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Why the Supreme Court Should Reject Attempts to Monopolize a Therapeutic Target

By Irena Royzman
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The U.S. Supreme Court is poised to decide one of the most impactful intellectual property cases of our nation's history. The case involves a dispute between innovator companies, Amgen and Sanofi/Regeneron, that independently developed life-saving antibody therapeutics that reduce low-density lipoprotein (LDL) or "bad" cholesterol. Both antibodies treat thousands of patients with elevated cholesterol by binding to the same naturally occurring therapeutic target, PCSK9, and blocking it from interfering with LDL receptors that remove cholesterol from the blood.

Irena Royzman, head of life sciences at Kramer Levin. Courtesy photo

The companies obtained a patent on their own PCSK9 antibody by disclosing the exact composition of each antibody, its amino acid sequence. The antibodies have different sequences and do not resemble each other. But years later Amgen obtained patents that broadly claim all antibodies purely by their function of binding to and blocking the therapeutic target PCSK9. These functional claims do not provide the composition of any of the antibodies. Instead, they lay claim to the potentially millions of antibodies with the desired function and attempt to corner the market on PCSK9 therapeutic antibodies. Such claims keep other innovators out of the same therapeutic space or have them pay a toll.

This gambit was rejected by the district court since patents have to enable the claimed invention by teaching how to make and use it. The scope of Amgen's functional patent claims is enormous, yet its patents only taught a few antibodies. This teaching did not meet the bargain on which the U.S. patent system is premised: a limited monopoly in return for a description of the invention and how to make and use it. The district court ultimately struck down the claims. The appellate court affirmed. Amgen and its

supporters argue that the enablement standard is impossible to meet and that antibody therapeutics will no longer be developed unless patent owners can monopolize a therapeutic target using functional claims. The Supreme Court will now consider whether to maintain the status quo or lower the standard for enablement.

The Biden administration and U.S. Patent Office urge the court to maintain the status quo, explaining that broad functional claims foreclose others from inventing antibodies that benefit patients and that such claims fail to meet the enablement requirement unless the patents teach how to make the full range of diverse antibodies covered by the claims. A Nobel Laureate, Sir Gregory Paul Winter, and other antibody specialists urge the same, explaining that the function of an antibody provides no information about its composition or how to make and use it, leaving it to others to make the inventions that are claimed by the functional claims through arduous and unpredictable trial and error experimentation.

While there is a divide in the pharmaceutical industry, many of the leading pharmaceutical innovators, Genentech, AstraZeneca, Bayer, Gilead and Johnson & Johnson among them, generic and biosimilar manufacturers and the high-tech industry decry broad functional claims as contrary to the "quid pro quo" of our patent system: a teaching that allows the public to make and use the full scope of the invention once the patents expire. And they stress to the court that functional claims suppress, not encourage innovation.

As money continues to pour in to the biotech industry and the number of therapies that are developed and approved by FDA grows, patients have more therapeutic options, including two PCSK9 antibodies and the future PCSK9 antibodies that others independently discover and develop. There is tremendous value to discovering new antibodies that bind to the same target. They can have different properties, including stronger efficacy and fewer side effects. Multiple treatment options help patients.

The Supreme Court has not addressed enablement in over a century. But it is critical in this case that it follow the ancient maxim of "first, do no harm." The biopharmaceutical industry is thriving. New therapies are being developed every day and therapies that were not possible before are now possible. American invention is changing lives. As the court recognized a century ago, and should do so again, overbroad functional claims cannot stand. They exclude others from making discoveries within the scope of non-enabled claims. They foreclose efforts to discover other and better products. They extend the patent monopoly far beyond the discovery actually made and discourage rather than promote invention. Broad functional claims hurt innovation, hurt the investment community and hurt patients when we need real solutions and new therapies.

The court's ruling will impact all industries and impacts the other developing areas of biotechnology that are revolutionizing treatment of Americans, such as CRISPR, CAR-T and other cell therapies, siRNAs, mRNA therapies. The entire industry is watching.

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