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Claim Drafting Considering the *Amgen v. Sanofi* US Supreme Court Decision

June 30 |

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Webinar開始の前に

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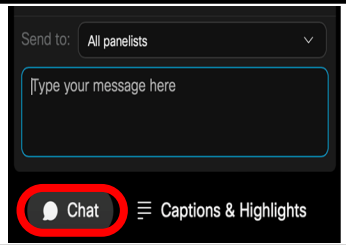

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AGENDA

1. RECENT *AMGEN* DECISION: ENABLEMENT
2. TRADITIONAL STRATEGIES FOR CLAIMING ANTIBODIES
3. EXEMPLARY CLAIMING TECHNIQUES IN LIGHT OF *AMGEN*
4. QUESTIONS

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1. RECENT *AMGEN* DECISION: ENABLEMENT

Enablement: *Amgen v. Sanofi*

> On May 18, 2023, the U.S. Supreme Court issued its much-anticipated decision affirming the Federal Circuit's decision in *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021) and requiring patentees enable the full scope of a claimed genus.

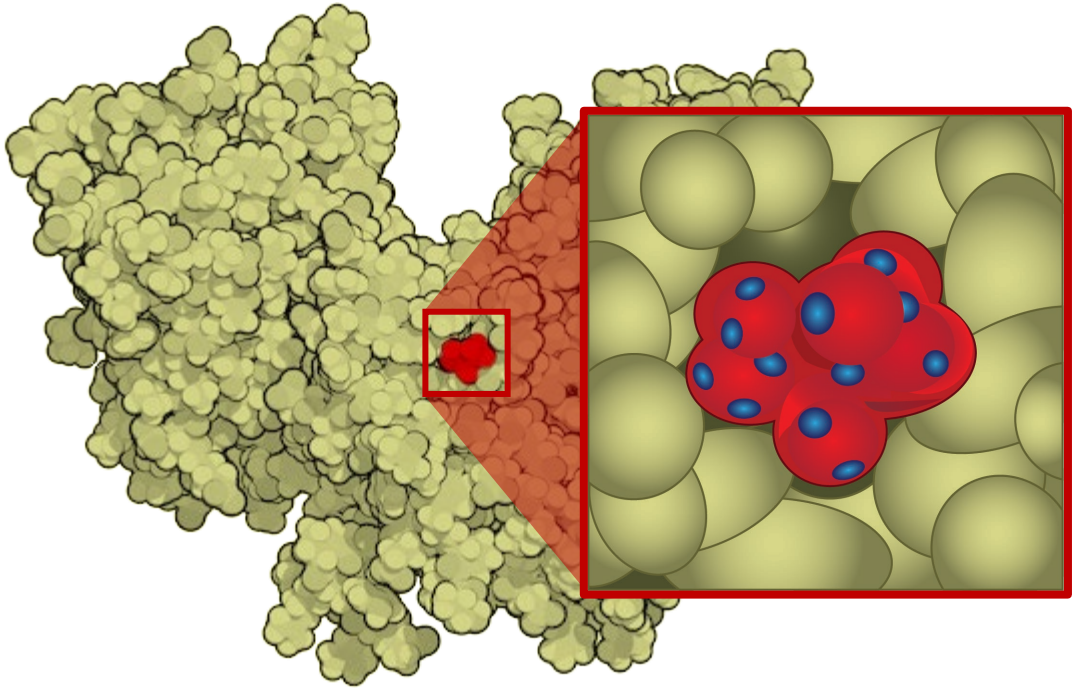
In other words, the ***specification must enable the full scope of the invention*** as defined by the claims. The ***more one claims, the more one must enable***.

Federal Circuit: *Amgen Inc. v. Sanofi*

> Exemplary claim:

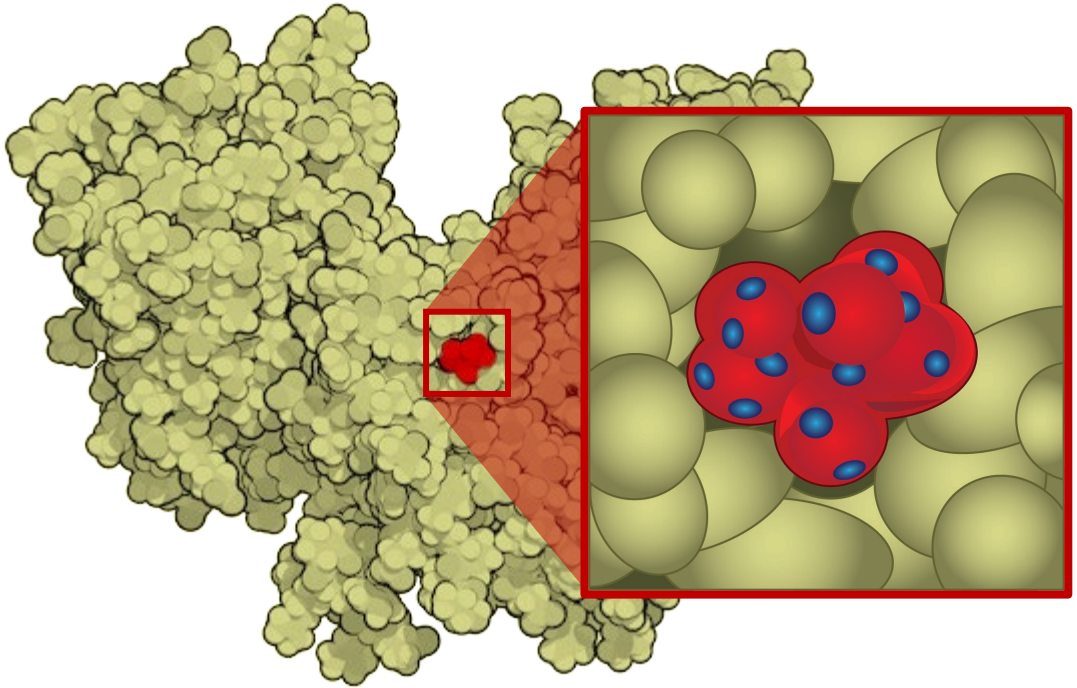
1. An isolated monoclonal antibody, **wherein, when bound to PCSK9**, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and **wherein the monoclonal antibody blocks binding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

Federal Circuit: *Amgen Inc. v. Sanofi*



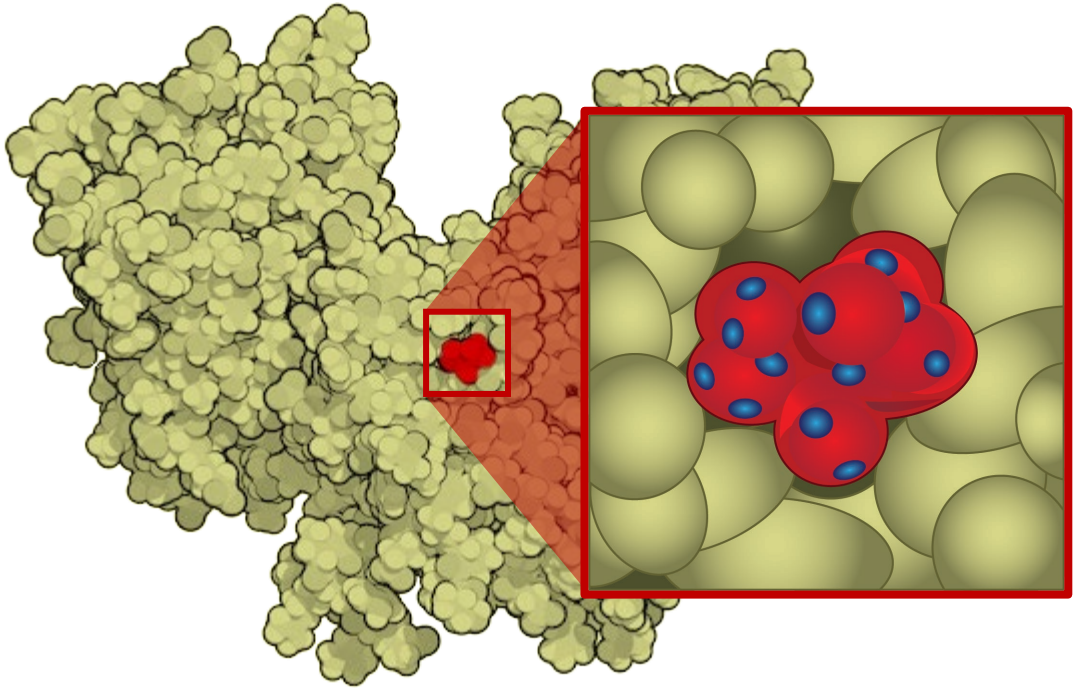
Federal Circuit: *Amgen Inc. v. Sanofi*

"To begin, unlike the claims in those cases, which merely required binding to an antigen, Amgen's claims require binding to a specific region on an antigen (PCSK9). It is that particular requirement that implicates the conceded unpredictability of generating antibodies to bind to specific residues (and the need to test such antibodies to determine if they do so)."



Federal Circuit: *Amgen Inc. v. Sanofi*

"The binding limitation is itself enough here to require undue experimentation."



Federal Circuit: *Amgen Inc. v. Sanofi*

- **Amgen expressly claimed more than 32,000 combinations of residues and was required to enable every combination.**

"Regardless of the exact number of embodiments, it is clear that the claims are far broader in functional diversity than the disclosed examples."

- **Determining where a particular antibody binds requires x-ray crystallography, a time-consuming and unpredictable methodology.**

"[E]ven assuming that the patent's "roadmap" provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's 'roadmap' produced."

Federal Circuit: *Amgen Inc. v. Sanofi*

- **Performing amino acid substitutions according to the specification's instructions would lead to "millions of candidates" that must be tested.**
  - Teaching non-working means of practicing the claimed invention can undermine enablement.

"[I]f the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."

U.S. Supreme Court: *Amgen Inc. v. Sanofi*

> **The Supreme Court agreed that the field of antibody drug design and development was unpredictable.**

Despite recent advances, aspects of **antibody science remain unpredictable**. For example, scientists understand that **changing even one amino acid in the sequence can alter an antibody's structure and function**. But scientists **cannot always accurately predict** exactly how trading one amino acid for another will **affect an antibody's structure and function**. Slip Op. at 3.

U.S. Supreme Court: *Amgen Inc. v. Sanofi*

> **The Supreme Court defined Amgen's claim genus as follows and noted the breadth of the genus:**

"In these claims, **Amgen did not seek protection for any particular antibody** described by amino acid sequence. Instead, **Amgen purported to claim** for itself '**the entire genus' of antibodies that (1) 'bind to specific amino acid residues on PCSK9,' and (2) 'block PCSK9 from binding to [LDL receptors]**.'" Slip Op. at 5.

"While **Amgen had identified** the amino acid sequences of **26 antibodies** that bind to PCSK9 and block it from binding to LDL receptors, Sanofi observed that **Amgen's claims cover potentially millions** more undisclosed antibodies that perform these same functions." Slip Op. at 6.

U.S. Supreme Court: *Amgen Inc. v. Sanofi*

> **After examining its precedents, the Supreme Court held as follows:**

"Our decisions in *Morse*, *Incandescent Lamp*, and *Holland Furniture* reinforce the simple statutory command. 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." Slip Op. at 13.

U.S. Supreme Court: *Amgen Inc. v. Sanofi*

- **The Supreme Court did leave room for genus claims based on exemplary disclosures where they disclosed a general quality common to every functional embodiment, even where some reasonable degree of adaptation or testing is required.**

"That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. 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.'** 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. **Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing**." Slip Op. 13-14.

U.S. Supreme Court: *Amgen Inc. v. Sanofi*

- **The Supreme Court declined to set definitative threshholds for permissible experimentation and instead left that determination to the lower courts based on the nature of the invention and predictability of the underlying art.**

"Decisions such as *Wood* and *Minerals Separation* establish that **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**." Slip Op. 15.

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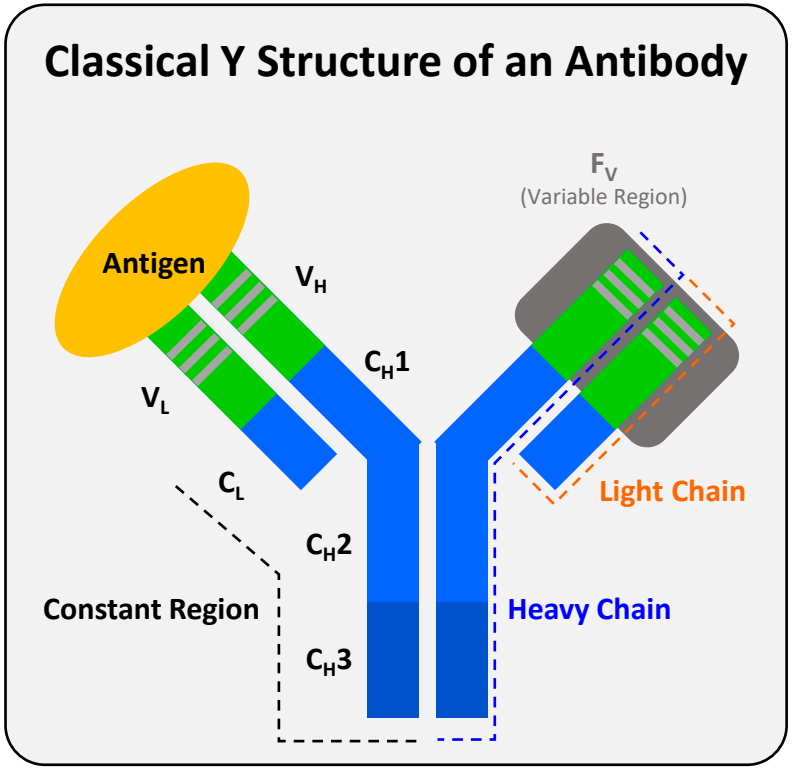
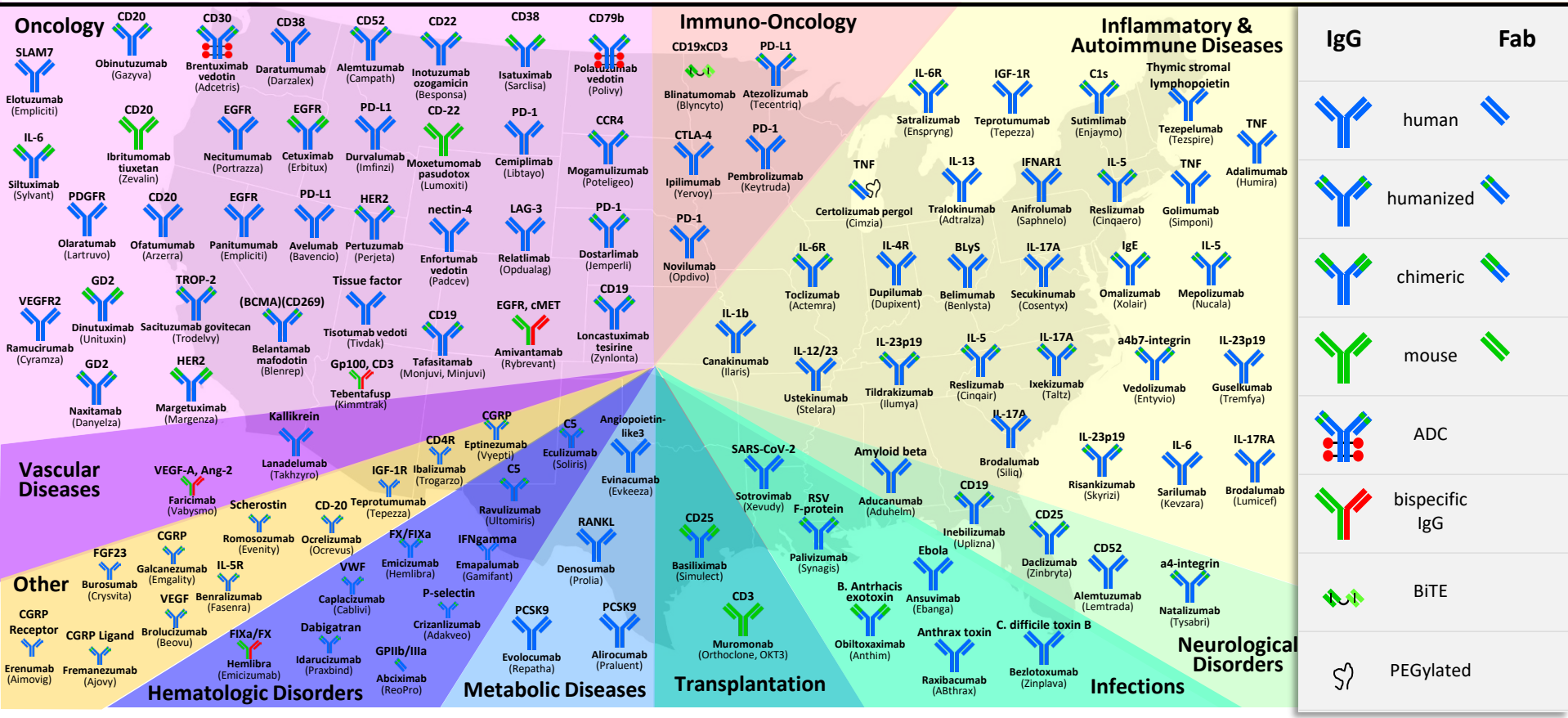
2. TRADITIONAL STRATEGIES FOR CLAIMING ANTIBODIES

What is an Antibody?

- Protein produced by a **B-cell** *(lymphocyte)* in response to the presence of a **foreign antigen** *(non-self)*
- Assist with the neutralization and removal of an antigen
- Typically engineered to bring payload to a target or disrupt biologic process
- Make up a very significant portion of biologic drugs on the market today many of which are now facing biosimilar entrants



US Branded Antibody Landscape



Strategies for Claiming Antibodies

Sequence & Structure

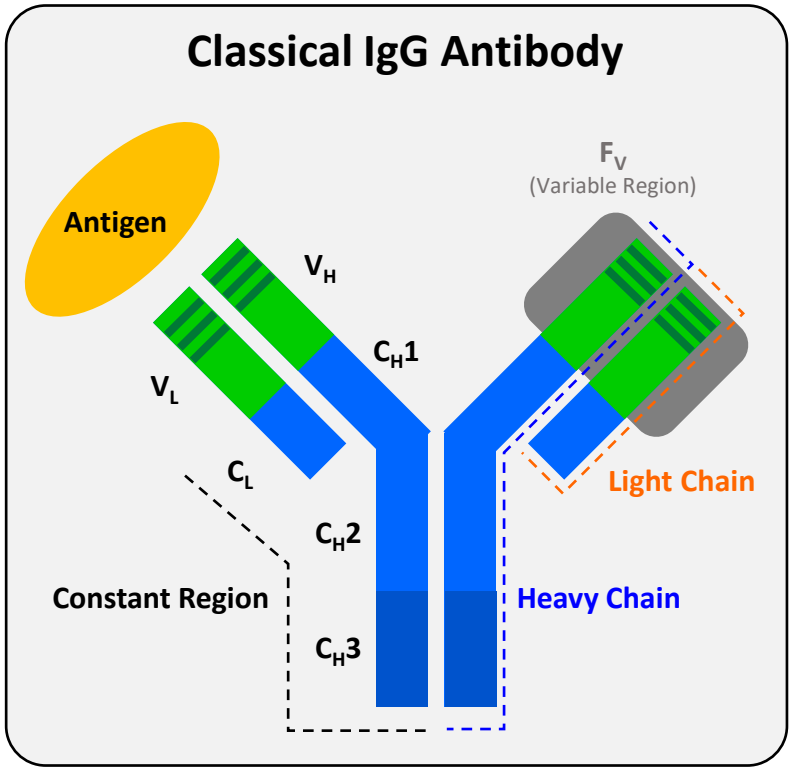
> Claim directed to entire heavy and light chain sequences.

Example:

An antibody that binds antigen X, comprising a heavy chain as set forth in SEQ ID NO: 1 and a light chain as set forth in SEQ ID NO: 2.

> Full-length heavy and/or light chain variable region (VH/VL).

> Heavy and/or light chain CDRs



Strategies for Claiming Antibodies

Sequence & Structure

> Homologous sequences

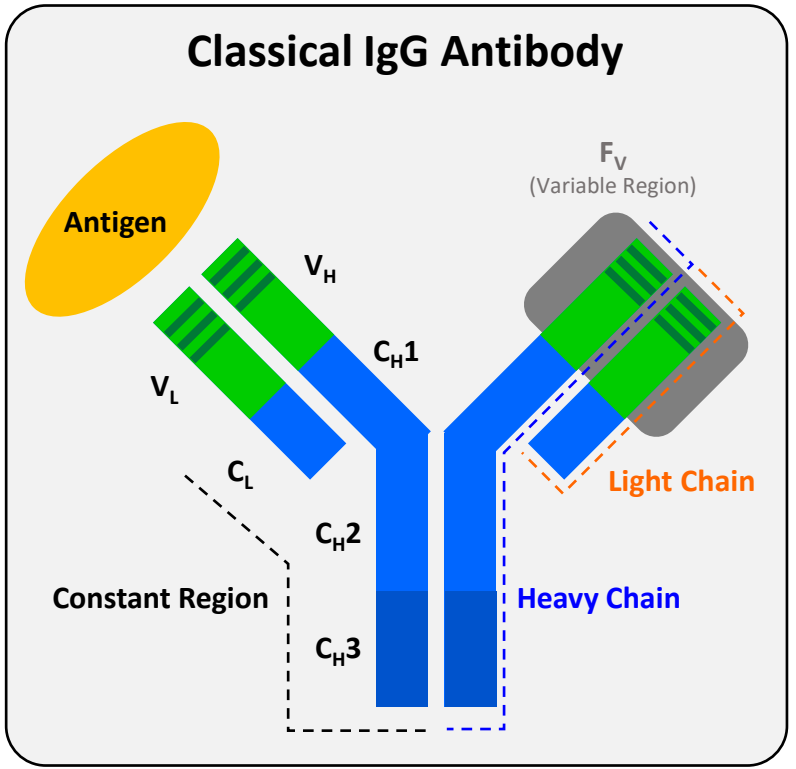
> 70%, 80%, 90%, 95% identical/similar

Example:

An antibody that binds antigen X, comprising a heavy chain having at least 95% sequence identity to SEQ ID NO: 1 and a light chain having at least 95% sequence identity to SEQ ID NO: 2.

> Fragments

> Epitope or paratope

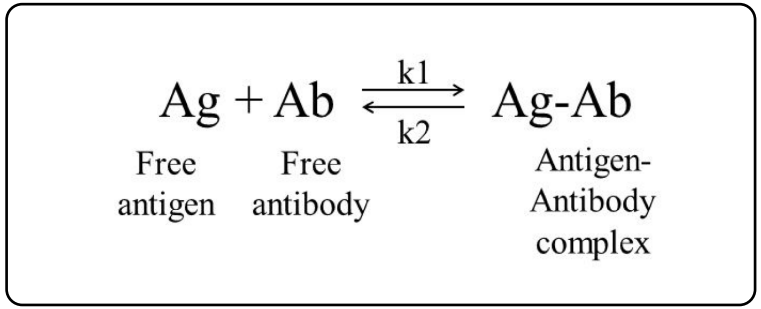


Strategies for Claiming Antibodies

Function

- Binding affinity (e.g., Kd, K_{off})
- Effect of binding interaction
  - Treatment of disease/disorder
- Competition for binding with other antibodies

Example: An antibody that binds antigen X, and competes with reference antibody Y for binding to antigen X.



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3. EXEMPLARY CLAIMING TECHNIQUES IN LIGHT OF RECENT SUPREME COURT CASE LAW

> Exemplary claim:

> **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.

Appropriate Claim Breadth for Proteins and Nucleic Acids

- **Traditional non-antibody sequence claiming strategies**
  - Locked-in CDRs with variability permitted in framework regions
    - Similarly nucleic acid/protein claims should lock in those regions that are central to the invention.
  - Epitope claims, binding properties, competitive binding
  - Show structure/function correlation

- **Non-traditional antibody claiming strategies**
  - Means-Plus-Function and Jepson claims

Locked-In CDRs with Flexibility in Variable Regions

- Goal is to reduce the size of the genus of claimed antibodies and eliminate any argument that the claims would require undue experimentation to identify additional members of the genus.
  - All members of the genus have the same CDR sequences.
    - Potentially allow one or two conservative amino acid substitutions in the CDRs.
  - All members of the genus share the same framework region sequences.

Locked-In CDRs with Flexibility in Variable Regions

> An antibody that binds human, wherein the antibody comprises:

a) three heavy chain CDR sequences consisting of amino acid sequences:

i. SEQ ID NO. 1 (CDR1 HC),

ii. SEQ ID NO. 2 (CDR2 HC), and

iii. SEQ ID NO. 3 (CDR3 HC), and

b) three light chain CDR sequences consisting of amino acid sequences:

i. SEQ ID NO. 4 (CDR1 LC),

ii. SEQ ID NO. 5 (CDR2 LC), and

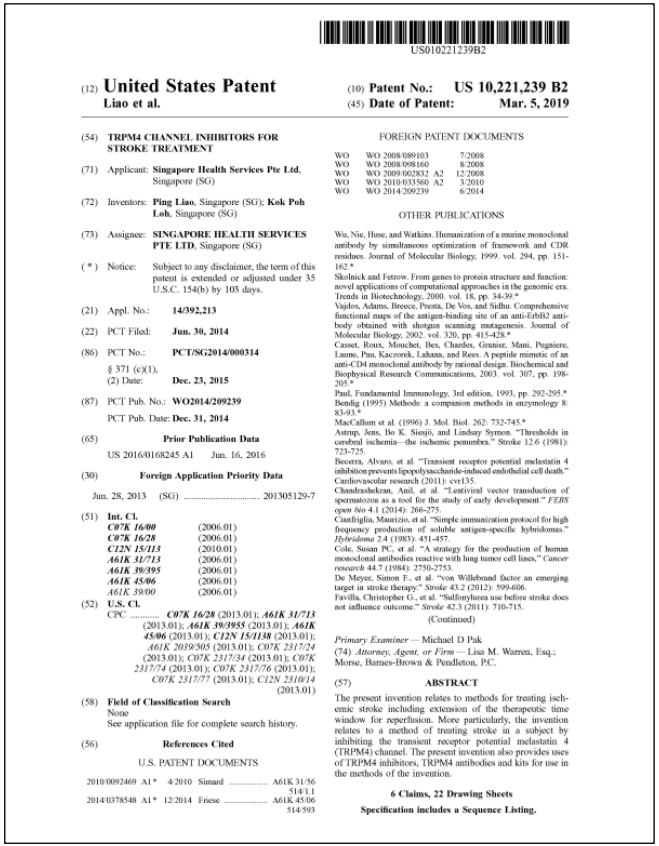
iii. SEQ ID NO. 6 (CDR3 LC), and

wherein the antibody comprises a heavy chain variable region sequence that is at least 95 % identical to SEQ ID NO. 7, and a light chain variable region sequence that is at least 95 % identical to SEQ ID NO. 8.

Epitope Claims

U.S. 10,221,239

- Titled “TRPM4 Channel Inhibitors for Stroke Treatment”
- Issued March 5, 2019
- Assigned to Singapore Health Services Pte, Ltd.
- Invention relates to a method of treating stroke in a subject by inhibiting the transient receptor potential melastatin 4 (TRPM4) channel



US010221239B2

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

(10) **Patent No.: US 10,221,239 B2**
(45) **Date of Patent: Mar. 5, 2019**

(54) **TRPM4 CHANNEL INHIBITORS FOR STROKE TREATMENT**

(71) Applicant: **Singapore Health Services Pte Ltd**, Singapore (SG)

(72) Inventors: **Ping Liao**, Singapore (SG); **Kok Poh Loh**, Singapore (SG)

(73) Assignee: **SINGAPORE HEALTH SERVICES PTE LTD**, Singapore (SG)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 103 days.

(21) Appl. No.: **14/392,213**

(22) PCT Filed: **Jun. 30, 2014**

(86) PCT No.: **PCT/SG2014/000314**
§ 371 (c)(1),
(2) Date: **Dec. 23, 2015**

(87) PCT Pub. No.: **WO2014/209239**
PCT Pub. Date: **Dec. 31, 2014**

(65) **Prior Publication Data**
US 2016/0168245 A1 Jun. 16, 2016

(30) **Foreign Application Priority Data**
Jun. 28, 2013 (SG) 201305129-7

(51) **Int. Cl.**
C07K 16/00 (2006.01)
C07K 16/28 (2006.01)
C12N 15/113 (2010.01)
A61K 31/713 (2006.01)
A61K 39/395 (2006.01)
A61K 45/06 (2006.01)
A61K 39/00 (2006.01)

(52) **U.S. Cl.**
CPC ***C07K 16/28*** (2013.01); ***A61K 31/713*** (2013.01); ***A61K 39/3955*** (2013.01); ***A61K 45/06*** (2013.01); ***C12N 15/1138*** (2013.01); *A61K 2039/505* (2013.01); *C07K 2317/24* (2013.01); *C07K 2317/34* (2013.01); *C07K 2317/74* (2013.01); *C07K 2317/76* (2013.01); *C07K 2317/77* (2013.01); *C12N 2310/14* (2013.01)

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

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Primary Examiner — Michael D Pak
(74) *Attorney, Agent, or Firm* — Lisa M. Warren, Esq.; Morse, Barnes-Brown & Pendleton, P.C.

(57) **ABSTRACT**

The present invention relates to methods for treating ischemic stroke including extension of the therapeutic time window for reperfusion. More particularly, the invention relates to a method of treating stroke in a subject by inhibiting the transient receptor potential melastatin 4 (TRPM4) channel. The present invention also provides uses of TRPM4 inhibitors, TRPM4 antibodies and kits for use in the methods of the invention.

6 Claims, 22 Drawing Sheets
Specification includes a Sequence Listing.

Epitope Claims

> Claims to antibody binding TRPM4 rejected on written description and enablement grounds, citing Amgen v. Sanofi.

1. (Currently Amended) An isolated antibody ~~or antigen-binding fragment thereof~~ specific to the transient receptor potential melastatin 4 (TRPM4) protein, ~~wherein~~ wherein:

the antibody ~~or antigen-binding fragment thereof~~ specifically binds to a peptide consisting of the amino acid sequence of SEQ ID NO: 1, a peptide consisting of the amino acid sequence of SEQ ID NO: 2, or a peptide consisting of the amino acid sequence of SEQ ID NO: 3,

the antibody specifically binds to an epitope comprising amino acids 949-952 and 985-1008 of SEQ ID NO: 11 or amino acids 955-958 and 991-1014 SEQ ID NO: 12, ~~a peptide sequence which lies between S5 and the P-loop of the TRPM4 protein~~ and

the antibody inhibits TRPM4 activity.

Epitope Claims

- Applicant amended claims to recite precise epitope sequences and explained that a 3D model was used to map the epitope to an exemplary antibody disclosed in specification.
  - Data also showed ability to disrupt TRPM4 activity after binding to that epitope.
- Examiner accepted this as sufficient characterization of structure-function correlation (WD), along with arguments about routine production of similar antibodies based on information provided about the epitope (enablement).

Epitope Claims

> Representative issued claims from U.S. 10,221,239

1. An isolated antibody specific to the transient receptor potential melastatin 4 (TRPM4) protein, wherein:

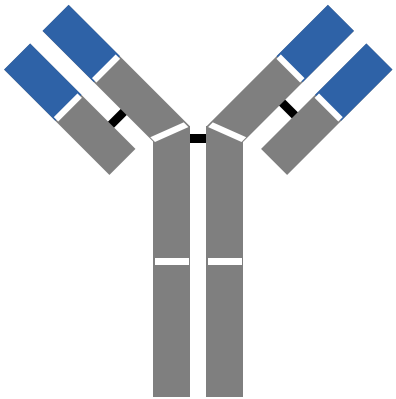
the antibody specifically binds to a peptide consisting of the amino acid sequence of SEQ ID NO: 1, a peptide consisting of the amino acid sequence of SEQ ID NO: 2, or a peptide consisting of the amino acid sequence of SEQ ID NO: 3,

the antibody specifically binds to an epitope comprising amino acids 949-952 and 985-1008 of SEQ ID NO: 11 or amino acids 955-958 and 991-1014 SEQ ID NO: 12, and

the antibody inhibits TRPM4 activity.

Jepson and Means-Plus-Function Claiming

- What other options are there to pursue antibody claims post *Juno*, *Amgen*, etc.
  - Take steps to limit having a claim analyzed under section 112 first paragraph
    - Jepson claims
    - Mean-Plus-Function (MPF) claims



Jepson Claims

- A claim drafted in Jepson format uses a preamble to recite elements or steps of the claimed invention that are conventional or known in the art, and adds new subject matter after the transition, typically "the improvement comprising . . .".
- This format is set forth in the Code of Federal Regulations:

> (e) Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:
>
> (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known,
>
> (2) A phrase such as "wherein the improvement comprises," and
>
> (3) Those elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.
>
> 37 C.F.R. §1.75(e).

Jepson Claims

- The Jepson form allows a patentee to use the preamble to recite "elements or steps of the claimed invention which are conventional or known."
  - The Federal Circuit has repeatedly acknowledged that what is conventional or well-known to one of skill in the art need not be disclosed in detail in order to satisfy the written description requirement.
- Exemplary Jepson claim (U.S. Patent No. 4,892,244):

  In a staple cartridge insertable within a surgical stapler and containing staples and comprising an elongated body including one or more longitudinal slots for slidably receiving one or more longitudinal pusher bars comprising a firing mechanism of said surgical stapler, and a plurality of drivers engageable by said pusher bars for ejecting the staples from the cartridge, said staple cartridge releasably fastened to a said surgical stapler, ***the improvement comprising*** a lockout mechanism connected to said longitudinal slots for preventing said pusher bars from passing more than one time through said longitudinal slots.

Mean-Plus-Function Claims

> The "means-plus-function" claim format is outlined in 35 U. S.C. §112, 6th paragraph (pre-AIA) or §121(f), (post AIA):

(f) Element in Claim for a Combination.—

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.

> "The `means' term in a means-plus-function limitation is essentially a generic reference for the corresponding structure disclosed in the specification." *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc*., 145 F.3d 1303, 1308 (Fed. Cir. 1998).

Mean-Plus-Function Claims

- To satisfy the written description requirement for a means-plus-function limitation, a patentee is required to disclose in the specification some enabling means for accomplishing the function set forth in the `means plus function' limitation. See, *D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574* (Fed. Cir. 1985).
  - The written description requirement specific to a means-plus-function limitation is that the specification disclose a structure that is sufficient to perform the claimed function. If it does not, then the limitation lacks adequate written description.
    - See MPEP § 2163.03, subsection VI ("If the specification fails to disclose sufficient corresponding structure, materials, or acts that perform the entire claimed function, then the claim limitation . . . lacks an adequate written description as required by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, because an indefinite, unbounded functional limitation would cover all ways of performing a function and indicate that the inventor has not provided sufficient disclosure to show possession of the invention.").

Mean-Plus-Function Claims

- Exemplary means-plus-function claim (U.S. Patent No. 7,736,644):

  25. An assay kit for the detection of EGFRvIII in mammalian tissues or cells comprising:
  the antibody of claim 1; and
  means for indicating the binding of the antibody with EGFRvIII, if present.

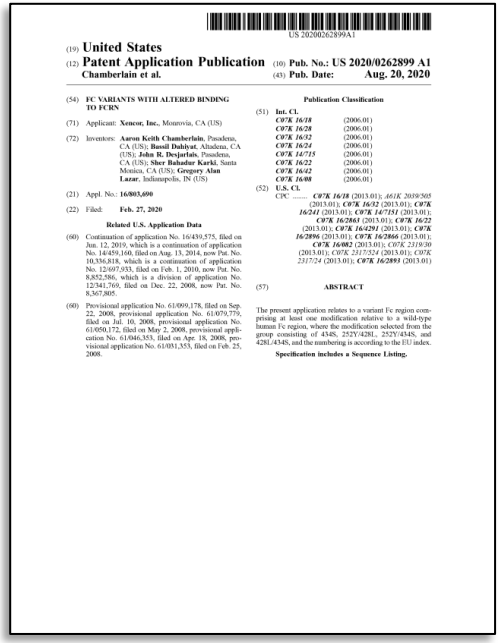
- Claim covers all means for "indicating the binding of the antibody" e.g., a labeled second antibody.

Possession of the Claimed Invention

- Unlike claims at issue in *AbbVie* and *Juno*, possession of the invention for a Jepson or a MPF claim does not require a description of a representative number of species or a disclosure of structure or other physical and/or chemical properties coupled with a known or disclosed correlation between function and structure.
- Different written description requirements:
  - **Jepson Claims** – *no need to provide written description for what is well-known and conventional (i.e., elements in the preamble).*
  - **MPF Claims** – *provide a single means for performing the claimed function in the specification.*

MPF Example 1: U.S. Patent Application No. 16/803,690

- Titled: Fc Variants With Altered Binding to FcRn
  - Pending appeal on ODP
  - Rejection for lack of written description withdrawn
- Includes both Jepson and means-plus-function claims
- Objective to pursue claims that are not limited by CDR or VH/VL sequences



US 20200262899A1

(19) **United States**

(12) **Patent Application Publication**
Chamberlain et al.

(10) **Pub. No.: US 2020/0262899 A1**
(43) **Pub. Date: Aug. 20, 2020**

(54) **FC VARIANTS WITH ALTERED BINDING TO FCRN**

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(21) Appl. No.: **16/803,690**

(22) Filed: **Feb. 27, 2020**

Related U.S. Application Data

(60) Continuation of application No. 16/430,575, filed on Jun. 12, 2019, which is a continuation of application No. 14/459,160, filed on Aug. 13, 2014, now Pat. No. 10,336,818, which is a continuation of application No. 12/697,933, filed on Feb. 1, 2010, now Pat. No. 8,852,586, which is a division of application No. 12/341,769, filed on Dec. 22, 2008, now Pat. No. 8,367,805.

(60) Provisional application No. 61/099,178, filed on Sep. 22, 2008, provisional application No. 61/079,779, filed on Jul. 10, 2008, provisional application No. 61/059,172, filed on May 2, 2008, provisional application No. 61/046,353, filed on Apr. 18, 2008, provisional application No. 61/031,353, filed on Feb. 25, 2008.

Publication Classification

(51) **Int. Cl.**

C07K 16/18	(2006.01)
C07K 16/28	(2006.01)
C07K 16/32	(2006.01)
C07K 16/24	(2006.01)
C07K 14/715	(2006.01)
C07K 16/22	(2006.01)
C07K 16/42	(2006.01)
C07K 16/08	(2006.01)

(52) **U.S. Cl.**
CPC ***C07K 16/18*** (2013.01); *A61K 2039/505* (2013.01); ***C07K 16/32*** (2013.01); ***C07K 16/241*** (2013.01); ***C07K 14/7151*** (2013.01); ***C07K 16/2863*** (2013.01); ***C07K 16/22*** (2013.01); ***C07K 16/4291*** (2013.01); ***C07K 16/2896*** (2013.01); ***C07K 16/2866*** (2013.01); ***C07K 16/082*** (2013.01); *C07K 2319/30* (2013.01); *C07K 2317/524* (2013.01); *C07K 2317/24* (2013.01); ***C07K 16/2893*** (2013.01)

(57) **ABSTRACT**

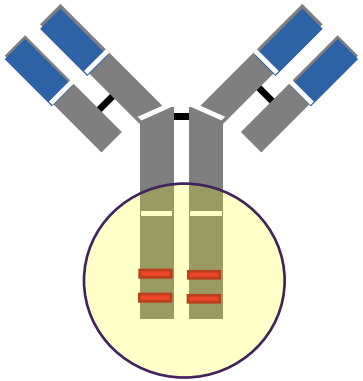
The present application relates to a variant Fc region comprising at least one modification relative to a wild-type human Fc region, where the modification selected from the group consisting of 434S, 252Y/428L, 252Y/434S, and 428L/434S, and the numbering is according to the EU index.

Specification includes a Sequence Listing.

Jepson Example 2: U.S. Patent Application No. 16/803,690

> Pending Jepson claim:

8. In a method of treating a patient by administering an anti-C5 antibody with an Fc domain, the improvement compri sing said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.



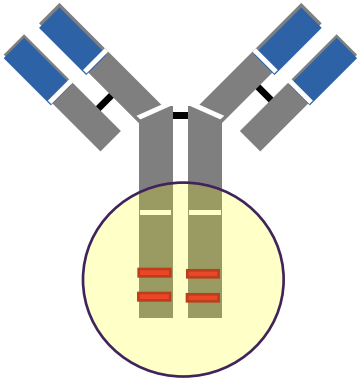
MPF Example 2: U.S. Patent Application No. 16/803,690

> Pending Means-Plus-Function claim:

9. A method of treating a patient by administering an anti-C5 antibody comprising:

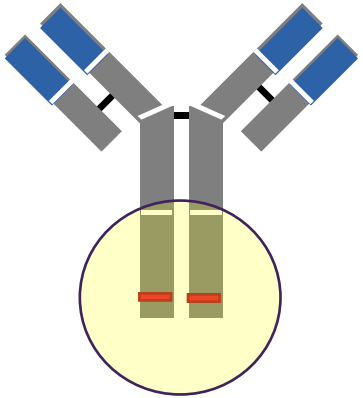
a) means for binding human C5 protein; and

b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.



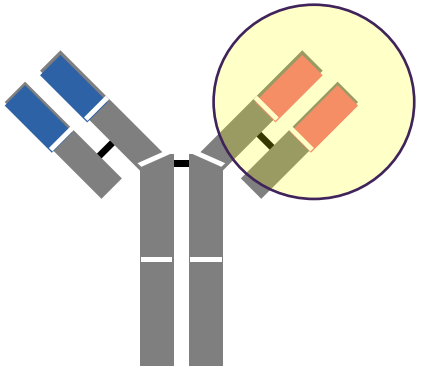
Claiming Strategies – Improved Antibodies

- Strategy may be useful to cover an amino acid substitution in a broad class of antibodies where the parent antibody itself is not novel.
  - CDR, Framework, Fc substitutions, *etc*.
    - ***Exemplary MPF Claim***: An antibody that binds Target A, the antibody comprising a means for binding Target A and an amino acid substitution at position X.
      - Provide example of such an antibody in the specification that binds to Target A.



Claiming Strategies – Bi-, Tri-, Multi-Specific Antibodies

- Strategy may be useful for covering bi, tri-, and multi-specific antibodies.
  - Recite one binding domain specifically and the other using MPF language
  - Exemplary MPF Claim: A bispecific molecule that binds to Target A and Target B, wherein the bispecific molecule comprises an antibody for binding Target A, wherein the antibody comprises a VH having SEQ ID NO: 1 and a VL having SEQ ID NO: 2; and a means for binding Target B.



Could the Outcome in *Juno* Been Different?

> Would *Juno* have had a different outcome if the claims were drafted using means-plus-function language?

Independent claim 1 of the 7,446,190 patent recites:

1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising:
(a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,
(b) a costimulatory signaling region, and
(c) a ~~binding element that~~ a means for specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

> Instead recite "a means for interacting with a selected target"

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THANK YOU