Drugmakers brace for generic versions of biotech blockbusters

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In 2001, Abbott Laboratories spent nearly $7 billion on the biggest acquisition in the company's 123-year history, primarily to access one drug, Humira.

Since then, the drug giant has raked in more than $24 billion in sales from Humira, a pricey medicine derived from human cells and used to treat a variety of autoimmune diseases. This year, Humira is forecast to have its biggest year ever, with some analysts projecting more than $7 billion in sales.

But the national health care law is intended to put the brakes on the profit bonanza from Humira, as well as many other biotechnology drugs, by opening up the sector to generic competition. That will make biotech drugs, also known as biologics, which are innovative treatments derived from living cells, affordable to more consumers.

Many patents on some top-selling biotech drugs will start to expire in the next few years. But when "biosimilars" or "biogenerics" will be available to U.S. consumers is unclear. The Food and Drug Administration is working on guidance on how the approval for this class of generic drugs will work.

"Biotech drugs are among the world's most expensive," said Dr. Sidney Wolfe, director of the health research group at Public Citizen, a consumer watchdog of the health care industry. "They have been good, but they have been expensive, so it is extraordinarily important to get

biogenerics as quickly as possible."

The Affordable Care Act, signed into law by President Barack Obama in March 2010, clears a path for the FDA to approve generic forms of biotech drugs. Biogenerics have been unavailable in the U.S. because they were not part of the 1984 landmark Hatch-Waxman Act, which allowed for cheaper generic versions of chemically derived drugs.

Thanks to the 1984 law, consumers have access to generic versions of many blockbuster treatments, including the cholesterol drug Zocor and the antidepressant Prozac, which can cost $3 to $5 a day. The generic forms of those drugs typically cost pennies a day.

But biotech drugs weren't developed until the 1980s, when technology cleared the way for genetic engineering on DNA, allowing drug companies to rake in huge profits from this relatively new class of treatments.

Humira is a monoclonal antibody, hailed for its ability to work like a smart bomb because of its ability to precisely attack disease cells. Abbott says more than 500,000 people worldwide are taking Humira to battle a range of autoimmune diseases, including rheumatoid arthritis, Crohn's disease and psoriasis, often halting progression of the condition.

But the innovation has come with a price. Humira costs patients, their employers and health insurance companies about $20,000 for one year of treatment. Doctors say costs can run higher depending on the patient and dosage needed to be injected into patients.

The anti-anemia drug Epogen can cost more than $10,000 a year per patient, while biologic medicines for cancer and other life-threatening diseases can cost tens of thousands, sometimes more than $100,000 a year.

While biotech drugs are very expensive for consumers, they can pay off for drug companies.

When Abbott engineered its $6.9 billion acquisition of Knoll Pharmaceuticals, which developed Humira, Wall Street analysts and investors thought the company spent too much. The drug industry at the time often touted the cost of researching and developing one drug at $800 million or more.

Knoll provided Abbott with a host of products, including the popular thyroid treatment Synthroid and the diet drug Meridia, which had a few years of good sales before the FDA requested the company take it off the market due to heart risks. When Abbott bought Knoll in 2001, which was before Humira won FDA approval, Knoll was generating about $2 billion in sales.

"They have more than recouped their investment," Wolfe said of Abbott.

Abbott Chairman and CEO Miles White recently indicated Humira will continue to be a blockbuster, given its first patents don't expire for another five years.

"Humira has been a phenomenally successful product with application in a lot of different disease categories," White said at the company's annual shareholder meeting last month. "Humira's got long legs, out until about at least 2016, when its first patents begin to expire."

White is banking on all of the FDA-approved indications for Humira, which has held up against competition from rival rheumatoid arthritis and Crohn's treatments derived from biotechnology, such as Johnson and Johnson's Remicade and Amgen Inc.'s Enbrel. The patent for Remicade also is expected to expire in the next few years.

"It is yet unclear what kind of competition we'll experience from biosimilars or the equivalent of generics at some point later in time," White said. "So I think some of the concern about Humira is exaggerated and overblown."

One primary obstacle that could delay entry of a Humira rival lies with the FDA. The agency this month said it continues to work on the regulatory review process, which will require clinical trials, unlike the process used to approve generic copies derived from chemicals.

Neither Abbott nor the FDA is aware of a company that has begun to work on a biosimilar version of Humira, but some companies are starting clinical trials of biosimilars of other drugs. Hospira Inc., for example, is selling a biogeneric of Epogen in Europe and last year began clinical trials in 20 U.S. hemodialysis centers.

Some analysts think it will be difficult for companies to replicate biologics as easily as pills and capsules derived from chemicals. Biologics are more complex to make, and there are not enough makers to drive prices down to the 60 to 80 percent discounts that are common among chemically derived pills and capsules, some analysts say.

"When Humira loses patent protection in 2016, it may become an albatross similar to Pfizer's Lipitor," Morningstar Inc. analyst Damien Conover said in a recent report, referring to the generic competition Pfizer's cholesterol pill faces in November. "However, since we believe the drug's biologic composition will dilute the impact of generic competition, we project an immediate sales decline of 20 percent following the patent loss, instead of the typical 80 percent crash."