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Are Broader Antibody Patents Possible in US Through Means-Plus-Function Claiming?

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Numerous court decisions over the past decade – such as ***Amgen Inc. v. Sanofi*** from the US Supreme Court and ***Juno Therapeutics, Inc. et al. v. Kite Pharma, Inc.*** from the US Court of Appeals for the Federal Circuit – have called into question the validity of broad antibody patent claims, leading some commentators to declare the death of the antibody genus claim.[1]

In the aftermath of those cases, some practitioners have suggested means-plus-function claiming as one strategy to obtain antibody claims that are broader in scope than the specific antibodies provided in the application as filed. This previously untested strategy cleared a first hurdle in the US Patent and Trademark Office (USPTO) decision in ***Ex parte Chamberlain***, where the USPTO held that a patent specification need not describe the "equivalents" to an antibody claimed in means-plus-function format.

Patent at issue and its initial rejection

Ex parte Chamberlain involved Xencor Inc.'s Patent Application No. 16/803,690, which included the following claim to an antibody in means-plus-function[2] format:

> "9. A method of treating a patient by administering an anti-C5 antibody comprising:
>
> a) means for binding human C5 protein; and
>
> b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions."

The specification described a "5G1.1" antibody as capable of binding to the C5 protein. Murine and humanized versions of the "5G1.1" antibody were known in the art, but the specification did not indicate which it was referring to and did not provide an amino acid sequence for either. The specification did not identify any other antibodies that were capable of binding to the C5 protein or were otherwise "equivalent" to 5G1.1.

The USPTO examiner rejected this claim under 35 US Code § 112 as lacking adequate written description because the specification's disclosure of the 5G1.1 anti-C5 antibody was insufficient to identify a particular structure that correlates to "means for binding human C5." Xencor subsequently appealed to the Patent Trial and Appeal Board (PTAB) at the USPTO.

The PTAB found:

- That "means for binding human C5 protein" lacked sufficient written description because the specification did not disclose "sufficient structure" corresponding to the claimed function of "binding human C5 protein."
- The specification's disclosure of the 5G1.1 antibody insufficient because "the claimed 'means for' is not restricted by the [s]pecification to this specific antibody species."

- That the term was indefinite because a skilled artisan would not know whether 5G1.1 referred to the mouse or humanized antibody and, thus, could not identify sufficient structure for the claimed means.

The PTAB subsequently denied a request for rehearing, and Xencor filed a notice of appeal to the Federal Circuit.

Late in 2023, the USPTO filed a motion requesting an administrative remand of the proceeding to the USPTO so an Appeals Review Panel (ARP) could clarify the USPTO's position on the proper analysis of "means-plus function claims in the field of biotechnology, and particularly in the antibody art" and "issue a revised decision." The Federal Circuit granted that motion on January 23, 2024, and the ARP issued its decision on May 21, 2024.

ARP's decision

In its decision, the ARP considered the PTAB's written description and indefiniteness rejections of the means-plus-function claim 9.[3] The ARP first found "that the phrase 'means for binding human C5 protein' is a means-plus-function limitation subject to 35 U.S.C. § 112 ¶ 6." The ARP further found that claimed function was "binding human C5 protein" and that the 5G1.1 antibody was the sole structure disclosed in the specification that performs the claimed function.

On the indefiniteness rejection, the ARP found that a person of ordinary skill would have understood "5G1.1" to refer to two related antibodies: the original mouse 5G1.1 antibody and a humanized version of the mouse antibody, known as ecluzimab, which were described in the specification. Thus, the ARP found the term to be definite and withdrew the PTAB's rejection on indefiniteness grounds.

With respect to the written description rejection, the ARP noted that a means-plus-function claim literally covers structures described in the specification and equivalents thereof, but it rejected the PTAB's reasoning that equivalents of the structure need to be described in the specification. The ARP reasoned that § 112 ¶6 explicitly distinguished between the "corresponding structure … ***described*** **in the specification**" and "equivalents." emphasis added). The ARP noted that while § 112 ¶6 specifically states that the corresponding structure must be described in the specification, it "does not state that the [s]pecification must also *describe* the equivalents of that structure." The ARP further cited Supreme Court and Federal Circuit case law that "supports reading 'equivalents' to cover structures, materials or acts beyond what is explicitly described in the [s]pecification." Accordingly, the ARP concluded that it was **not necessary** for the specification to describe equivalents of 5G1.1 to meet the written description requirement.

As a result, the ARP disagreed with the PTAB and concluded that the claim limitation "means for binding human C5 protein" met both the written description requirement of 35 USC § 112 ¶ 1 and the definiteness requirement of 35 USC § 112 ¶ 2.[4]

Implications of ARP's decision

Although Xencor's means-plus-function claims remain rejected for lack of written description on other grounds, the ARP decision suggests that the use of this format might provide applicants with a chance to obtain broader antibody claims that could potentially cover those antibodies specifically recited in a specification as well as "equivalent" antibodies. However, it is unclear how the USPTO will view the use of means-plus-function language in composition of matter antibody claims, as opposed to the method of treatment claims presented in *Xencor*. In addition, it remains to be seen whether the federal courts will abide by this decision and, if they do, how they will determine what antibodies are deemed to be "equivalent" to antibodies explicitly described in a specification. Moreover, it is important to note that the ARP's decision only addressed the written description of means-plus-function claims and did not consider enablement.

While we wait to see what comes next, patent applicants should consider including means-plus-function claims when drafting new

antibody applications.

Notes

1. *See* Karshtedt, Dmitry, Lemley, Mark A., and Seymore, Sean B., "The Death of the Genus Claim," 35 Harv. J.L. & Tech. 1 (Fall 2021).
2. Means-plus-function claims contain an element that is "expressed as a **means** … for performing a specified function without the recitation of structure, materials, or acts in support thereof … " (35 USC § 112 (pre-AIA), sixth paragraph (emphasis added)). This type of claim is "construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." (*Id.*).

   While this application was filed prior to the enactment of the Leahy-Smith America Invents Act of 2011 (AIA), we note that means-plus-function claims persist under the AIA, which did not significantly change means-plus-function claiming.
3. The application also contained antibody claims in the so-called Jepson format, which include "(1) [a] preamble comprising a general description of all of the elements or steps of the claimed combination which are conventional or known, (2) [a] phrase such as 'wherein the improvement comprises,' and (3) [t]hose elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion." (37 Code of Federal Regulations 1.75(e)). The USPTO found that the Jepson format claim in the Xencor patent lacked adequate written description for the phrase "an anti-C5 antibody" because the specification disclosed only a single representative species of an anti-C5 antibody.
4. The ARP ultimately upheld the PTAB's written description rejection, but based on a different limitation – "treating a patient" – because the specification failed to "provide adequate disclosure to support treating any and all human and non-human patients having any and all diseases with 5G1.1." (*Id.* at page 38).

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