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Biologics Face Tougher Patent Scrutiny After Amgen Ruling

By **Dani Kass**

Law360 (February 18, 2021, 8:07 PM EST) -- A recent Federal Circuit decision clamping down on broad antibody patent claims may have some biologics makers scrambling to save their existing intellectual property and questioning whether to patent future drugs at all.

In Amgen v. Sanofi , the Federal Circuit **ruled Feb. 11** that, with rare exceptions, patenting antibodies based on what they bind to doesn't meet enablement requirements under Section 112 of the Patent Act. While the ruling falls in line with past Federal Circuit decisions, it veers from how the scientific community defines antibodies and puts existing patents for top-dollar biologics on the road to invalidation.

"I think it's fair to say Amgen v. Sanofi just set a torch to tens of billions of dollars," said University of Illinois College of Law professor Jacob Sherkow. "That is not an understatement."

Amgen's patents for its cholesterol drug Repatha covered a genus of antibodies that bind to a protein called PCSK9 and featured 26 examples of amino acid sequences that bind to PCSK9.

In a precedential decision, the Federal Circuit said it would have taken "undue experimentation" to identify the hundreds or millions of other antibodies that bind to that protein, meaning the patents didn't meet requirements that someone skilled in the art must be enabled to follow the patent to carry out the claimed invention.

Patent claims that describe what an invention does as opposed to what the invention is — in this case, binding to a certain protein rather than a set list of amino acid sequences — are called functional claims, and experts say the Federal Circuit made it clear in Amgen v. Sanofi that functional claims are going to be hard to keep from being invalidated.

"The Federal Circuit did not completely slam the door on functional claiming, but the space that they provided is so narrow, it's hard to imagine anyone fitting through it," said University of California, Hastings College of the Law professor Robin Feldman.

George Washington University Law School professor Dmitry Karshtedt — who last year published a **paper showing** the Federal Circuit rarely lets genus claims survive — expressed frustration that while the court left the door open, it didn't actually give any guidance for how to go through it.

Amgen can still appeal the Federal Circuit's ruling, but both the en banc Federal Circuit and U.S. Supreme Court recently **refused** to consider whether genus claims meet enablement standards, albeit not in an antibody case.

There has long been a debate about whether antibodies should be allowed to be claimed at a genus level, since scientists tend to define antibodies based on what they bind to, but the Federal Circuit has now made it

unquestionable that there is not an exception for antibodies, Sherkow said.

"Six of the top 10 drugs by revenue in the United States are antibody drugs or antibody fragment drugs," he said, adding later, "Those patents are all 'up for grabs' now."

On the patent prosecution side, Casimir Jones SC shareholder Lisa Mueller said decisions like Amgen have made it far harder to know what to advise clients hoping to patent antibodies. The Federal Circuit said patenting a genus is theoretically possible, but the 26 examples in Amgen weren't enough, and neither were the 300 in a **2014 decision** involving AbbVie Inc.

"It's challenging for these companies that spend millions and billions of dollars making these," she said. "I'm not entirely clear what you need to satisfy written description and enablement requirements at the Federal Circuit."

Mueller said she expects to start seeing patent examiners become more conservative with their grants and reject these broader claims, meaning those who want to fight for their patent application will have to appeal to the Patent Trial and Appeal Board and then the Federal Circuit.

To work around this ruling, Sherkow suggested a series of possible paths. Among them, he said, are that companies may rely on the 12 years of exclusivity they get from the U.S. Food and Drug Administration, skip the patents and hold onto their inventions as trade secrets. That would raise big questions about what happens with the Biologics Price Competition and Innovation Act and biosimilar competition though, he added.

"It's going to make it nigh on impossible to really make a real biosimilar at that point," Sherkow said. "If you don't have a patent disclosing exactly what [the epitope the antibody binds to is], we'd have to figure out whether it would necessarily come out in a [Biologics License Application] approval process and whether biosimilars would have access to that information or not."

Another option would be to patent a specific sequence along with any antibody that has a certain level of homology — or similarity — with the provided example, he said. Companies could also get a patent that covers everything but the antibody, like the pharmaceutical compositions and the methods of manufacturing, although he said those can also raise functional claiming questions.

Lastly, he suggested using a "totally crazy historical option," which is almost never done, called accession deposit. There, companies can deposit a sample of the antibody at an accession deposit organization and refer to that deposit in the patent claims.

But realistically, he said fewer patent protections don't mean biologics makers are about to shut their doors. Antibody drugs are massively profitable, with ones like AbbVie's Humira bringing in tens of billions of dollars a year.

"The exclusivities pertaining to biologics are still large enough that even without the best form of patent protection, [they are] still worth the candle," Sherkow said. "I think these biologics companies would do anything for a $1 billion a year drug, let alone a $10 billion a year drug."

But for patients and makers of biosimilars, there could be some upsides to this ruling. Duke University School of Law professor Arti Rai said the decision could lead to an increase in competition.

"This will definitely suggest that there are ways you can invent around or at least challenge a claim that precludes you from inventing around a particular antibody patent that got there before you," she said. "I think it will spur some competition, which from a practical standpoint, I think is pretty good in that we really do need biologics competition, and we haven't seen nearly as much of that."

UC Hastings' Feldman, who is a critic of functional claiming because it lets parties claim more than they have

actually discovered, said getting rid of the practice will help lower the price of biologics and be a boon for patients.

"It's no secret that drug prices are skyrocketing," she said. "One driver of skyrocketing drug prices is the ability to pile on protections, meaning the ability to keep cheaper competitors out of the market for an extended period of time. If you can obtain extremely broad patents and pile on lots of them, you can make a lot of money that way."

--Editing by Jill Coffey.
