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Summary of *Amgen v. Sanofi* 143 S.Ct. 1243 (2023)

Andrea Grossman
Office of Patent Legal Administration

Biotechnology, Chemical, and Pharmaceutical Partnership Meeting
September 7, 2023

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Scientific background

- Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) is a naturally occurring protein that binds to and degrades low density lipoprotein receptors (LDLR).
  - This prevents low density lipoprotein (LDL) cholesterol from binding to these receptors and from being removed from the bloodstream.
  - Inhibiting PCSK9 from binding to LDLR may be effective in treating patients with elevated LDL.
- Pharmaceutical companies sought to develop antibodies that bind to PCSK9.
  - Amgen developed and obtained FDA approval for Repatha® (evolocumab).
  - Regeneron/Sanofi developed and obtained FDA approval for Praluent® (alirocumab).

Patents

- Both parties obtained patents on PCSK9 antibodies.
  - Some patents claimed antibodies by their amino acid sequences.
  - Amgen also obtained patents with broad functional claims to a genus of PCSK9 antibodies, including:
    - U.S. 8,829,165 (the ‘165 patent)
    - U.S. 8,859,741 (the ‘741 patent)

Representative claim

29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein

- **the isolated monoclonal antibody binds to** at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of **PCSK9** listed in SEQ ID NO: 3 and
- **blocks the binding of PCSK9 to LDLR** by at least 80%.

U.S. Patent 8,829,165 (owned by Amgen Inc.); ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)

Disclosure

- The ‘165 and ‘741 patents share a common disclosure.
- The specification disclosed:
  - Amino acid sequences for 26 antibodies;
  - 3D structures for two antibodies;
  - The roadmap method; and
  - The conservative substitution method.

First district court case (D. Del. 2017)

- In 2014, Amgen brought an action against Sanofi et al., alleging infringement of multiple patents.
  - Including the '165 patent and the '741 patent
- The defendants stipulated to infringement.
  - The district court granted the defendants' motion for a judgement as a matter of law (JMOL) of no willful infringement.
- The jury found that the claims were adequately described and enabled.
  - The jury instructions included the "newly characterized antigen" instructions.
  - The district court excluded post January 2008 evidence.
- The district court denied Sanofi's motion for a JMOL that the claims lacked written description and were not enabled.
- The district court granted a permanent injunction enjoining sales of Praluent® (alirocumab).

First U.S. Court of Appeals for the Federal Circuit (CAFC) case (2017)

- The CAFC concluded that the district court erred by:
  - Excluding evidence and
  - Improperly instructing the jury re: written description.
- The court reversed the decision to exclude evidence & remanded for a new trial on written description and enablement.
  - Consequently, the court vacated the permanent injunction.
- The CAFC affirmed the denial of the defendants' motion for a JMOL of no written description and enablement.
- The court also affirmed the district court's JMOL of nonobviousness.

Second District Court case (D. Del. 2019)

- There was a new jury trial on written description and enablement.
  - The jury found claim 7 of the '741 patent and claims 19 and 29 of the '165 patent valid, but invalidated claims 7 and 15 of the '165 patent for lack of written description.
- Sanofi moved for a JMOL on lack of written description and enablement for claims 19 and 29 of the '165 patent and claim 7 of the '741 patent.
  - Sanofi also moved, in the alternative, for a new trial.
- The district court granted the motion for a JMOL for lack of enablement, but denied the motion for a JMOL for lack of written description and conditionally denied the motion for a new trial.
  - The district court's analysis utilized the *Wands* factors.

Second CAFC case (2021)

- Amgen appealed the JMOL for lack of enablement.
- The CAFC affirmed the district court's determination that claims 19 and 29 of the '165 patent and claim 7 of the '741 patent were not enabled.
  - The CAFC weighed the *Wands* factors and distinguished *Wands* based on the facts.

Summary of the Supreme Court (SCOTUS) Decision

- History of enablement
- Patent bargain:
  - Quid pro quo:
    - Inventor discloses the invention.
    - Inventor receives a limited term of protection.
- Congress has revised patent laws, but has left the enablement requirement intact.
- The Court has addressed the enablement requirement many times over the past 150 years.

Previous SCOTUS precedent

- *Morse*, *Incandescent Lamp*, and *Holland Furniture*
- *Wood* and *Mineral Separation:*
  - A specification may call for a **reasonable amount of experimentation.**
  - Reasonableness depends on the nature of the invention and the underlying art.

Holding

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

Amgen, 143 S.Ct. at 1254.

Amount of disclosure

- The specification does not always need to "describe with particularity how to make and use every single embodiment within a claimed class." *Amgen,* 143 S.Ct. at 1254.
- "For instance, it may suffice to give an example (or a few examples) if the specification also discloses some general quality . . . running through the class that gives it a peculiar fitness for the particular purpose." *Id.*
- "In some cases, disclosing that general quality may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset." *Id.* at 1255.

Analysis

- The Court analyzed the claims in light of the Court's precedent: *Morse*, *Incandescent Lamp*, and *Holland Furniture*.
- The Court found that just as "Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering, Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies." *Amgen,* 143 S.Ct. at 1256.
- The Court further stated that "if our cases teach anything, it is that the more a party claims, the broader the monopoly it demands, the more it must enable. That holds true whether the case involves telegraphs devised in the 19th century, glues invented in the 20th, or antibody treatments developed in the 21st." *Id.*

The *Wands* factors

- The specification may call for a reasonable amount of experiment.
- The Court did not cite *Wands*.
- However, the *Wands* factors appear at least probative of the essential inquiry in determining whether one must engage in reasonable experimentation.

Takeaways

- The specification must enable the full scope of the invention as defined by its claims.
- Experimentation is allowed, but the experimentation must be reasonable.
- *Wands* has been applied by the U.S. Court of Appeals for the Federal Circuit in at least two cases since *Amgen* has been decided.
- The claims in all patents, across all technologies, are required to be enabled.

Thank you!

Andrea Grossman

Legal Advisor

Andrea.Grossman@uspto.gov

(571) 270-3314

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