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Generics Versus Brands: New Fronts on a Shifting Battleground

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The long-running conflict between brand-name and generic drug manufacturers always has been hard-fought—but there are signs it could become even more intense. With the Obama administration's effort to severely hamper "pay-for-delay" settlement agreements between generic and brand name drugs, and the increasingly aggressive tactics by both sides in areas such as carve-outs, at-risk launches, and extended-release drugs, the industry can expect to find the two sides fighting harder than ever.

On some fronts, generics makers may have the advantage; on others, the innovators may have the better odds. But for both, the outcome of several in-progress skirmishes could be more uncertainty, more disruption, and more expense.

Two elements of President Obama's proposed budget for 2012, announced in February, likely would heighten the battle between innovators and generics (9 PLIR 207, 2/18/11). First, the president wants to give the Federal Trade Commission the power to block settlement agreements—an even more far-reaching move than the FTC's current lawsuit against Cephalon. The budget also calls for reducing the number of years—from 12 to seven—that innovators could exclusively market biologics, setting up a potential new battleground between generic and brand-name pharma.

Both proposals will face stiff opposition. But even if the administration fails to end the settlement agreements through the budget proposal, it still could prevail in the Cephalon case. Yet, if it succeeds through either path, the result could be far from what the administration intended.

For the most part, the settlements have been beneficial to drug companies on both sides, and have amounted to something of a rare truce. In exchange for delaying their entry into the market, generics often receive financial compensation, or enter into related agreements concerning providing ingredients to the brand-name maker.

The administration contends that these so-called "pay-for-delay" settlements amount to collusion, and hurt the public by keeping generics off the market—a charge that both brand-name and generics makers strongly deny. In its suit against Frazer, Pa.-based Cephalon, the FTC alleged that the company engaged in anti-competitive conduct by paying four firms more than $200 million to refrain from selling generic versions of the stay-awake drug Provigil until 2012.

If the FTC wins the case—the judge's ruling could come in 16 months or more—the government likely will seek to unravel many similar settlements that involved an exchange of money. At the same time, an FTC victory likely would shut down future agreements, also the goal of President Obama's new budget proposal. Though the administration believes this would put more generics on the market, it actually would have the opposite effect.

If the two sides are unable to settle, every abbreviated new drug application (ANDA) challenge will become a death-match. Innovator companies, which generally are more well-heeled than generic manufacturers, will pull out all stops to protect their patents, and will seek to make ANDA challenges prohibitively expensive. Instead of lasting two years, trials will drag on for three or even four. The challenges will become so costly that many generic makers that now are quick to file ANDAs—hoping for a settlement—will simply wait for the patents to expire. Although the driver of any generic company is the filing of ANDAs, such filings may be scaled back causing less market competition between branded drugs and generics, and less between the generic companies themselves.

Without the possibility of settlement, many more ANDA cases will go to trial, and the federal district and appellate courts dockets will become more crowded—even further dragging out the cases. It is ironic that the Food and Drug Administration, in an effort to speed the approval and marketing of generic drugs, is moving toward imposing user fees on ANDA filers for the first time. The Obama administration clearly wants to keep the courts from becoming overwhelmed—but blocking all settlement agreements creates a deepening quagmire. Indeed, from a generic manufacturer's perspective, the settlement agreements are not the *per se* problem. Rather, it is the parked 180-day exclusivity period of the first-to-filer bottlenecking the generic pipeline coupled with the "poison pill" provisions in these agreements further preventing subsequent filers from timely market entry that causes problems.

For branded companies, settlements carry a critical benefit. Because they know precisely when the generic versions will be entering the market, they are able to manage both their product pipelines. If a case goes to trial, and the judge might rule in one week or one year, companies have no way of knowing when they should stop detailing the drugs. The entire product lifecycle becomes fraught with uncertainty.

Generic drugmakers will be hurt as well if settlements are blocked. Not only will they get fewer drugs to market, but the added costs of litigation will make introducing new drugs a more expensive proposition.

Biologics

President Obama's budget proposal to reduce the exclusivity period for biologics to seven years likely would create a fierce new front between innovators and generic manufacturers. The new health care law, which mandates a 12-year exclusivity period, currently gives a strong advantage to the brand-name makers. Since branded drugs generally have about 16 years of protection once on the market, assuming a 20-year patent expiry with no extensions, a 12-year exclusivity forces generics to fight for only four years of market access. And since ANDA cases could take nearly that long, most generic makers will forgo spending millions on litigation and simply will sit tight and wait for the biologics' patents to expire.

With a seven-year exclusivity period, makers of biologics would have the opportunity to enter the market much sooner, potentially making even a costly court battle worth the expense. If, on the other hand, the 12-year period remains intact, the brand-name makers will continue to have the biologics market mostly to themselves. As a result, it is likely they would increasingly focus their resources and efforts on developing biologics, because of the protection they offer.

Carve-Outs

One area that already is becoming more volatile is the generics makers' growing use of carve-outs. By seeking to have a generic drug approved for medical uses that are not listed in the FDA's *Orange Book*—and so are not protected—the generics makers say they hope to get the product on the market faster, to benefit consumers. Brand-name manufacturers can respond by filing a citizen's petition asking the FDA not to approve the medical indication carve-out—and have done so with increasing frequency. So far, the FDA has taken a mostly hands-off approach, and has turned down the petitions. However, the innovators have found another way to fight back—by proactively getting more medical indications protected in the *Orange Book*. And here the FDA generally has favored the brand-name drugmakers.

These tactics by the competing sides are akin to an escalating arms race and they shift much of the battle space from the courts to the FDA. All signs suggest that the generics will get even more aggressive with carveouts, and that innovators will get equally aggressive in protecting more indications.

Eventually, this issue likely will be decided by the U.S. Supreme Court. Indeed, the Supreme Court has asked for the solicitor general's view in the Prandin certiorari petition involving use codes and Hatch-Waxman (the solicitor general recently issued a brief in support of review of the case). Regardless, resolution could still be years away, and in the meantime, the carve-out fight will continue to intensify.

At-Risk Launches

Another tactic that the generics increasingly are using with success is the at-risk launch. This occurs when the generic company puts its product on the market at the end of the 30-month stay that brand-name companies are granted at the beginning of litigation but before the case is decided.

The risk is that if the generics lose, the brand-name makers will likely sue for lost profits. But the generics have shown more of a willingness to take that chance, an expression of their growing confidence that they can win ANDA disputes. At-risk launches not only give generics faster access to the market, they have proven particularly effective in forcing the brand-name makers to the bargaining table. When the generics announce that their delivery trucks are loaded and ready to roll, the brand-name companies are often inclined to settle the case rather than watch their market share instantly erode.

At-risk launches tend to give generic makers a great deal of leverage in their battle with brand-name drug makers, making it likely that the tactic will see increased, and more aggressive, use in the coming months and years.

Life-Cycle Extensions

Yet another front that is heating up is taking place neither in the courts nor the FDA, but in the marketplace. Branded drug companies are increasingly seeking to keep market share after their patents expire by extending the life of their products through so-called life-cycle extension. This process includes the patenting and marketing of different forms of their drugs (*e.g.*, isomers or polymorphs), slightly modified formulations (including extended-release versions) or new or slightly different indications. Once the original patents expire, the market typically is flooded with generics. If, however, the brand-name manufacturers can persuade physicians—and the market in general—that the newer versions or indications are better for patients, the innovators can stay a step ahead of the generics.

As innovators have turned to these life-cycle patents, generics makers have responded by challenging those patents as well—while at the same time trying to influence the market in favor of the already genericized versions.

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