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Federal Circuit Friday

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In *Amgen v. Sanofi* (October 5), the Federal Circuit effectively killed the so-called "antibody exception" to the written description requirement.

The case involved a patent on Amgen's Repatha®, an antibody drug product for reducing levels of low-density lipoprotein ("LDL" -- *i.e.,* bad cholesterol). The patent claimed a genus of antibodies that (i) bind to specific amino acid residues on an enzyme called PCSK9, and (ii) block PCSK9 from binding to low-density lipoprotein receptors ("LDL-Rs"). Preventing PCSK9 from binding the LDL-Rs allows those receptors to remove LDLs from the blood stream.

Pursuant to the "antibody exception," Amgen argued that a description of the *antigen*, PCSK9, sufficiently described the claimed *antibodies* because of an established correlation between structure of an antibody and its function of binding a specific antigen. The district court agreed and instructed the jury that as long as "production of antibodies against . . . an antigen was conventional or routine," then the "disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties" satisfies the written description requirement for the antibodies.

The Federal Circuit held the jury instruction erroneous because it "effectively permitted the jury to dispense with the required finding of a 'written description of the invention.'" The court framed the issue as whether it could take judicial notice that "knowledge of the chemical structure of an antigen gives the required kind of structure-identifying information about the corresponding antibodies." Because that correlation was "hotly disputed" it would not take judicial notice and hence would not impose a "legally-required inference" that description of an antigen necessarily sufficiently describes antibodies that bind thereto.

The Federal Circuit did not need to hold so broadly. For example, it could have focused on the substantive disconnect between the jury instruction and the claims – the jury instructions merely addressed antibodies that bound the antigen, not antibodies that bound to specific amino acid residues and that block binding of PCSK9 to LDL receptors, thereby allowing the jury to find written description for the *specific subset* of claimed antibodies based on an ability to generate the *broader class* of antibodies that merely recognize or bind to the antigen.

But the Federal Circuit decided to attack the underlying proposition that description of an antigen necessarily satisfies written description for *any* corresponding antibodies – *e.g.,* "the 'newly characterized antigen' test flouts basic legal principles of the written description requirement" by "allow[ing] patentees to claim antibodies by describing something that is not the invention, i.e., the antigen."

Nevertheless, the Federal Circuit did not close the door entirely. Refusing to impose a legal inference of structure-function correlation is not the same as precluding fact-finding on the issue. Thus, in a particular case one *might* be able to show a common structural feature (*i.e.,* written description) of a genus of antibodies inferentially via a correlation between functional characteristics of the antibodies and the well-characterized structure of their antigen. The ability to do so seems to me inversely related to the specificity of functional limitations, with the basic function of being able to bind an antigen being the easiest-to-prove scenario and the addition of other requirements (*e.g.,* binding to specific residues or blocking biological function) making proof of the correlation more difficult.