OPINION: 3rd Circ. Should Rehear Doryx Product-Hopping Case

Law360, New York (November 3, 2016, 11:39 AM EDT) -- How is a panel of the Third Circuit Court of Appeals like Donald Trump? It wants to build a wall preventing drug competition and have consumers pay for it.

David Balto

A recent decision by a panel of the Third Circuit Court of Appeals, in the case of Mylan Pharmaceuticals Inc. v. Warner Chilcott PLC,[1] will leave consumers out on the lurch for billions of dollars, giving large branded drug manufacturers a blank slate to avoid generic competition. Moreover the decision is divorced from established precedent of sister courts as well as Third Circuit precedent.[2]

The case, which is currently on petition for rehearing en banc, deals with a major drug manufacturer's strategy, called product-hopping, attempting to keep generic drug competition from entering the market. Product-hopping is accomplished when the branded manufacturer slightly modifies a drug and removes the old drug from the market, forcing doctors to change their patients' prescriptions to the new drug. This prevents pharmacists from being able to give their customers the cheaper generic version of their medications once they become available.

Product-hopping takes advantage of the safety aspect of state substitution laws. Such laws are designed to give patients safe access to affordable generic medication by permitting or requiring pharmacists to substitute an exactly equivalent generic alternative for a prescription for often high-cost branded medication. These automatic substitution laws are vital in the pharmaceutical industry where generic versions of drugs enter the market and drive prices down 80 percent or more once branded drugs are no longer protected by a patent. Automatic substitution laws support a generic pharmaceutical industry that saved U.S. consumers $254 billion in 2014 alone.[3] These savings are a key part of reducing the high cost of health care that is a threat to our economy.

Product-hopping undermines a regulatory system that is designed to make drugs both safe and affordable. After a slight or inconsequential change to a drug, with little or no improvement to the effect or outcome of the drug, a manufacturer can prevent sales of generic medications by circumventing automatic substitution laws. These branded manufacturers can even obtain a new patent and a new period of exclusivity on these minor changes. After a product hop occurs, patients are stuck paying high prices for branded medication even though a lower cost drug can give them the same benefits. Product-hopping essentially creates a wall that blocks off consumer access to generic medications, and consumers are left footing the bill.

Antitrust law has a critical role to play in policing strategies used to prevent generic entry. Indeed, antitrust litigation has in many instances stepped in to prevent branded drug manufacturers from finding ways to get more monopoly profits than they are entitled to,

deeming anti-competitive in certain circumstances practices such as reverse payments, sham regulatory filings and even product hopping. For example, in a white paper for the Center for American Progress I explained how state and federal antitrust enforcers, bolstered by private actions, have approached pharmaceutical competition concerns in a disciplined fashion, using antitrust enforcement to bring cases to clarify the law and stop conduct that deny consumers the benefits of lower priced generic drugs.[4]

Despite these efforts, there are still numerous forms of anti-competitive conduct that continue in pharmaceutical markets because of the ability of companies to manipulate the regulatory process and some misguided decisions of the courts.[5]

The Mylan Pharmaceuticals case, which concerns the antibiotic Doryx, is the latest such example of a misguided court decision. Mylan, a generic drug firm, brought suit against Warner Chilcott and Mayne Pharma Group Ltd., two branded drug firms who manufacture and market Doryx, an acne treatment, for violation of Sections 1 and 2 of the Sherman Antitrust Act, as well as a state law claim of tortious interference. Mylan claimed that defendants' product hopping scheme monopolized the market for branded and generic Doryx and resulted in anti-competitive conduct which delayed generic market entry. In 2004 defendants in this case received a patent on a tablet version of Doryx, after switching from a capsule version and subsequently pulling all capsule versions of Doryx from the market, forcing doctors to prescribe the tablet version. At this time Mylan had been working on an equivalent generic form of the capsule version and was forced to switch to the development of a generic tablet. However, defendants subsequently switched the Doryx product three more times by changing dosages and adding scoring lines so the pill could be divided for self-medication. None of the switches improved the product, but rather preserved their monopoly pricing over Doryx.

The district court ultimately found in favor of defendants by granting their motions for summary judgment. While the district court did find that the product hops were made primarily to delay generic market entry, it also found that Mylan's antitrust claims failed as a matter of law. Specifically, it held that Mylan did not provide sufficient evidence of defendants' monopoly power rejecting a narrow market of branded and generic Doryx for a broader one consisting of all oral tetracyclines prescribed to treat acne. It further held that Mylan failed to put forth sufficient evidence of anti-competitive conduct, finding that defendants did not exclude competition when they made product changes.

The Third Circuit followed the district court's lead and upheld the decision in favor of defendants. The panel found that Mylan failed to establish that Warner Chilcott and Mayne had sufficient market power in the relevant market. It affirmed the district court's finding that Mylan pushed an overly narrow market definition, and found that defendants actually controlled no more than 18 percent of the broader oral tetracycline market.

The Third Circuit's opinion rejected established law from the Second Circuit by making conduct determinations that would largely condone product-hopping practices. This decision is a substantial and dangerous departure from that of its sister court. In State of New York v. Actavis PLC,[6] the Second Circuit addressed the product-hopping question, finding that the practice can be anti-competitive when a firm coerces consumers to switch to a new product, rather than permitting new products to compete on the merits. It went further to explain that evidence that the prior product was successful and that there was no legitimate business justification for withdrawal of that prior version demonstrated the conduct was anti-competitive.

The panel of the Third Circuit took a diametrically opposite approach. Despite the four product hops that the defendants engaged it to delay generic entry into the market, it opined that Mylan could have entered the market at anytime and in fact successfully did so on previously released drug versions. The panel also gave credit to a wide range of irrelevant and disputed justifications by the branded manufacturer for changing its product without connecting those justifications to the conduct alleged to be anti-competitive. These justifications included safety concerns, shelf-life claims, and the need to compete with other tablet products. However, the panel never connected these justifications to withdrawal of a perfectly good product at enormous cost to the defendants. This analysis of conduct is simply wrong, and will have devastating effects in the pharmaceutical industry.

The panel's decision strayed from mainstream antitrust law in two major ways: (1) The Third Circuit largely ignored the consumer impact of barring competitors from their most cost-efficient means of competing; and (2) the Third Circuit appeared to categorically reject established methods of proving monopoly power.

The analysis of exclusionary conduct incorrectly focused on the conduct's effects on Mylan, and ignored the effects that product-hopping has on competition and consumers through automatic substitution at the pharmacy. The district court and Third Circuit largely put the blame on Mylan for not entering the market through its own marketing efforts.

However, automatic substitution is the regulatorily intended and most cost-efficient means that generic drugs get into consumers' hands, by allowing pharmacists to automatically substitute a brand name prescription for a lower cost generic substitute. Consumers reap the benefits of automatic substitution laws in the form of cost savings due to generic manufacturers not having to promote their own drugs. Because state lawmakers created the regulatory system to work through automatic substitution, there is no motivation for generic manufacturers to promote their own products since there is no guarantee that a sale to a generic obtained through marketing will go to their company over other generic manufacturers as pharmacists substitute for the lowest cost generic regardless of manufacturer.

This misunderstanding of the pharmaceutical market has prompted a brief from the Federal Trade Commission in support of a rehearing. As stated above, it would make no business sense for Mylan to market directly to consumers or doctors and the FTC rightly points out that the real question is whether "Warner Chilcott competed on the merits in barring Mylan from its most cost-efficient means of competing — automatic substitution."

The FTC's brief also rightly took issue with the decision's implication that total foreclosure is required to prevail on a monopolization claim. A total foreclosure standard would allow anti-competitive behavior as long as there was some way for a competitor to enter the market. In this case, Mylan could have entered the market by marketing generic medications to doctors and the public so that prescriptions were written for the generic drug rather than a brand name. However, doing this would raise Mylan's costs without necessarily leading to sales because a pharmacist filling a generic prescription does not have to fill that prescription with Mylan's generic drug. This is where a total foreclosure standard breaks down, because the court can imagine a method of entry that would not provide meaningful competition in reality because it is not the most cost-efficient means of competition.

The Third Circuit's decision is additionally problematic because it appears to categorically reject several methods of proving monopoly power through direct and indirect evidence. At trial, Mylan provided direct evidence of monopoly power through actual detrimental effects and inferred from conduct that would be irrational absent monopoly power. Mylan also

provided indirect evidence of monopoly power through the hypothetical monopolist test, which asks whether a hypothetical monopolist can profitably impose a small but significant and nontransitory increase in price, typically 5 percent, in the relevant product market.

The court appeared to categorically reject these methods of proving monopoly power. Instead the court focused on product interchangeability and cross-elasticity of demand.[7] Particularly, it departed from its very recent holding in FTC v. Penn State Hershey Medical Center, which held that antitrust analysis must account for its economic and competitive consequences, and recognized the hypothetical monopolist test as relevant to defining monopoly power.[8] Moreover, the court's holding is odd because the defendants' expenditure of large sums to buy back and destroy the old Doryx product makes no sense in the absence of a desire to protect their market power.[9]

Handicapping private plaintiffs and antitrust enforcers by substantially limiting the methods of proving monopoly power would be a disaster. Showing monopoly power is a fundamental first step in proving a monopolization claim, and limiting the methods of proving monopoly power would create tremendous new burdens on state and private antitrust enforcement. The FTC was rightly concerned by this, and filed a brief to ask the court to clarify that monopoly power can be shown through the methods used by Mylan at trial. These methods have sound basis in law and economics and therefore should be accepted by the courts.

If the panel's decision stands it will create a new highway for branded pharma companies to delay generic entry. Antitrust enforcement in the pharmaceutical industry is a top priority, saving consumers billions of dollars. However, the panel's decision would greatly weaken that enforcement by simultaneously raising the bar to prove a case while lowering the bar for defending against a monopolization claim.

The petition to rehear the Mylan Pharmaceuticals case should be granted to prevent widespread harm against the consumers. Consumers are only able to take advantage of low cost generic medication because the antitrust laws prevent that anti-competitive conduct. The panel's wall needs to be demolished to reunite consumers will the benefits of competition — choice and lower prices.

—By David Balto, Law Offices of David Balto

David Balto is a former policy director of the Federal Trade Commission Bureau of Competition and a former antitrust lawyer at the U.S. Department of Justice.

DISCLOSURE: Balto authored an amicus brief to the Third Circuit in support of Mylan in this matter. The amicus brief was on behalf of: AARP, Consumers Union, DC 37, Consumer Action, Consumer Federation of America, Families USA, Sergeants Benevolent Association, National Health Law Program, Center for Medicare Advocacy, and US PIRG, urging reversal of the district court's opinion granting summary judgment for Warner Chilcott and Mayne Pharma.

[1] No. 15-2236 (3d Cir., Sept. 28, 2016).

[2] Also see my original editorial on this case, available

at https://www.law360.com/articles/816387/opinion-stop-pharma-hopping-mischief.

[3] Generic Drug Savings in the U.S., Generic Pharmaceutical Association (2015), available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

[4] See David A. Balto, Removing Obstacles to Generic Drug Competition: A critical priority for health care reform, Center for American Progress (June 2009).

[5] Id.

[6] 787 F.3d 638 (2d Cir. 2015).

[7] The court erroneously found cross-elasticity of demand without examining the level of price change, even though the change was an order of magnitude well in excess of 5 percent.

[8] No. 16-2365 (3d Cir. Sept. 27, 2016) (monopoly pricing is not unconstrained pricing, but rather is pricing a product five percent or more over the price levels that would prevail in a competitive market).

[9] FTC v. Actavis, 133 S. Ct. 2223, 2236 (2013).
