IAM

US Supreme Court to review a false dichotomy in Amgen v Sanofi

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The US Supreme Court recently granted certiorari in *Amgen Inc v Sanofi.* The court has thus undertaken to answer the question:

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> *Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to “make and use” the claimed invention, 35 USC §112, or whether it must instead enable those skilled in the art “to reach the full scope of claimed embodiments” without undue experimentation - ie, to cumulatively identify and make all or nearly all embodiments of the invention without substantial “time and effort".*
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> ”

In its petition for certiorari, Amgen painted a picture of a Federal Circuit run amok, noting that it had overturned two jury decisions to hold that its claims were not enabled, and alleging that the Federal Circuit “invalidates genus claims if it believes “‘substantial time and effort’ would be required *to reach the full scope* of claimed embodiments” - ie, to identify and make all or nearly all possible embodiments of the invention”.

At issue in *Amgen* are claims of two US patents reciting antibodies that have two functions: binding to one or more of sixteen specified amino acid residues of a particular protein and blocking that particular protein from binding to a receptor. Both patents share a common specification which discloses the amino-acid sequence of 26 antibodies and depicts the three-dimensional structure of two of them.

In ruling that the claims were not enabled as a matter of law, the Federal Circuit agreed with the district court’s finding that the specification did not enable the full scope of these “double-function” claims without undue experimentation. Indeed, the Federal Circuit held that the binding limitation was itself enough to require undue experimentation.

While acknowledging that the parties disputed the exact number of embodiments falling within the claims, the Federal Circuit panel noted that “we are not concerned simply with the number of embodiments but also with their *functional* breadth. Regardless of the exact number of embodiments, it is clear that the claims are far broader in functional diversity than the disclosed examples”. The panel noted that “[t]here are three claimed residues to which not one disclosed example binds… And although the claims include antibodies that bind up to sixteen residues, none of Amgen’s examples binds more than nine”.

The dichotomy presented by Amgen in its petition for certiorari is thus premised on its allegation that the Federal Circuit has created a new enablement test for genus claims; a test that goes beyond the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention.

However, this dichotomy is a false one.

If §112 requires a patentee to teach those skilled in the art how to "make and use" the "claimed invention", one must first define what the "claimed invention" is. If the "claimed invention" encompasses a broad functional genus, then what must the patent teach to those skilled in the art if not how to "make and use" that broad functional genus?

The Federal Circuit did not hold that the claims were not enabled because of the "cumulative" effort required to identify and make all or nearly all embodiments of the claimed invention. In its decision, the Federal Circuit explained that "[w]e do not hold that the effort required to exhaust a genus is dispositive. It is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance. The functional limitations here are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but "substantial time and effort" would be required to reach the full scope of claimed embodiments".

Conspicuously absent from Amgen's petition was any discussion of the breadth of the functional language of its claims, or the Federal Circuit's note that "although the claims include antibodies that bind up to sixteen residues, none of Amgen's examples binds more than nine".

Amgen and its amici, such as the Association of University Technology Managers (AUTM), rightfully point out that genus claims are important for protecting early-stage discoveries, in particular in the life sciences. A rule that would require a patentee to enable those skilled in the art "to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort" would impose an undue burden on patentees seeking genus claims.

But Amgen's claims were not doomed by imposition of such an elevated enablement standard by the Federal Circuit. If a claim recites antibodies that bind any one of sixteen amino acid residues, then the patent needs to teach a person of skill in the art how to make and use antibodies that bind any one of those sixteen residues. And if a claim recites antibodies that bind up to sixteen residues, then the patent needs to teach a person of skill in the art how to make and use antibodies that bind up to the sixteen residues.

That much should not be controversial to anyone prosecuting or defending genus claims.

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