response to that kind of claim ... the brand name company then can sue for infringement ... [and] that dispute must be resolved in the courts before the FDA can clear the generic substitute for marketing.”

That said, there is a risk associated with the brand name company commencing a patent-infringement action against the generic. Such a lawsuit exposes the patent to a potential finding of invalidity or enforceability, whereupon the patent monopoly will be lost. Faced with this risk, branded drug companies have designed the pay-for-delay tactic.

So, how does pay-for-delay work? Keeping in mind that generic drugs are created to provide the same medicinal treatment qualities as their brand name counterparts, but are offered at significantly lower prices, a simple illustrative scenario can be described as follows. A brand name manufacturer is the owner of patent protection covering a drug with US sales that generate billions of dollars a year in revenue. A generic drug company, desiring to offer a substitute drug, makes a claim that this patent is invalid and that there can be no infringement of an invalid patent. The branded drug company sues for infringement.

However, exposed by this challenge to the validity of its patent and the potential loss of billions annually, the branded drug company negotiates a settlement of the lawsuit under which the generic drug company abandons its effort to invalidate the patent and is offered a licence under the patent,

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but with the understanding that it will not enter the marketplace with its substitute drug for several years. This settlement includes payment of many millions of dollars to the generic drug company by the branded drug company—hence the term pay-for-delay.

Both parties to pay-for-delay settlements wind up being beneficiaries of this tactic, at the expense of consumers. The generic drug company enjoys the receipt of these extraordinary sums without having had to incur the considerable costs associated with the original development of the drug, or obtaining its approval from the FDA, or establishing the brand recognition associated with bringing the branded version to market.

Furthermore, the generic drug company avoids the costs of litigation and enjoys the pay-for-delay payment without having to bring the substitute drug to market for a number of years. And the branded drug company enjoys a continuing monopoly for its drug, the patent protection for which has not been exposed to possible invalidation.

Nothing in Congress’s actions was ever intended to leave patents intact improperly, or immune from challenges to their validity. Assuming that a generic drug company’s claim of patent invalidity is based on sound facts, the pay-for-delay tactic effectively serves as a bribe to discourage patent-invalidity challenges.

The very nature of the lawful patent monopoly has its origins in Article 1, Section 8, Clause 8 of the US Constitution, sometimes referred to as the Patent and Copyright Clause, which empowers the Congress to “promote the progress of science and useful arts, by securing *for limited times* to authors and *inventors* the exclusive right to their respective writings and discoveries”. Brand name drug companies, through the clever pay-for-delay tactic, effectively turn the law on its head in an effort to continue to reap billions for as long as they can.

It is hoped by many that the US Supreme Court will find that the pay-for-delay tactic runs foul of US antitrust laws and will put a stop to this practice. ■

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