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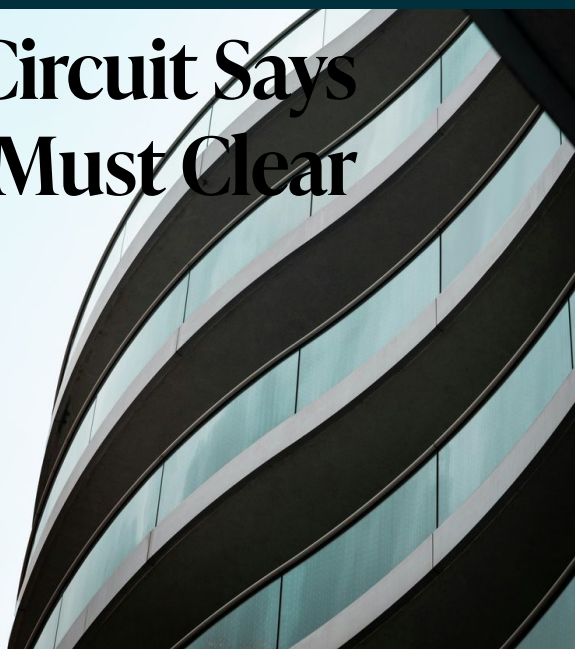
Axinn IP Update: Federal Circuit Says Functional Patent Claims Must Clear "High Hurdles"



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Axinn Update

In a precedential decision that has important implications for patents with functional claim language, the Federal Circuit ruled on February 11, 2021, that claims directed towards an antibody's binding function require undue experimentation to practice and are invalid for lack of enablement under Section 112. *Amgen Inc. v. Sanofi, Aventisub LLC*, No. 20-1074, 2021 WL 501114 (Fed. Cir. Feb. 11, 2021). Patents covering antibodies or biologic drugs may now have to clear a high bar to show that any functional patent claims are enabled.

In this case, Amgen asserted patent claims directed to antibodies used to treat high cholesterol. The claims encompassed any antibody that bound to certain amino acids of the PCSK9 protein. Despite a jury verdict finding the claims valid and infringed, the District Court judge determined that the claims were invalid under Section 112 for lack of enablement. *Amgen Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 494620 (D. Del. Feb. 8, 2019).

In the patents at issue, the specifications identified 26 antibodies that fell within the claims, but fully described the attributes of only two. The parties disputed how many antibodies fell within the full scope of the claims, but Amgen admitted it was at least around 400. Amgen argued that the specifications enabled the claims because they taught routine methods to generate and screen for the claimed antibodies. Sanofi countered that enabling the full scope of the claims would unduly require screening millions of additional candidate antibodies. The District Court

agreed with Sanofi, and held that enabling the full scope of the claims would require unduly screening hundreds or thousands of additional candidates.

In affirming the District Court's decision, the Federal Circuit noted that it previously found undue experimentation where a "large number of possible candidates [fall] within the scope of the claims and the specification [has a] corresponding lack of structural guidance." *Amgen Inc.*, 2021 WL 501114, at *4. The Court went on to say that functional limitations in patent claims "pose high hurdles in fulfilling the enablement requirement." In particular, the Court noted that "[t]he binding limitation is itself enough here to require undue experimentation." *Id.* at *5.

In drafting functional genus claims for biologic products, patentees should be aware that functional claims must provide guidance on the corresponding structures in the specification. Simply including techniques to screen for claimed molecules will likely be found insufficient, unless the specification adequately describes the corresponding structures that result in the claimed functions. Likewise, biosimilar developers should consider that patents claiming broad genera based on functional attributes may not be valid if they do not adequately tie the claimed functions to any specific structural attributes.

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