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'Pay for delay' cases illustrate struggle between competition vs. regulation policies

By DAN MOGIN
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Editor's note: This is the first of a two-part series.

The genome of the drug market may be re-mapped by health care reform. Courts and parts of the administration, however, may not embrace competition as a tool to achieve economies. "Pay-for-delay" or "reverse payments" by brand name pharmaceutical companies to generic-drug makers to keep a competing generic drug from coming to market illustrates one context where the struggle between competition and markets as opposed to regulation and government control will play out. It is not the first time in our economic history and legal history.

It is generally agreed that the United States needs to reduce health care costs; prescription drug costs are a big part and, compared to many other therapies, are frequently highly cost-effective; generic drugs are priced significantly less than their branded (patented) counterparts and thus are especially cost-effective.

The Drug Price Competition and Patent Term Restoration Act, known as Hatch-Waxman, was enacted in 1984 to promote generic drugs while preserving a financial incentive for research and development through the patent system. The patent laws are designed to promote innovation and invention by granting a limited term monopoly, whereas the antitrust laws are designed to promote innovation and efficiency through competition so that market participants, including businesses and ordinary consumers, have more choices and receive better goods and services at the lowest economic cost ("economic cost" includes a normal profit).

The administration has acknowledged that it cut a political deal to limit potential cuts to drug maker revenues in order to bring a major industry to the legislative table. The deal reportedly includes protection from competition for prices and supplies. Members of Congress are reported to feel unconstrained by this deal. This raises the question in the legislative context of whether such a deal will trump attempts to use the free market to rein in drug prices.

Shortly before the political deal came to light, 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. Such deals occur in patent settlements under Hatch-Waxman; the patent holder who has alleged infringement 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. Bayer's patent expired in December 2003 and its Hatch-Waxman marketing exclusivity expired six months later. Pursuant to Hatch-Waxman, Barr filed an abbreviated new drug application for a generic version of Cipro. Barr contended 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 and Barr counterclaimed that the patent was invalid and unenforceable and that the generic would not infringe. Just before trial, Bayer and Barr and certain others entered into a series of agreements. The agreements provided that Barr would not challenge the validity or enforceability of the patent and would not market its generic for a defined period. 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 and Bayer defeated challenges to the validity of its patent.

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 violation of Sections 1 and 2 of the Sherman Act and various state antitrust and consumer protection laws. The court determined that any adverse effects to competition stemming from the reverse payment agreements were within the exclusionary zone of the patent, and therefore could not be redressed by antitrust law.

Because the Cipro appeal was deemed to arise under the patent laws, it was heard by the Federal Circuit. The Federal Circuit has a reputation for being hostile to antitrust claims and for issuing opinions that erode the rights of market participants relative to patentees. Not surprisingly, it held that a settlement agreement between a patent holder and an accused infringer cannot violate the antitrust laws if the patent litigation was not 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.

Thus Cipro and similar decisions in other pay-for-delay generic drug cases stand for the proposition that an agreement between competitors that might be per se unlawful if struck in another context is lawful, if not fully immunized, because it was struck as part of the settlement of a patent dispute. Further, Courts' refuse to allow scrutiny of settlements between potential competitors to determine if they meet the public's need for competitive markets. In any other words, a private agreement trumps legislative attempts to rein in drug prices via competition.

Cipro is yet another indication that judicial attitudes are less than consistent with competitive markets and Congressional intent as expressed in the antitrust laws. The Rehnquist court's antitrust health care decisions paved the way for the enormous rise in market power by insurers. More recently, the Roberts' court has radically altered longstanding antitrust precedents, particularly hampering private enforcement by market participants.

Mogin is the managing attorney of The Mogin Law Firm in San Diego; teaches antitrust at University of San Diego School of Law; chaired the Antitrust and Unfair Competition Law Section of the State Bar; and co-authored "California Antitrust and Unfair Competition Law."