SPECIAL EDITION – SUPREME COURT DECISION

***Amgen Inc. v. Sanofi*, No. 21-757 (May 18, 2023) (9-0, Opinion by Justice Gorsuch); U.S. Patent Nos. 8,829,165; 8,859,741**

Key point(s):

- Claims that cover a vast class that is defined by its function while only being enabled for a small number of species of that class via a method requiring elaborate experimentation do not meet the enablement requirement of §112 of the Patent Act.
- For enablement, a specification need not describe how to make and use every single embodiment within a claimed class, but should disclose some general quality running through the class that gives it a "peculiar fitness for the particular purpose."
- A specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art.

Facts/Background: Amgen owns the '165 and '741 patents directed to antibodies that block the PCSK9 protein from impairing the body's mechanism for removing LDL cholesterol from the bloodstream. Amgen sued Sanofi for infringement. Sanofi argued that Amgen's patents were invalid for lack of enablement because they claimed an entire genus of antibodies potentially encompassing millions of amino acid sequences while only having identified the amino acid sequences of 26 antibodies in the patents, thus requiring undue experimentation. The district court and the Federal Circuit held the claims invalid for lack of enablement. Amgen appealed.

Holding: Affirmed. The Court held that for enablement, if an inventor claims a lot but only enables a little, the public does not receive its benefit of the patent bargain. In the context of Amgen's patents, the Court agreed with Sanofi that the enablement provided by the specification did not meet the enablement requirement that a description include "such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the [invention]." 35 U. S. C. §112(a). Amgen claimed an entire class of antibodies defined by their function (without any structure), and the Court analogized such functional use format to that of the claims of the Court's precedents in *Morse*, *Incandescent Lamp*, and *Holland Furniture*. Amgen's patents, according to the Court, amounted to research assignments that would require painstaking trial and error, which does not constitute proper enablement. Amgen argued that the lower courts conflated the time and effort required to create every embodiment of the claim with the question of enablement and thus was applying a heightened enablement standard. The Court disagreed, emphasizing that there is in fact one statutory enablement standard, and the Federal Circuit correctly recognized that the more a party claims for itself, the more it must enable, which is consistent with Congress's directive and the Court's precedents. The Court reiterated that proper enablement should provide a person skilled in the art with more than advice to engage in trial and error. The claims in this case were therefore invalid for lack of enablement.