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Q&A: life sciences expert Irena Royzman on the patent-enablement dilemma before the Supreme Court

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The U.S. Supreme Court on March 27 heard oral argument over the patent-enablement requirement embodied in Section 112(a) of the Patent Act, 35 U.S.C.A. § 112(a).

Amgen Inc. brought the issue to the justices in November 2021, claiming two of its patents covering cholesterol-lowering drugs were unfairly invalidated.

The high court asked for the U.S. government's advice, but when the solicitor general advised against reviewing the issue, the Supreme Court decided to grant certiorari anyway in *Amgen Inc. v. Sanofi*, 143 S. Ct. 399 (2022).

Since that decision, a slew of pharmaceutical and biotech companies have come forward in support of or rejecting Amgen's position.

The enablement requirement requires that the patent enable any person skilled in the art to make and use the claimed invention. It is one of the pillars of the U.S. patent system.

But many patent attorneys, particularly those working in the life sciences, say the dilemma is far too complex for the justices to resolve with a simple rule or threshold.

Westlaw Today interviewed Kramer Levin head of life sciences Irena Royzman to provide some insight into the complex questions the Supreme Court is set to answer.

Westlaw Today: First of all, how did a dispute over the "Repatha patents" come about?

Irena Royzman: It is interesting you say "Repatha patents." The patents before the court encompass Amgen's Repatha, an antibody to the naturally occurring therapeutic target, PCSK9, but they are not Amgen's patent to Repatha. The Amgen patents before the court encompass millions of other antibodies to PCSK9, antibodies that Amgen did not make or discover, antibodies that others independently discovered, such as Regeneron/Sanofi, and millions of antibodies that may be independently discovered by others in the future.

Amgen first obtained a patent to its Repatha antibody, disclosing its amino acid sequence. But that antibody is completely different from Regeneron/Sanofi's PCSK9 antibody. The antibodies do not resemble each other. For that reason, Amgen's Repatha patent is not infringed and Amgen did not assert it against Regeneron/Sanofi or anyone else.

Pfizer also independently developed a PCSK9 antibody. Pfizer's antibody just did not succeed in the clinic. Pfizer's antibody also is different from Repatha and does not infringe Amgen's Repatha patent.

So years later, Amgen obtained two patents that broadly claim antibodies by their function of binding to and blocking the therapeutic target PCSK9. The claims are purely functional and do not provide any structure or amino acid sequence of the claimed genus of antibodies. They broadly extend to antibodies that Amgen did not describe or teach how to make. As a result of jettisoning any structure or sequence, these functional genus claims encompass not only Regeneron/Sanofi's antibody and Pfizer's but any of the millions of antibodies that have the function of binding and blocking PCSK9. As soon as Amgen obtained these patents, it sued Regeneron/Sanofi for patent infringement in October 2014, more than eight years ago. It is these patents that were invalidated for lack of enablement and are now before the Supreme Court.

WT: What exactly is the patent-enablement requirement and what are its policy objectives?

IR: The enablement requirement requires that the patent enable any person skilled in the art to make and use the claimed invention. It is one of the pillars of the U.S. patent system. The bargain on which the U.S. patent system is premised is that inventors obtain a limited monopoly in return for a description of the invention and a teaching of how to make and use it. The broader the claimed invention, the broader that teaching of how to make and use it must be. The teaching must allow the public to make and use the full scope of the claimed invention once the patents expire. That is why many consider broad functional claims to be contrary to the basic bargain of our patent system. They monopolize vast subject matter without providing sufficient disclosure to allow one to make and use that vast subject matter once the patents expire.

WT: Many have called the Supreme Court's decision to take up the dispute a "surprise move" given the solicitor general's recommendation to reject Amgen's certiorari petition. In what

way does this litigation history reflect the views of the U.S. Patent and Trademark Office and the U.S. Court of Appeals for the Federal Circuit?

IR: The litigation history reflects the views of the Patent Office, United States and the U.S. Court of Appeals for the Federal Circuit well. There were two trials and two appeals. After the first trial, Regeneron/Sanofi appealed the exclusion of Amgen's failed attempts to make certain antibodies within the scope of the claims and also the use of known antibody techniques to identify antibodies that bind and block a therapeutic target of interest to satisfy the requirement for written description without actually describing what antibodies bind to the therapeutic target.

The Federal Circuit ordered a new trial on written description and enablement. It explained that there was no antibody exception to the written description requirement and that known techniques and a known target did not suffice as a written description for broad functional antibody claims. The Federal Circuit also held that later trial-and-error search for antibodies within a claimed genus could be used as evidence of non-enablement.

The Patent Office promptly revised its guidance for antibody claims based on this decision, repudiating any antibody exception to the written description requirement and requiring sufficient disclosure of a claimed genus of antibodies.

At the second trial, the jury found two of Amgen's claims invalid but upheld three of the claims. The district court found the claims invalid for non-enablement as a matter of law. The district court held that the functional antibody claims were vast, the guidance limited and the art unpredictable. The Federal Circuit affirmed based on the detailed factual inquiry required by its *Wands* factors [from *In re Wands*, 858 F. 2d 731 (Fed. Cir. 1988)]. The Federal Circuit emphasized that the claims were vast, that Amgen did not provide guidance as to how to make and use the diversity of antibodies within the scope of the claims, and that undue trial-and-error experimentation would have been required to enable the claims.

The Patent Office and Biden administration urge the Supreme Court to affirm the Federal Circuit and maintain the status quo, without lowering the standard for enablement or creating an antibody exception to the enablement requirement.

WT: The pharmaceutical and biotech organizations that have weighed in on the dispute stress the importance of broad functional genus claims, with some saying such claims should not be patentable. Others say many industries depend on the protection of functional genus claims. What are some of the advantages and disadvantages to patenting functional genus claims?

IR: Functional genus claims allow patents owners to monopolize a therapeutic target without any limitation based on what they actually discovered and teach the public to make and use. They lay claim to the future work and discoveries of other scientists. For over a century, the Supreme Court has found such claims to be problematic, explaining that such claims extend the patent monopoly well beyond the discovery actually made and stifle rather than promote innovation. Broad functional genus claims keep other innovators out of the same therapeutic area or require them to pay a toll for discoveries that they made independently. Amgen and its supporters argue that functional antibody claims are necessary for innovators to invest in research and development and protect their investment. But the tech industry and some of the leading biotech and pharmaceutical innovators that invest billions in biopharmaceutical research in development, including Genentech, Bayer, AstraZeneca, Gilead Sciences and Johnson & Johnson, disagree.

The Biden administration emphasized how pernicious functional genus claims are.

The reality is that function provides no information about the structure of an antibody. That was explained to the Supreme Court in an amicus by Sir Gregory Paul Winter, a Nobel Laureate, and other antibody experts. The hard work of discovering the millions of antibodies with the claimed function is left to trial-and-error experimentation of others without any meaningful guidance. The public is left with what it had without the patents, known techniques for making antibodies and a known natural therapeutic target, PCSK9.

WT: Can a rule allowing broad functional genus comport with the patent-enablement requirement, and is every patent-enablement question fact specific?

IR: The current law allows for broad functional claims as long as they are enabled. But patent enablement is highly fact specific. The art has to be considered. The scope and nature of the claims have to be considered, the quantity of experimentation required to enable the claims. When the functional claims are broad and the patent disclosure is limited and narrow, the claims have been invalidated.

WT: In addition to the patent-enablement requirement, Section 112(a) of the Patent Act contains a written-description requirement. How do these requirements differ? And why did the Supreme Court agree to answer Amgen's question and not a question over the written-description requirement such as one recently presented by the Sloan Kettering Institute for Cancer Research and Juno Therapeutics Inc., which was rejected in *Juno Therapeutics Inc. v. Kita Pharma Inc.*, 143 S. Ct. 402 (2022)?

IR: That is an interesting question. Juno argued that there is no separate written description requirement and that there was only a requirement to enable the invention. As a matter of statutory interpretation, the Federal Circuit rejected that proposition en banc in *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010). The Supreme Court may well agree. The written description requires a description of the invention, not just of how to make and use it. The written description and enablement requirements are related but also different in that sense.

WT: Based on the way the justices grilled both sides of the patent-enablement debate at the March 27 oral argument, how do you predict the Supreme Court will ultimately decide the issue?

IR: The Supreme Court is likely to affirm the Federal Circuit's decision. The questioning indicated that the justices see the case as presenting a fact-bound dispute, not a dispute about the law. The parties and the United States agree that the full scope of the claims must be enabled and that, as a general matter, the broader the claims are, the more that has to be enabled. The parties and the United States also agree that the test for enablement is whether experimentation is undue and that the *Wands* factors are useful in that assessment. The court also is likely to provide guidance on the enablement inquiry but appreciated the fact that any guidance has to be applicable across technologies and should not be antibody specific. Indeed, the Biden administration emphasized how pernicious functional genus claims are and that the court should not create any antibody exception to enablement of functional genus claims — the exception that Amgen is asking for in this case.

About the author

Irena Royzman is the head of Life Sciences at **Kramer Levin**. She concentrates on pharmaceutical and biotech patent litigation and proceedings before the Patent Trial and Appeal Board. She holds a Ph.D. in biology from MIT and the Whitehead Institute, where she was an NSF fellow. Based in New York City, she represents plaintiffs and defendants in some of the most complex pharmaceutical and biotech patent cases. She can be reached at iroyzman@kramerlevin.com.

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