CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
July 2015 (1)

Reverse Payments Post *Actavis*: A Litigation Quagmire?

Keith N. Hylton
Boston University

www.competitionpolicyinternational.com

Reverse Payments Post *Actavis*: A Litigation Quagmire?

Keith N. Hylton[1]

For the last decade or so, the FTC has had a bee in its bonnet over "reverse payment settlements." Such a settlement occurs when a pioneer pharmaceutical firm terminates a patent infringement lawsuit against a generic drug maker by forming an agreement under which the generic enters the market at some later date (still before expiration of the patent) in exchange for a payment from the pioneer.

In theory, reverse payment settlements could be observed in any area of litigation. One famous nuisance dispute, *Spur Industries v. Del E. Webb Development Co.*,[2] resulted in a reverse payment remedy, and probably many such disputes have been settled under similar terms. But reverse payment settlements have been especially noticed in pharmaceutical patent litigation—and not just because they must be reported by law.

The U.S. Federal Trade Commission ("FTC") argues that these settlements are designed to unduly protect a patent-based monopoly and to share the profits from the monopoly between pioneer and generic. Without such settlements, says the FTC, generics would prevail in the infringement lawsuits brought by pioneer firms, and drug markets would be opened to generic competition earlier. From this it follows that reverse payment settlements should be deemed to violate the antitrust laws, because they harm consumers.

This argument was somewhat persuasive to a majority of the Supreme Court in *FTC v. Actavis*, decided in 2013, which changed the law on patent infringement settlements from a rule favoring such settlements to a searching "rule of reason" inquiry that attempts to balance the pro-competitive and anticompetitive effects of a reverse payment settlement.[3] The Court didn't give much guidance to lower courts on how to conduct the balancing test other than to say that a large reverse payment may be taken as evidence that the underlying patent is weak.[4]

For the past year, lower courts have been struggling mightily to figure out how to apply the *Actavis* balancing test.

Unfortunately for the courts, and for consumers as well, much of the reasoning behind the FTC's decade-long attack on reverse payment settlements is flawed. The rash of reverse payment settlements observed in recent years, and similar deals transferring resources from pioneer to generic firms, may have benefitted consumers over the long term, and almost certainly

---

[1] Keith Hylton is the William Fairfield Warren Distinguished Professor of Boston University and Professor of Law at Boston University School of Law.

[2] *Spur Indus. v. Del E. Webb Dev. Co.*, 494 P.2d 700 (Ariz. 1972). The court required the nuisance source (a cattle feedlot) to move and the developer to compensate the nuisance source.

[3] *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2234 (2013).

[4] *Id.* at 2236.

left consumers better off than under the new FTC-created legal environment that obstructs such settlements.

The main argument against reverse payment settlements is that they permit a pioneer firm with a weak patent—one likely to be held invalid—to buy off the generic challenger and split the monopoly profits from a protected market. Yes, this is possible, and even plausible given that the Hatch-Waxman Act of 1984 stimulated generic challengers by reducing regulatory obstacles and giving the first challenger a period of exclusivity on the market.[5] But in assessing whether costly and intrusive—and, in this area, seemingly never-ending—antitrust scrutiny of patent infringement settlements is preferable to the earlier rule that favored such settlements, attention should be focused on the general case over the long term rather than the worst-case scenario.

The mere fact that a pioneer pays a reverse payment settlement—even one that exceeds its expected litigation cost—is not strong evidence that its patent is invalid. Even if the patent is 99 percent likely to be upheld, a pioneer with a blockbuster drug may still be willing to pay a lot of money to avoid the 1 percent risk that it will be invalidated. To return to my nuisance comparison based on the *Spur* case, the reverse payment order in *Spur* did not reflect a belief on the court's part that the developer's nuisance theory was weak. Instead, it reflected, in part, a perception that the gain to the developer was large relative to the loss suffered by the cattle feedlot from having to move.[6] Similar economics underlay many reverse payment settlements in pharmaceutical litigation.

Moreover, reverse payment settlements have provided an excellent escape option from litigation for generic challengers, one that has given them supercharged incentives to challenge pioneer patents. Knowing that a reverse payment or some other lucrative deal might be offered to put an end to litigation, generics have been quick to file challenges.

Overall, reverse payment settlements and similar deals have led to an enormous wealth transfer from pioneer firms to the generic sector. Generics have pocketed the money and used it to fund more dissemination, research, and patent challenges.

Indeed, the framework of streamlined patent challenges introduced by the Hatch-Waxman Act has had the general effect of transferring part of the investment return from pioneer firms to generics, thus increasing the hurdle rate for new drug innovation—and the prices necessary to justify that innovation—and pumping up the vigor of generic challengers.

This transfer appears to have been a windfall for consumers, as long as you try not to look at its effects on drug innovation. If you take into account effects on incentives for innovation, the overall impact of Hatch-Waxman on consumers may have been harmful: consumers received the benefit of greater generic competition in exchange for a slower innovation cycle that pumps out pricier drugs.

---

[5] *See, e.g.*, Garth Boehm *et al.*, *Development of the Generic Drug Industry in the U.S. After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013); Ashlee B. Mehl, *The Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive*, 81 CHI.-KENT. L. REV. 649, 653 (2006).

[6] *Spur Indus. v. Del E. Webb Dev. Co.*, 494 P.2d at 708.

By obstructing the pioneer to generic wealth transfer, the emerging legal prohibition of reverse payment settlements promises more undesirable consequences. As lower courts have expanded *Actavis* to cover *all* settlements that appear to benefit generic challengers, money exchanged or not, the rule is quickly morphing into a roach motel for litigation: drug firms can check in but never check out. The burden on new drug innovation remains and has likely worsened as a result, while the incentive to challenge patents has decreased.

The *Actavis* litigation itself offers an example of the burden and waste created by the new regime. The patent infringement litigation at its core began in 2003, settled in 2006 with a reverse payment that was perfectly legal at the time,[7] and now continues today in the form of antitrust litigation against the FTC with no apparent end in sight—and the class action lawyers have only started to circle around this litigation quagmire.

Of course, drug firms don't have to fight the FTC. They can settle, as Cephalon, now owned by generic Teva, just did, agreeing to pay $1.2 billion after the FTC threatened to seek a $5 billion disgorgement of alleged ill-gotten gains from a nearly decade-old reverse payment deal.[8] The $1.2 billion includes a $500 million previously agreed payment to class action lawyers, so it is arguably a good deal for Teva under the circumstances.

Taking money out of the drug development and dissemination system and giving it to a coalition consisting of the FTC and class action lawyers is not just a dollar-for-dollar exchange. The Hatch-Waxman transfer from the pioneer to the generic sector, though probably harmful to innovation, wasn't smoked up in the pipes of generic owners. Each dollar transferred resulted in a dollar more for development and dissemination by generic firms, and at the same time permitted pioneer firms to retain more money for research and development—decisions with positive global health implications. Now much of the transfer goes to litigation.

Eventually drug firms will figure out a way to settle their patent disputes without exposing themselves to this huge litigation tax. One judge recently dismissed the core of the FTC's reverse payment settlement case against pioneer Abbvie on the ground that the deal offered benefits to consumers.[9] Drug firms will be advised to read the decision as a primer on how to avoid liability.

Still, for now, an impenetrable fog of uncertainty sits over the law in this area. The FTC has no incentive to clear up this fog, because the combination of uncertainty and huge threatened disgorgement fines enhances settlement pressure on targeted firms.[10]

---

[7] *FTC v. Actavis, Inc.*, 133 S.Ct. at 2229; *see also* Press Release, Watson Pharmaceuticals, Inc., Watson and Unimed Pharmaceuticals, Inc. Settle Lawsuit Over AndroGel(R) Testosterone Gel (Sept. 13, 2006), http://actavis.com/news/news/thomson-reuters/watson-and-unimed-pharmaceuticals,-inc-settle-law.

[8] Rebecca R. Ruiz & Katie Thomas, *F.T.C. Settles Suit With Drug Maker*, N.Y. TIMES, May 2, 2015, at B1.

[9] *FTC v. AbbVie Inc.*, 2015 U.S. Dist. LEXIS 59115 (E.D. Pa. May 6, 2015).

[10] When a targeted firm pays off the FTC to put an end to antitrust litigation, its motive appears to be the same as when it pays off a generic to put an end to the patent challenge. In one case, the patent-based "monopoly profits" are shared with the generic; in the other with the FTC. This suggests that the only way the FTC could protect consumers would be to seek to invalidate the patent. The settlement is merely a sideshow.

There is no evidence so far that the new legal regime has led to any benefits for the average consumer. Generic prices have been skyrocketing since *Actavis*.[11] While there may be many reasons for this (e.g., regulation-induced shortages), the transfer of capital that could be used for drug development and dissemination into an expanding litigation black hole may be one of them.

Prices must rise to cover unpredictable legal expenses. Generic firms have to be big to handle all of this litigation, which at the same time is making fast bedfellows of pioneer and generic firms. Mergers and acquisitions, such as the one between Cephalon and generic Teva in 2011,[12] can help keep money in house.

All of this reduces the amount of competition in the long run. As the law of unintended consequences goes, this one may turn out to be generic.

[11] Trefis Team, *Why Are Generic Drug Prices Shooting Up?*, FORBES, (Feb. 27, 2015, 8:38 AM) http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/; *see also* Elisabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, N.Y. TIMES, July 9, 2014 at A16.

[12] Chris V. Nicholson, *Teva to Pay $6.8 Billion For Cephalon*, N.Y. TIMES, (May 3, 2011, 4:30 PM) http://query.nytimes.com/gst/fullpage.html?res=9B03E3D91F30F930A35756C0A9679D8B63.