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Antitrust Law A Practice Focus

We'll Sell Generics, Too

Innovator drug makers are gaming the regulatory system and harming competition.

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Few industries have generated as much antitrust litigation and government enforcement actions as the pharmaceutical industry.

This is partly due to efforts by branded pharmaceutical manufacturers to exploit loopholes in the regulatory system to improperly extend the patent life of their drugs. The latest strategy involves "authorized generics," the term for a company's introduction of a generic version of its own patented drug a short time before patent expiration. With billions of dollars worth of drugs due to go off patent in the next few years, this and other efforts to manipulate the regulator process will be the next antitrust challenge.

The development of new, truly innovative pharmaceuticals is a high-risk, high-reward endeavor. Relatively few pharmaceuticals in development actually come to market, and those that succeed offer the opportunity for very substantial financial rewards. It is that opportunity for monopoly rewards that creates the incentives both for innovation and for the pursuit of legal gamesmanship, such as manipulating the regulatory system.

Generic pharmaceutical companies that manufacture copies of drugs after patent expiration play a vital role in the market. Generic alternatives offer tremendous potential savings to consumers, since they are typically priced at about 80 percent less than the corresponding brands. Consumers save billions of dollars annually because of generics. Generic markets contain all the ingredients of a highly competitive market: easy entry, minor product differentiation, and numerous competitors.

Slightly more than 20 years ago, Congress enacted a landmark statute to balance the interests of innovator and generic firms and provide a somewhat clear regulatory path for generic entry. The Hatch-Waxman Act sought to protect the incentives of innovator firms while creating a formalized system for generic firms to enter the market.

Just as the patent laws provide incentives to innovate (monopoly profits for a period of time), the Hatch-Waxman Act created a system to reward generic makers for creating non-infringing versions of a drug or successfully challenging patents. One of the key aspects of the Hatch-Waxman Act is a 180-day period, in which the first firm to successfully challenge a patent on an innovator drug is allowed to be the only generic on the market. During this exclusivity period the generic firm reaps substantial profits.

The bounty from challenging a patent is very important. Pharmaceutical patent litigation is a multimillion-dollar proposition. But for the potential reward of six-month exclusivity that represents the vast majority of potential profits from generic entry, many firms might forgo challenging patents.

Unfortunately, antitrust history teaches that the combination of potential monopoly rewards and a regulatory system often leads firms to manipulate the regulatory process. Some firms will seek out loopholes to secure monopoly rents.

Securing monopoly through the regulatory system is perhaps one of the most pernicious types of anti-competitive conduct. When a firm acquires a monopoly through skill, foresight, and industry, we do not worry as much—because we can expect someone to use the same skill and industry to restore competition. But when a firm secures monopoly power through the regulatory system, no natural competitive force can displace it.

That is why during the Clinton and Bush administrations, pharmaceutical antitrust has become the main course on the government's antitrust menus. Over the past decade, the Federal Trade Commission and state antitrust enforcers attacked a variety of tactics innovator firms were using to exploit loopholes in the Hatch-Waxman Act to delay generic entry. Some of these practices included alleged evergreening of patents, patent settlements between branded and generic firms, and sham regulatory filings.

In response to this anti-competitive conduct and guided by a landmark FTC study of the generic market, Congress amended the Hatch-Waxman Act in 2003 to address several of these anti-competitive practices.

Despite Congress' good intentions, the search for regulatory loopholes is ongoing. The innovator firms have again sought to exploit these loopholes to delay generic entry.

The latest addition to the arsenal of anti-competitive practices is the creation of authorized generics. The "authorized" or "branded" generic undercuts the inevitable market penetration and profitability of the other would-be generic competitors by capturing a large part of the generic market before traditional generics enter it.

In some cases the innovator firm enters with its own version of a quasi generic. In other cases it enters into arrangements with traditional generic firms to enter with a quasi-generic version. And more recently, alleged authorized generic firms have been created with the sole purpose of being a front for these alliances.

There are benefits with the earlier entry of a generic. But these benefits are relatively modest because the quasi generic is priced at only a small margin below the branded drug, perhaps as little as a 5 percent discount.

One must wonder why any branded firm would enter with a generic version of a high-value product. After all, we do not see Apple coming up with lower-cost knockoffs of an iPod. How is it in the economic interest of the branded firm to genericize a market? It makes sense only if the branded firm sees some long-term benefit, such as diminished generic competition.

What is the potential effect of an authorized generic strategy? With the authorized generic coming to market before the entry of the generic firm that has marketing exclusivity, the value of that exclusivity decreases substantially. As the value of the exclusivity decreases, generic companies will lose part of their incentives to enter markets. In turn, consumers are deprived of the benefits of that generic competition.

Is the reduction of these generic incentives sufficiently significant to have an anti-competitive effect? Perhaps so. As FTC Commissioner Jon Leibowitz has observed: "For some blockbuster drugs the pot of gold will still be large enough so that some generics will fight to be the first to file and the first to market. But we could very well see fewer generic applications for smaller drugs—the ones that warrant several hundred million dollars a year in revenue—and this could lead to fewer generic products on the market, which would be bad for consumers."

In response to these concerns, Rep. Henry Waxman (D-Calif.) and Sens. Chuck Grassley (R-Iowa), Patrick Leahy (D-Vt.), and John Rockefeller IV (D-W.Va.) have asked the FTC to conduct a study of the impact of authorized generics on generic-drug competition. The FTC agreed in November to do so.

Antitrust Concerns

What are the potential antitrust concerns raised by authorized generics? Obviously, there is a trade-off between the apparent short-term benefits of having a new product come to market sooner and the potential long-term harm of reducing the incentive and perhaps the ability of generic firms to effectively enter the market.

The U.S. Court of Appeals for the D.C. Circuit in *United States v. Microsoft* (2001) was keenly aware of the dangers of eliminating even potential competition, calling it "inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will." The court's statement on the importance of potential competition rings particularly true in the arena of authorized generics. With the elimination or the reduction of the rewards from the 180-day exclusivity period, generic firms might just decide not to enter these markets. In other cases the generic firms might not challenge certain patents if the potential rewards do not seem significant.

Could such a strategy succeed? There is an interesting historical analogy. After World War II, cigarette manufacturers faced the increasing threat of black-label or generic cigarettes. In response, the branded firms came out with their own black-label cigarettes. They priced these in a predatory fashion and eventually drove the independent manufacturers out of the market. Once the independents were gone, the cigarette manufacturers eliminated black-label cigarettes and significantly increased prices. Ultimately, the Justice Department successfully challenged this.

Another potential competitive concern is that a manufacturer may develop a reputation for introducing authorized generics when entry by traditional generic competitors seems likely. Although this type of strategic conduct will not immediately foreclose generics the first time it is used, it may diminish competition in the long term by signaling to generic manufacturers that their attempts to enter will be pre-empted by an authorized generic. By diminishing the incentive for generic firms to challenge patents, the innovator could effectively raise the barriers to entry.

Sham Settlements

Finally, the threat of a patent holder entering into an authorized generic agreement may compel generic challengers to drop their patent challenges and enter into settlements. The generic challenger knows that even if it is successful, the patent holder actually controls the conditions of entry. This severely dampens the incentive to litigate aggressively against a potentially invalid patent.

The goal of generic companies will no longer be to be the first to successfully challenge a patent, but rather to be the first to enter into an alliance with the patent holder. Not surprisingly, since the authorized generic strategy began, there has been a tremendous increase in branded-generic settlements. That type of strategy—sham settlements between branded and generic firms—has already been challenged by the antitrust enforcers and struck down by some courts.

The potential for anti-competitive effects calls for more intense antitrust scrutiny. Regulatory self-correction will not occur. Despite the efforts of the generic industry, the Food and Drug Administration has eschewed its regulatory role, and the courts have concurred.

The potential long-term effects on the generic industry through the exploitation of this loophole in the Hatch-Waxman Act can be deleterious to consumer welfare and competition.

Ultimately, the full exploitation of the authorized generic strategy could vanquish the generic industry. Generic competitors would spend their time looking simply to partner with branded companies, rather than seeking to play an active role in challenging patents and entering independently.

When regulatory loopholes are manipulated and generic manufacturers are compelled to divert their efforts away from entering markets independently, it is, of course, consumers—those who benefit the most from generic competition—who stand to lose the most.

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