

FDA's Plan To Boost Biosimilar Drugs Could Stall at the Patent Office

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While the FDA is streamlining regulation of copycat versions of the expensive drugs that millions take for arthritis, cancer, and other diseases, the U.S. patent office is making it harder for the cheaper medicines to get on the market, industry officials say.

These officials were thrilled October 29 when FDA Commissioner Marty Makary announced the agency's plan, which he said would halve the time and money needed to get what are called "biosimilar" drugs to market. Biosimilars are essentially generic versions of biologics — such as Humira, Keytruda, and Xolair — which are made from living organisms. Biosimilars can cost up to 90% less.

Under the guidance the FDA proposed, the agency would begin overseeing biosimilars similarly to the way it regulates generics, which are copies of simpler molecules, usually pills. This change in approach could allow companies to save up to \$100 million for each drug they develop, enabling them to make more products for underserved patients, said Stefan Glombitza, CEO of Formycon AG, a maker of biosimilars based in Germany.

But President Donald Trump's patent office is working at cross-purposes with the FDA, biosimilar makers charge, by narrowing the opportunities for companies that try to challenge the throngs of patents that brand-name drugmakers file to protect their products from competition.

In the past, biosimilar makers have been able to invalidate some of those patents through a sped-up process called "inter partes review," or IPR. But the new administration has denied most IPR requests and issued a [proposed rule](#) in October that makes IPRs harder to get.

Heavyweights on Pricing

Biosimilars have the potential to nibble or even gouge away at a major U.S. health care cost. Only 5% of prescriptions are for biologic drugs, but they account for more than half of the [\\$600 billion](#) the nation annually spends on medicines.

“Generic and biosimilar competition is the crucial way that we bring down prescription drug prices,” said William Feldman, a pharmaceuticals policy researcher at UCLA.

The FDA announcement “is a good thing that may ease barriers,” he added, “but there are a lot of caveats.”

In fact, biosimilar industry officials say, FDA regulation is often the least of the three major hurdles they face in marketing their products.

To protect their market share, brand-name biologics makers file scores or even hundreds of patents, continuing to do so long after their drugs hit the market. The “patent dance” that occurs when biosimilar makers seek to launch competitor drugs can drag on for many years.

For example, the FDA approved the first biosimilar of the rheumatoid arthritis drug Humira in 2016, but legal battles delayed competitors from entering the market — until nine FDA-approved products were [launched in 2023](#). At his [October 29 news conference](#), Makary blamed FDA “red tape” for the delay, but it was mostly due to the baffling patent machinery, industry officials say.

The new rules, which could take effect next year, would formalize recent FDA practices aimed at speeding along approval for biosimilars. For example, the FDA has recently allowed drugmakers to waive expensive clinical testing contemplated under a 2009 law. The agency now lets companies employ less costly analytical tests, if they can show that the biosimilar has no clinically meaningful differences from the brand-name drug.

A ‘Switching’ Burden

Because biologic drugs are large molecules produced from live cells, copies of them cannot be chemically identical. So the FDA had required biosimilars to go through clinical studies like the ones required for the original drugs. But [research has shown](#) that analytic techniques can replace the need to test biosimilars on large numbers of patients.

The new rules would also confirm the FDA’s move away from requiring what are known as “switching” tests, in which patients first go on the brand-name drug and then the biosimilar, or vice versa, to see if their responses are the same. Such tests are required in many states for the biosimilar to obtain “interchangeable” status, which enables pharmacists to substitute an often cheaper version for the prescribed brand-name drug.

In short, the new rules would mean biosimilar makers would spend less money getting drugs to market, said Sean Tu, a law professor at the University of Alabama. “What that won’t do is get you on the market earlier,” he added.

After biosimilars launch, it can take years for them to gain a foothold. In 2023, Humira biosimilars made barely a dent in the market, and in 2024 they accounted for only about a quarter of sales, though they cost as little as 10% of the roughly \$6,500 monthly price tag for the brand-name drug.

That's because brand-name drug companies offer lucrative rebates for sales of their drugs to the go-between companies that design formularies — tiered lists that tell doctors and pharmacies which drugs are covered by insurance. These middlemen, pharmacy benefit managers, pass along some of that money to health plans.

Essentially, the insurance plans are “charging higher costs to people who require expensive drugs as a way to subsidize the whole population,” said Wayne Winegarden, an economist at the Pacific Research Institute.

The Patent Thicket Thickens

Biosimilar makers are particularly worried about the direction the U.S. Patent and Trademark Office has taken under Trump.

Patent challenges are already 10 to 20 times as expensive in the United States as in Europe, and restricting inter partes reviews is making it worse, said Formycon's Glombitza.

The FDA recently gave his company a waiver from conducting a costly clinical trial of its biosimilar substitute for Keytruda, a blockbuster cancer drug. But Merck & Co., which got about half of its \$17 billion third-quarter revenue from Keytruda, is expected to fight tooth and nail to protect its many patents on the drug. The Trump administration's new obstacles to challenge them “counteract the waiver,” Glombitza said.

Merck protects its innovations, said spokesperson Julie Marie Cunningham. However, noting that Merck is touting a new, injectable Keytruda formulation, she said the company does not expect it to affect “the potential marketing” of biosimilars for the older, intravenous form of the drug.

The Pharmaceutical Research and Manufacturers of America, or PhRMA, the industry group representing most large brand-name companies, “welcomes the administration's focus on increasing biosimilar access and affordability,” said spokesperson Alex Schriver.

But Big Pharma companies favor the patent office's swing toward more protection of filed patents, according to attorneys who work in intellectual property litigation.

“I don't think the Trump administration has any kind of coherent plan here,” said Mark Lemley, director of the Stanford Program in Law, Science & Technology. While Trump officials want to bring drug costs down, “they also want to make it more expensive to figure out whether patents are valid by effectively eliminating IPRs,” he said.

The patent office did not respond to repeated phone calls and emails.

Patents and patent litigation are the biggest impediments to getting biosimilars onto the market, UCLA's Feldman said.

For instance, the FDA licensed Sandoz's biosimilar for Enbrel, a popular drug to treat autoimmune

disorders, in 2016, but Sandoz won't be able to market its competitor in the U.S. until 2029 at the earliest because of patent challenges. Without insurance, Enbrel costs about \$7,000 to \$9,000 a month.

A Patient's Perspective

Judy Aiken, a retired Portland, Maine, nurse who has taken Enbrel since 2007 to treat psoriatic arthritis, would be interested in trying the copycat if it costs her less. After retiring in 2019 and going on Medicare, she has spent thousands each year on the drug.

The Biden-era Inflation Reduction Act capped her out-of-pocket drug costs at \$2,000 this year, and Aiken and her husband used the savings to replace their roof and furnace. But with health care changes on the horizon, "now I'm scared the other shoe is going to drop," she said.

Only about 10% of the 118 biologics set to come off patent in the next decade have biosimilars in development, reflecting poor incentives in a system that biosimilar makers and patient advocates say is stacked against them.

But lower costs could enable companies like Formycon to expand their product lines — focused now on cancer and autoimmune diseases — to less common or even rare conditions, said CEO Glombitza.

"People have talked about the promise of biosimilars reducing out-of-pocket costs and creating more choices for consumers, and I feel like we're still waiting," said Anna Hyde, chief of advocacy and access for the Arthritis Foundation, which lobbies for research and treatment.

Although biosimilars could save everyone money, patients generally don't care whether they get one or not, Hyde noted. Some don't want to switch if they've found a brand-name drug that works for them, since the search can be grueling for people suffering from autoimmune diseases, she said.

"Generally, they can't access them anyway," she said, "because they are not available on the formulary."

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