Supreme Court poised to alter patentability of pharmaceutical, life-science innovations

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The U.S. Supreme Court has granted certiorari in *Amgen v. Sanofi*, (Appeal No. 2021-0757 (Fed. Cir. 2022)), a case that challenges the current interpretation of the requirements applicable to patent claims directed to antibodies, small molecules, and other pharmaceutical agents. The question presented on appeal is:

> Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation — i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort."

This question relates to one of the statutory requirements for patentability. Specifically, in order to obtain a valid and enforceable patent, the patent application must include a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms 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)).

The so-called "enablement" requirement has long been revered as the mechanism of the patent statute responsible for maintaining the balance between affording the patentee a limited monopoly over his invention (on the one hand) and providing the public with a meaningful disclosure to promote future research and development (on the other). Because striking this balance speaks to the heart of the patent law constitutional mandate "to promote the progress of science and useful arts," it has been subject to endless policy debate and common-law re-interpretation over the past decade. (U.S. Const. Art I. Sec. 8. cl. 8).

For instance, the U.S. Court of Appeals for the Federal Circuit in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.* (Fed. Cir. 2019), found a patent on a genus of therapeutic molecules invalid under § 112 where the patent described a few example compounds, but "billions and billions of compounds literally meet the structural limitations of the claim."

Other cases, like *Enzo Life Scis. Inc. v. Roche Molecular Sys Inc.* (Fed. Cir. 2019) and *Wyeth & Cordis Corp. v. Abbott Labs.* (Fed. Cir. 2013), similarly compared the number of possible embodiments within a genus claim to the number of examples provided in the specification.

The present dispute between Amgen and Sanofi began in 2014 in Delaware district court. Amgen filed suit against Sanofi and Regeneron arguing that the defendants' PCSK9 cholesterol drug Praluent (alirocumab) infringed Amgen's patent on the class of antibodies used in the active ingredient. Amgen's own drug, Repatha, is FDA approved for the same use.

Amgen v. Sanofi presents the justices with an opportunity to dramatically redefine the stringency with which 35 U.S.C. § 112(a) ties the scope of patent protection to the detail and comprehensiveness of the written description.

In defending the validity of its patent, Amgen presented evidence regarding the kinds of routine techniques and level of knowledge that defined the current state of the art in the relevant field. A jury upheld Amgen's patent as enabled, finding that one of ordinary skill in the art could practice the claims of the patent (including identifying and testing different antibodies within the claimed class) without *undue* experimentation.

The judge overturned the jury verdict, finding that the patent failed to satisfy the enablement requirement as a matter of law. The Federal Circuit agreed, finding that the disparity between the breadth of the claims (the size of the class of antibodies) and the written description (a largely functional description with a few structural examples) was statutorily inadequate. Amgen challenged that holding in a petition for certiorari, and the Supreme Court granted review of the Federal Circuit's enablement holding.

The Federal Circuit's trend of increasing the enablement burden on patentees and narrowing the scope of protection afforded by those

patents has been the subject of controversy for some time. (*See e.g.*, Karshtedt, Dmitry and Lemley, Mark A. and Seymore, Sean B., The Death of the Genus Claim, 35 Harv. J.L. & Tech. 1 (Fall 2021); Bloomberg Law, INSIGHT: "The Scope of a Sextillion — How Courts Misapply Law of Enablement to Life Sciences" (May 1, 2020)). Pharmaceutical giants and scrappy start-up innovators alike have been struggling with the perceived imbalance of incentives created by overly onerous patentability requirements in the "unpredictable" arts like biology and chemistry.

What the high court makes of this opportunity to clarify the standard will shape patent strategy, innovation strategy, and research investment for years to come.

Some of the controversy and migration in the law has been policy-based, some merely a reflection of the ever-changing state of the art. As science evolves, so does the scientific community's concept of what constitutes "undue experimentation." The kinds of screening tests that used to take months can now be performed with automation in a matter of hours. Computer-assisted molecular modeling can identify drug or antibody candidates for a particular application without the kind of blind trial-and-error that once demanded hundreds of mice and man-hours.

The conclusion that follows (for some) is that patentees who discover a new and useful class of molecules need not describe every variation or member of the class in order to claim the entire thing. Indeed, it is often physically impossible (and arguably unnecessary) to describe on paper all the billions of molecules in a class with any structural specificity. If any skilled artisan could use conventional techniques to "find" various molecules within the class based on a functional description, why should it matter that the patentee only provided one or two structural examples?

It matters (for others) because a patent is a monopoly. It is a legal right to exclude others from making or using any of the molecules within the claimed class — even for many research purposes. Patent monopolies thus funnel money to the first explorer in an area, at the expense of the follow-on research that often produces the better consumer product. Why should a patentee be able to claim exclusive ownership over *all* of the molecules in a class of potentially billions when the patentee has only described a few, leaving it to others to "find" the rest?

Amgen v. Sanofi presents the justices with an opportunity to dramatically redefine the stringency with which 35 U.S.C. § 112(a) ties the scope of patent protection to the detail and comprehensiveness of the written description.

If, as Amgen argues, enablement is a factual inquiry, then it should change as the conventions of the applicable science change, requiring less disclosure as the state of the art advances. If, as Sanofi, the U.S. Solicitor General, and the Federal Circuit maintain, it is a primarily legal inquiry, then the language of the statute and the court's interpretation of the requirement for specificity control. What the high court makes of this opportunity to clarify the standard will shape patent strategy, innovation strategy, and research investment for years to come.

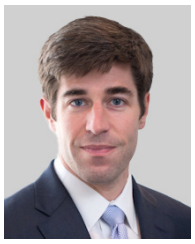
If the Court endorses the current trend of increasing the burden and narrowing the reward for patents, it may make patents less valuable, and make it harder for innovators to recoup (and therefore justify) investments in research and development. It will also threaten to invalidate thousands of patents that are currently in force, disrupting the financial status quo.

On the other hand, if the Court reverses the trend, making patents easier to defend and broader in their reach, it may curtail competition and discourage follow-on innovation in exploding fields like antibody and small-molecule therapy.

The Supreme Court is scheduled to hold oral argument this spring.

The writers are regular, joint contributing columnists on patent law for Reuters Legal News and Westlaw Today.

About the authors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