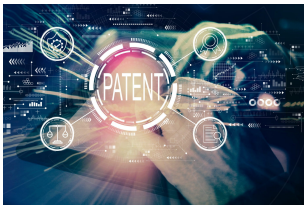

Supreme Court Decision Could Have Impact on Health Care Patent Applications

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In a crucial U.S. Supreme Court decision issued on May 18, in *Amgen Inc. v. Sanofi*, the Court applied the "enablement" requirement of the Patent Act, affirming that patent applicants must fully, clearly, and concisely describe their invention. In doing so, it highlighted the importance of the patent "bargain"—the delicate balance between promoting invention and ensuring the public can access and build upon new technologies.

Amgen and Sanofi, two pharmaceutical companies, had each developed drugs using engineered antibodies to reduce "bad cholesterol." The dispute arose when Amgen obtained additional patents in 2014, claiming all antibodies that bind to specific amino acid residues on a protein called PCSK9 and block it from binding to LDL receptors, far beyond the 26 examples they initially provided.

Sanofi contended that Amgen's new patents were invalid under the enablement requirement, arguing that the methods Amgen provided for generating additional antibodies amounted to little more than trial-and-error, failing to meet the requirement to teach persons skilled in the art to make potentially millions more antibodies.

The Supreme Court agreed with the lower courts that sided with Sanofi, ruling that Amgen had indeed failed to meet the enablement requirement. In essence, the claims were too broad and did not sufficiently detail how to produce all the antibodies they aimed to monopolize.

The Key Takeaway?

As the Supreme Court wrote in the decision: "If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the

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specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."

This simple statutory command reaffirms the necessity for patent applicants to fully describe their invention in their patent applications—without excessively broad or functional claiming. It also serves as a reminder for businesses to ensure their patents are not overly broad and meet the enablement requirement to avoid potential litigation and invalidation.

This decision could have far-reaching implications on patenting strategy, particularly for those in the life sciences industry. It underlines the need for comprehensive yet precise patent applications that strike a balance between protection and accessibility.

Understanding this can be vital for businesses and attorneys alike.

For more information, please contact any attorney with Frost Brown Todd's Intellectual Property practice group.

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