“Authorized” Generics May Pose Unauthorized Problems: Government Worries about Potential Brand-Name Blocking Technique

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There is a new political football in the war between generic and brand-name drug companies, namely, authorized generics. These are copies of brand-name drugs that are just going off patent, but they are produced by the brand-name company to either hold on to a blockbuster’s market share or to scare off independent generic copies. Which of those two rationales is at play depends on which side one is on. The fact is that the number of authorized generics produced by the big research and development companies has increased considerably over the past few years, and the political ramifications are now being felt.

At a time when federal and state Medicaid programs and private insurers—and their P&T committees—are trying to wrestle drug prices to the ground, anything that impedes the development of generic drugs is viewed with a jaundiced eye. But generics do threaten the markets of blockbuster drugs just going off patent. In an environment where brand-name companies are producing fewer blockbusters, they are casting about for ways to squeeze all the revenue they can from their current stars.

A company called Cutting Edge Information has published a study stating that more than $80 billion worth of blockbuster drugs risk losing 80% or more of the market share when generic copies hit the market. The report examines a variety of product-based and legalistic strategies available to product-management teams for retaining market share, even as generic competition reaches the market. Cutting Edge refers to one of those strategies as “flanking” generics. Jon Hess, a senior analyst at the company, says:

The industry is developing fewer blockbuster drugs today, so companies are realizing the grave importance of protecting the assets that will enable them to continue developing new medicines over the next decade. This translates to anticipating generic competition (even before patents expire), planning ahead, and pursuing a course of action that often combines several defensive and proactive strategies to retain market share when generics come into play.

Whether we call them flanking or authorized generics, their increasing presence has caused some influential people in Washington to wonder about their impact.

Attorney Jon Leibowitz, a member of the Federal Trade Commission (FTC), addressed the issue in a May speech. The question he posed—a scenario that he did not endorse—was whether brand-name companies are pursuing a strategy to scare off generic companies by producing the “authorized” generics. Under the Hatch–Waxman law, the first (or sometimes second) independent generic drug is granted 180 days of market exclusivity. The brand-name company’s generic product can also enter the market during the first 180 days. The smaller generic companies may hesitate to develop copies if they believe that the authorized generic drug will have the effect of diminishing their initial profits and market share. They may decide that they simply cannot afford to produce a copy. The brand-name company, having discouraged generic competition with its authorized generic, can then raise the price because it has the generic market to itself—at least that is the theory.

Mr. Leibowitz is not the only one who feels that way. In May, Senator Chuck Grassley (R-Iowa), chairman of the Senate Finance Committee, and Senator Patrick Leahy (D-Vermont), a ranking Democrat on the Senate Judiciary Committee, requested that the FTC investigate the potentially anticompetitive effects of authorized generics.

So far, though, it appears that any concerns may be a bit overblown. For example, in April 2004, Schering-Plough’s wholly owned subsidiary, Warbeck Pharmaceuticals, launched a generic version of Schering’s Rebetol® (ribavirin), which is used to treat chronic hepatitis C. Warrick’s generic product was competing against two other independent generics. (In the case of ribavirin, the Food and Drug Administration authorized two independent generics because Warrick had challenged different aspects of Schering’s patents.)

In the same fashion, Pfizer’s Greenstone Limited last October debuted a generic version of Pfizer’s Neurontin® (gabapentin). Greenstone’s decision was apparently forced by announcements by Alpharma, Inc., and Teva that they were launching generic gabapentin capsules.

However, theory is one thing, reality is another. With ribavirin, for example, two generics, not just one, barreled into the market when Rebetol® went off patent, even though Schering-Plough was introducing its Warrick generic. All three generic drugs are still being sold. Moreover, Roche actually jumped into the market with a rival brand-name product, Copegus®, which is being sold to compete against Rebetol®. Bob Consalvo, a Schering spokesman, admits that this action has caused Rebetol® to lose considerable market share.

REFERENCE