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U.S. FTC Scrutinizes Interplay Between Authorized Generics and Patent Settlements

Eric J. Stock (Gibson, Dunn & Crutcher) · Monday, November 14th, 2011

The U.S. Federal Trade Commission has recently released two reports relating to the pharmaceutical industry. A significant theme in both reports is a concern that brand name pharmaceutical companies are using the threat of launching an authorized generic to make deals that delay generic entry. These reports shine a spotlight on the interplay between authorized generics and pharmaceutical patent settlements, and indicate strong FTC opposition to a practice that has never been found unlawful.

Report on Authorized Generics

On August 31, the FTC issued its final report analyzing the competitive significance of authorized generics. In the U.S., generic pharmaceutical products are typically sold by pharmaceutical manufacturers that receive authorization from the U.S. Food and Drug Administration ("FDA") to manufacture and sell a generic copy of an existing brand name drug sold by another firm. The term "authorized generic" is generally used to describe a generic pharmaceutical product that is sold not by a separate firm under a generic drug authorization, but rather by the brand name manufacturer itself (or its licensee) under the brand name drug authorization. This is important because under U.S. law, the first generic drug to reach the market is generally entitled to 180 days of exclusivity – which constitutes a major incentive to challenge the brand name manufacturer's patents and rush one's generic drug to market. But that marketing exclusivity only applies to standard generic products — it does not preclude the brand name manufacturer from launching its own "authorized generic" during the exclusivity period. A brand name manufacturer's ability to launch an authorized generic during that period is therefore a major threat to the first generic's profits, and generic firms have argued that this serves as a significant disincentive to bringing new generics to market.

The FTC drew a number of conclusions about authorized generics in its final report. First, it found that the launching of an authorized generic during the 180 day exclusivity period results in "modestly" lower generic prices for consumers. Second, the FTC found that this entry also has the effect of substantially reducing the profits of the first generic entrant – possibly as much as 40%-50%. While noting that this decreased profitability could diminish the incentives of generic firms to challenge patents and seek to bring their products to market, the FTC found little to no empirical evidence that authorized generics were actually having this effect.

The FTC also concluded – in what its Chairman called its "clearest and most disturbing finding" –

that “some brand companies may be using the threat of launching an authorized generic as a powerful inducement for generic companies to delay bringing their drugs to market.” In other words, the FTC is linking authorized generics to its overall concern with what it refers to as “pay-for-delay” patent settlements (sometimes called “reverse payment” patent settlements). Analogizing a promise not to launch an authorized generic as a “reverse payment” from the brand name manufacturer to the generic company, the FTC argues that brand name manufacturers are using the leverage of an authorized generic to convince generic companies to agree to compromise entry dates that are later than they would have agreed to in the absence of the commitment not to launch an authorized generic.

Report on Pharmaceutical Patent Settlements

The FTC’s recent report on pharmaceutical patent settlements also highlights the role of authorized generics in pharmaceutical patent settlements. In the U.S., certain types of pharmaceutical patent settlements must be filed with the FTC, and the FTC periodically releases reports summarizing their content. On October 25, 2011, the FTC released its latest report, which found that out of 156 total settlements filed with the FTC in the past fiscal year, 28 such settlements were “potential pay-for-delay” deals. In other words, in 28 settlements, a generic manufacturer had agreed to a specific compromise date for entry, and the deal also included a term that the FTC believed might constitute consideration to the generic company (which the FTC believes could have influenced — i.e., delayed — the compromise entry date). The FTC found that 10 of these 28 settlements included a commitment by the brand name manufacturer not to launch an authorized generic (or an agreement that the generic company would have the “exclusive” right to sell an authorized generic).

Implications

These statements and findings by the FTC are noteworthy because they illustrate significant FTC opposition to a practice that has never been found illegal – and which is being undertaken openly by pharmaceutical companies that know that they will have to file these agreements with the FTC. Given all of the difficulties that the FTC has faced in proving that patent settlements with consideration flowing to the generic manufacturer (so-called “reverse payments”) violate the antitrust laws, it is far from clear that the FTC would be able to convince a court that a promise not launch an authorized generic (or the granting of an exclusive authorized generic license) in the same context violates the U.S. antitrust laws. This may explain why the FTC has not brought any test cases in court, and is instead seeking to change the law in the U.S. Congress. But given all of the FTC attention and concern regarding this issue, it is likely that the FTC is actively looking for opportunities to act against these types of deals.

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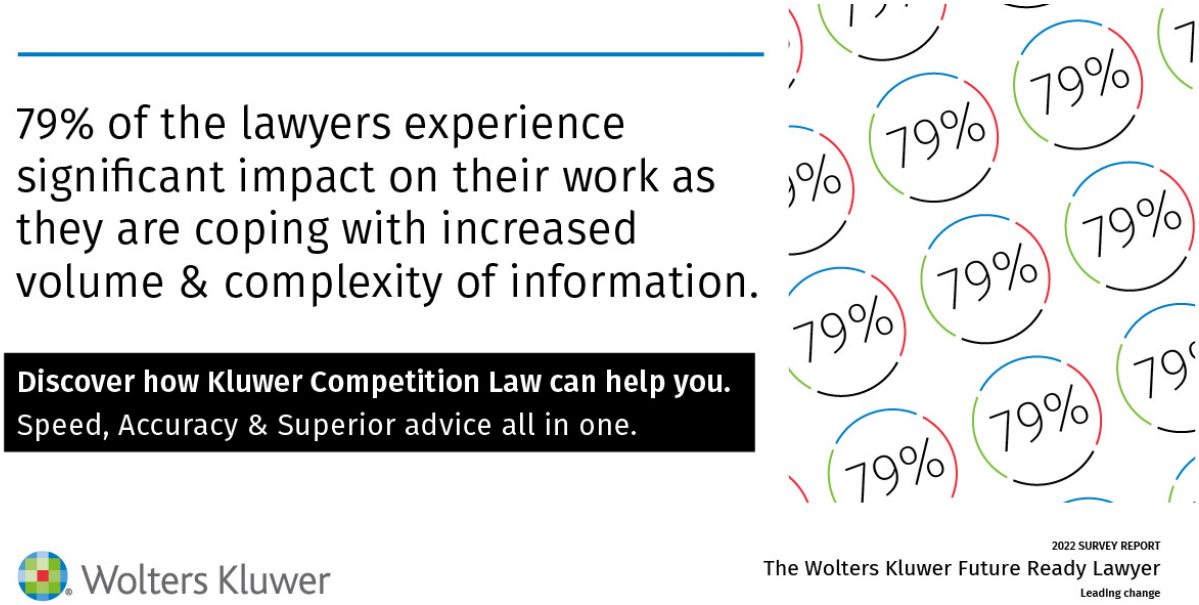

This entry was posted on Monday, November 14th, 2011 at 3:00 pm and is filed under Source: OECD">Antitrust, Source: OECD">Competition, United States of America
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