Amgen v. Sanofi: Discussing the SCOTUS Decision

Tuesday, June 6th

FISH.

Meet the Speakers

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Overview

Topics

- *Amgen v. Sanofi* Case Overview
- Enablement Standard for Genus Claims
- Functional Claiming of Antibodies
- Guidance Moving Forward

Housekeeping

- CLE
- Questions
- Materials
- http://www.fr.com/webinars

Amgen v. Sanofi Case Overview

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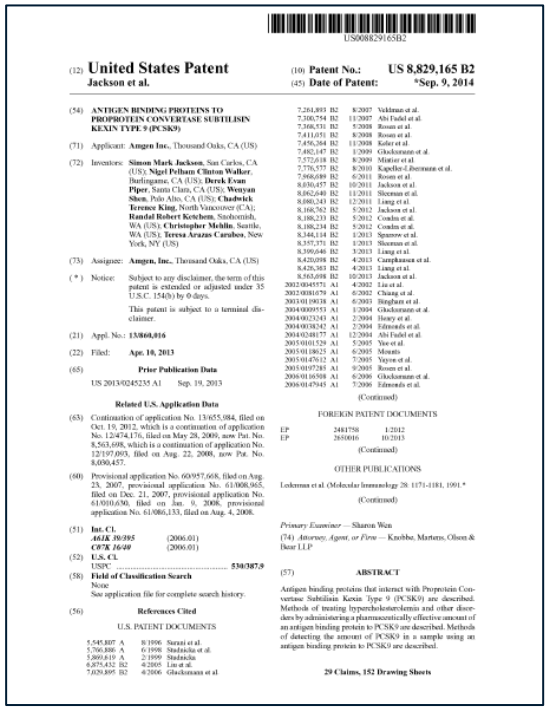
Amgen v. Sanofi: Technology

Broad Functional Claims

Amgen, Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

- Drug Repatha®: Cholesterol-lowering monoclonal antibody therapy
  - Also known as 21B12 or evolocumab
- Patents: 8,829,165 and 8,859,741: Antigen Binding Proteins to Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9)



US008829165B2

(12) **United States Patent**
Jackson et al.

(10) **Patent No.: US 8,829,165 B2**
(45) **Date of Patent: *Sep. 9, 2014**

(54) **ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)**

(71) Applicant: **Amgen Inc.**, Thousand Oaks, CA (US)

(72) Inventors: **Simon Mark Jackson**, San Carlos, CA (US); **Nigel Pelham Clinton Walker**, Burlingame, CA (US); **Derek Evan Piper**, Santa Clara, CA (US); **Wenyan Shen**, Palo Alto, CA (US); **Chadwick Terence King**, North Vancouver (CA); **Randal Robert Ketchem**, Snohomish, WA (US); **Christopher Mehlin**, Seattle, WA (US); **Teresa Arazas Carabeo**, New York, NY (US)

(73) Assignee: **Amgen, Inc.**, Thousand Oaks, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/860,016**

(22) Filed: **Apr. 10, 2013**

(65) **Prior Publication Data**

US 2013/0245235 A1 Sep. 19, 2013

Related U.S. Application Data

(63) Continuation of application No. 13/655,984, filed on Oct. 19, 2012, which is a continuation of application No. 12/474,176, filed on May 28, 2009, now Pat. No. 8,563,698, which is a continuation of application No. 12/197,093, filed on Aug. 22, 2008, now Pat. No. 8,030,457.

(60) Provisional application No. 60/957,668, filed on Aug. 23, 2007, provisional application No. 61/008,965, filed on Dec. 21, 2007, provisional application No. 61/010,630, filed on Jan. 9, 2008, provisional application No. 61/086,133, filed on Aug. 4, 2008.

(51) **Int. Cl.**
A61K 39/395 (2006.01)
C07K 16/40 (2006.01)

(52) **U.S. Cl.**
USPC **530/387.9**

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

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Lederman et al. (Molecular Immunology 28: 1171-1181, 1991.*

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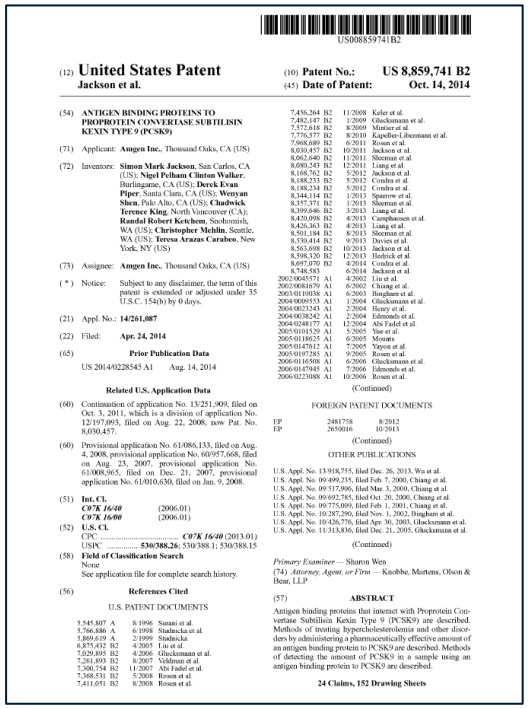
Primary Examiner — Sharon Wen
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Antigen binding proteins that interact with Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) are described. Methods of treating hypercholesterolemia and other disorders by administering a pharmaceutically effective amount of an antigen binding protein to PCSK9 are described. Methods of detecting the amount of PCSK9 in a sample using an antigen binding protein to PCSK9 are described.

29 Claims, 152 Drawing Sheets



US008859741B2

(12) **United States Patent**
Jackson et al.

(10) **Patent No.: US 8,859,741 B2**
(45) **Date of Patent: Oct. 14, 2014**

(54) **ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)**

(71) Applicant: **Amgen Inc.**, Thousand Oaks, CA (US)

(72) Inventors: **Simon Mark Jackson**, San Carlos, CA (US); **Nigel Pelham Clinton Walker**, Burlingame, CA (US); **Derek Evan Piper**, Santa Clara, CA (US); **Wenyan Shen**, Palo Alto, CA (US); **Chadwick Terence King**, North Vancouver (CA); **Randal Robert Ketchem**, Snohomish, WA (US); **Christopher Mehlin**, Seattle, WA (US); **Teresa Arazas Carabeo**, New York, NY (US)

(73) Assignee: **Amgen Inc.**, Thousand Oaks, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/261,087**

(22) Filed: **Apr. 24, 2014**

(65) **Prior Publication Data**

US 2014/0228545 A1 Aug. 14, 2014

Related U.S. Application Data

(60) Continuation of application No. 13/251,909, filed on Oct. 3, 2011, which is a division of application No. 12/197,093, filed on Aug. 22, 2008, now Pat. No. 8,030,457.

(60) Provisional application No. 61/086,133, filed on Aug. 4, 2008, provisional application No. 60/957,668, filed on Aug. 23, 2007, provisional application No. 61/008,965, filed on Dec. 21, 2007, provisional application No. 61/010,630, filed on Jan. 9, 2008.

(51) **Int. Cl.**
C07K 16/40 (2006.01)
C07K 16/00 (2006.01)

(52) **U.S. Cl.**
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USPC **530/388.26**; 530/388.1; 530/388.15

(58) **Field of Classification Search**
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See application file for complete search history.

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EP 2650016 10/2013

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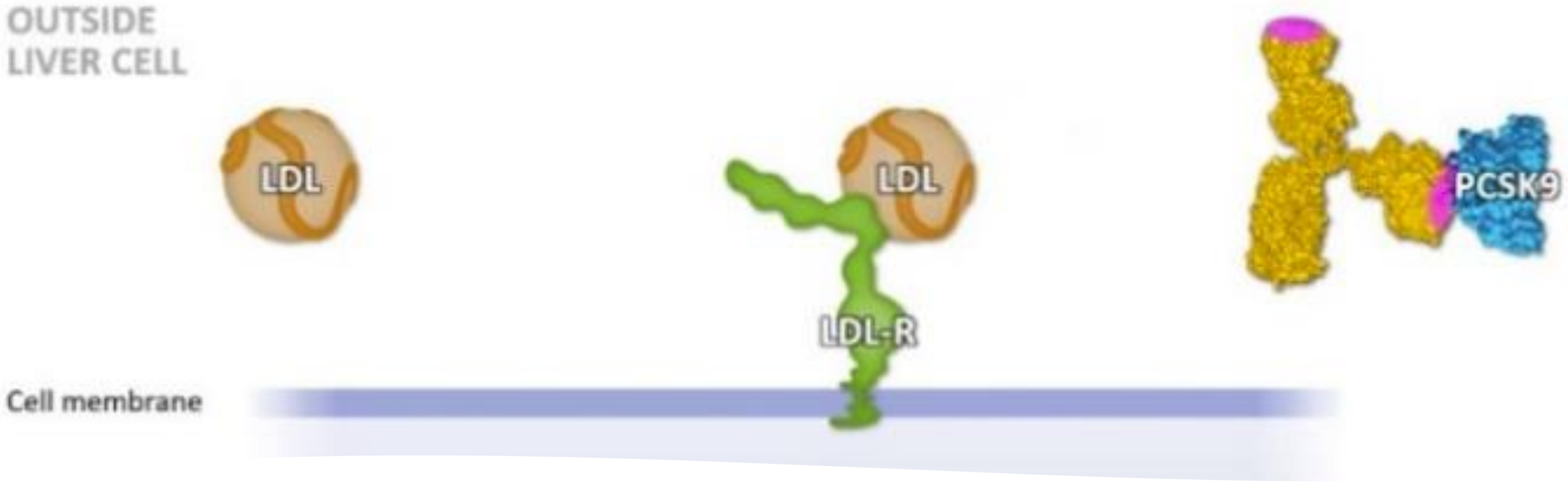
(Continued)

Primary Examiner — Sharon Wen
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

Antigen binding proteins that interact with Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) are described. Methods of treating hypercholesterolemia and other disorders by administering a pharmaceutically effective amount of an antigen binding protein to PCSK9 are described. Methods of detecting the amount of PCSK9 in a sample using an antigen binding protein to PCSK9 are described.

24 Claims, 152 Drawing Sheets



Amgen v. Sanofi: Technology

- **Broad Functional Claims**
- *Directed to a genus of monoclonal antibodies that bind and block an enzyme (PCSK9) involved in LDL regulation*
  - Low-density lipoprotein (LDL) cholesterol contributes to heart disease
  - Human body regulates LDL levels through cellular receptors
  - PCSK9 binds LDL receptors, causing them to degrade – result is increase in circulating LDL
  - Blocking or inhibiting PCSK9 prevents degradation of LDL receptors, allowing LDL to be regulated

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Exemplary Amgen Claims

Claims at issue: ’165 Claims 19, 29; ’741 Claim 7

Exemplary Claim: ’165 Claim 19

1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody 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 monoclonal antibody blocks binding of PCSK9 to LDLR.

19. The isolated monoclonal antibody of claim **1** 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.

An isolated monoclonal antibody that:

1) Binds specific residues of PCSK9; and

2) Blocks binding of PCSK9 to LDL receptor

Common Specification

Amino acid sequences for **26 antibodies** (including antibody sequence for evolocumab/21B12)

3D structures of two antibodies (including 21B12)

Binding location for PCSK9 with 21B12

FIG. **19**A is a depiction of the structure of PCSK9, the 31H4 Ab, and the 21B12 Ab.

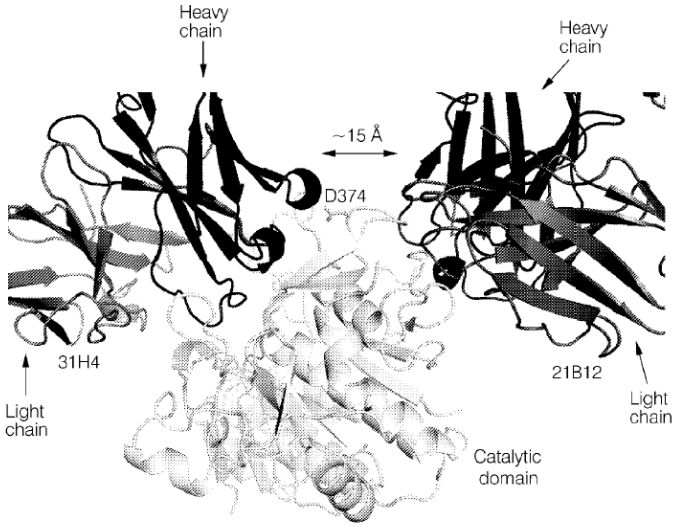


FIG. 19A

FIG. **20**A is a depiction of the structure of PCSK9 and EGFa from the LDLR superimposed with the structure of antibodies 31H4 and 21B12 bound to PCSK9.

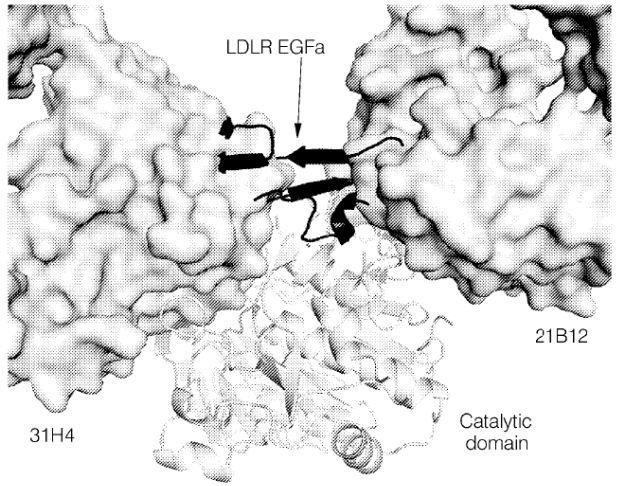


FIG. 20A

Specification: Two Methods for Making Antibodies

1. **Roadmap**
   - Generate antibodies in lab
   - Test to see if bind PCSK9; if yes
   - Test to see if bind “sweet spot”
   - Test blocking of PCSK9 from binding LDLR
2. **Conservative Substitution**
   - Start with antibody known to bind and block PCSK9
   - Sub AAs with other similar AA
   - Test resulting antibody for binding/blocking PCSK9

35 U.S.C. § 112(a): Enablement Requirement

"The specification shall contain a written description of the invention, and of the manner and process or making and using it, in such full, clear, concise, and exact terms as to ***enable any person skilled in the art*** to which it pertains, or with which it is most nearly connected, ***to make and use the same***. . . ."

Procedural History

2011: Amgen receives a patent for a PCSK9-inhibiting antibody employed in drug Repatha

2011: Sanofi receives a patent for a PCSK9-inhibiting antibody employed in drug Praluent

2014: Amgen receives two patents (‘165 and ‘741) claiming the entire genus of antibodies inhibiting PCSK9

2014: Amgen sues Sanofi for infringing its ‘165 and ‘741 patents with Sanofi’s drug Praluent

2017: A jury finds Amgen’s ‘165 and ‘741 patents not to be invalid and Sanofi stipulates to infringement

2017: Federal Circuit reverses and remands for trial court’s error in excluding Sanofi’s written description and enablement evidence, and improperly instructing the jury on the written description requirement

2019: District Court grants Sanofi’s JMOL motion for lack of enablement

2021: Federal Circuit affirms finding no reasonable factfinder could conclude that the ‘165 and ‘741 patents provided adequate guidance to make and use the claimed antibodies beyond the examples provided

2022: Supreme Court grants certiorari

2023: Supreme Court decision

District Court: JMOL of No Enablement

***Amgen, Inc. v. Sanofi*, No. 14-CV-1317-RGA, 2019 WL 4058927 (D. Del. Aug 28, 2019)**

Second trial between Amgen and Sanofi

- Jury verdict: Sanofi failed to prove asserted claims invalid for lack of written description and enablement
- JMOL Granted: Lack of Enablement
  - Emphasized need to enable *full scope* of claimed invention without *undue experimentation*
  - Walked through *Wands* factors
    - Breadth of claims: **Broad**
    - Predictability of the Art: **Unpredictable**
    - Nature of the Invention; State of Prior Art; Relative Skill of Those in the Art: Routine, well-known methods disclosed in patent/familiar to POSITA; techniques disclosed could allow POSITA to make at least *some* antibodies falling within claims
    - Amount of Direction/Guidance; Presence/Number of Working Examples: 26 working examples do not teach POSITA how to predict binding ability from antibody sequence; **trial and error required** even for suggested substitutions
    - Quantity of Experimentation Necessary: **Substantial**

Federal Circuit: JMOL of No Enablement Affirmed

***Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021)**

Undue experimentation required to make and use the full scope of the claims

- Functional claims "raise[] the bar for enablement"
- Where functional limitations are broad, disclosed examples and guidance cannot be "narrow"
- *In re Wands* is "go to" precedent for guidance on enablement, also involved claims re antibody technology.
  - *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) – "No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. . . ." *Id.* at 740.

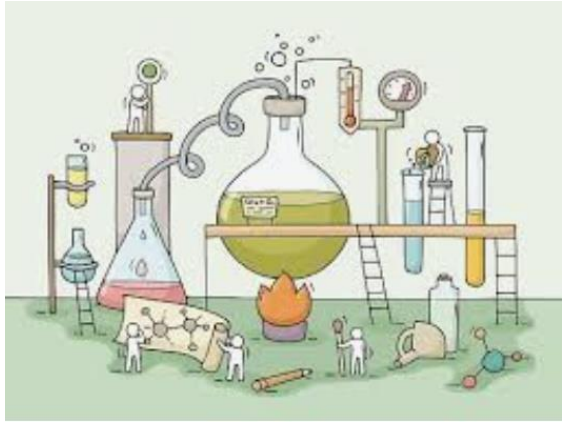
Federal Circuit: JMOL of No Enablement Affirmed

***Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021)**

- Key Cases re functional claiming: "[T]he enablement inquiry for claims that include functional requirements can be particularly focused on the ***breadth*** of those requirements, especially where predictability and guidance fall short." *Id.* at 1086.
  - *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385-86 (Fed. Cir. 2013):
    - Claims required particular structure and functionality;
    - Large number of possible candidates within claimed scope + spec's lack of structural guidance = undue experimentation.
  - *Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc.,* 928 F.3d 1340 (Fed. Cir. 2019)
    - Claims required particular structure and functionality;
    - Spec failed to teach POSITA whether the many embodiments of broad claims would exhibit required functionality.
  - *Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019)
    - Claims required particular structure and functionality;
    - Undue experimentation would have been required to synthesize and screen billions of possible compounds, given lack of guidance across full scope. "[N[eedle in a haystack."

Federal Circuit: JMOL of No Enablement Affirmed

***Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021)**



- Application of *Wands:*

1. Scope of claims: Broad
    - Concerned with "functional breadth"
2. Predictability of field: Unpredictable
    - Amgen expert: translating sequence into known 3-D structure is "not possible"
    - Amgen expert #2: substitutions in AA sequence can affect function, and testing required to ensure that substitution does not alter binding/blocking functions
    - Evidence that only a small subset of examples of antibodies can predictably be generated
3. Guidance/direction: Not significant.
    - No reasonable factfinder could conclude there was adequate guidance beyond the narrow scope of the working examples that the "roadmap" produced;
    - Only ways to discover undisclosed antibodies: (1) trial and error by making changes to disclosed antibodies and screening for desired properties, and (2) *de novo* discovery through "roadmap." Both require "substantial amount of time and effort.

Supreme Court Enablement Standard for Genus Claims

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Supreme Court: Question Presented

***Amgen, Inc. v. Sanofi, et al.* 598 U.S. ____ (2023)**

- Certiorari granted on Question 2 of Amgen petition:
  - 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."

Supreme Court: Restates Enablement Standard

***Amgen, Inc. v. Sanofi, et al.* 598 U.S. ____ (2023)**

- Unanimous decision; opinion by Justice Gorsuch

- **"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."** *Id.* at 13.

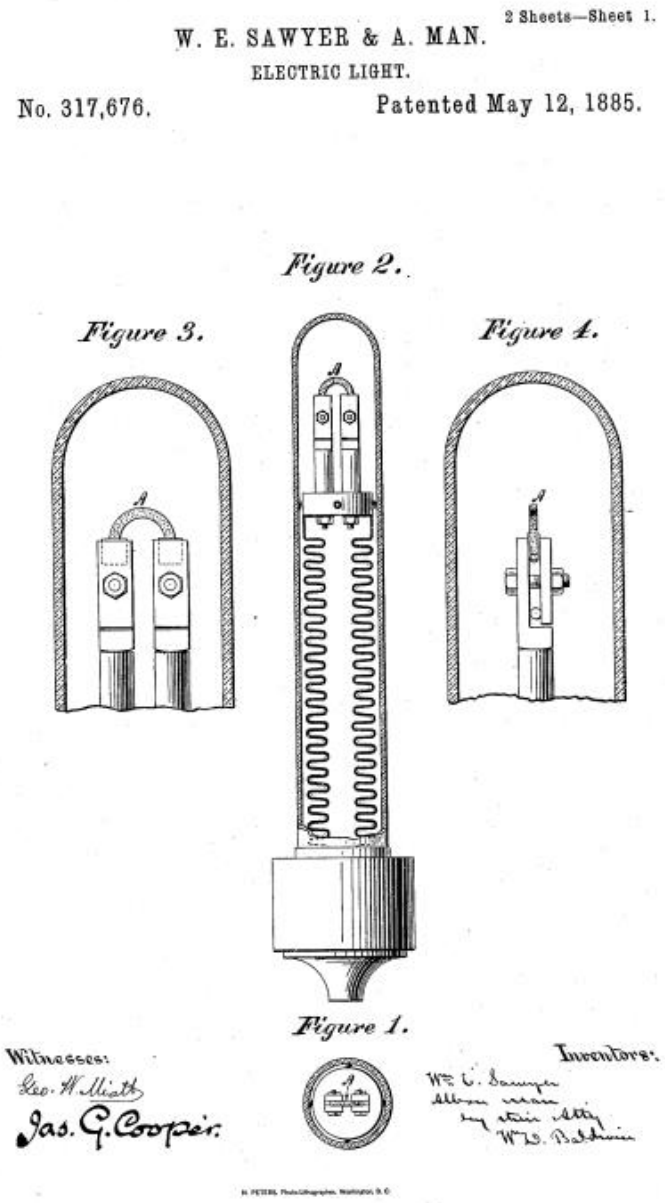
- **"In other words, the specification must enable the full scope of the invention as defined by its claims."**
  - Applies to all genus claims (not just antibodies)
  - *Wands* not mentioned
  - Opinion emphasizes that functional/genus claims are *not* held to stricter standard of enablement, but ***scope of the claim matters***

O'Reilly v. Morse (1854)

15 How. 62 (1854)

- Claim 8 "too broad, and not warranted by law"
- Claim 8 "covered *all* means of achieving telegraphic communication, yet Morse had not described how to make and use them all."
- If Claim 8 allowed, there would be "no necessity for any specification" besides stating the discovery itself

8. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims, the essence of my invention being the use of the motive power of the electric or galvanic current, which I call "electro-magnetism," however developed, for marking or printing intelligible characters, signs, or letters at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.



2 Sheets—Sheet 1.

W. E. SAWYER & A. MAN.

ELECTRIC LIGHT.

No. 317,676. Patented May 12, 1885.

Figure 2.

Figure 3.

Figure 4.

Figure 1.

Witnesses:
Geo. W. Smith
Jas. G. Cooper.

Inventors:
Wm E. Sawyer
Albon Man
by their Atty
Wm. Baldwin

The Incandescent Lamp Patent (1895)

159 U.S. 465 (1895)

- Specification describes use of “carbonized paper” and wood carbon
- Claims cover any “carbonized fibrous or textile material”
- Sawyer and Man “claimed much but enabled little”
- Edison (alleged infringer’s) discovery of bamboo required “painstaking experimentation”
- **Potentially enabled if inventors disclose “a quality common” each functional embodiment, and others would know how to “select among such materials.”**

Holland Furniture Co. v. Perkins Glue Co. (1928)

277 U.S. 245 (1928)

- Perkins invented specific starch glue
- Specification described "use or function" instead of the "physical characteristics or chemical properties" of the key ingredients
- Required gluemakers to engage in "elaborate experimentation"

28. A glue comprising cassava carbohydrate rendered semi-fluid by digestion and having substantially the properties of animal glue.

30. A wood and fiber glue formed of a starchy carbohydrate or its equivalent by union therewith of about 3 parts or less by weight of water and alkali metal hydroxid.

Oral Argument: Size of Class v. Extent of Disclosure

JUSTICE THOMAS: Mr. Lamken, would you take a minute and tell us exactly what the invention is?

MR. LAMKEN: Yes. It's the class of antibodies that bind to a particular spot --

JUSTICE THOMAS: Well, let's -- let's deal with that. The -- you only have 26 that you have invented, right?

JUSTICE THOMAS: So, in other words, you can't say how many?

Mr. Lamken (counsel for Amgen) responding to Justice Thomas
Amgen v. Sanofi Oral Arguments, 5:13-20, 6:18-19

Oral Argument: Policy Argument

I also completely agree that I do think it would be helpful -- to the extent there are scientists still out there making these broad genus claims that are going to stifle innovation, I -- I do think that that's a -- a danger to innovation and especially in the medical field, where, from what people who know better than me tell me, antibody innovation is key, and -- and we don't want people claiming more than they've really invented.

Ms. Sinzdak (Assistant to the Solicitor General) responding to Justice Kavanaugh about the importance of affirming the Federal Circuit's approach to broad genus claims
Amgen v. Sanofi Oral Arguments, 105:5-14

Functional Claiming of Antibodies

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What Worked: *Wands*

In re Wands, 58 F.2d 731, 737 (Fed. Cir. 1988)

Antibody claims – Immunoassay methods for detection of hepatitis B surface antigen by using high-affinity IgM monoclonal antibodies, and the chemically modified IgM monoclonal antibodies used in such an assay.

- "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. Wands, 858 F.2d at 737.
  - Disclosure adequately taught using hybridoma technology to produce needed claimed antibodies.
  - "[N]o evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen." *Id.* at 740.

What Didn't Work: *Amgen*

***Amgen, Inc. v. Sanofi, et al.* 598 U.S. ____ (2023)**

Antibody claims – all antibodies that bind PCSK9 "sweet spots" and block PCSK9 from binding LDLR.

- 26 antibodies described by amino acid sequence
- Only two 3-dimensional structures shown
- "[A]t least a million candidates" that may fall within claims
- POSITA cannot predict whether antibody will bind PCSK9 or block PCSK9 activity based on amino acid sequence
- POSITA cannot predict 3-dimensional structure of antibody based on amino acid sequence

Guidance Moving Forward

FISH.

Supreme Court: Key Takeaways

***Amgen, Inc. v. Sanofi, et al.* 598 U.S. ____ (2023)**

- Focus on scope of claims
  - **"**The specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Id.* at 13.
- More predictability in underlying art = more likely experimentation will be "reasonable"
  - "A specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* at 15.
- Don't "monopolize" the genus
  - "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." *Id.* at 13.
  - "Amgen seeks to monopolize an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors. The record reflects that this class of antibodies does not include just the 26 that Amgen has described by their amino acid sequences, but a 'vast' number of additional antibodies it has not." *Id.* at 16.
- Guidance can't amount to recipe for trial and error
  - Roadmap and conservative substitution "approaches amount to little more than two research assignments . . . [that] leave a scientist . . . Forced to engage in 'painstaking experimentation' to see what works." *Id.* at 16-17.

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