Insights: Perspectives

5 Takeaways How Do We Ensure Effective Protection of Antibodies?

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Written by **Yifan Mao**

KILPATRICK TOWNSEND

5 KEY TAKEAWAYS

How Do We Ensure Effective Protection of Antibodies?

As part of the Life Sciences Patent Network's *2018 NORTH AMERICA-FALL Conference*, Chemistry & Life Sciences Associate Yifan Mao led a roundtable discussion group on "How Do We Ensure Effective Protection of Antibodies?" Well attended by a diverse group of in-house counsels and private practitioners, the roundtable gave participants an opportunity to share knowledge and opinions, while yielding five key takeaways:

1. While the United States is tightening up the written description requirement for antibody claims, functional claiming to antibodies is still acceptable in other jurisdictions. Counsel should consider retaining support for different types of claiming language in the application so that the maximum protection can be obtained under the law in each jurisdiction.

2. The USPTO is increasingly requiring claiming antibodies by its six complementarity-determining regions (CDRs). Since CDRs can be defined by different ways, counsel should clearly describe the method(s) used to define the claimed CDRs.

3. Counsel may consider claiming CDRs with degenerate sequences to broaden the claim scope. Counsel can consider submitting data showing a structure-function correlation to support broader claim scope, for example, crystallography data demonstrating that certain positions in the antibody sequence can be varied without affecting the antibody-antigen interaction.

4. Despite of #3 above, counsel should work closely with the company's business and R&D group in determining the timing of filing antibody applications under the current legal climate. Whether to file a patent application when there are more variant data available or as soon as the lead antibody is identified is a patent decision, as well as a business decision.

5. Notwithstanding *Amgen v. Sanofi* (Fed. Cir. 2017), recent case law development indicates that when the point of invention is not the antibody itself, the structure information of the antibody is not required to be recited in the claims.

Related People

Yifan Mao

t 650.324.6311

ymao@ktslaw.com