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Is it in the public's interest to have two similar cholesterol drugs on the market?

Alex Hogan/STAT

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As Sanofi prepares a do-or-die appeal to continue selling a pricey cholesterol drug, a key issue may turn on the extent to which patient access to the medicine is considered to be in the public interest.

The drug maker and its partner, Regeneron Pharmaceuticals, lost a stunner when a federal court judge late Thursday issued a permanent injunction preventing the companies from marketing their Praluent injectable cholesterol medicine. The judge did so in response to a jury verdict last year that found the product infringed patents held by Amgen on its own drug, which is called Repatha. A lawsuit[1] had been filed in 2014.

Both drugs, which are known as PCSK9 inhibitors, became available in 2015 to treat patients who struggle to control their cholesterol using statins, particularly those with an inherited disorder known as familial hypercholesterolemia. The medicines cost about $14,000 annually, before rebates, and doctors and investors are awaiting study data on whether the drugs can lower cardiovascular risks.

For the moment, nothing has changed, because Sanofi has 30 days to file an appeal and already vowed to do so. But if its appeal fails, patients will no longer have a choice between two similar medicines that lack any other direct competition in what is forecast to become a multibillion-dollar market. And this weighed heavily on US District Court Judge Sue Robinson, even as she sided with Amgen.

"The public generally is better served by having a choice of available treatments. Therefore, the court finds itself between a rock and a hard place, i.e., being a patent holder and a verdict winner should be a meaningful factor in the balancing test, but taking an independently developed, helpful drug off the market does not benefit the public," she wrote in her 7-page order.

Nonetheless, Robinson endorsed Amgen's argument that it suffered "irreparable harm" that could not be compensated by damages. But going forward, the final outcome of this closely watched case may turn on whether a federal appeals court agrees with this assessment or determines that patient choice is important enough to allow Praluent to remain on the market, according to attorneys.

"This is a close call. They're both equally important factors," said Leanne Rakers, a principal at the Harness Dickey law firm, who specializes in pharmaceutical patent litigation. "In this case, I think Sanofi has strong arguments and can possibly win the appeal, because monetary damages should be adequate to compensate Amgen. Why isn't that sufficient, especially when there is a public interest?"

And as Emily Rapalino, a partner at the Goodwin Procter law firm, who also specializes in pharma patent disputes, noted, the "public interest factor can be a little more important in pharmaceuticals than other industries. The courts are likely to weigh that more heavily… It's a little bit unusual for there to be a permanent injunction that takes one [drug] off the market."

One patient advocate agreed, but cited cost as a key consideration.

"The biggest public benefit I see is that the presence of two PCSK9 inhibitors on the market leads to more pricing pressure on both companies. For example, some insurance companies have cut a deal with one company or the other to cover their drug exclusively in exchange for a lower price," said Marilyn Mann, who has family with familial hypercholesterolemia and helps administer a Facebook group for FH patients.

"Patients benefit from lower prices, either because their out-of-pocket costs are lower or because lower prices keep health care costs down in general, which helps keep the cost of health insurance affordable. In addition, lower prices in the long term should encourage insurance companies to be less restrictive in covering PCSK9 inhibitors."

In addition, Mann maintained that the different drugs offer different choices. Specifically, she pointed to a low-dose version of Praluent that, she explained, can be more efficient for some patients, either because of side effects or because they do not need to lower their cholesterol quite as much as some other people. Sanofi has made the same argument in court documents.

Nonetheless, the betting on Wall Street appears divided.

Some analysts who track these companies believe Amgen is likely to prevail. “Chances of reversal are likely low unless the decision is deemed faulty for some reason. For Sanofi and Regeneron, the one chance could be if the [appeals court] sees that damages as not being irreparable and sufficient monetarily,” wrote RBC Capital Markets Adnan Butt in an investor note.

Even so, the process can take a year or more. As Barclays analyst Geoff Meacham noted, Sanofi and Regeneron will challenge the jury verdict on patent infringement as well as a recent ruling that denied a new trial and, of course, seek to reverse the permanent injunction. “This case is far from over,” he wrote. He added that he could also imagine a settlement in which Amgen receives royalties.

Baird analyst Brian Skorney expressed a similar view. “Ultimately, we expect that Regeneron and Sanofi will be forced to settle and pay Amgen a substantial royalty, but that Praluent will not be pulled from the market.” Both analysts speculate that royalties might reach as high as 20 percent or so.

However, Cowen analyst Phil Nadeau is not so sure. “Amgen does not appear at all inclined to settle this case,” he wrote. And he sounded skeptical Sanofi and Regeneron can keep Praluent on the market and eventually overturn the decision. “We have a difficult time handicapping the odds of success on either front,” he wrote, “but prevailing on both would seem an uphill battle given the lower court verdict.”

Correction: A previous version of the headline on this story implied that Sanofi and Regeneron each had their own cholesterol drug. They are partners.

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1. http://freepdfhosting.com/cf34a798e2.pdf

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