ENABLEMENT: the U.S. Supreme Court speaks

Biotech Chemical Partnership Meeting
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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.”
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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(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 EGFα domain that interact within 5 angstroms 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)
  ➢ Holland Furniture Co. v. Perkins Glue Co. (1928)
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
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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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The Incandescent Lamp Patent:
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 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 ‘peculiarly’ adapted to incandescence”
 T. Edison: bamboo species w/ parallel fibers
 Sawyer & Man did not aid in selecting materials w/ parallel fibers

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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“covered ‘the essence’ of the invention”

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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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- much broader than 26 antibodies
- at least millions of candidates
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- cannot accurately predict how trading one amino acid will affect an antibody's structure and function
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- 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
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- [I]t may suffice to give an example…if the specification discloses “some general quality…running through” the class the gives it “a peculiar fitness for the particular purpose.”
  - that general quality which “reliably enables” a person of skill in the art to make and use all of what is claimed….”
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  - guidance regarding selection of elements with “some peculiarity” in performance of testing
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- **The more a party claim, the more it must enable!**
THANK YOU!