



# Authorized generics stave off competition

By AMANDA BALTAZAR

Branded pharmaceutical companies can lose millions of dollars when their blockbuster drug goes off patent and generic competition enters the market. In fact, 71 percent of branded companies enter into legal battles to defend their patents, even though most of these result in a win for the generic companies, according to a 2004 report from research and consulting firm, Cutting Edge Information.

To get over this hurdle, branded drug companies increasingly have been following a different tactic: launching an authorized generic onto the market. For all intents and purposes, an authorized generic drug is identical to the branded drug, but in this case it's disguised as a generic and is allowed onto the market during (or before) the 180-day period of exclusivity that's granted to the first generic drug in class to be approved. This allows a branded drug company to continue to hold on to a large por-

tion of the sales it would otherwise have lost, but it means major decreases in revenue for generic drug manufacturers.

Eric Bolesh, research team leader with Cutting Edge Information, pointed out that

an authorized generic can take 50 percent of the revenues of a particular drug. This discourages many companies from bringing generics to market at all because the already small profit margins

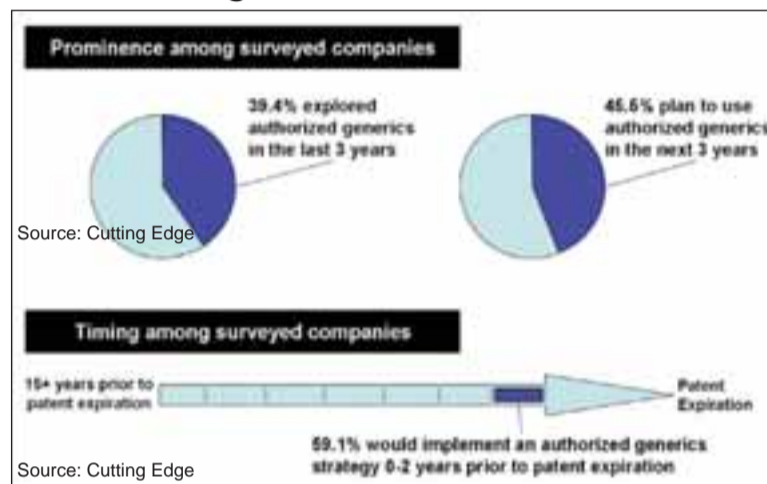
will be sliced even thinner.

There is, however, an upside. Some branded drug companies prefer not to manufacture the authorized generic, so they outsource this work to a generic company, which will pay the

branded company royalties. In fact, Cutting Edge's research shows that half of all branded manufacturers begin negotiating with generic companies two to four years before the patent

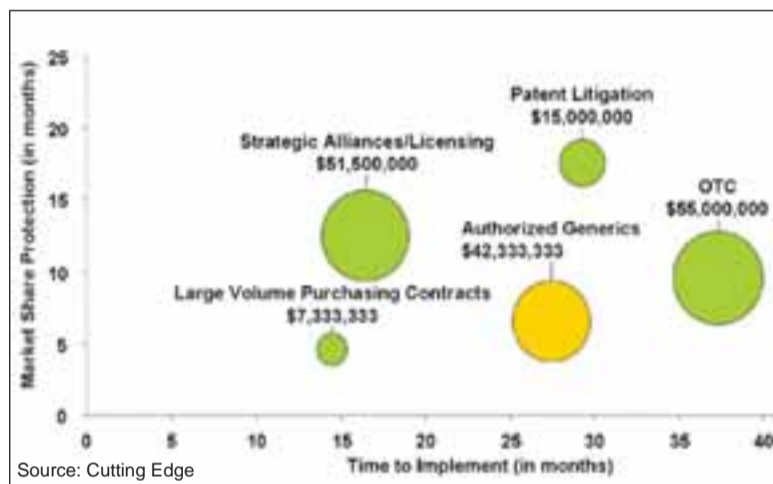
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## Manufacturers considering authorized generics



Authorized generics are a growing trend among pharmaceutical companies. Forty percent of companies explored authorized generics in the last three years, and 45.5 percent will look into the strategy in the near future. Fifty percent of companies begin negotiations with generics firms two to four years prior to patent expiration, while implementation occurs fewer than two years before expiration for 59.1 percent of companies.

## Are authorized generics worth the investment?



The above chart compares the average time required to implement a number of generics defense strategies and the extent each strategy can protect a brand from market-share erosion. Research reveals that authorized generics take an average of 27.5 months to implement, and delays market share erosion an additional 6.5 months. Companies spend an average of \$42.3 million to execute such an alliance with a generics distributor.

# Future for biogenerics approval pathway remains murky

Twenty-three years ago there was no approval pathway for generic drugs in the United States. Consumers had one option, and that was costly brand-name pharmaceuticals.

The passing of the Hatch-Waxman Act in 1984 changed all that, and now both biogeneric manufacturers and consumers are waiting to see if a similar law will be passed to bring biogeneric drugs (also known as biosimilars or follow-on biologics) to the market.

This is not an impossible mission. Four follow-on biologics have been approved in Europe just this summer. The first to be approved, in April 2006, was Sandoz's human growth hormone Omnitrope. More recently, there are biosimilars of epoetin alfa from Sandoz, Hexal Biotech and Medice Arzneimittel Putter—all generic versions of Johnson & Johnson's anemia blockbuster Eprex.

Biogenerics remain controversial because, unlike chemical drugs, they do not—and cannot—exactly replicate the biotech drugs they are intended to replace.

Earlier this year, Sens. Edward Kennedy (R-Mass.), Michael Enzi (R-Wyo.), Chuck Schumer (D-N.Y.), Hillary Rodham-Clinton (D-N.Y.) and Orrin Hatch crafted legislation—

The Biologics Price Competition and Innovation Act of 2007—to authorize the Food and Drug Administration to create a pathway for the approval of biogenerics. The legislation was approved by the Senate HELP Committee and may be attached to the FDA Revitalization Act that is under discussion by a House-Senate conference committee.

A number of matters would need to be considered before such a bill is

passed, according to David Schenkein, vice president of clinical hematology/oncology of biotech firm Genentech. In June, he spoke on behalf of the Biotechnology Industry Organization before the House Committee on Energy and Commerce, Subcommittee on Health.

"It is essential that Congress adopt six key principles as it explores the creation of any regulatory pathway for follow-on biologics," he said. These are:

- Ensure patient safety, so that there are no greater risks for patients. "Clinical trial evidence and data must be a fundamental requirement and must be conducted on a product-by-product basis," he pointed out.

- Recognize scientific differences between drugs and biologics, since the latter are much more complex. "[Biologics] are relatively unstable and are sensitive to how they are handled, processed and stored as they have the ability to assume many forms and variants," he said.

- Maintain the physician-patient relationship to ensure that patients are only given follow-on biologics when expressly prescribed by a doctor.

- Preserve incentives for innovation, so that branded biotech firms can continue research and development.

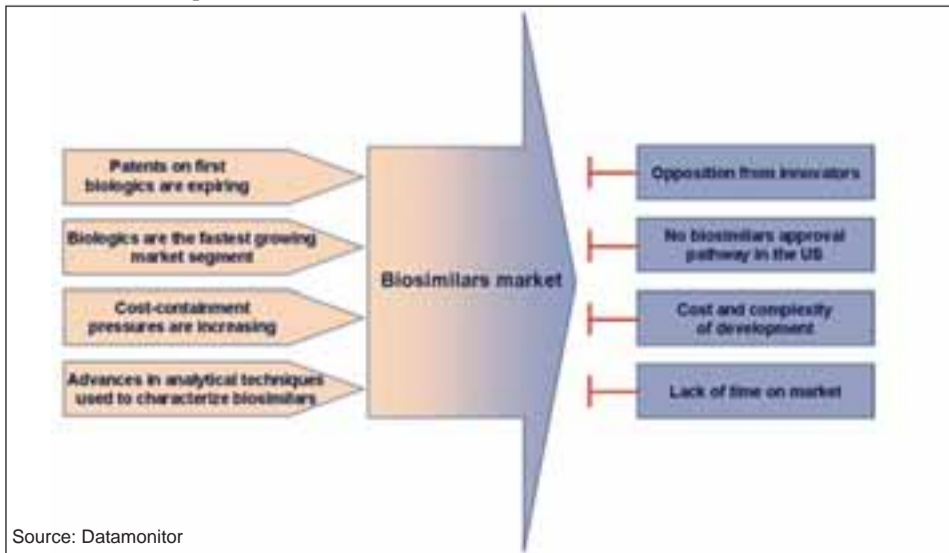
- Ensure transparent regulatory processes regarding data requirements for the approval of biogenerics.

- Continue to prioritize Food and Drug Administration review and approval of new therapies and cures.

Others in the industry have voiced their own concerns about the legislation, which proposes to extend market exclusivity for branded biotech drugs

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## Push and pull continues in biosimilars market





## Future murky

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to 12 years, seven years longer than the period granted to branded small molecule drugs.

“Such an arbitrary and excessive period of time is not

only unprecedented and unwarranted, but more importantly, would unjustifiably delay access to affordable competition and choice for consumers and businesses alike,” said Kathleen Jaeger, president and chief executive

officer of the Generic Pharmaceutical Association.

She pointed to another provision that would allow branded companies to make minor changes to their products and receive an additional 12 years of exclusivity. “This

provision could allow brand companies to make multiple minor changes to their products and receive 12 years for each change, in effect maintaining their monopolies in perpetuity,” she said.

This practice is commonly

known as “evergreening,” and would essentially keep biogenerics off the U.S. market indefinitely.

Legislation for these drugs remains controversial, but even the very feasibility of biogenerics is getting a mixed review from the industry.

The average biotech prescription costs close to \$1,500 per month, said Steve Miller, chief medical officer of PBM Express Scripts. “People cannot afford this; it can devastate a family, but with biogenerics, we would love to see discounts of 20 to 25 percent.”

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He pointed to the example of the Hatch-Waxman Act. “We have 20 years’ experience with Hatch-Waxman, and it’s saving us tens of thousands of dollars every year. [With biogenerics], the savings will grow dramatically and slowly because as many drugs lose their patents, we’ll see more biogenerics.”

However, Jason Napodano, a senior biotech analyst with Zack’s Equity Research, said he doesn’t see a place for biogenerics because they are so different from the biotech drugs they attempt to replicate.

Biosimilar companies would have to incur “a whole lot of costs” to prove their drug is the same as the biotech equivalent, he said, and there would likely be too many patents to get around. Unlike with small molecule pharmaceuticals, which tend to have just one patent, biotech drugs are covered by numerous patents covering molecules, cells and manufacturing. “The whole process is patented, so to produce a generic biologic patent, [a company] would have to either violate patents or pay a royalty.”



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