EAGLE ALERTS

Is it Sufficient to Claim an Antibody only by Describing its Antigen?

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Things may be brewing with respect to antibody inventions. Just how much description is sufficient? After losing in the Federal Circuit, Amgen has decided to ask the US Supreme Court to weigh in on a standard that could vastly influence the pharmaceutical and biotech industry.

The story relates to Repatha™, an LDL-lowering drug from Amgen whose active ingredient is a monoclonal antibody called *evolocumab*. The monoclonal antibody binds to PCSK9 protein, preventing it from destroying LDL receptor protein (LDL-R), a protein that removes LDL from the bloodstream.

Amgen sued Sanofi, who created its own PCSK9 antibody. Sanofi sued back, arguing that Amgen's patents were invalid for failing to comply with, among other things, the written description requirement.

The key issue is whether the language in Amgen's patents sufficiently described Amgen's antibody inventions when it never described the structure of the antibody. Instead, the claims described the structure of the antigen (to which the antibody binds) and the function of the antibody. In other words, Amgen's claims covered any antibody that bound to Amgen's antigen as long as it exhibited a particular activity (in this case, blocked activity of a particular protein). See example claim 1.

> Claim 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal blocks binding of PCSK9 to LDL-R.

Most notably, Amgen did not have a single claim identifying the antibody by its specific sequence.

Up until this point in time, it was reasonably well-established (based on several Federal Circuit cases) that Amgen's claim language was acceptable. In fact, the USPTO used the "newly characterized antigen test", which stated that a novel antibody satisfied the written description requirement as long as it fully described a novel antigen or target, provided that the methods used for generating the corresponding antibody were routine and conventional. Most importantly, no actual description of the antibody was needed.

With this latest decision, the Federal Circuit Court has rejected this standard and has ruled that actual description of the antibody itself is needed to satisfy the written description requirement, such as, for example, sequence listings.

This decision hugely impacts the pharmaceutical industry. The USPTO has already issued updated guidelines that are consistent with the Federal Circuit Court's decision. Due to the importance and potential impact of this case, there is a reasonable chance that the Supreme Court may actually decide to hear this case. As of now, a group of pharma companies including Bristol Myers Squibb and UCB Biopharma has submitted an Amicus Brief to the Supreme Court strongly arguing why the Federal Circuit's interpretation is overly restrictive, will hurt innovation and progress in the field, and should be overturned.

Interestingly, China has always had the stricter standard of what they call "sufficiency of disclosure" when it comes to antibodies. In China, applicants must provide specific examples of antibodies that they have actually made, with at least certain key regions described with sequence listings.

The specification should clearly describe the structures of example antibodies, such as by reciting nucleotide sequences or amino acid sequences. If there are no means to know or identify the structures, then the antibody's properties, biological functions and/or manufacturing methods may be used to define the antibodies. In China it would be very difficult to obtain granted claims on antibodies defined only by their functions or by the structure of their antigens.

Things may be actively changing in the US. We will keep you updated as this case develops! Stay tuned for more important updates on IP law.

Amgen v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017)
Petition for Writ of Certiorari
Amicus Brief – BMS Morphosys Bavarian Nordic UCB Biopharma

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