Legal News & Data

NY AG Stops Harm To Alzheimer's Patients — For Now

Law360, New York (January 14, 2015, 10:41 AM ET) -- Controlling drug costs, especially increases in drug costs, is critical for the nation's economic survival. Antitrust enforcement has played a critical role in the past decade preventing anti-competitive conduct that would otherwise increase drug prices or hamper price decreases. Essential to this effort is protecting the opportunities for competition from generic drugs, which typically cost less than 20 percent of a comparable branded drug. This is why states have enacted laws to preserve the ability of pharmacists to easily substitute generic drugs.

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Antitrust enforcement by the state attorneys generals, private plaintiffs and the Federal Trade Commission have been at the battleground when branded firms engage in practices to delay generic competition. Because of their efforts, generic substitution in the past decade has increased from about 60 percent to almost 87 percent.

The current battleground involves a practice known as "product hopping." This strategy is employed to move customers from drugs whose patents are expiring to drugs with newer patents. Often, these drugs only have minor changes that may have no therapeutic benefit. Branded drug manufacturers can significantly reduce the opportunities for generic competition by switching their customers to these new drugs before generics have a chance to enter.

The case at issue is a challenge to a product-switch strategy by Forest Laboratories LLC on its Alzheimer drug Namenda IR, which earned Forest $1.6 billion in revenues in 2014. The New York attorney general won a preliminary injunction to prevent Forest from forcing its customers to switch to its new drug Namenda XR. This decision is now on appeal to the Second Circuit.

There is no therapeutic difference between Forest's Alzheimer drugs Namenda IR and Namenda XR. The only change to Namenda XR is that it is an extended release formulation rather than a twice a day instant release formula. This forced switch was timed to avoid the "patent cliff" and prevent generic versions of Namenda IR, which will be able to enter into the market in July 2015, from lowering prices and taking market share. The patent on Namenda XR won't expire until 2029.

Forest announced plans to discontinue Namenda IR and only make it available to patients who get a medical necessity order form from their physicians. This form requires the physician to certify that Namenda IR tablets are medically necessary for the patient. Doctors are unlikely to be comfortable making this certification because Namenda IR is pharmacologically identical to Namenda XR — meaning there is no likely medical necessity keeping patients from switching. The defendants in this case believed that only 2.4 percent of patients would be able to obtain Namenda IR under this medical necessity standard.

Forest's product-hopping strategy comes at a time when strategies to limit generic entry are becoming more popular. Some of the most important drugs sold in recent years, including Nexium, Lipitor, Androgel, Cardizem CD, Remeron, Relafen, Buspar, Taxol, Augmentin, Paxil, Coumadin, Hytrin, Tricor and Platinol were subject to anti-competitive conduct that delayed or impeded generic entry. This is problematic because generic drugs offer a safe, effective and affordable alternative to branded drugs. A 2011 study found that generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but consume just 27 percent of total drug spending.

Antitrust law plays an important role in keeping generic pharmaceuticals available to U.S. consumers. Antitrust enforcers and private parties have brought a number of cases that have successfully challenged generic blocking strategies, including product hopping. In one such case, Abbott Laboratories v. Teva Pharmaceuticals USA Inc., 432 F. Supp. 2d 408 (D. Del. 2006), the court said that the rule of reason balancing approach of the D.C. Circuit in United States v. Microsoft Corp. was appropriate for product-hopping claims due to the nature of pharmaceutical drug markets. The court denied a motion to dismiss, relying heavily on the fact that Abbott's conduct limited consumer choice between the old product and the new one.

While the law on product hopping is somewhat nascent, there is case law to support that an action is unlawful under the antitrust laws when it has no legitimate business purpose and only makes sense because it eliminates competition, In re Adderall XR Antitrust Litig., 754 F.3d 128, 133 (2d Cir. 2014), and that removing a product to force purchasers to switch to a new product can be such an anti-competitive action, Berkey Photo v. Eastman Kodak, 603 F.2d 263, 287 n.39 (2d Cir. 1978).

A Section 2 claim of unlawful monopolization is clearly appropriate in a case like this where Forest removes a product depriving consumers of choice for no reason other than to harm competitors. Abbott Labs. v. Teva Pharms. USA Inc., 432 F. Supp. 2d 408, 422 (D. Del. 2006). Forest's conduct clearly qualifies as exclusionary conduct, as CEO Brenton Saunders stated in an earnings call: "[I]f we do the hard switch ... it's very difficult for the generics then to reverse-commute back ... They don't have the sales force, they don't have the capabilities ... . It is an obstacle."

Of course, any antitrust case involves carefully balancing the potential efficiencies from the conduct at issue. But "efficiencies" under the antitrust laws does not just mean "the company makes more money." Rather, efficiencies that count under the law are those that lead to lower prices and higher quality. But the court found here that there were no efficiencies gained in withdrawing the old product from the market. The only purpose in withdrawing Namenda IR is to delay generic entry and avoid the patent cliff. Moreover, the only benefit of the new drug was a slight reduction in the number of doses. Going from two pills a day to one is not worth the disruption and risk of changing medications for most Alzheimer patients, especially since the majority of patients are taking several prescription medications throughout the day.

What makes this product-hopping case stand out is the impact it has on a class of extremely vulnerable patients. Alzheimer's disease currently afflicts over 5 million people in the U.S., and that number is expected to triple by 2050. Namenda is the only drug on the market for treating Alzheimer patients at the moderate to late stages of the disease. The other drugs on the market are generally used at early stages of the disease and are often prescribed alongside Namenda when patients reach later stages of the disease. This means that most Alzheimer patients will have to take Namenda at some point in the progression of their disease.

Changing drugs is also problematic for these patients. Stability is important for Alzheimer patients, and even small changes in medication raises the risk of an adverse event. In addition, most Alzheimer patients require caretakers who have to be educated on how the new medication is to be taken. Changes increase the risk of mistakes in administering the medication.

Forest's plan to force patients to switch medications will result in patients having to pay more while also facing the risks inherent in switching medications. The product-hopping plan also harms generics that have invested in bringing an important drug to the market at an affordable price.

More than 30 years ago, then-D.C. Circuit Judge Robert Bork observed that "[p]redation by abuse of governmental procedures, including administrative and judicial processes, presents an increasingly dangerous threat to competition." Forest's manipulation of the drug substitution system presents that type of harm. Hopefully, the New York AG action and U.S. District Judge Robert W. Sweet's decision (now on appeal to the Second Circuit) will provide a roadmap to stopping this type of anti-competitive conduct.

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