FTC Gives Generics Victory On “Pay for Delay” Reverse Payments Crimped, Patent Thickets Untouched

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This is a “good news, bad news” column. The Federal Trade Commission (FTC) just settled a “pay for delay” case it filed 10 years ago, a case that had and still has implications for the entrance of generics into U.S. markets. The case involved charges that the brand-name drug company Solvay and three generic drug companies, including Actavis Holdco, a subsidiary of Teva, illegally agreed to restrict generics competition to Solvay’s branded testosterone-replacement drug AndroGel for nine years. But more significant legal impediments to the introduction of generics remain, and were untouched by that consent decree.

In essence, the settlement went beyond a 2013 Supreme Court decision backing the FTC over Solvay, with the FTC listing a number of actions by patent companies that might be construed as “reverse payments,” which would be considered either legal or illegal. Cash payments from branded companies to generics companies (i.e., reverse payments) to ensure the delayed introduction of rival generics has been greatly diminished since the Supreme Court decision, but not completely eliminated because of some loopholes. For example, the agreement allows “reverse payments” of less than $7 million.

Michael A. Carrier, Distinguished Professor at Rutgers Law School and Co-Director of the Rutgers Institute for Information Policy and Law in Newark and Camden, New Jersey, says, “The Actavis settlement is a strong one, similar to the one the FTC had entered into with Teva a week before this agreement.” Various Teva subsidiaries were embroiled in antitrust cases in various federal courts. Teva had purchased Cephalon, which had manufactured Provigil, a sleep disorder drug that was the focus of reverse payment lawsuits. In the FTC settlement, Teva agreed to pay $1.2 billion to various parties as compensation for the higher prices they had paid for Provigil in the absence of generic competitors.

That $1.2 billion “disgorgement” agreed to by Teva made the consent decree, on the face of it, a stronger action by the FTC than its agreement with AbbVie. The Association for Accessible Medicines believes the Actavis consent decree provides additional clarity about some of the types of provisions in settlement agreements that should not be deemed “payments” under the antitrust laws. In fact, Karin Hessler, Assistant General Counsel of the AAM, says the Actavis agreement “provided guideposts” for many such provisions and invites Congress to consider these provisions (and other potentially pro-competitive provisions) that should be included in the pending legislation.

However, “reverse payments” are no longer the top bugaboo for the generics industry; that would be “patent thickets,” where branded companies gain approval via one base patent and then extend their drug’s patented, no-competition life by filing tens of additional patents around features such as packaging and dosage, among other subsidiary properties.

“Addressing abuse of the patent system must be front-and-center if Congress is effectively going to reduce drug prices for patients,” Chester “Chip” Davis, Jr, AAM President, told the House Energy and Commerce Subcommittee on March 13, 2019.

The “poster child” for patent thickets is AbbVie’s Humira. On the market since 2002, Humira’s 132 patents block competition for three decades. Its base patent in the U.S. expired in 2016. Patent litigation proceeded and in order to avoid hellacious legal costs, Amjevita agreed to wait until 2023 to introduce a generic in the U.S. and pay a licensing fee for that privilege, instead of waiting until 2034 when the last of the Humira thicket patents expires.

There have been at least four bills introduced in Congress to break the patent logjam. The leading contender appears to be the Preserve Access to Affordable Generics and Biosimilars Act, introduced in the Senate by Democratic presidential candidate Senator Amy Klobuchar (MN) and co-sponsored by Senate Judiciary Committee Chairman Chuck Grassley (R-Iowa). It says that the act of offering and receiving a license in exchange for a generic delay, along with agreeing to forego research and development or marketing, would be considered “anti-competitive.” The bill has some standing owing to the stature of its bipartisan sponsors but has not attracted a broad enough roster of supporters to inject it with momentum.

One would think the generics industry would back such a bill. It does not; it opposes the bill as introduced. Erik Komendant, Vice President, Federal Government Affairs at AAM, explains that licensing agreements allow generics companies to bring generics to market much sooner than they would otherwise be able to do if they had to spend millions on patent lawsuits whose future, both in terms of duration and outcome, would be up for grabs. With regard to Humira, for example, he points out the value to consumers of making a biosimilar available in 2023 instead of in 2034.

AAM does support the Orange Book Transparency Act (H.R. 1503) and Purple Book Continuity Act of 2019 (H.R. 1520), which require the FDA to publish more information about brand-name patents in the existing databases the FDA already uses. Those minor technical bills, which are likely to pass the House and maybe
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WASHINGTON

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even the Senate, will do nothing to untangle the “patent thicket” problem, which is the major impediment to faster generic introductions.

Untangling the thicket could be accomplished by legislation stating that once a pharmaceutical company’s original patent on the key active ingredient expires, it’s open season for generics competitors. That bill hasn’t been introduced, and undoubtedly won’t be, because of the political power of the brand-name industry and the timidity of Congress. ■