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Supreme Court Rejects Antibody Drug Patent, Clarifies Patent "Enablement" Requirement

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Decided May 18. 2023 ***Amgen Inc. et al. v. Sanofi et al.*, No. 21-757 Today, the Supreme Court unanimously held that the Patent Act's enablement requirement is satisfied only when a patent's specification allows persons skilled in the art to make and use the full scope of the invention without more than a "reasonable" amount of experimentation under the circumstances. Background:** Amgen and Sanofi produce antibody medications to treat high LDL cholesterol. In 2011, each party obtained a patent covering the specific antibody used in its drugs. The antibodies in the drugs work by preventing a protein from interfering with the body's natural regulation of LDL cholesterol. In 2014, Amgen obtained two patents that covered not only 26 specifically listed antibodies by their amino acid sequences, but also the "entire genus" of antibodies that performs this function—a claim that arguably covers millions of antibodies. Amgen then sued Sanofi for patent infringement. Sanofi argued that the relevant claims were invalid because they did not satisfy the enablement requirement of the Patent Act, which requires a patent specification to describe "the manner and process of making and using" the invention in such a way "as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112(a). According to Sanofi, the claims for the antibodies beyond the 26 specifically listed essentially required scientists to engage in a trial-and-error process of discovery. After lengthy proceedings, the district court agreed, and the Federal Circuit affirmed. **Issue:** Where a patent claims an entire class of processes, machines, manufactures, or compositions of matter, must the patent specification enable a person skilled in the art to make and use the entire class? **Court's Holding:** Yes. To satisfy the Patent Act's enablement requirement, a patent's specification must enable the full scope of the invention as defined by the patent's claims, subject to a reasonable amount of adaptation or experimentation.

> *"[T]he specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."*

Justice Gorsuch, writing for the Court **What It Means:**

- The Patent Act's enablement requirement is not satisfied when a patent claims a broad class but its specification requires undue experimentation or trial-and-error discovery to make and use the entire class.
- The Court stopped short of requiring that a patent specification need always describe with particularity how to make and use every embodiment within a claimed class. In some cases, it may be sufficient to provide an example that discloses a general quality running through the class.
- The Court stated that a specification is not necessarily inadequate simply because it involves some measure of adaptation or testing, but such experimentation must be reasonable. Reasonableness will depend on the nature of the invention and the underlying art, meaning that courts will likely make this determination on a case-by-case basis.
- Overall, the decision reinforces the enablement requirement as a defense to patent-

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infringement claims, and will likely incentivize more detailed specifications in patent applications.

The Court's opinion is available here. Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Supreme Court. Please feel free to contact the following practice leaders:

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