

The Supreme Court released an opinion in *Amgen v. Sanofi* on May 18, 2023. The opinion addresses the law of patent enablement and highlights the requirement that a patent's specification must describe in full, clear, concise, and exact terms sufficient information to practice the **full scope** of the claimed invention. The case appeals a decision of the District Court of Delaware granting Judgment as a Matter of Law (JMOL) of lack of enablement, which the Federal Circuit affirmed on appeal. The Supreme Court affirmed, holding that the full scope of Amgen's claims were neither supported by the specification's 26 exemplary antibodies nor was enough direction provided beyond a simple trial-and-error method for finding functional antibodies.

Codified in 35 U.S.C. § 112(a), the law of enablement ensures that patent specifications provide sufficient information for a skilled artisan to make and use the claimed invention without undue experimentation. To invalidate a claim for lack of enablement, a challenger must demonstrate by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without undue experimentation. After the patent challenger has put forth evidence that some degree of experimentation is required to practice the claims, the *Wands* factors provided below are used to help determine whether that amount of experimentation is "undue" or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out.

1. The quantity of experimentation necessary;
2. The amount of direction or guidance presented;
3. The presence or absence of working examples;
4. The nature of the invention;
5. The state of the prior art;
6. The relative skill of those in the art;
7. The predictability or unpredictability of the art; and
8. The breadth of the claims.

At the first stage of appeal, the Federal Circuit held that the claims in question were not enabled due to the broad functional limitations, lack of guidance, and the need for undue experimentation to create antibodies within the claims' scope. The Federal Circuit found that the claims were defined, not by structure, but by broad functional limitations, which "pose high hurdles in fulfilling the enablement requirement." The Federal Circuit also found that the disclosed antibody examples and experimental guidance only covered a small portion of the functional diversity within the claims. Regarding the *Wands* factors, the field of antibody technology was deemed unpredictable, and there was insufficient evidence to show that the full scope of the claims could be predictably generated.

The Supreme Court upheld the Federal Circuit's decision, finding that Amgen failed to enable any person ordinarily skilled in the art to make and use the invention as defined by the relevant claims. Amgen's claims covered a class of antibodies defined by their function, but the company failed to enable the vast number of additional antibodies that fell within that class beyond the 26 examples specifically described by their amino acid

sequences. Further, Amgen’s proposed methods for generating additional antibodies amounted to trial-and-error processes of discovery, which failed to satisfy the enablement requirement. In rendering its decision, the Court emphasized the importance of the patent “bargain,” which grants inventors limited-term protection in exchange for disclosing their inventions for the benefit of the public. The Court applied cases addressing enablement from long ago, such as *O’Reilly v. Morse*, *The Incandescent Lamp Patent*, and *Holland Furniture Co. v. Perkins Glue Co.* to reinforce the simple statutory requirement that if an entire class of subject matter is claimed, the specification must enable a person skilled in the art to make and use **the entire class**. Providing guidance as to how an inventor might meet such a requirement, the Court stated that examples in the specification may suffice if the specification also discloses “some general quality . . . running through” the class that gives it “a peculiar fitness for the particular purpose.”

In the end, the Court emphasized the significance of the statutory enablement mandate and its role in maintaining the balance sought by Congress since 1790. Applicants seeking to claim entire classes of processes, machines, manufactures, or compositions of matter should take extra care to provide sufficient support when such claims can be characterized by their functional limitations.



Samuel Raque | Associate Attorney