Drug Policy 101: Pay-for-Delay

The term "pay-for-delay" refers to a tactic used by brand name drug manufacturers to delay a potential competitor from bringing a generic drug alternative to market. Usually in the form of a cash payment, pay-for-delay transactions result from a patent dispute settlement between a brand name and generic company. The Federal Trade Commission (FTC) has cited these arrangements as anticompetitive, and estimates that they cost consumers and taxpayers $3.5 billion in higher drug costs every year due to a lack of competition from cheaper generics.

Hatch Waxman Act: Patents and Market Exclusivity

When brand name drug manufacturers receive a patent, which typically lasts for 20 years, they have sole rights to produce their drug. However, generic drug companies have the right to challenge the validity of a patent in order to enter the market, and have been encouraged to do so due to a provision in the Hatch Waxman Act of 1984 that grants six months of market exclusivity to the first generic drug filed to compete with a branded drug.

The Act, which was passed to encourage faster market entry of generic drugs to compete with brand name drugs, allows generic drug manufacturers to go through an abbreviated approval pathway by filing what is called Abbreviated New Drug Application (ANDA). This pathway establishes whether the drug is "bioequivalent" – or essentially identical – to the brand name drug. The first manufacturer to file an ANDA for a generic of a branded drug is granted the six months of market exclusivity.

If the patent on the brand name drug has not expired, the generic drug manufacturer must declare that its product does not infringe on a patent or that the patent is invalid. The brand name drug manufacturer typically challenges this declaration by suing the generic drug company for patent infringement. These patent disputes can be costly and time consuming; therefore, brand name and generic manufacturers may decide to settle before a court decision is made.

As part of the patent dispute settlement, the brand name company might offer monetary compensation to the generic drug manufacturer, and in exchange, the generic manufacturer agrees to refrain from entering the market for a specified amount of time. This type of interaction is called pay-for-delay.

Antitrust Concerns

From the FTC's point of view, pay-for-delay discourages generic drug makers from becoming true competitors, and instead promotes profit sharing of a monopolistic market generated by the patent. Further, they claim that such anticompetitive activity causes consumers harm by limiting choice and lower-priced alternatives. Because over 75% of pay-for-delay settlements occur between the brand name manufacturer and the first generic to seek entry, such settlements can prevent all related generic drugs from entering the market, as they have to wait until the first generic has been marketed for 180 days.

Defenders of these settlements, such as drug manufacturers, say they are not violating antitrust laws as long as the settlement of patent litigation does not generate greater exclusivity to a seller than patent law already presumptively affords. Additionally, drug makers maintain that pay-for-delay settlements may actually save money because settlements allow generic drugs to reach consumers earlier than if patent litigation continued.

What specifically constitutes a pay-for-delay deal, and whether or not it is subject to antitrust review, has been contested in the courts. The Supreme Court ruled in 2012 that pay-for-delay deals may be subject to antitrust review, but they did not specify whether cash payment is the only type of transaction deemed questionable when a settlement is reached. Since that decision, courts have disagreed as to whether non-cash payments indicate anticompetitive behavior. Recently, two federal appeals courts determined that settlements involving more than just cash payments are subject to antitrust scrutiny. In one case, a brand name oral contraceptive manufacturer, Warner Chilcott, reached deals with two generic drug makers after filing patent infringement lawsuits. Instead of making cash payments, Warner offered various deals, such as the right to produce the first generic for other Warner products.

In another case involving Endo Pharmaceuticals, the FTC – for the first time – is challenging what are known as "no authorized generic (or no-AG) commitment" agreements as anti-competitive pay-for-delay deals. In this type of agreement, the brand name drug manufacturer keeps generic competition off the market not only through payment, but also through an agreement to not market their own generic version of the drug. This is important because although

the 180-day exclusivity for generic drugs is enjoyed by the first generic to file, this does not prevent brand name dug manufacturers from marketing their own authorized generic version of its branded product during this time.[12]

Conclusion

During a 2017 FTC hearing, Michael Carrier of Rutgers Law School noted that over the last three years the number of potential pay-for-delay settlements fell from 40 to 14. Carrier cited antitrust scrutiny from the courts and enforcers as the cause for these parties settling in ways other than payment.

Building on the FTC's perspective that these settlements are anticompetitive and need to be addressed, stakeholders in the health care industry are raising this issue as well. The Campaign for Sustainable Rx Pricing, of which Kaiser Permanente is a member, recently called on policymakers to "encourage robust oversight and opposition" to tactics such as pay-for-delay that aim to delay market entry of generic drugs. As policymakers evaluate options for reform in the drug pricing issue space, it is likely that pay-for-delay, and rigorous antitrust enforcement, will be an item of discussion.

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