Benjamin Pelletier in BioProcess Online: ‘Patenting Antibodies: The 4 Tactics to use in 2021’

June 7, 2021 Benjamin Pelletier

PRACTICES Precision Medicine and Digital Health, Patent Prosecution and Counseling, Intellectual Property

In my first article, I reviewed the nuts and bolts of antibody epitope claims and summarized the evolution of the Federal Circuit’s current position on their validity under the written description and enablement requirements of 35 U.S.C. § 112. In this article, I provide some useful approaches that you and your antibody patent lawyer (here we call patent lawyers “practitioners”) can implement in order to improve your chances of obtaining valid antibody claims with functional attributes.

1. Show Your Work

In *Amgen v. Sanofi*, one major point of discussion was the amount of work that Amgen had put into its original antibody discovery campaign, in comparison to the amount of work that one of ordinary skill in the art would need to do to produce the full scope of the antibodies falling within the claim language. During oral arguments, Sanofi hammered on this topic, stating “the road map requires the same amount of work as the original work,” and “I can’t think of a better definition of undue experimentation than ‘more work than any scientist would even contemplate doing.’”1

In light of this, it’s important for practitioners to capture evidence of the amount of work that went into the applicant’s antibody discovery campaign in order to at least attempt to rebut this type of argument. If thousands of antibodies were screened for activity before settling on a handful of lead sequences that possess the desired functional properties, be sure to include this information in your patent application.

2. Introduce Some Structure, But Don’t Overdo It

Some antibody discovery techniques involve grouping antibody-producing cells into clonotypes based on observed similarities in the complementarity-determining region (CDR) sequences of the antibodies that those cells produce.

Excerpted from *BioProcess Online*. To read the full article, click here.