

ENABLEMENT:

the U.S. Supreme Court speaks

Biotech Chemical Partnership Meeting

U.S Patent & Trademark Office

Duane C. Marks

Sept. 7th, 2023

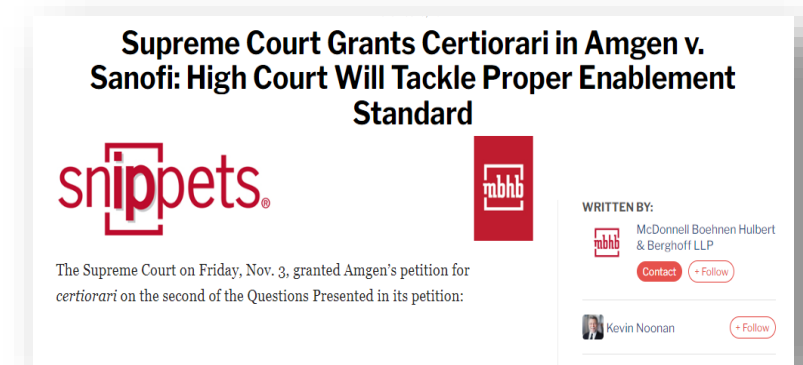
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Certiorari Granted

The Question Presented

Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art **to “make and use” the claimed invention**, 35 U.S.C. §112, **or** whether it must instead enable those skilled in the art **“to reach the full scope of claimed embodiments”** without undue experimentation – *i.e.*, to cumulatively identify and make all or nearly all embodiments of the invention without substantial “time and effort.”



BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record

Representative Claim at Issue

U.S. Patent No. 8,829,165

(Claim 19). An isolated monoclonal **antibody**, wherein, when bound to PCSK9, the Ab **binds** to at least one of the following residues: **S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381** of SEQ ID **NO:3**, and wherein the Ab **blocks** binding of PCSK9 to LDLR, wherein the Ab binds at least 2 of the residues.

(col. 32, ln. 40) an intact immunoglobulin of **any isotype**, or a **fragment thereof** that can compete with the intact antibody for specific binding to the target antigen, and includes, for instance, **chimeric, humanized, fully human, and bispecific antibodies**

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(jury instructions) **interacts** with residues and **contributes to affinity** and specificity of the PCSK9-antibody interaction

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(example 28) core **PCSK9** amino acid **residues** of the interaction **interface with** the **LDLR** EGFa domain that interact within 5 angstroms (a.k.a, "**the sweet spot**")

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(example 28) core PCSK9 amino acid residues of the interaction interface with the LDLR EGFa domain that interact within 5 angstroms

(jury instructions) prevents binding of PCSK9 to LDLR

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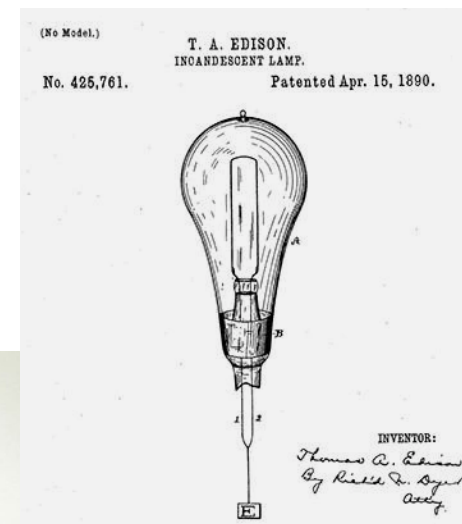
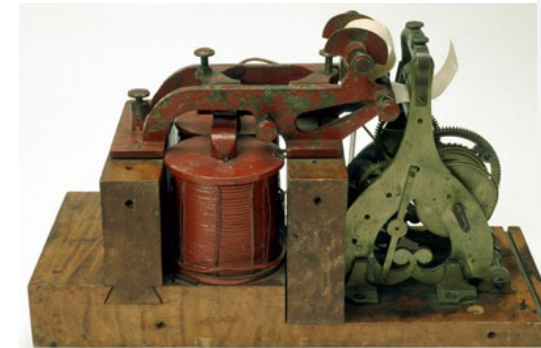
An isolated *chimeric, humanized, fully human or bispecific IgG, or fragment thereof, of any isotype*, wherein when bound to PCSK9 *interacts and contributes to the affinity & specificity with PCSK9* at one or more *PCSK9 residues that are part of the “sweet spot” (PCSK9-LDLR binding domain)* and which *prevents PCSK9 binding to LDLR*.

Enablement

the Supreme Court speaks

Enablement at the Court – a Historical Perspective:

- “*the quid-pro-quo premise of patent law*” dating back to 1790 patent act!
 - “distinguish the invention... from other things before known and used.”
 - “...enablement a workman...to make, construct, or use the [invention].”
 - “...give the public [after the monopoly expires] the advantage for which the [monopoly] is allowed.”
- Five precedential Court opinions addressing enablement
 - *Wood v. Underhill* (1846)
 - *O’Reilly v. Morse* (1854) ★
 - *The Incandescent Lamp Patent* (1895) ★
 - *Minerals Sep. Ltd. v. Hyde* (1916)
 - *Holland Furniture Co. v. Perkins Glue Co.* (1928) ★



Enablement

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O'Reilly v Morse:

(claim 8)

- “covered ‘**the essence**’ of the invention”
 - ❖ “the use of the motive power of the electric or galvanic current...**however developed for** marking or printing intelligible characters, signs, or letters, at any distances.”
- Covered **all means** of achieving telegraphic communication
 - ❖ not limited to any particular means



Enablement

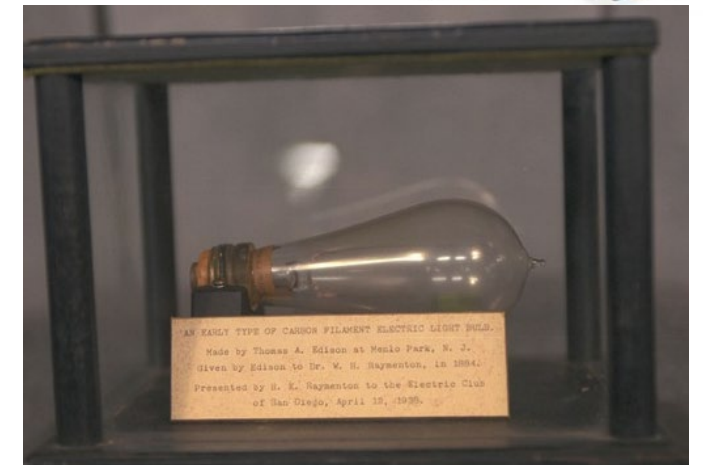
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O'Reilly v Morse:

(claim 8!)

The Incandescent Lamp Patent: (Sawyer & Man)

- Claims “an ‘*electric lamp*’ with an ‘*incandescing conductor*’ made of ‘*carbonized*’ fibrous or textile material”
 - ❖ disclosed only the use of carbonized paper but **claimed** “**every fibrous or textile material**”
 - ❖ no “**quality common**” to the materials “**peculiarly adapted to incandescence**”
- T. Edison: bamboo species w/ parallel fibers
 - ❖ Sawyer & Man did not aid in selecting materials w/ parallel fibers



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O'Reilly v Morse:

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➤ “The Incandescent Lamp Patent:

(Sawyer & Man)

➤ Claims “an ‘incandescing fibrous or tery

❖ disclosed claimed

❖ no “qual”
“peculia

➤ T. Edison: b

❖ Sawyer & Man materials

Holland Furniture: (Perkins Glue Patent)

➤ Claimed “***all starch glues*** made from whatever starch happened to perform as well as animal glue”

❖ key character of the glue “described **solely by use or function**”

➤ Entitled to glues described defined by “***characteristic ingredients***” by “***physical characteristics or chemical properties***” achieving the function



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(Sawyer & Man)

➤ Claims “

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Breadth:

- structural & functional
- essence of a field ; an entire class
- key element defined solely by function

Unpredictability:

- common quality peculiarly adapted for a use
- all means (however developed)
- aid in selecting functional element

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Monopolizes an entire class of antibodies:

- much broader than 26 antibodies
- at least millions of candidates

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“Roadmap” or “conservative substitution”

process:

- mere “research assignments”
- **random** “trial-and-error”

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Disclosure “offers...little more than advice to engage in ‘trial and error.’”

- Lacks identification of a “**quality common**” to the functional element

Enablement

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 - ❖ guidance regarding selection of elements with “some peculiarity” in performance of testing

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 - ❖ guidance regarding selection of elements with "some peculiarity" in performance of testing
- **The more a party claim, the more it must enable!**

**THANK
YOU!**