IP Alert: Federal Circuit Discredits Special Disclosure Rule for Antibodies

Federal Circuit Discredits Special Disclosure Rule for Antibodies

By Sarah A. Kagan

For decades, patents claiming antibodies have enjoyed a charmed life. Rather than requiring a written description of the antibodies per se, the U.S. Patent and Trademark Office has allowed claims based on a written description of the antigen to which the antibodies bind. This leniency was perhaps based on the state of the art at some time in the past. It was considered routine to obtain an antibody specific for an antigen by inoculating an animal and collecting antibodies made by the animal. The animal was a black box; an innovator did not need to understand how the animal made the antibody or know the structure of the antibody.

Fast forward to the present, when antibodies are highly engineered and determining their structures is routine. Now, the reasons for the past leniency may no longer pertain.

As a result of past leniency, antibody patent claims were often broad and specifications may not have described making any antibodies at all. Without any disclosed antibodies, moreover, a patent applicant could not obtain narrower claims based on actual properties of real antibodies.

The U.S. Court of Appeals for the Federal Circuit recently considered a jury instruction based on the past Patent and Trademark Office practice and found it improper, remanding the case to the district court. Amgen Inc. v. Sanofi (No. 17-1480) (decided October 5, 2017). While the outcome of the dispute between the litigants is unknown, subject to the remand, the legal issue of written description of antibodies is decided.

The Federal Circuit traced the leniency back to guidelines published by the Patent and Trademark Office in 2000, and revised in 2008. The guidelines state that "functional characteristics when coupled with a known or disclosed correlation between function and structure" may satisfy the written description requirement of 35 U.S.C. § 112. See also M.P.E.P. § 2163(II)(3)(a). The court in Enzo Biochem, Inc. v. Gen-Probe Inc., explained the leniency as applied to antibodies by pointing to the "well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology is well developed and mature." 323 F. 3d 956, 960 (Fed. Cir. 2002).

The Federal Circuit previously declined to apply the Patent and Trademark Office guideline, pointing to the absence of a novel antigen, the non-routine nature of making the claimed antibodies, and the lack of evidence in support of the patentee's contentions of the state of the art. Centocor Ortho Biotech, Inc. v. Abbott Laboratories, 636 F. 3d 1341 (Fed. Cir. 2011). But the court did not thoroughly discredit the guideline as it does in the recent Amgen Inc. v. Sanofi opinion.

The Amgen panel found the following problems with the jury instructions (and implicitly with the Patent and Trademark Office guidelines): (a) they improperly substitute an enablement analysis for a written description analysis; (b) no evidence connects an antigen's structure with corresponding antibodies' structure; and (c) they flaunt the statutory requirement for a written description of the invention (antibodies) and substitute a description of the antigen.

The Amgen holding puts the onus squarely on the patent applicant to provide a written description of the claimed antibodies per se in its specification. The written description may, for example, be based on sequencing of one or more antibodies, or based on one or more deposited hybridomas. [1] If an applicant can show that disclosed antibodies share structural features that correlate with their binding specificity, then generic claims may still be available, albeit narrower than previously possible. If no such showing can be made, then an applicant is likely in the future to obtain

narrower claims than previously possible. Such claims may be limited to particular sequenced antibodies or deposited antibodies. Applicants may, however, secure claims of some more modest breadth based on complementarity determining regions, stability modifications, detectability modifications, half-life in the body modifications, or complement recruitment modifications.

As the Amgen holding heralds the end of special treatment for antibody claims, it simultaneously brings this subject matter back in line with all other technologies. The U.S. patent system has generally run on a technologically neutral basis, generally eschewing special exceptions to patentability. Additionally, under the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, the United States is obligated to make patent rights available without discrimination for technological type. The downfall of the leniency to antibodies is a gain for the integrity of the overall system.

Click here to download the decision in Amgen v. Sanofi.

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[1] The Amgen panel did not address the issue of deposited hybridomas acting as a written description.

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