



Patent Defenses

2022 Review

January 12, 2023

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Klarquist

Quiz

In patent law, which of the following is least like the others?

- A. An act.
- B. A function.
- C. A result.
- D. Information.

Topics

1. Bedrock principles
 - a) Conforming Laws and Rules
 - b) Questionable Laws and Rules
2. *Amgen v. Sanofi*
 - a) Possible Impacts
 - b) Practice Pointers
3. 2022 Case Highlights

Public Policy Goals

1. Foster invention.
2. Induce public disclosure of inventions to enrich public domain.
3. Induce follow-on inventors to invent different solutions.
4. Do not encumber what's already public domain.

<https://patentdefenses.klarquist.com/public-policies-limiting-patents/>

Two Engines of Innovation

1. Promise of monopoly profits/royalties induces invention and public disclosure.
2. Clear claim boundaries free others to confidently invent next to patent's boundary.

See [Amici Brief](#)

**BRIEF FOR HIGH TECH INVENTORS
ALLIANCE AND THE COMPUTER &
COMMUNICATIONS INDUSTRY
ASSOCIATION AS *AMICI CURIAE* IN
SUPPORT OF NEITHER PARTY**

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Quiz

On which of the following issues, is current Federal Circuit case law least justifiable under bedrock principles of the patent system?

- A. Requirements for showing nexus for “secondary considerations”.
- B. The doctrine of equivalents.
- C. Criteria for when a process in a product-by-process claim has patentable weight.
- D. The negative presumption under *Williamson*.

Quiz

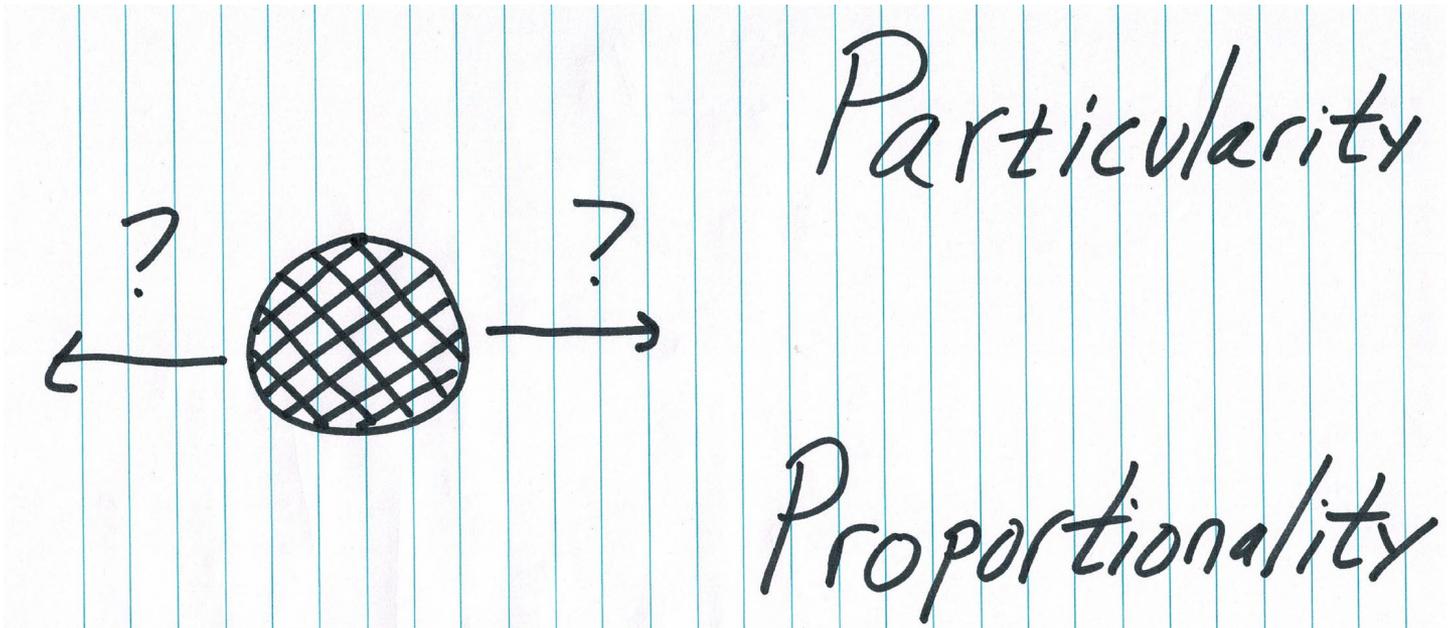
Claim: An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.

What best characterizes this claim?

- A. Invalid under Section 112(a).
- B. Invalid under Section 112(b).
- C. Invalid under Sections 112(a) and 112(b).
- D. Invalid under Section 112(f).
- E. Not facially invalid under Section 112.

Bedrock Principles

1. **Proportionality**: Give inventors what they contributed and no more.
2. **Particularity**: Patents are granted on structures, materials, and acts, not functions, results, or information.



Laws / Rules Conforming to Particularity Principle

1. 35 U.S.C. § 112(b).

“The specification shall conclude with one or more claims **particularly pointing out** and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”

Laws / Rules Conforming to Particularity Principle

1. Naked functional claim elements prohibited.
 - a) *Halliburton Oil* (1946), *General Electric* (1938), *Morse* (1853)
 - b) Section 112(6/f) (1952)
 - c) *In re Hyatt* (Fed. Cir. 1983) (Judge Giles Rich)



<https://patentdefenses.klarquist.com/particular-and-distinct-claims-aka-indefiniteness-sec-1122b-other-than-sec-1126f/#f-functional-and-result-claims>

Laws / Rules Conforming to Particularity Principle

<i>Morse</i>	<i>General Electric</i>	<i>Halliburton Oil</i>
the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for <u>marking or printing intelligible characters, signs, or letters, at any distances</u>	A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to <u>prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.</u>	means associated with said pressure responsive device for <u>tuning said receiving means to the frequency of echoes from the tubing collars of said tubing sections to clearly distinguish the echoes from said couplings from each other.</u>

Laws / Rules Conforming to Particularity Principle

1. BPAI:

- a) [Ex parte Miyazaki](#) (BPAI 11/19/08) (precedential) (“the claimed ‘sheet feeding area operable to feed ...’ is a purely functional recitation with no limitation of structure” and thus unpatentable for lack of definiteness and lack of enablement).
- b) [Sanada](#) (BPAI 03/19/03) (Informative) (“purely functional” claim language that for some reason does not invoke Sec. 112(6/f) is in a “**dead zone**” and indefinite under [Halliburton Oil](#) (U.S. 11/18/1946), but here claim language does invoke Sec. 112(6/f)).

Laws / Rules Conforming to Particularity Principle

1. *Alice* patent eligibility law.

- a) [IBM \(Zillow\)](#) (Fed. Cir. 10/17/22) (patent “is result-oriented, describing required functions (presenting, receiving, selecting, synchronizing), without explaining how to accomplish any of the tasks”).
- b) [SG Brief](#) (05/24/22) (urging *cert.* grant in *American Axle*; “The long-settled patent law meaning of ‘process’ requires not merely a ‘result,’ but also ‘a mode of treatment’ or ‘series of acts’ that will ‘produce’ it. *Diehr*, 450 U.S. at 183 (citation omitted).”).

Laws / Rules Conforming to Particularity Principle

1. “No patentable weight” law.
 - a) “It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof.” [In re Gardiner](#) (CCPA 12/07/48).
 - b) [Kamstrup](#) (Fed. Cir. 08/12/22) (aff’g PTAB that “being cast in one piece” is product-by-process limitation in part because it says “being,” and it has no patentable weight as patent owner “fails to show that the process claimed imparts ‘structural and functional differences’ distinguished from the prior art”).

Laws / Rules Conforming to Particularity Principle

1. Doctrine of Equivalents and Reverse DOE.
 - a) [Warner-Jenkinson](#) (U.S. 03/03/1997) (“An analysis of the role played by each element in the context of the specific patent claim will ... inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.”).
 - b) [Graver Tank](#) (U.S. 05/29/1950) (“where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee’s action for infringement”).

Laws / Rules Conforming to Particularity Principle

Take-away: The following are different sides of the same coin, implementing the **Particularity Principle**:

- “Particularly pointing out” in Section 112(b)
- *Halliburton Oil* and Section 112(f)
- *Alice* patent ineligibility
- No-patentable-weight rules
- Doctrine of equivalents
- Reverse doctrine of equivalents

Questions / Comments ?

Laws / Rules Conforming to Proportionality Principle

1. Damages apportionment law.
 - a) [Exmark](#) (Fed. Cir. 01/12/18) (even when claim directed to entire product (mower), damages must be apportioned to the allegedly improved part: “the patent owner must apportion or separate the damages between the patented improvement and the conventional components of the multicomponent product”).

Laws / Rules Conforming to Proportionality Principle

1. Nexus requirement for objective indicia of non-obviousness.
 - a) [In re Vamco](#) (Fed. Cir. 01/17/85) (“What it *claims* has nothing to do with the question of what it was that enjoyed commercial success and filled a felt need in the industry or was copied by competitors.” “The commercial success of a machine ‘claimed’ may be due entirely to improvements or modifications made by others to the invention disclosed in a patent. Such success, we are holding, is not pertinent to the non-obviousness of the invention disclosed.”).

Laws / Rules Conforming to Proportionality Principle

1. Identifying contributions sufficient to be deemed co-inventor.
 - a) [Plastipak](#) (Fed. Cir. 12/19/22) (vacating Summ. J. of invalidity under Sec. 102(f) for failure to join co-inventor; genuine disputes of fact over what third party's disclosures disclosed, whether named inventors made invention independently, and dispute of fact whether third party contributed anything beyond state of the art as shown in some prior art patents).

Laws / Rules Conforming to Proportionality Principle

1. Full-scope enablement.
 - a. [In re Hyatt](#) (Fed. Cir. 06/06/83) (Judge Giles Rich) (aff'g rejection of single “means” claim under “the requirement of the first paragraph of § 112 that the enabling disclosure of the specification be commensurate in scope with the claim under consideration”).

Laws / Rules Conforming to Proportionality Principle

1. Full-scope written description.

- a) [Festo](#) (U.S. 05/28/2002) (“What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue.”).
- b) [Schriber-Schroth I](#) (11/07/1938) (“the patent monopoly does not extend beyond the invention described and explained as the statute requires; that it cannot be enlarged by claims in the patent not supported by the description”).

Laws / Rules Conforming to Proportionality Principle

Take-away: The following implement the **Proportionality Principle**:

- Damages apportionment rules
- Co-inventorship criteria
- Requirements for showing objective-indicia nexus
- Full-scope enablement
- Full-scope written description

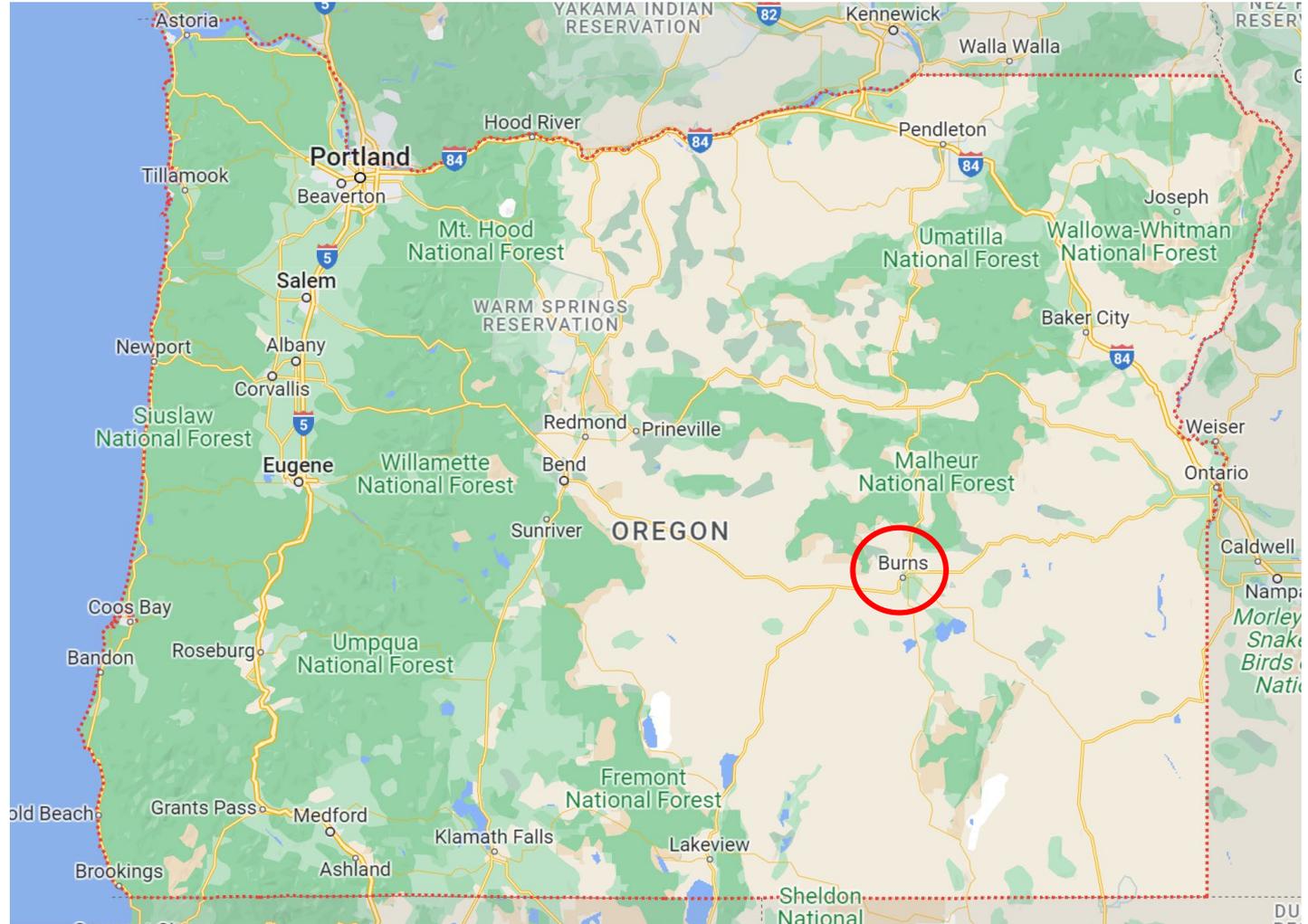
Questions / Comments ?

Quiz

Is Burns
in “central
Oregon”?

A. Yes.

B. No.



Laws / Rules Questionable Under Bedrock Principles

1. CRM claims.

- a) Claim: A ~~Fourier transform processor~~ computer-readable medium having computer executable instructions for performing a method of generating Fourier transformed incremental output signals in response to incremental input signals, said ~~Fourier transform processor~~ medium comprising ~~incremental means~~ instructions for incrementally generating the Fourier transformed incremental output signals in response to the incremental input signals.
- b) [In re Hyatt](#) (Fed. Cir. 06/06/83) (“The long-recognized problem with a single means claim is that **it covers every conceivable means for achieving the stated result**, while the specification discloses at most only those means known to the inventor.”).

Laws / Rules Questionable Under Bedrock Principles

1. *Williamson's* negative presumption where claim element does not literally recite “means for” or “step for.”
 - a) “The language of the claim . . . describes this most crucial element in the ‘new’ combination in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus. We have held that a claim with such a description of a product is invalid.” [Halliburton Oil](#) (U.S. 11/18/1946).
 - b) “An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” 35 U.S.C. § 112(f).

Laws and Rules Questionable Under Bedrock Principles

1. Equating information with structure, materials, or acts.
 - a) [Dyfan](#) (Fed. Cir. 03/24/22) (the claim limitations (“system comprising ... code, when executed, further configured to ...,” “application [configured to ...],” and “system [configured to ...]”) do not trigger 112(6/f) where challenger’s expert testified that skilled artisans would have understood that “conventional” “off-the-shelf” applications and code were available to perform the functions), [petition for rehearing en banc](#) (05/02/22) (treating “code” as structure is contrary to *Williamson*).
 - i. See IP Professors’ [Amici](#) in support of rehearing (05/16/22) (“If software patentees can avoid *Williamson* and write purely functional claims merely by using the word ‘code’ in place of actual structure, this Court will have rendered *Williamson* a dead letter.”).

Laws and Rules Questionable Under Bedrock Principles

Some Fed. Cir. panels follow *Halliburton Oil*:

- Uniformly invalidate under 112(b) claim with Sec. 112(f) element lacking sufficient structure, material, or acts in Specification.
- [Ergo Licensing](#) (Fed. Cir. 03/26/12) (explaining Sec. 112(6/f): “Failure to specify the corresponding structure in the specification amounts to impermissible pure functional claiming.”; “Requiring disclosure of an algorithm properly defines the scope of the claim and prevents pure functional claiming.”).

Laws and Rules Questionable Under Bedrock Principles

But other Fed. Cir. panels do not:

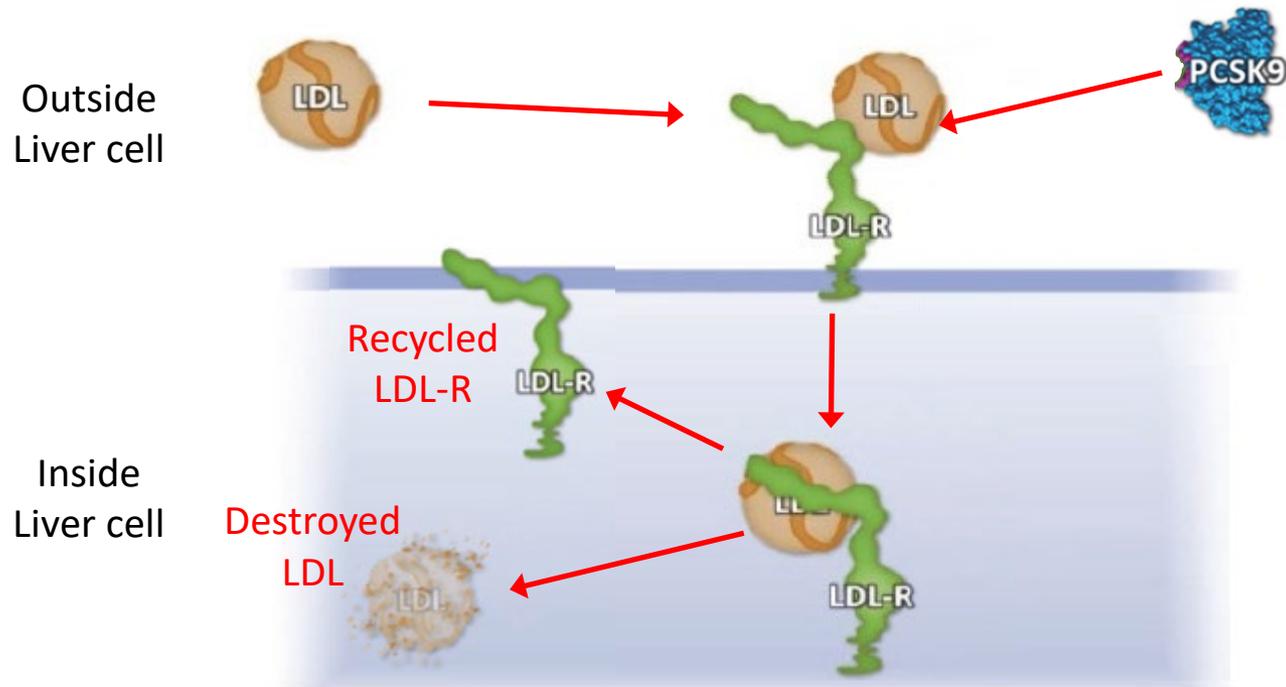
- “The *Nautilus* standard of ‘reasonable certainty’ does not exclude claim language that identifies a product by what it does. Nothing inherent in the standard of ‘reasonable certainty’ precludes a relevant skilled artisan from understanding with reasonable certainty what compositions perform a particular function. Not surprisingly, we have long held that nothing in the law precludes, for indefiniteness, ‘defining a particular claim term by its function.’” [BASE](#) (Fed. Cir. 11/20/17).

Laws and Rules Questionable Under Bedrock Principles

1. Many Fed. Cir. panels on 112(b):
 - a) Do not consider second engine of innovation, *i.e.*, whether claim chills inventive efforts adjacent claim's boundary.
 - b) Conflate clear identification of some embodiments inside claim boundary (Bend, OR) with clear claim **boundary** ("central Oregon").
2. None:
 - a) Consider whether uncertainty over triggering of Section 112(f) renders claim scope uncertain.

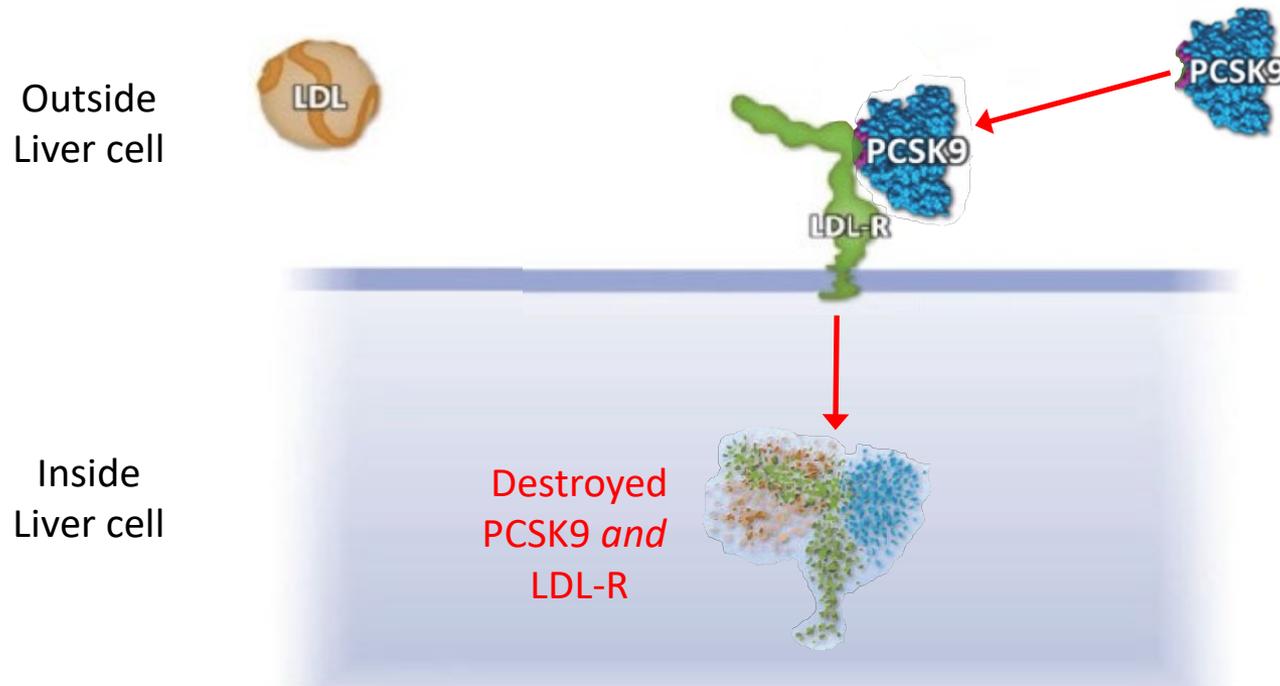
Amgen v. Sanofi

Underlying Technology: Monoclonal antibodies to reduce LDL cholesterol



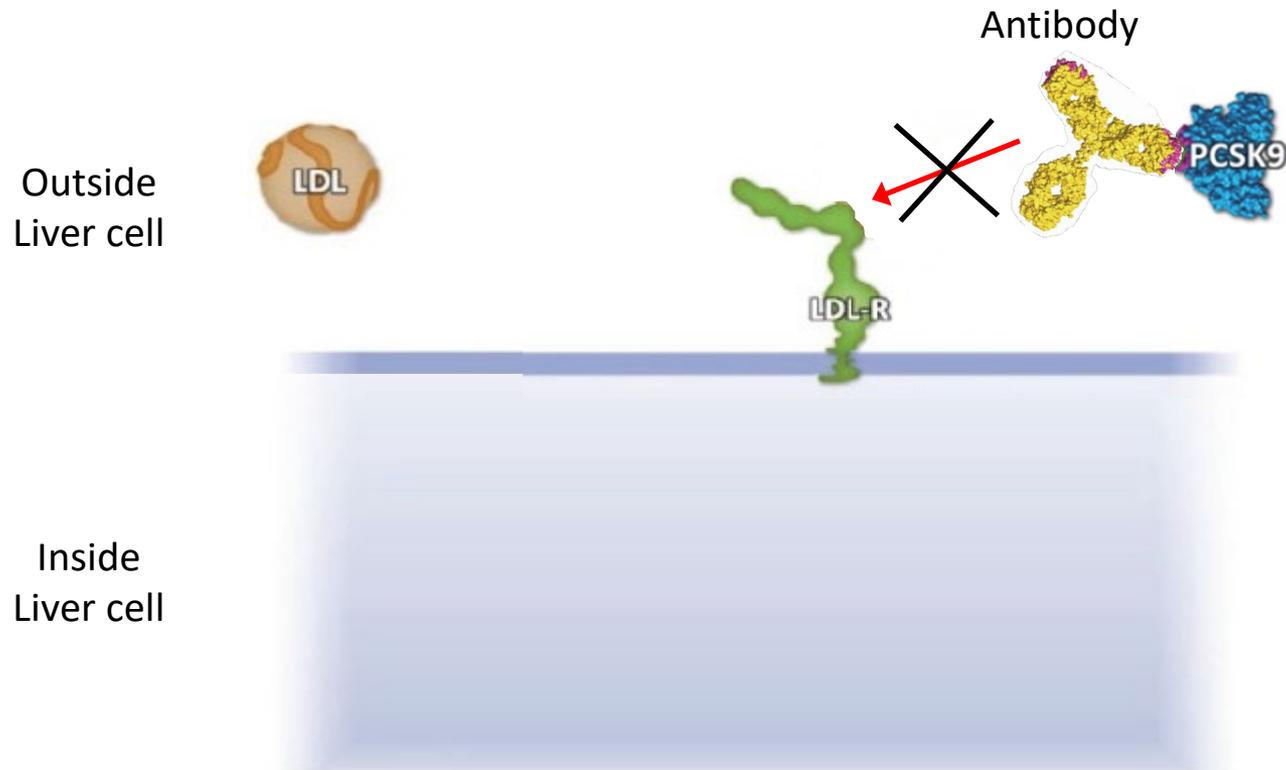
Amgen v. Sanofi

Underlying Technology: Monoclonal antibodies to reduce LDL cholesterol

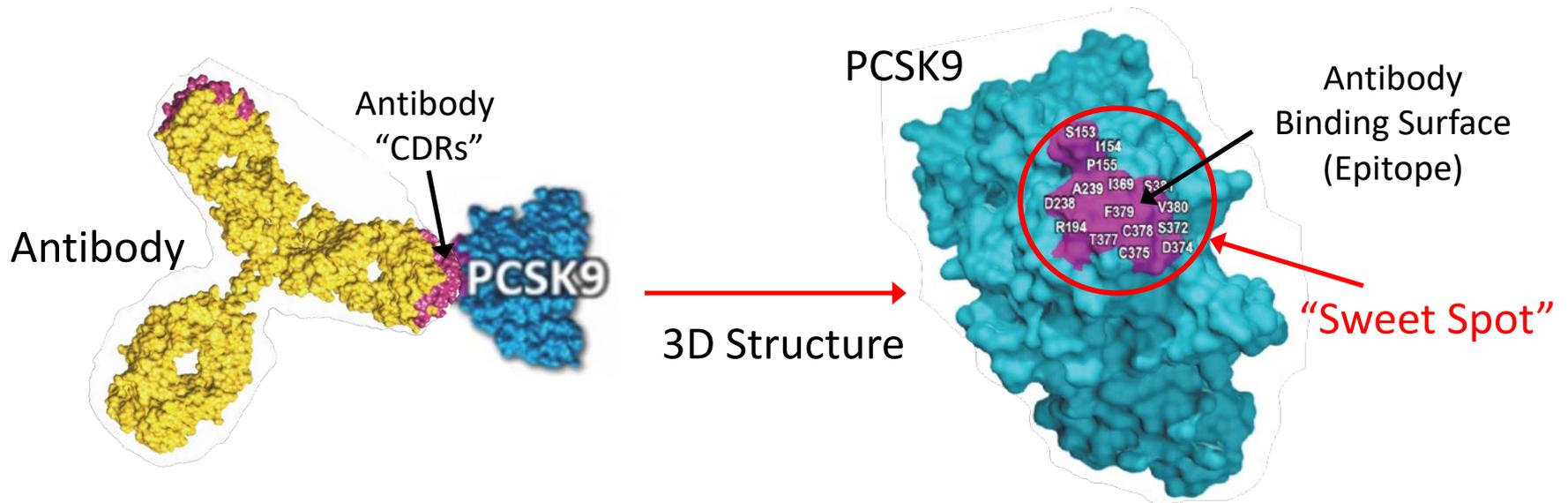


Amgen v. Sanofi

Underlying Technology: Monoclonal antibodies to reduce LDL cholesterol

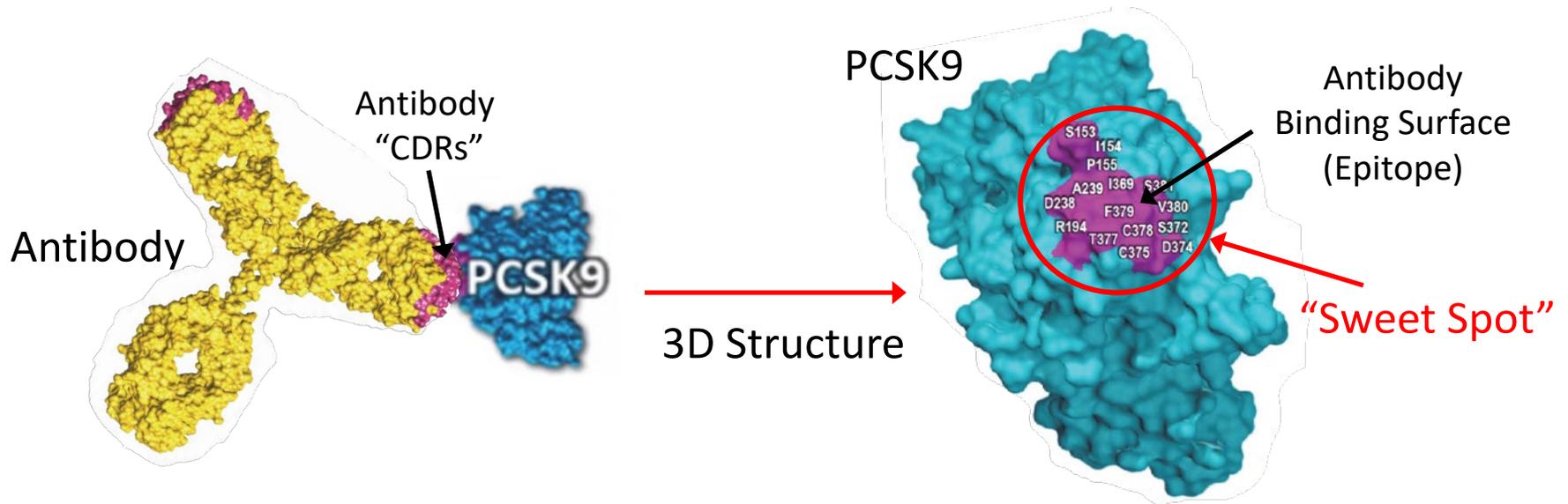


Amgen v. Sanofi



19. [reformatted] An isolated monoclonal antibody, wherein, when bound to PCSK9, the 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.

Amgen v. Sanofi



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%.

Amgen v. Sanofi

“Structures, materials, and acts” not recited in these claims:

1. Antibody 3D structure
2. Antibody amino acid sequence
3. Antibody CDR sequence
4. How antibody specifically binds to epitope on PCSK9
5. How antibody specifically blocks PCSK9 binding to LDL-R

Amgen v. Sanofi

Related Amgen patent (non-asserted) claims antibody function + structure:

- 15. An isolated neutralizing human **monoclonal antibody** that binds to a PCSK9 protein comprising:

*a heavy chain polypeptide comprising the following **complementarity determining regions (CDRs)**: a heavy chain CDR1 that is a CDR1 in SEQ ID NO: 67; a heavy chain CDR2 that is a CDR2 in SEQ ID NO: 67; a heavy chain CDR3 that is a CDR3 in SEQ ID NO: 67; and*

*a light chain polypeptide comprising the following **CDRs**: a light chain CDR1 that is a CDR1 in SEQ ID NO: 12; a light chain CDR2 that is a CDR2 in SEQ ID NO: 12; and a light chain CDR3 that is a CDR3 in SEQ ID NO: 12,*

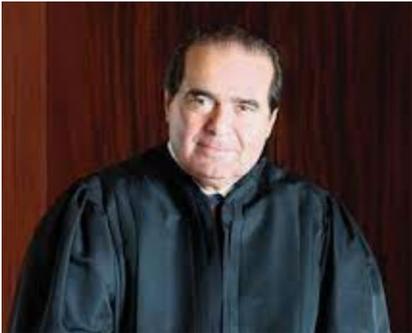
wherein each CDR is defined in accordance with the CDR definition of Kabat.

U.S. Pat. No. 8,168,762, claim 15.

Proceedings Below

1. Two patents disclosed amino-acid sequences of 26 antibodies, one for Amgen's Repatha[®], the first PCSK9 inhibitor approved to treat high LDL cholesterol.
2. Sanofi-Regeneron stipulated to infringement.
3. Two successive juries rejected written description and enablement defenses.
4. After second trial, district court granted JMOL overturning jury verdict on enablement.
5. "It is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim." [Amgen \(Sanofi\) II](#) (Fed. Cir. 02/11/21) (aff'g JMOL).

Why Court Granted Cert. on Sec. 112 Before



3 JUSTICE SCALIA: If that's -- if that's what
4 it held we wouldn't have taken this case. I thought we
5 took it because it had some really extravagant language.

6 MR. HARRIS: The court, the court below used
7 the word --

8 JUSTICE SCALIA: I mean, it's one thing to
9 run away from that language, as your brief does. It's
10 another thing to deny that it exists.

Amgen v. Sanofi

1. Amgen Brief (Dec. 27):
 - a) Disclosure must “permit skilled artisans to **reasonably** make and use individual embodiments as needed.”
 - b) But Fed. Cir. created new standard, requiring skilled artisans be able to “**reach the full scope of claimed embodiments**”—i.e., to **cumulatively identify and make all, or nearly all, possible variations** of the invention—without “ ‘substantial time and effort.’ ” {**full-scope identification**}
 - c) “Cut[s] off patent protection for the most significant inventions simply because they have too many useful applications.”
 - d) “If the **claim truly exceeds what the patent enables**, challengers will always be able to show, through evidence, that skilled artisans cannot reasonably ‘make and use’ large areas of the claimed invention by following the patent’s teachings.”

Amgen v. Sanofi

Brief for High Tech Inventors Alliance and the Computer & Communications Industry Association
as Amici Curiae in Support of Neither Party (Jan. 3)

1. These are naked functional claims.
2. Naked functional claims prohibited.
3. Sec. 112(f) saves some “combination” facially naked functional claims, but not single-element ones.
4. Antibody claim single-element; “composition” perhaps combination.
5. But PTO, parties, lower courts ignored this law and Sec. 112(f).
6. So, DIG, or cabin this poor vehicle to not disturb Sec. 112’s delicate balance codifying bedrock principles promoting innovation.

Amgen v. Sanofi

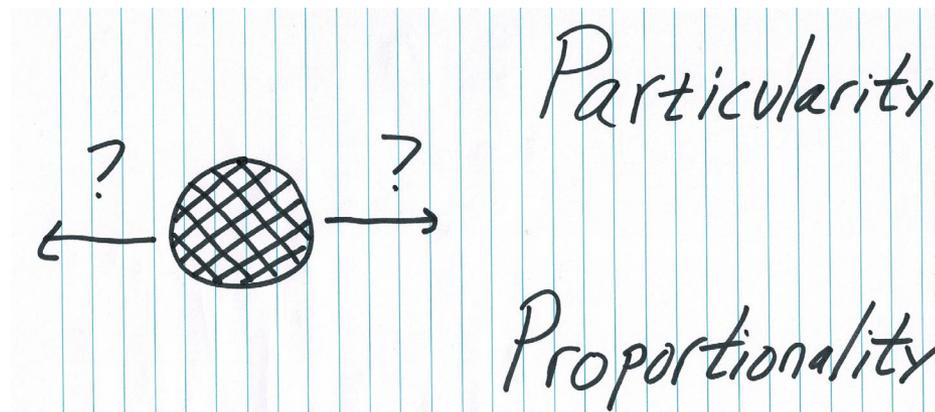
Which public policy will prevail?

Favoring Amgen:

1. Foster invention.
2. Induce public disclosure of inventions to enrich public domain.

Favoring Sanofi:

1. Induce follow-on inventors to invent different solutions.



Amgen v. Sanofi: Possible Impacts

1. Impact on antibody patenting? Limited, unless changes written description law.
2. 112(a): Change full-scope enablement law? Beyond refuting any full-scope **identification** mandate?
3. 112(a): Change full-scope written description law?
4. 112(a)/(b): Weaken Court's historical ban on functional claiming?
5. 112(b): Allow patents to leave it to public to experiment to identify most embodiments within scope of the claim?
6. 112(b)/(f): Apply Section 112(f) to antibody (molecule) claims?
7. 112(b)/(f): Confirm single-element naked functional claim invalid?

Amgen v. Sanofi: Prosecution Pointers to Consider

1. Don't settle for only:
 - a) single-element functional claims.
 - b) claims w/ naked functional claim elements.
 - c) claims that depend on *Williamson's* negative presumption being the law when claim litigated.

Amgen v. Sanofi: Prosecution Pointers to Consider

1. Consider accompanying function with *materials and/or acts*, not just structures.
2. Ask whether Spec. and claims identify nearly all claimed embodiments or instead leave that mostly to the public.

Amgen v. Sanofi: Prosecution Pointers to Consider

1. Ask how the claims measure up to Particularity and Proportionality.
2. Use Particularity and Proportionality as criteria for claim diversity—between claims and between patents.

Amgen v. Sanofi: Litigation Pointers to Consider

1. Be more persistent challenging naked functional claim elements.
 - a) Assert *In re Hyatt* against CRM claims.
 - b) Emphasize Sec. 112(f) (like 112(d) and 112(e)) mandatory on PTO and courts at each stage (“shall be construed”).
 - c) Emphasize Sec. 112(f) advances Particularity and Proportionality principles.
 - d) Argue that uncertainty whether element triggers Sec. 112(f) renders claim scope uncertain.

... even if co-defendants, co-counsel, and district court are *Halliburton Oil* and Section 112(f) skeptics.

Acts

In patent law, which of the following is least like the others?

- A. An act.
 - B. A function.
 - C. A result.
 - D. Information.
- “An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” 35 U.S.C. § 112(f).

2022 HIGHLIGHTS

<https://patentdefenses.klarquist.com/recent-updates/>

1. Requirements for Showing Inducement Infringement by an ANDA
2. *Alice* and Data Structures
3. *Alice* and Naked Functions
4. Issue Preclusion: When Ripe? When Forfeited?
5. Chief Justice Stays Mandate in Novartis “Negative Limitation” Written Description Case
6. Assignor Estoppel on Remand from S. Ct.
7. Stop Short-Changing the Central Character in any Pretrial Patent Invalidity Movie
8. Where Claim Requires Capability, Need to Show Accused Device Without Alteration Reasonably Capable of Such Use
9. Generic Claim Element Loses Entitlement to Ancestor Application’s Filing Date

2022 HIGHLIGHTS

10. A Negative Limitation Must Be Disclosed Expressly, Such as a Reason to Exclude That Element, or Inherently
11. “Code” Configured to Perform Function Does Not Trigger Sec. 112(6/f) Where Conventional Code Available to Perform the Function
12. Fed. Cir. Continues Mixed Enforcement of Mandate That Claims Have Clear Boundaries
13. Indirect Infringement Damages Limited to Extent of Direct Infringement
14. Another Application of *Williamson*
15. Information Now is “Structure”?
16. Two En Banc Rehearing Denials Divide Fed. Cir.: Skinny Label and Disclosure Support for End Point of a Range
17. Fed. Cir. Divided on Whether Alleged Priority Application, or Issued Application, Is Subject of Written Description Invalidity Analysis
18. Obviousness: Carefully Compare Skilled Artisan’s Field of Endeavor to Reference’s Field
19. Oops!: Our Expert is Less Than Ordinary

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