SUPREME COURT OF THE UNITED STATES

Amgen Inc. v. Sanofi

598 U.S. ___ (2023) · No. No. 21-757 · Decided May 18, 2023

SUMMARY

The Supreme Court held that Amgen's antibody patent claims were invalid under the Patent Act's enablement requirement because the specification did not enable skilled artisans to make and use the full claimed genus of antibodies. The Court affirmed the Federal Circuit, explaining that functional claims covering an entire class must be supported by disclosure sufficient to enable the entire class, subject to a reasonable amount of experimentation. The decision was unanimous.

CASE DETAILS

COURT	Supreme Court of the United States
WRITING FOR THE COURT	Justice Gorsuch
JURISDICTION	Federal
DECIDED	May 18, 2023
DOCKET	No. 21-757
DISPOSITION	affirmed
PROCEDURAL POSTURE	Amgen sued Sanofi for infringement of patent claims covering a genus of PCSK9-inhibiting antibodies. Sanofi defended on the ground that the claims were invalid for lack of enablement under 35 U.S.C. § 112(a). The district court granted Sanofi judgment as a matter of law, the Federal Circuit affirmed, and the Supreme Court affirmed on certiorari.
STANDARD OF REVIEW	The Supreme Court reviewed the lower courts' judgments on the enablement issue and considered whether the patent claims satisfied the statutory requirement of 35 U.S.C. § 112(a).
PRECEDENTIAL VALUE	binding
PARTIES	Amgen Inc., et al. v. Sanofi, et al.

TOPICS

patent law · patent infringement · intellectual property

PRACTICE AREAS

patent law | patent infringement | intellectual property

QUESTIONS PRESENTED

1. Whether Amgen's patent specifications enabled a person skilled in the art to make and use the full scope of the claimed genus of PCSK9-inhibiting antibodies under 35 U.S.C. § 112(a).
2. Whether the Federal Circuit improperly applied a heightened enablement standard to genus claims defined by function.
3. Whether enablement is measured by the cumulative time and effort required to make every embodiment within a broad claim.

HOLDINGS

1. Amgen's patent specifications failed to satisfy the enablement requirement because they enabled 26 disclosed antibody embodiments but did not enable the full scope of the much broader genus of antibodies covered by the claims.
2. The Federal Circuit did not apply an impermissibly heightened standard; there is one statutory enablement standard, and the principle that broader claims require broader enabling disclosure is consistent with § 112(a) and Supreme Court precedent.
3. Enablement is not measured by the cumulative time and effort required to make every embodiment within a claim, although the need for extensive trial-and-error experimentation may demonstrate that the specification fails to enable the claimed invention.

KEY QUOTATIONS

> *"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."* (at 13)

> *"The more one claims, the more one must enable."* (at 13)

> *"They leave a scientist about where Sawyer and Man left Edison: forced to engage in "painstaking experimentation" to see what works. That is not enablement. More nearly, it is "a hunting license.""* (at 17)

> *"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."* (at 19)

FACTUAL BACKGROUND

Amgen developed a PCSK9-inhibiting antibody drug and obtained two 2014 patents claiming an entire genus of antibodies that bind specified regions of PCSK9 and block PCSK9 from binding to LDL receptors. Amgen disclosed the amino acid sequences of 26 working antibodies and proposed a roadmap and conservative-substitution methods for identifying additional functional antibodies. The claims covered potentially millions of additional antibodies, but the proposed methods required researchers to generate or modify candidates and test

them through trial and error. The district court and Federal Circuit concluded that the specification did not enable the full scope of the claimed genus.

PROCEDURAL HISTORY

Amgen obtained the 2014 ’165 and ’741 patents and sued Sanofi for infringement. The United States District Court for the District of Delaware granted Sanofi judgment as a matter of law, concluding that the claims were not enabled. The Federal Circuit affirmed, holding that no reasonable factfinder could conclude that Amgen had provided adequate guidance beyond its 26 working examples. The Supreme Court granted certiorari and affirmed.

DISPOSITION

affirmed

CASES CITED

- United States v. Detroit Timber & Lumber Co., 200 U.S. 321, 337 (1906)
- Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-151 (1989)
- O'Reilly v. Morse, 15 How. 62, 113-119 (1854)
- The Incandescent Lamp Patent, 159 U.S. 465, 472, 475-476 (1895)
- Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245, 251, 255-258 (1928)
- Wood v. Underhill, 5 How. 1, 4-5 (1846)
- Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270-271 (1916)
- United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933)
- Grant v. Raymond, 6 Pet. 218, 247 (1832)
- Whittemore v. Cutter, 29 F. Cas. 1120, 1122 (No. 17,600) (C.C. Mass. 1813)
- Béné v. Jeantet, 129 U.S. 683, 684-686 (1889)
- Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358, 385 (1928)
- Ives v. Hamilton, 92 U.S. 426, 429, 432 (1876)
- Tilghman v. Proctor, 102 U.S. 707, 732-733 (1881)
- Mowry v. Whitney, 14 Wall. 620, 644 (1872)
- Bilski v. Kappos, 561 U.S. 593, 602-603, 612 (2010)
- Brenner v. Manson, 383 U.S. 519, 536 (1966)
- Black v. Cutter Laboratories, 351 U.S. 292, 297 (1956)