



# 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

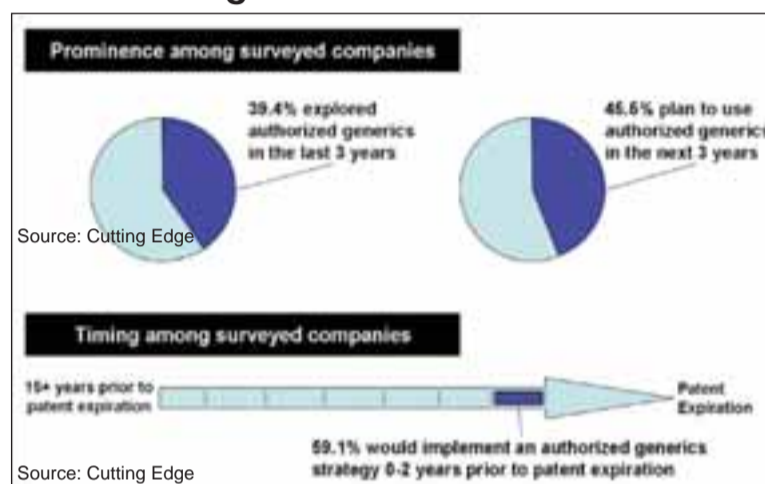
will be sliced even thinner.

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

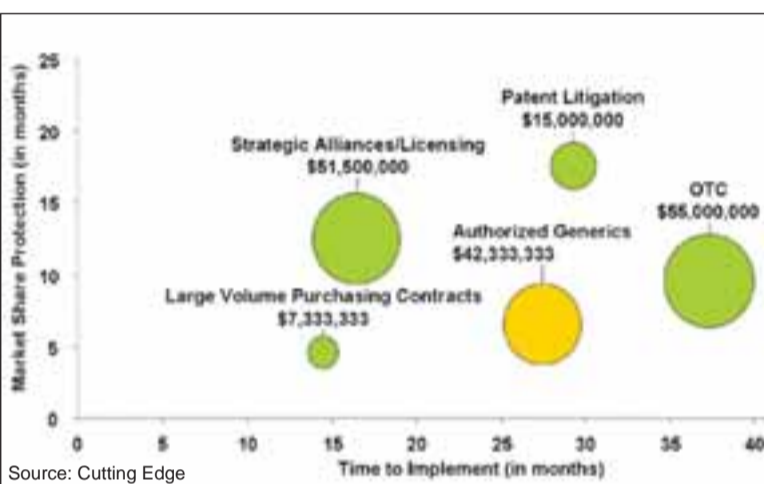
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## Manufacturers considering authorized generics



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.

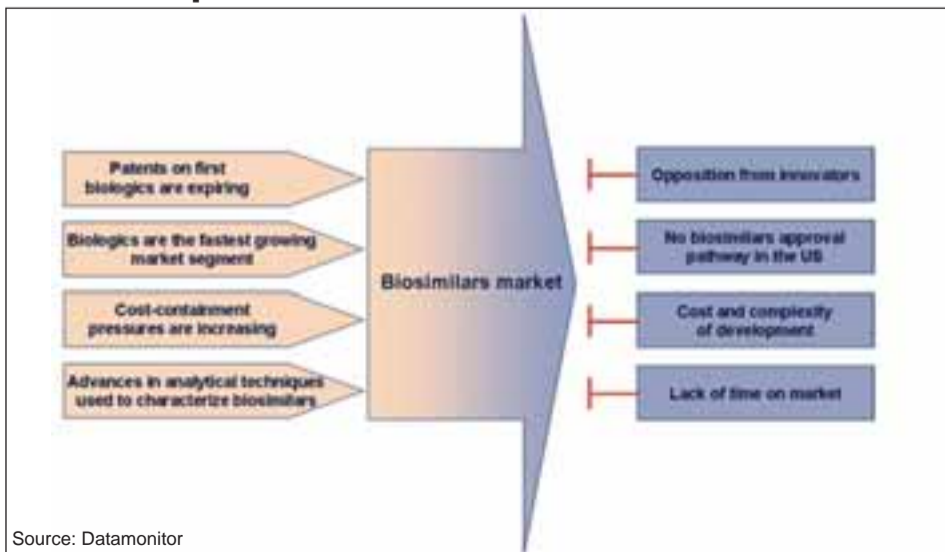
- Ensure transparent regulatory processes regarding data requirements for the approval of biogenerics.

- 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





## Who's who

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more than 20 acquisitions in the past seven years while maintaining strong organic growth.

Actavis reported revenues increasing by 138.2 percent from 2005 to 2006, which was helped by strong growth performances in North America, as well as Central and Eastern Europe and Asia.



The company recently went private, removing its name from the Icelandic Stock Exchange last month.

The company has starting launching generic products of the brand name drugs Coreg, Duragesic and Inderal LA.

Actavis currently is among the five largest generic pharmaceutical companies in the world.



**Greenstone** has been the generic subsidiary of Pfizer since 2003. The company has a robust product pipeline.

Greenstone products are the same size, shape and color as branded versions and the company leverages its experience, dedicated people and strong pipeline to guarantee a continuous supply of generic medicines that benefit both patients and Greenstone's trading partners.

Back in May, the company released a generic version of Norvasc in response to Mylan Laboratories' announcement of launching a generic of Pfizer's high blood pressure treatment drug.

**Watson's generics** division develops, manufactures and markets products that are the

therapeutic equivalent to its brand name counterparts. The portfolio for this business includes products it has internally developed, products it has licensed and products it distributes for third parties. Watson is the third-largest supplier of generic pharmaceutical products in the United States, based on prescriptions dispensed.

The company offers one of the broadest generic product lines in the United States, with more than 70 abbreviated new drug applications pending with the FDA.

Watson has more than 150 pharmaceutical product families in its portfolio, including 13 new products launched in 2006 which helped lead to sales of \$1.5 billion, 77 percent of Watson's total annual revenue.



**Dr. Reddy's Laboratories** founded in 1984 by Dr. K. Anji Reddy, has become India's biggest pharmaceutical company. The company has more than 190 medications ready for patients to take, 60 active pharmaceutical ingredients for drug manufacture, diagnostic kits, critical care and biotechnology products. The company had revenue of \$1.5 billion for the year ended May 2007.

With the goal of developing a robust clinical pipeline containing multiple novel drug molecules in different stages of clinical development, a large number of discovery-stage and



clinical-development stage programs have been strategically planned. Powerful discovery infrastructure that combines world-class biology in important disease pathways with functionally integrated chemistry capabilities drives its programs.

The company currently is working on a pipeline that includes such therapeutic areas as metabolic and cardiovascular disorders, as well as cancer treatments.

## Authorized

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on their drug expires, and almost 60 percent even introduce an authorized generic drug to the market two years before the patent expiration.

Since 2003, 103 authorized generics have been launched onto the U.S. market. The notable fact of these statistics is that generic companies launched 69 percent of these drugs. Brand subsidiaries launched the remainder.

Why would generic companies, who are only hurt by competition from authorized generics, get into that very business themselves?

"The one-word answer is revenue," according to Bolesh. "If you can guarantee investment, it's hard to turn it down. This is money going in the door, and it's money Wall Street is going to see."

It also gives smaller generic companies an opportunity to get drugs on the market, if they work with the branded companies, he added. "A small company is never going to invest in R&D and in having a law firm to bring the branded companies to court. So author-

ized generics make sense."

The Generic Pharmaceutical Association has announced its disapproval of authorized

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Cutting Edge Information**

generics, saying the practice "is a brand tactic aimed at discouraging generic competition." But last year, the Pharmaceutical Research and Manufacturers of America issued a report stating that authorized generics save consumers money by increasing price competition between drug makers. The report says that those generics are sold to pharmacies and healthcare facilities at greater discounts than regular generics.

These savings are hard to ignore, said Mark Merritt, president of the Pharmaceutical Care Management Association, which supports payers and consumers "I think it's unclear

whether, long-term, the generics companies will be hurt," he said. "It's very hard for us to turn down short-term savings until we know more about the long-term [impact]. It's a trickier issue than it seems."

Bolesh questioned the so-called savings, citing studies that have shown prices actually drop more significantly in the long-term if there are many generic products on the market.

"There's a correlation between the number of generics on the market and price," he said. "Authorized generics can be a disincentive to many [companies] to launch a generic, so in the long run, prices will be higher."

While authorized generic drugs continue to appear regularly on the market, action is being taken to stop this practice. Bills have been introduced to both the House and the Senate, asking for authorized generics to be blocked during a generic drug's 180-day period of exclusivity. The Federal Trade Commission also is conducting a study of the use, and likely short- and long-term competitive effects, of authorized generics in the prescription drug marketplace, but as yet has drawn no conclusions.



## Established and Thriving.

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