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# New Antibody IP Ruling Still Needs To Be Tested In Courts

By **Dani Kass**

*Law360 (May 31, 2024, 4:04 PM EDT)* -- A May decision from top U.S. Patent and Trademark Office officials is giving some attorneys renewed hope that they'll be able to secure antibody patents, but they say the agency's ruling may not be enough to overcome courts that have been hostile toward these patents.

The USPTO's Appeals Review Panel on May 17 determined that Xencor Inc. didn't have to write out all antibodies equivalent to the one it identified when pursuing claims defined by their function, opening the door for patents with a broader scope. The decision came down about a year after the U.S. Supreme Court in Amgen v. Sanofi ordered a narrower approach, and the intersection between the courts and the USPTO is something attorneys say they'll be watching closely.

"I always tell my clients that this is like next-gen claiming or next-gen patent strategy, just because it's something that really hasn't been done," said Joanna Brougher, the owner of BioPharma Law Group PLLC. "It's uncharted territory. We don't know what the courts are going to decide on these claims down the road, but hopefully the fighting is going to be over the important stuff like what is an equivalent, instead of whether or not these claims are even permitted."

**Backdrop for Antibody Patents**

The Supreme Court set a high bar for antibody patents in May 2023, holding that the full scope of the patent must be enabled in order to comply with the Patent Act.

Specifically, the justices found Amgen couldn't claim an entire genus of antibodies defined by how they bind to part of a protein — in turn, lowering cholesterol — by listing 26 antibody species in the patent. Reaching the full scope of that patent would take "undue experimentation," the justices held.

The pharmaceutical industry was divided on whether Amgen met enablement requirements under Section 112 of the Patent Act. The prevailing position was that it was nearly impossible to identify all possible antibodies based on the patent, meaning Amgen was claiming more than what it actually invented.

On the other end, companies trying to patent antibodies warned that the narrower interpretation contradicts how science works, and that the actual invention was figuring out how to use those antibodies to lower cholesterol, rather than the individual antibodies themselves. They failed to win over both the Federal Circuit and the Supreme Court.

**Xencor's Novel Response**

The Xencor decision provides a possible path forward for the latter group through the use of claims based on the result of an invention, rather than the steps to recreate it. It's extremely hard to get those so-called functional patents, but not impossible through the use of means-plus-function claims, where there is a corresponding structure in the patent's written description.

Now, the USPTO says such claims can cover both the antibodies listed and those "equivalent" in structure to what's being claimed.

"The Amgen-Sanofi decision really eviscerated the ability of a patent applicant to broadly protect their invention," said Morgan Lewis & Bockius LLP partner Christopher Betti, who represents Xencor. "I think where means-plus-function falls is in between. It's not as narrow as a species claim might look like, but it's certainly not as broad as a traditional genus claim."

The USPTO's decision — officially titled Ex parte Chamberlain after the inventor, former Xencor scientist Aaron Chamberlain — was the first ever released by the agency's new Appeals Review Panel, comprised of Director Kathi Vidal, Commissioner for Patents Vaishali Udupa and Chief Administrative Patent Judge Scott Boalick.

The ruling should be used by patent examiners when trying to review whether means-plus-function claims should be allowed in pharmaceutical patent applications, attorneys said.

"It requires a lot of education and a lot of discussion with examiners to make them comfortable with allowing such a claim in the first place," Brougher said.

Betti said examiners will likely be "slow to adopt" the ruling, but he's "hoping Ex parte Chamberlain provides them a framework for such examinations going forward."

That adjustment will likely be aided by guidance on means-plus-function claiming that Vidal provided examiners in March.

While Xencor got everything it wanted in terms of the broader claiming structure, according to Brougher, the company did not walk away with an approved patent application for its autoimmune treatment. The panel found one term — "treating a patient" — was too broad, since it was unclear what was being treated.

That flaw also was present in another unusual claiming method for pharmaceuticals used by Xencor, referred to as Jepson claims. Jepson claims feature a preamble where the applicant states what's already known in prior art, and then how the applicant has improved it.

The USPTO said both the newly claimed material and the preamble must have written description support. The preamble in Xencor's Jepson claim likewise discussed treating a patient, and therefore fell short of meeting that requirement.

Jepson claims are rare in life sciences, according to Harness IP principal Kisuk Lee, who called them "outdated," and said he's been taught not to use them given the risks associated with laying out prior art for examiners so directly.

Such claims are a "tried and true simple format" in the mechanical arts or more straightforward areas, said McDermott Will & Emery LLP partner Judy Mohr, but the risks are much higher in something as complicated as antibody science.

When talking to Law360, attorneys largely highlighted the Jepson claims for their novelty, but focused on means-plus-function claims when discussing a tangible result.

Still, Mohr said it's exciting to watch a party investing the time and money to dig deeper into alternative claiming.

"I work with a lot of companies in the antibody space, more on the diagnostic end, where undertaking an expensive fight like this is not worth it," she said. "It's better just to keep the antibodies as trade secrets, which also really undermines the whole point of the patent system to disclose your invention so people can build on it."

**Will the USPTO's Opinion Last?**

While the USPTO cleared the use of means-plus-function claims broadly, the fact that Xencor failed on the merits has some attorneys skeptical about the scope of any effect.

Lathrop GPM LLP partner Laura Labeots called Xencor's approach "clever," but wasn't convinced it would be change the game.

"Patent attorneys have been racking their brains on how to obtain broad claims to cover a broad genus of antibodies," she said. "The ultimate result was that they still weren't successful."

Xencor is appealing, and its case was docketed at the Federal Circuit on Tuesday.

On a more optimistic note, Brougher said the means-plus-function claiming strategy doesn't have to work all the time to be significant.

"It's just one additional tool in one additional tool box to protect these inventions," she said.

Attorneys are curious — albeit doubtful — whether federal courts on the heels of the Amgen decision will be open to the type of claiming allowed by the panel. It will be up to judges to decide what counts as an equivalent, and whether those equivalents meet written description and enablement standards.

"This is fine and well at the patent office level in terms of getting the claim ... but how is a court going to find the breadth of those equivalents?" Mohr asked. "Is that any substitution? Any position in the antibody? Is it a really large field of equivalents or just a few? A court's going to have to decide that, and that's where the interesting litigation will be."

"I'm of the view that as a patent prosecutor, it's our job to get patents issued so that there's the opportunity for the court to figure out these downstream questions," she continued. "So if the court says no equivalents are described, therefore the claim is invalid because you can't determine the equivalent, then yes, this is a loss at the end of the day. But we have to get there and have that fight to know."

Even with the USPTO's take on equivalents, it's likely that the Federal Circuit could still find the clams too broad, given that they could be "so impossibly large in the antibody space," Mohr said.

"Then we're left right back with what the Amgen court found," she concluded.

The USPTO is giving inventors the opportunity to test meeting enablement and written description requirements without having to pursue narrow claims that focus on one antibody, which are extremely easy for competitors to then design around, Brougher said.

"What means-plus-function claiming is going to offer people is just an opportunity to do something a little bit broader," she said. "Is it going to be the golden solution to everything? Who knows. The courts haven't gotten that far where they're interpreting what a means-plus-function claim is [and the equivalent language]. That's where I think the interesting battles are going to happen down the road."

The cases are Ex parte Chamberlain, case number 2022-001944, before the U.S. Patent and Trademark Office's Appeals Review Panel, and In re: Xencor, Inc., case number 24-1870. in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Adam LoBelia.

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