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Pay for Delay

FORUM COLUMN

By Dan Mogin

The Hatch-Waxman Act was enacted in 1984 to promote generics while preserving a financial incentive for research and development through patent extension. Likewise, the patent laws are designed to promote innovation and invention by granting a limited term monopoly. The antitrust laws are designed to promote competition so that market participants, including businesses and ordinary consumers, have economic choices and receive better goods and services at the lowest economic cost (economic cost includes a normal profit or rate of return). In other words, antitrust tries to enhance efficiency and innovation by protecting competition and markets. Consider those policies in the context of the current congressional debate over health care reform: We need to reduce health care costs, prescription drugs are big part of those costs; generic drugs are typically priced significantly less than their branded (patented) counterparts. Health care, patent and antitrust laws came into conflict on June 22, when the Supreme Court refused to grant review in an antitrust case involving "pay for delay" or "reverse payments" by a brand name pharmaceutical company to a generic-drug maker to keep a competing generic drug off the market. There have been a number of these cases in recent years involving payments by branded drug companies to potential generic competitors to stay out of the market that occur in the context of patent settlements arising under the Hatch-Waxman Act. Notably, the patent holder pays the alleged infringer. In turn, the alleged infringer agrees not to challenge the validity of the patent or market the generic version of the drug until the patent expires.

In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008), involved an antitrust challenge to millions of dollars in payments made by Bayer, the manufacturer and patent holder of Cipro, a powerful antibiotic, to generic-maker Barr Laboratories Inc. Bayer's patent expired in December 2003 and its FDA-granted marketing exclusivity extension expired six months later. Pursuant to the Hatch-Waxman Act, in October 1991, Barr filed an abbreviated new drug application for a generic version of Cipro. Barr did not certify that its product did not infringe Bayer's patent. Rather, Barr said that Bayer's patent was invalid and unenforceable because it was obvious, double patenting and procured by inequitable conduct or fraud on the Patent and Trademark Office. Bayer sued Barr for patent infringement. Barr counterclaimed for a declaratory judgment that Bayer's patent was invalid and unenforceable and that Barr's generic version would not infringe. Just before trial, Bayer and Barr and certain others entered into a series of agreements. Abbreviated, the agreements provided that Barr would not challenge the validity or enforceability of the patent and would not market its generic until after the patent expired. In exchange, Bayer agreed to pay Barr an initial \$49 million and subsequent payments totaling \$398 million. Thereafter, four other companies filed abbreviated new drug applications for generic versions of Cipro. Bayer sued each of them for infringement. The issue of inequitable conduct was not adjudicated in any of the actions. Bayer defeated two challenges to the validity of its patent on summary judgment. The validity of the patent was upheld after a bench trial in another case.

Direct and indirect purchasers of Cipro and advocacy groups filed antitrust actions challenging the Bayer-Barr reverse payment agreements. They alleged that the agreements constituted an illegal market allocation in restraint of trade in violation of Sections 1 and 2 of the Sherman Act and various state antitrust and consumer protection laws. The district court denied the plaintiffs' motion for partial summary judgment that the agreements were per se unlawful. The plaintiffs then amended their complaint to add a state law antitrust claim under *Walker Process Equipment Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), alleging that Bayer unlawfully monopolized the ciprofloxacin market by enforcing a patent obtained by inequitable conduct or fraud on the Patent and Trademark Office and sham litigation in enforcing the Cipro patent against Barr. The parties filed cross-motions for summary judgment regarding whether the agreements had anti-competitive effects. The district court denied the plaintiffs' motion and granted Bayer's and the generic defendants' motion. The court determined that any adverse effects on competition stemming from the reverse payment agreements were within the exclusionary zone of the patent, and therefore could not be redressed by antitrust law. Bayer also filed a

motion to dismiss the state law Walker Process claim as pre-empted by federal patent law. The district court agreed that the claim was pre-empted because the plaintiffs alleged no theory did not depend on a showing of misconduct before the Patent and Trademark Office and that there was no separate allegation of marketplace misconduct. The district court also reasoned that Bayer's success in its litigation against the four other generic companies foreclosed any argument that its lawsuits were shams. Because the appeal was deemed to arise under the patent laws, it was heard by the Federal Circuit. The Federal Circuit has a reputation as being hostile to antitrust claims generally and as determined to erode the rights of market participants. It held that a settlement agreement between a patent holder and a party accused of infringement cannot violate antitrust laws so long as the patent litigation was not a sham or otherwise baseless, and the settlement does not impose restrictions on the alleged infringer beyond the scope of the patent. It further relied on the sanctity of settlement agreements and essentially ruled that the courts' needs for finality and encouragement of settlements trumps the markets' needs for freedom from adverse competitive effects.

The *Cipro* decision and similar ones in other pay-to-delay cases stand for the proposition that an agreement between competitors that might be per se unlawful if struck in another context is made lawful, if not fully immunized, by the fact that it was struck as part of the settlement of a patent dispute. Further, the court's refusal to allow scrutiny of settlements between potential competitors to see if they comply with the public's need for competitive markets. Another view is that patent law, which involves the creation of limited property rights for public purposes automatically trumps antitrust law. Once again, judicial attitudes toward antitrust enforcement, particularly at the Supreme Court level, are less than consistent with competitive markets. The Rehnquist court's antitrust decisions shaped our health care system and paved the way for the enormous rise in market power by insurers at the expense of patients and rewarding efficiency rather than lobbying prowess. More recently, the Roberts court has radically altered longstanding antitrust precedents, particularly hampering enforcement by market participants.

In contrast to most of the federal courts, the FTC has been aggressive in its approach to reverse payment cases. Notably, the day after the Supreme Court announced its refusal to review the Federal Circuit's *Cipro* decision, in a speech before the Center for American Progress in Washington, D.C., Jon Leibowitz, chair of the FTC, said that an internal analysis projected that stopping collusive "pay-for-delay" settlements between brand and generic pharmaceutical firms would save consumers \$3.5 billion a year and also reap significant savings for the federal government, which pays approximately one-third of all prescription drug costs. Leibowitz urged Congress to pass pending legislation to ban or restrict such anticompetitive patent settlements, as a way to control prescription drug costs, restore the benefits of generic competition, and help pay for health care reform." From my perspective ... the decision about whether to restrict pay-for-delay settlements should be simple," Leibowitz said. "On the one hand, you have savings to American consumers of \$35 billion or more over 10 years - about \$12 billion of which would be savings to the federal government - and the prospect of helping to pay for health care reform as well as the ability to set a clear national standard to stop anticompetitive conduct. On the other hand, you have a permissive legal regime that allows competitors to make collusive deals on the backs of consumers." Leibowitz stated that "eliminating these [pay-for-delay] deals is one of the Federal Trade Commission's highest priorities."

The Obama administration has indicated that "antitrust must be among the frontline issues in the government's broader response to the distressed economy" and that "antitrust authorities - as key members of the government's economic recovery team - will ... need to be prepared to take action." In light of current judicial attitudes, however, that they may well have a very tough row to hoe and health care may be the skirmish lines.

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