Benjamin Pelletier in BioProcess Online: 'Making Sense of Antibody Epitope Claims'

By Benjamin Pelletier | April 16, 2021

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The antibody therapeutics industry has mushroomed into a sector whose value is estimated to reach $138.6 billion by 2024. And this astounding economic growth has been accompanied by equally astonishing technological advancement. Obtaining certain types of patent rights to antibodies has become increasingly challenging in the United States. To comprehend this evolution, we must first take a careful look at what antibodies are, and then understand how they are claimed in a patent.

Antibodies and Patent Claims

An antibody is, at its core, a professional binding molecule, whose sole purpose is to bind to its epitope – the three-dimensional arrangement of molecules to which it is attracted under the laws of physics. Each peptide subunit of an antibody contains a stretch of amino acid residues that are highly variable from one antibody to the next (aptly named the “variable region”), which contains three short complementarity determining regions (CDRs) interspersed between four framework regions. The CDRs project out from the variable region to help form the unique peaks and valleys of the antibody’s binding surface, or paratope. The physicochemical characteristics (i.e., charge, hydrophobicity, etc.) of the amino acid residues in the CDRs and framework regions determine the unique attributes of the antibody’s paratope, which in turn governs which epitope that antibody will bind to, and how tightly it will do so: structure begets function.

Based on this structure/function relationship, antibody claims in a patent application fall along a spectrum, ranging from mostly structural limitations (what the antibody is) to mostly functional limitations (what the antibody does). On the far-left “structural” end of the spectrum, antibody claims recite a specific sequence of amino acids that makes up the antibody itself. The narrowest such claim would recite the entire amino acid sequence of each protein subunit of the antibody, from tip to tail (or N-terminus to C-terminus). Moving toward a more moderate position on the spectrum, an antibody claim might recite just the variable region sequence of the antibody, or a sequence that is at least 95% identical to the variable region sequence. This type of claim allows for a small handful of amino acid substitutions to be made in the variable region sequence, while still falling under the scope of the claim. Finally, nearer to the center of the structure/function spectrum is the antibody claim that recites just the CDR sequences of the antibody’s variable region(s).

As antibody claims slide further toward the far-right “functional” end of the spectrum, the structural elements of the antibody itself fall away, and the focus is on the epitope that the antibody binds to. For this reason, these “functional” claims are also referred to as epitope claims, and they are the ultimate weapon on the antibody exclusivity battlefield due to the broad scope of protection they provide. These claims allow the patentee to block competitors from making, using, or selling any antibody that binds to the same epitope, without having to specify the amino acid sequence of the antibody itself. This prevents a competitor from changing the amino acid sequence of its own antibody just enough to sidestep infringement of a structural feature, while still achieving the same

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functional effect. In other words, finding a slightly different antibody that still does the same thing.

But with great claim power comes great disclosure responsibility – in this case, in the form of a requirement to provide voluminous experimental data in the patent application, typically including crystal structures, alanine scanning results, binning experiments, and other work that fully describes the epitope and its interaction with the antibodies that the patentee has created. This represents a huge resource investment by the patentee, which is only undertaken when there is certainty that such enormous efforts will bear fruit.

Excerpted from *BioProcess Online*. The article was also published in sister publications *Outsourced Pharma* and *Pharmaceutical Online*. To read the full article, click here.

(Note: This is Part 1 in a series of articles by Pelletier.)

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