

Biosimilar products

What the future holds for biotech companies

A large number of biopharmaceutical companies will see the patents for their products expire over the next five years, which is creating a regulatory path for “biosimilar” products and rapid growth of the generic drug market.

Smart Business learned from Christian J. Scognamillo, a senior counsel at Stubbs Alderton & Markiles, LLP with nearly 10 years of experience working with life science companies, what biotechnology companies are doing to pave the way for development of generic versions, or biosimilars, of expensive biopharmaceuticals used in the treatment of complex life-threatening diseases.

What is a biosimilar product?

Biosimilars, also referred to as ‘follow-on proteins,’ are to biopharmaceuticals what generics are to chemical drugs. Biosimilars are new versions of existing biopharmaceuticals whose patents have expired. A biopharmaceutical is created by manipulating living cells into ‘mini-factories’ to manufacture the desired molecules for the drugs. Any deviation from the manufacturing process can change the entire function of the product, and it is impossible to manufacture biologically identical products, which is why generic versions are referred to as ‘biosimilars.’

What is the market potential for biosimilar products?

Many believe that the future of the pharmaceutical industry rests with biotechnology. According to some studies, patented biopharmaceuticals account for 10 to 15 percent of the current pharmaceutical market and biopharmaceuticals are currently outperforming the pharmaceutical market as a whole in terms of growth. A settled market for biosimilar products is essential to exploit the growing number of biopharmaceuticals, which will lose patent protection in the next five years.

Most biopharmaceuticals are high-cost specialty drugs, used to treat relatively few conditions with a currently unmet clinical need, such as certain forms of cancer. Thus, another compelling need for biosimilars is to treat the same conditions at a potentially lower cost to the manufacturer. Biosimilars also present the potential for biotech companies to gain a larger market share in a time when the rising research and development expenses for such companies are getting harder to finance.



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What is the current regulatory framework for biosimilar products?

Currently, there is no formal procedure in the U.S. for the testing and approval of biosimilar products. European regulatory agencies, however, have set forth a regulatory path, outlined by the European Medicines Agency (EMA), which is not easy. The process is based on a thorough demonstration of ‘comparability’ of the biosimilar drug to the existing biopharmaceutical drug. Where generics can be brought to market quickly and cheaply by merely demonstrating that the generic is chemically identical to the brand-name drug, the EMA guidelines require a minimum of two clinical trials and extensive testing for toxic side effects. This makes the approval process in Europe for biosimilar drugs nearly as rigorous and expensive as the approval process for new biopharmaceuticals.

How is Congress addressing the growing demand for development of biosimilar drugs?

Escalating health-care expenditures are forcing the U.S. Congress to consider legislation that would create an abbreviated review process by which the FDA could approve biosimilars. Last year, two bills addressing such an approval process were introduced in the House and are still pending.

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The key provisions of the first bill are:

- the granting to FDA authority to approve biosimilars;
- the approval process will require showing that there are no clinically meaningful differences between the two products;
- the first biosimilar able to establish that it is ‘interchangeable’ with the original product will receive six months of exclusive marketing; and
- an original product with a novel molecular structure is entitled to five years of exclusivity and can be extended by up to one year if it can be established that the product can be used for a new disease or that it conducts pediatric studies.

The key provisions of the second bill are:

- establishes safety standards for establishing interchangeability;
- establishes exclusivity for the first product found to be ‘interchangeable’ for a period of 24 months;
- the original product with a novel molecular structure is entitled to 12 years of exclusivity and 14 years in the event that a new indication is found for the product in the first 8 years after licensure; and
- an additional exclusivity period for pediatric studies and use of product.

The main sticking point between the two bills is the length of the company’s ‘data exclusivity.’ Data exclusivity refers to the period after the FDA approves a new drug product for the market during which an imitation, or generic, can’t rely on the name-brand drug’s clinical data with respect to safety and efficacy. Data exclusivity can extend during and longer than the brand-name drug’s patent protection. Consumer groups are lobbying for five years of data exclusivity for biosimilars, which is the same length as a chemical drug’s data exclusivity (i.e., brand name and generics). The biotech industry supports the 14-year period to allow biotech companies to recoup their investment in their ‘brand-name’ biopharmaceutical products and conduct further clinical trials to improve them.

With the length of time it takes for new biopharmaceuticals to be developed, reach the market and become profitable, the ability for biotech companies to extend the data exclusivity period for brand-name biopharmaceuticals they have already developed and pave the way for the manufacturing of biosimilars will be an important factor in their future success and profitability. <<

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