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CLIENT ALERT

Clarifying the Enabling Obligation of the Patent Act: *Amgen Inc. v. Sanofi*

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In a unanimous decision issued May 18, 2023, the Supreme Court found that certain claims of Amgen Inc.'s patents for PCSK9-inhibiting antibodies are too broad to enable a claim of infringement and affirmed the Federal Circuit's judgment in favor of Sanofi that invalidated Amgen's asserted patents.

Background

In 2011, Amgen patented a new antibody drug to help people lower their cholesterol. This drug reduces levels of low-density lipoprotein (LDL) cholesterol, also known as bad cholesterol, which can lead to cardiovascular disease, heart attacks, and strokes. Previously discovered antibodies directly targeting bad cholesterol are not universally effective and carry unknown side effects.

Unlike previous antibodies, the antibody-based treatment Amgen patented in 2011 targets PCSK9, a gene that controls and regulates LDL receptors. LDL receptors remove LDL cholesterol from the bloodstream, naturally reducing the level of LDL cholesterol over time. But PCSK9 binds to LDL receptors and degrades them, preventing them from performing their natural function.

Enter the PCSK9-inhibiting antibody. These antibodies bind themselves to PCSK9 proteins and block PCSK9 from binding to LDL receptors. Rather than target LDL cholesterol directly, Amgen's drug allows the body's own filtration system to remove the bad cholesterol.

Amgen was not the only pharmaceutical company developing these antibody drugs. Around the same time Amgen patented its antibody drug, Sanofi patented its own PCSK9-inhibiting antibody. Both Amgen and Sanofi's 2011 patents cover a single PCSK9-inhibiting antibody, and both identify and describe the relevant antibodies by their unique amino acid sequence.

In 2014, Amgen obtained two new patents that were at issue in this case. The patents claimed 26 unique PCSK9-inhibitors, identified by their amino acid sequence. They also included methods patents for the "roadmap" and "conservative substitution" methods.

Unlike Amgen's 2011 patent, these 2014 patents focused on the *function* of these antibodies rather than the *structure*. Together, the patents claimed dominion over the "entire genus" of antibodies that can both bind to PCSK9 and block it from attaching to LDL receptors. These genus claims have become popular for pharmaceutical companies seeking to control broad markets of drugs.

But let's step back for a moment and return to high school chemistry and biology. To understand the Court's decision, it is important to understand the science behind Amgen's patents.

Unpacking the Science

Antibodies are the body's natural defenders. A virus, bacterium, or other foreign agent (known as an antigen) will trigger the body to produce antibodies. These antibodies bind to the antigen and stop it from causing harm, maybe by preventing the antigen from reproducing, or maybe by blocking the antigen from binding to a healthy cell and infecting it. In other words, different antibodies have different "functions." Some antibodies may have just one function, or they may have multiple functions.

Similarly, antibodies have different structures. The structure of the antibody is determined by the specific sequence of amino acids, which link together to form a chain. The order of amino acids in the chain affects how those amino acids interact with one another. These interactions create folds in the antibody, producing a 3D shape. Removing, or switching the placement of, an amino acid in the chain can have an unpredictable effect on its structure, which in turn might (and likely will) change its functions. This process of shifting amino acids is highly unpredictable, and the scientific community agrees that it is impossible to know what effect a change in the amino acid chain will have on its structure and functions.

And it is this lack of predictability that lies at the center of the Court's decision.

Holding and Analysis

The Court rejected Amgen's claim over the entire genus of antibodies that can bind to and block PCSK9. Focusing on the text of the Patent Act, the Court held that Amgen's patents failed to meet the Act's "enabling" requirement. This provision requires all patent applicants to describe their inventions by "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 make and use the [invention]." 35 U.S.C. § 112(a).

Justice Neil Gorsuch, writing for the Court, emphasized the "bargain" that undergirds patent law: in exchange for bringing "new designs and technologies into the public domain," patent holders gain a limited term of "protection from competitive exploitation." *Amgen Inc. v. Sanofi*, 598 U.S. ____, *7 (2023) (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989)). In turn, once a patent expires, the public may benefit from the new design or technology. The description of a patent, required by the Patent Act, should allow one "skilled in the art" to create the invention themselves.

Whether one skilled in the art could develop PCSK9-inhibiting antibodies based on Amgen's patents is the issue at the heart of this case. Neither the Court nor Sanofi disputed Amgen's ability to patent the 26 unique amino acid sequences that function as PCSK9-inhibitors and are listed explicitly in the 2011 and 2014 patents. These were specific and could be replicated by anyone with the knowledge and means. As a result, the Court found that Amgen satisfied the "enabling obligation" of the Patent Act for those 26 antibodies.

But the two methods for developing new antibodies were not, according to the Court, sufficient to enable someone skilled in the art to reliably develop PCSK9-inhibitors beyond the 26 identified by Amgen. These methods would still necessitate scientists engaging in "painstaking experimentation," developing new PCSK9-inhibitors through "trial-and-error discovery." *Amgen*, 598 U.S. at *17.

The Court determined that the methods claimed in the 2014 patents did not meet the statutory standard. While some amount of experimentation will be required, someone skilled in the art should be able to recreate the invention with

reasonable certainty.

Just what is reasonable? The Court does not lay out a bright-line definition. However, it is clear that pharmaceutical companies seeking to make genus claims in future patents cannot simply point to a method and say that it meets the requirements of the Patent Act's enabling obligation. The methods described in a patent must "enable the full scope of the invention as defined by the claims." *Id.* at *13. Here, scientists seeking to create unique amino acid chains that perform both the binding and blocking functions for PCSK9 cannot use either the roadmap or conservative substitution methods with any degree of reliability. Simply saying that someone could use a method to *eventually* discover a new PCSK9-inhibiting antibody is not enough.

If this sounds like a warning to companies seeking to assert broad patent claims, that's because it likely is. In the words of Justice Gorsuch, "the more a party claims, the broader the monopoly it demands, the more it must enable." *Id.* at *16.

KEY TAKEAWAYS

- To make a claim over an "entire kingdom," an inventor needs to enable others to manufacture these items without "painstaking experimentation" or "trial-and-error discovery."
- "Section 112 of the Patent Act reflects Congress's judgment that if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain."

Winston & Strawn summer associate Scott Shimizu contributed to this briefing.

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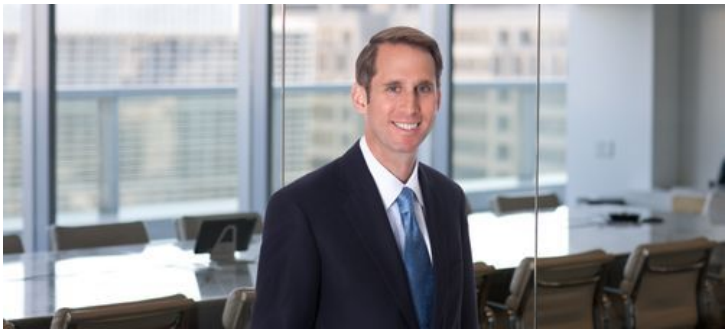

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