Cantor Colburn LLP

Cantor Colburn Client Alert: Supreme Court Rules that a Patent Specification Must Enable the Full Scope of the Invention

Justice Neil Gorsuch wrote for a unanimous Supreme Court in *Amgen Inc. v. Sanofi* (May 18, 2023), that agreed with the Court of Appeals for the Federal Circuit, the lower District Court, and Sanofi, that Amgen's patents on its cholesterol drug Repatha were invalid. The Court held that the broad functional "genus claims" in those patents would require a person of ordinary skill in the art to engage in "undue experimentation" to make every species of antibody covered by the claims, contrary to the Patent Laws. This was the first time since 1928 that the Supreme Court has ruled in a patent enablement case.

Facts and Holding

The relevant Amgen patents (U.S. Patent Nos. 8,829,165 and 8,859,741) are both directed to a genus of antibodies that help reduce the levels of low-density lipoprotein cholesterol ("LDL cholesterol"). Specifically, these patents claim any antibody that performs (1) binding to specific amino acids on the PCSK9 protein and then (2) blocking that PCSK9 protein from then impeding the body's mechanism for removing LDL cholesterol from the bloodstream. Thus, the patents claimed any such antibody that performed those two functions, but the patent disclosures only identified 26 specific antibodies that performed those two necessary functions. The claims did not recite any structural features of the claimed antibodies, defining them only by their function with the PCSK9 protein.

Based on the claim language and scope, the Court held that the patents did not enable a skilled artisan to "make and use" the full scope of the invention, as required by § 112(a) of the Patent Act. The Court noted that if "a patent claims an entire class of . . . composition of matter, the patent's specification must enable a person skilled in the art to make and use the entire class." To the Court, the patents at issue did not satisfy this requirement, largely due to the broad functional language recited in the claims.

The Court similarly found that the two methods Amgen provided to discover the other antibodies embraced by the claimed genus that were also inadequate to enable the full scope of the claims, stating that these methods "amount[ed] to little more than two research assignments." Both required an artisan to undergo a "trial-and-error method for finding functional antibodies." However, the Court noted that a "specification [is not] necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." And determining whether such adaptation or testing "is reasonable . . . will depend on the nature of the invention and the underlying art."

The Court cautioned against reading its opinion as holding that a specification must always describe "how to make and use every single embodiment within a claimed class." For some inventions, the Court noted that only a few examples may be sufficient to enable an entire class if there was "some general quality . . . running through" that class. Offering those skilled in the art "little more than advice to engage in 'trial and error'" was not sufficient to survive an enablement challenge.

Conclusion

The Supreme Court did not create a new test for enablement or adopt or overturn any prior Federal Circuit holding on enablement. On its face this decision leaves the law on enablement unchanged, i.e., the statutory requirement under 35 USC § 112 that a patent must enable those skilled in the art to "make and use" the claimed invention. But, before the Court's Amgen holding patents claiming antibodies with only functional limitations were routine and presumed valid. Now such patents are much less likely to be issued and those already issued are more likely to be invalidated. Patent applicants should understand the importance of including sufficient examples, direction, and guidance in the specification, and be wary of claiming in functional claim language, particularly in the absence of any structural elements. We recommend including claims that recite structural features, in applications that also have claims with only functional limitations. Where worked examples aren't available at the time of filing, inventors should consider adding detailed hypothetical examples. As Gorsuch's opinion explained, "[i]f 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."

For Further Information and Assistance

Cantor Colburn has substantial experience representing clients in patent matters. Please do not hesitate to contact Anne Maxwell, Partner and Chair of Cantor Colburn's Pharmaceutical Patent Practice at amaxwell@cantorcolburn.com and +1 (860) 286-2929, ext. 1119 or your Cantor Colburn attorney with any questions you may have regarding this matter and your IP in general.

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