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Supreme Court Hears Oral Argument on Legal Standard for Patent Enablement

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On March 27, 2023, the US Supreme Court heard oral argument in *Amgen Inc. v. Sanofi*, a case that asks it to clarify how much information a patent applicant must include in its patent application to satisfy the statutory requirement under 35 USC § 112 that a patent must enable those skilled in the art to "make and use" the claimed invention.

Amgen asked the Supreme Court to overturn lower court precedents holding that an enabling disclosure must allow those skilled in the art to "reach" the full scope of claimed embodiments – that is, to cumulatively identify and make **all or nearly all** variations of the invention – without substantial time and effort. This "undue experimentation" standard has resulted in the invalidation of many patents that contain genus claims that cover many species (especially in the context of antibody patents) and was the rationale for invalidating Amgen's patents in the lower courts.

The case attracted significant attention, with several "friend of the court" briefs filed on each side from industry groups, large pharmaceutical companies and Nobel laureates. Many are watching the case to determine whether the Supreme Court appears likely to change the long-standing "full scope" standard to the seemingly more permissive "make and use" standard that Amgen argued for in its briefing and in the lower courts.

At oral argument, however, it appeared that the parties all agreed that § 112 law required patentees to enable the "full scope" of the claims. Because of this, several justices questioned whether the case was a proper vehicle for Supreme Court review. Advocates for both sides, and the government, suggested any opinion that might issue from the Supreme Court should "clarify" the law around enablement. Based on the questioning, it appears unlikely that the Supreme Court's decision will announce a radical shift in enablement law, as some had predicted.

Although all parties apparently agreed that the law should require a patent applicant to enable the "full scope" of patent claims, they disagreed strongly over what that means. According to Amgen, it was enough in this case to disclose 26 antibodies covered by the claims, along with a description of the trial-and-error process that Amgen scientists followed as a "road map," notwithstanding evidence that millions of potential antibodies are covered by its patent. By contrast, the respondents and the government insisted that under existing law, a genus patent claim is not enabled unless every species covered by the claim is described in the patent, **or** the patent describes the genus by sufficient structural details that are shared by every species in the genus – in keeping with long-standing precedent from the Federal Circuit.

Amgen's take on the "full scope" standard proposed a more relaxed analysis that considers whether a patent "reasonably" enables a skilled artisan to make and use the embodiments that fall within the scope of its claims. Under this interpretation, according to Amgen, a patent would have an enabling disclosure so long as it provides enough disclosure for those skilled in the art to make and use all of the embodiments covered by the claimed invention that "matter" (that is, without regard to "outlier" embodiments). In practice, this means a patent claim would be enabled if the patent included enough detail to make and use at least **some** embodiments of the claimed invention, **unless** an accused infringer could identify a particular undisclosed embodiment that the patent did not teach how to make and use and show why that embodiment "mattered" for achieving the purpose of the invention. Amgen urged that its proposed standard is necessary to preserve incentives for drug companies to invest billions of dollars in new drug development because it would allow discoveries to be broadly protected with patent claims that are difficult to design around with minor modifications.

Sanofi, Regeneron and the government argued that existing law appropriately requires patent applicants who "claim a lot, to enable a lot," and that the Supreme Court should not dispense with the "full scope" and "undue experimentation" tests because they are informative and useful. The respondents and government disagreed that genus claim patent protection, at least when it takes the form of broad functional claims like Amgen's, is essential to the pharmaceutical industry and asserted that broad genus claims inhibit (rather than advance)

progress in the life sciences by preventing healthy competition that can result in the discovery of drugs that are more effective than the first drug to obtain a patent.

The Supreme Court will likely decide this appeal within the next few months.

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