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Product-Hopping Cases: A Bad Prescription For Consumers

Law360, New York (August 14, 2015, 10:41 AM ET) --

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Almost a decade ago Judge Douglas Ginsburg of the D.C. Circuit helped create the circuit split that permitted the U.S. Supreme Court to retire price-squeeze as an antitrust cause of action. Price-squeeze involved a claim that a supplier that sold at both the wholesale and retail levels could "squeeze out" competitors that relied upon its wholesale offering either by pricing its wholesale product too high, or retail product too low. In linkLine the Supreme Court ended the 75-year tenure of the price-squeeze doctrine, holding that where a supplier has no antitrust duty to deal with a competitor in the first place, the terms on which the supplier subsequently chooses to deal cannot form the basis for an antitrust claim. Pacific Bell v. linkLine, 555 U.S. 438 (2009)

More recently, Judge Ginsburg seems to be working to limit if not eradicate another suspect antitrust cause of action known as "product-hopping." In short, the general allegation in a product-hopping case is that a branded drug manufacturer's introduction of a reformulated version of an existing drug — combined with a withdrawal from the market of the now obsolete version — violates the antitrust laws because it denies the generic manufacturers the opportunity to use the various state substitution laws to grab a significant share of the market. This issue arises because state substitution laws do not apply to reformulations. As a result, if the branded company has shifted all of its customers to a reformulation (with its own new patent) before the patent on the older version expires (permitting generic entry), the state substitution laws are not triggered. This is not to say that generics cannot compete for customers with the prior version of the drug, or that customers who switched to the new reformulated medication cannot switch back to the old version to take advantage of its lower price.

In May 2015, the Second Circuit became the first Circuit court to address "product-hopping." The court upheld a lower court's injunction against Forest Laboratories LLC (owned by Actavis) that required Forest to keep the old version of a drug in the market (despite Forest's development of an improved formulation) until after the patent expired on the old version. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015). The court's obvious goal was to keep as many customers as possible on the old version of the drug so that when the patent expires and the generics enter the market a vast majority of those customers automatically become generic customers. In early August, the full circuit refused to reconsider the ruling of the three-judge panel.

The Second Circuit's strained reasoning ignores the Supreme Court's repeated admonitions — most recently in Trinko and linkLine — that a firm has no duty to aid a competitor. Moreover, unlike Trinko, where the plaintiff at least alleged that the defendant had violated the underlying regulations intended to enable competition, there is no such allegation in Actavis.

The Actavis ruling could lead a cynical reader to believe that the court's primary goal was to secure lower-priced drugs for consumers. As was recently noted by Judge Ginsburg (and his co-author, Joshua Wright, a commissioner at the Federal Trade Commission) in comments submitted to the Canadian Competition Bureau, using the antitrust laws to effectuate this goal is inappropriate and misguided.

In the first place, the authors admonish, such precedent poses the very real risk of chilling innovation in the pharmaceutical industry — where, as the authors note, even minor innovations can result in significant consumer welfare gains.

Perhaps more important from a jurisprudential perspective are the other two issues identified by Ginsburg and Wright. First, competition law, the courts and enforcement agencies are "not suitable mechanisms" for "micromanaging product design and innovation." To that point, the authors suggest a more realistic and appropriate test; that antitrust liability only attach in the event a court determines that the reformulation is nothing more than a sham. While the commenters do not provide examples of what might be considered a "sham innovation," the FTC's amicus brief in Actavis suggests the test may be whether the formulation offers any therapeutic value "at all."

Second, and equally important, despite Forest's alleged "product-hop," the generic manufacturers that New York seems bent on protecting remained free to produce the drug upon the expiration of the patent and compete with Forest's reformulated version. In short, the actions of the branded company did not thwart competition, they simply thwarted free riding via the state substitution laws. Hence the Second Circuit's opinion seems more consistent with the actions of a legislator seeking to shore up existing legislation, than with an antitrust court.

While insightful and correct, the views of Judge Ginsburg and Commissioner Wright have no real precedential value aside from the stature of the authors and the inherent logic and reasonableness of their arguments. Branded pharmaceutical companies must still factor in the risk of a product-hopping lawsuit in devising a strategy for the introduction of a new drug formulation. They would do well also to keep in mind that because a product-hopping suit appears, at least superficially, to be pro-consumer, it may remain an attractive cause to certain enforcement agencies.

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