# OPINION: Stop Pharma Hopping Mischief



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In the classic "Peanuts" gag, Lucy holds out a football for Charlie Brown to kick. Lucy promises Charlie she will hold it still. Charlie, believing Lucy, runs full speed at the ball — only to fall flat on his back as she pulls it away. When this happens in the funny papers, we laugh. When it happens in the drug industry — consumers lose tens of billions of dollars.

David Balto

On July 14, the Third Circuit will hear oral arguments in a case where branded manufacturers will argue that it is OK to be Lucy, always pulling the ball away from generic manufacturers, causing their new drug releases to fall flat on their back. At issue in Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Ltd. is “product hopping.” Product hopping is making a small change to a product in order to secure a new patent or other regulatory restriction so generics are kept off the market. It is a clever tactic used by pharmaceutical companies to avoid the “patent cliff,” or the moment in time when a patent expires and generic entry causes drug prices drop substantially. This moment is intended; it is the agreement between inventors and the government that patent law is based on.

An inventor is allowed to exclusively profit off their invention for a time on the condition that when that time is over the invention will be made available for the benefit of society. Product hopping allows branded drug manufacturers to hijack state regulation and the normal operation of the pharmaceutical market to renege on that agreement and keep their inventions for themselves indefinitely. Product hopping occurs when a patent is being challenged or set to expire. The brand-name manufacturer simply tweaks the medication in a cosmetic or inconsequential way and obtains a new patent. The brand-name manufacturer then switches all patients to the “new” drug before generics can obtain necessary regulatory approval to enter the market.

An insignificant change to the drug has significant consequences for generic entry because of substitution laws, which allow pharmacists to fill brand-name prescriptions with lower-cost

generics unless otherwise directed by a physician. If the generic medication does not perfectly match the brand — even if the difference has no medical consequences — the pharmacist cannot fill the prescription with the money-saving generic. And because the overwhelming majority of generics are dispensed under substitution laws, product hopping has an immediate effect on consumers.

The defendants in Mylan engaged in four separate product hops. None of these changes — switching from capsules to tablets, changing dosage and adding scoring lines for easy tablet splitting — brought substantial consumer benefits but rather were efforts to secure additional patent protection. The defendants also allegedly used various anti-competitive methods to limit consumer access to an old version of Doryx, including destroying older versions of the drug, thus disallowing generic substitution otherwise guaranteed in many states. Although the district court found in favor of the defendants, it "was compelled to find that Defendants made the Doryx 'hops' — even the six-year developmental 'hop' from capsules to tablets — primarily to defeat generic competition."

Consumers, competition and innovation would suffer mightily if this type of hopping was just fine under the antitrust laws. The Federal Trade Commission, perhaps realizing the damage this case could do to its Actavis win, filed an amicus brief to the Third Circuit that argues that product hopping can be exclusionary if a monopolist raises rivals' costs without countervailing pro-competitive justifications. Depriving them of their most efficient distribution mechanisms harms consumers by impeding the rivals' competitive ability to discipline monopoly prices. The FTC also criticized the decision, stating that the district court misunderstood the special characteristics of the pharmaceutical marketplace, resulting in a flawed analysis on the question of monopoly power.

The question of when product hopping is unlawful is incredibly important to health care policy and the consumers it impacts. Prescription medications are a driving force behind ever-increasing health care expenditures. Improved access to generic medications helps to bend the cost curve and combat the high price of prescription medications overall. In 2013 alone, generic medications saved consumers $239 billion. A recent study of product reformulations between 1995 and 2009 found 32 changes that had little or no consumer value and were temporally linked to prospective generic entry — suggesting they were product hops. The total annual revenue generated by these 32 product-hopping drugs was $28.1 billion. Given that generic entry can reduce prices by 80 percent, these product hops cost consumers tens of billions of dollars per year.

In State of New York v. Actavis, 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. The Second Circuit further explained that evidence that the prior product was successful and that there was no legitimate business justification for withdrawal may point to an anti-competitive practice.

If the Third Circuit rules differently than the Second Circuit, it would create a circuit split ripe for review by the U.S. Supreme Court. However, this seems entirely unnecessary. No one, including the district court, is denying that product hopping is, under certain instances, being abused to prevent competition. And the special characteristics of the pharmaceutical marketplace, as the FTC points out in its amicus brief, makes product hopping particularly effective. The only argument left for not enforcing the antitrust law is that, when it comes to product hopping, it is impossible for courts to sort pro-competitive activity from anti-competitive activity — an argument made by the district court. But that argument only serves to abdicate the court of its duty in the enforcement of antitrust laws. The Third Circuit is free to rule widely or narrowly against the practice of product hopping in this case, and the Second Circuit has already demonstrated how courts can determine when product reformulation rises to the level of being unlawful under the antitrust laws.

The Third Circuit should join its sister court and advance the law on product hopping by adopting a test for when it is unlawful under the antitrust laws.

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***DISCLOSURE: David Balto authored an amicus brief in this case 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.***

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