Dear Sir or Madam,

Please find attached a topic submission for the Case Studies pilot program, relating to the 35 USC 112, written description requirements for patent applications claiming antibodies. If you have any issues with the PDF file or questions concerning the submission, please do not hesitate to contact me.

We would appreciate it if you could please acknowledge receipt of this submission via return email.

Respectfully submitted,

Electronic signature:

/Walter Wu/

Walter Wu, M.D.
Attorney at Law
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304-1018
Telephone: (650) 813-5659
Fax: (650) 494-0792
E-mail: WWu@mofo.com
MORRISON | FOERSTER

Title: Application of 112, Written Description in Applications Claiming Antibodies

Proposal for Study: There is significant variation among Examiners/Supervisory Patent Examiner Groups at the USPTO in application of the written description requirement to claims reciting antibodies defined by function, without structural limitations (i.e., amino acid sequences).

Explanation: Under the written description requirement, a patent specification must describe the invention sufficiently so that one of ordinary skill in the art would understand that the inventor possessed the subject matter claimed. *See* 35 USC 112(a). In recent opinions from the Federal Circuit, the court stated that one needs to show that one has truly invented the genus, i.e., that one has conceived and described sufficient representative species encompassing the breadth of the genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus. In AbbVie Deutschland GmbH v. Janssen Biotech, Inc. (Fed. Cir. 2014) ("AbbVie"), the claimed invention was a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen. AbbVie's patents disclosed a variety of amino acid sequences of the CDRs of its antibodies; however, the patents did not disclose structural features common to the members of the claimed genus.

In view of the recent case law such as AbbVie, some Examiners are only granting narrow claims directed to the amino acid sequences of the disclosed specifically antibodies and not allowing a broad, functionally defined antibody genus based on a functional property of those specific antibodies. Conversely, other Examiners are granting such broad claims.

The USPTO should study current application of 112, written description, and determine if there are significant variations which arise between Examiners/Supervisory Patent Examiner Groups at the USPTO. Discovery of such correlations could lead to (a) a better understanding of USPTO application of recent 112, written description case law as applied to antibodies, (b) identify whether additional training is needed and which groups could benefit from the training, and (c) ensure consistency across the hundreds of antibody applications.