SATISFYING THE WRITTEN DESCRIPTION REQUIREMENT FOR LIVING INVENTIONS

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SETTER ROCHE LLP

OVERVIEW

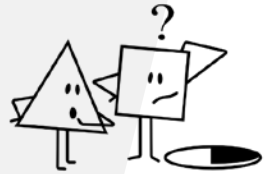
Written description requirements & goals

Reduction to practice – the biological deposit 

Requirements for a gene versus a genome

History of relevant caselaw 

Structure and function for patenting purposes

The unique challenges of trait and gene based claims 

WRITTEN DESCRIPTION REQUIREMENTS & GOALS

The specification shall contain a written description of the invention, and of the manner and process of 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….

35 U.S.C. 112(a)

WRITTEN DESCRIPTION REQUIREMENTS & GOALS

Goals of adequate written description

- Clearly convey that an Applicant has invented that which is claimed
- Satisfy the obligation to disclose the technical knowledge upon which the patent is based
- To demonstrate that the patentee was in possession of the invention *as claimed*

What is Sufficient to Satisfy the Written Description Requirement?

Detailed drawings

Structural chemical formulas

Any description of sufficient, relevant, identifying characteristics

An actual reduction to practice (biological deposit)

REDUCTION TO PRACTICE – THE BIOLOGICAL DEPOSIT

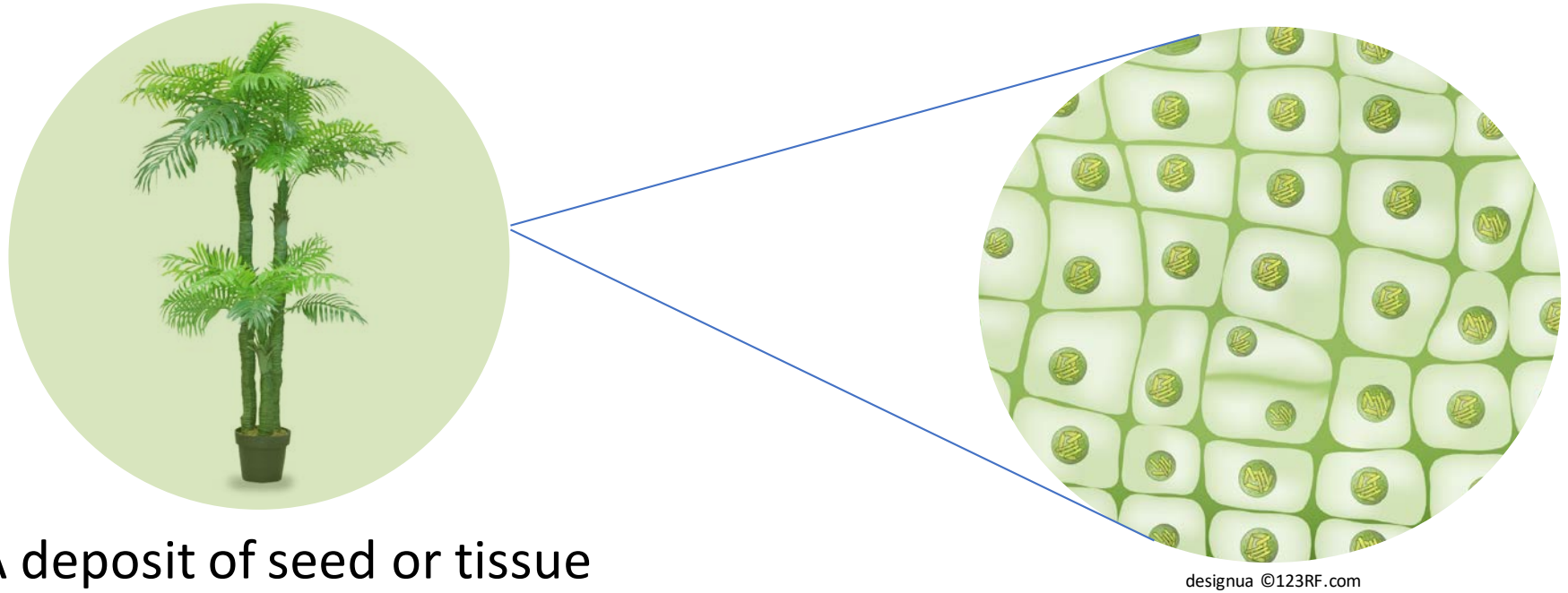
- A biological deposit shows actual reduction to practice
  - But this is not a substitute for a written description of the claimed invention
  - Additional identifying characteristics are required

Nilssonia

an extinct genus
of plants

REQUIREMENTS FOR A GENE VERSUS A GENOME

Claiming the plant line as a whole

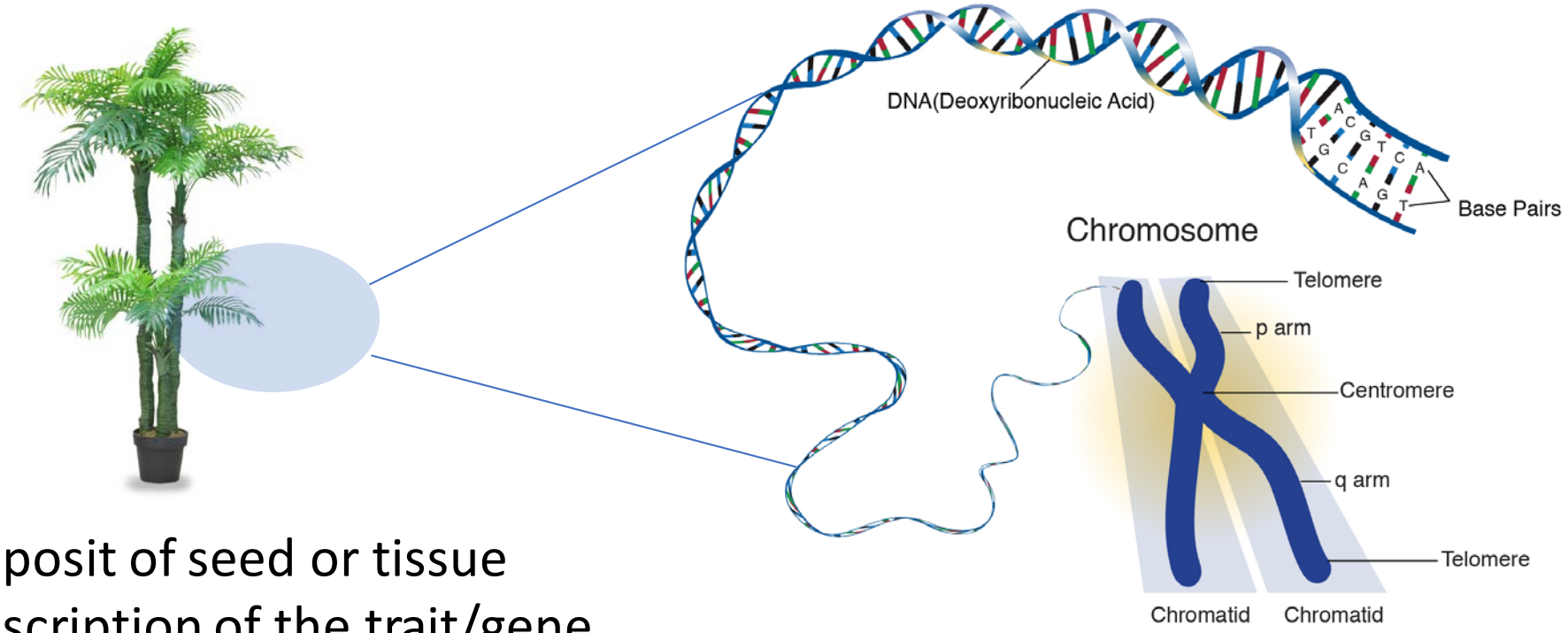


designua ©123RF.com

- A deposit of seed or tissue
- A description of the line

REQUIREMENTS FOR A GENE VERSUS A GENOME

Claiming a specific trait or gene

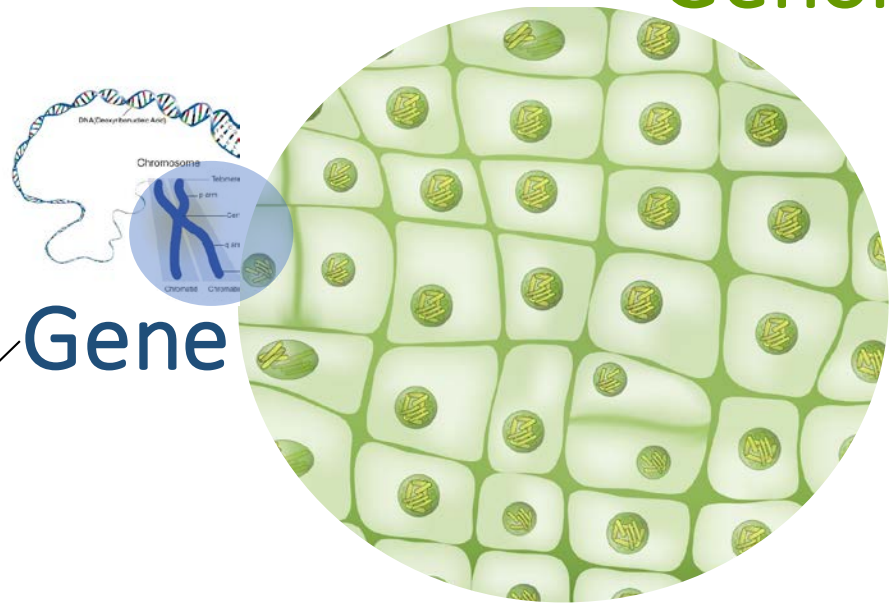


- A deposit of seed or tissue
- A description of the trait/gene

REQUIREMENTS FOR A GENE VERSUS A GENOME

Genome

Self propagation maintains the invention; crossing with another plant could create a new line/invention

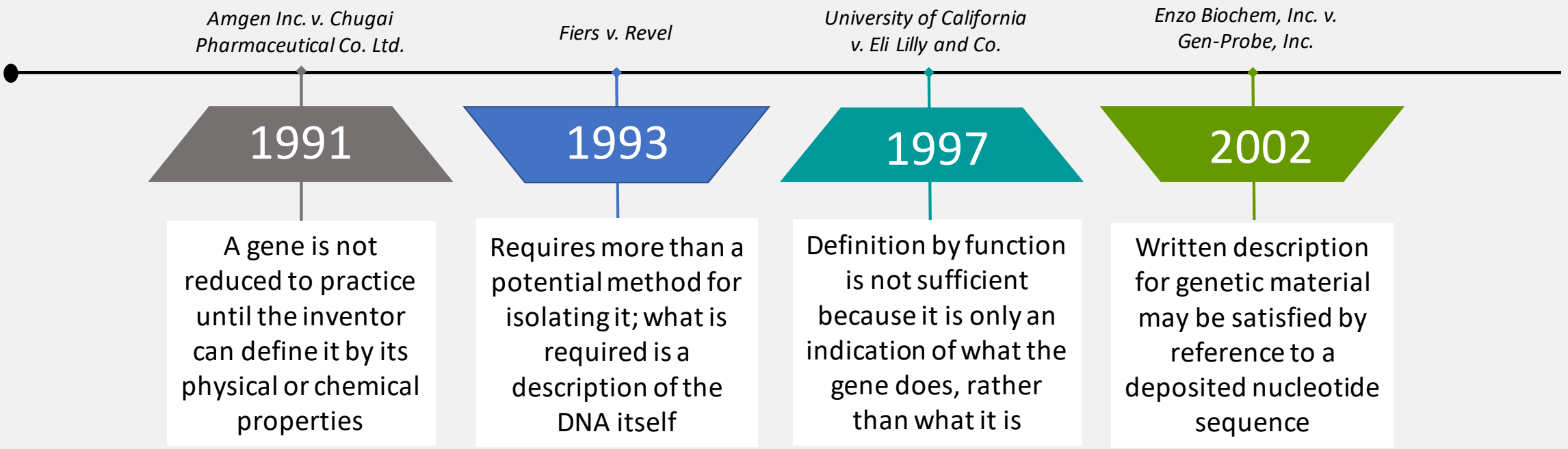


Gene

Self propagation may or may not maintain the invention; crossing with another plant can *transfer* the invention

The issue ultimately lies with separation due to a self-replicating invention/technology

HISTORY OF RELEVANT CASELAW



HISTORY OF RELEVANT CASELAW

Noelle v. Lederman

2004

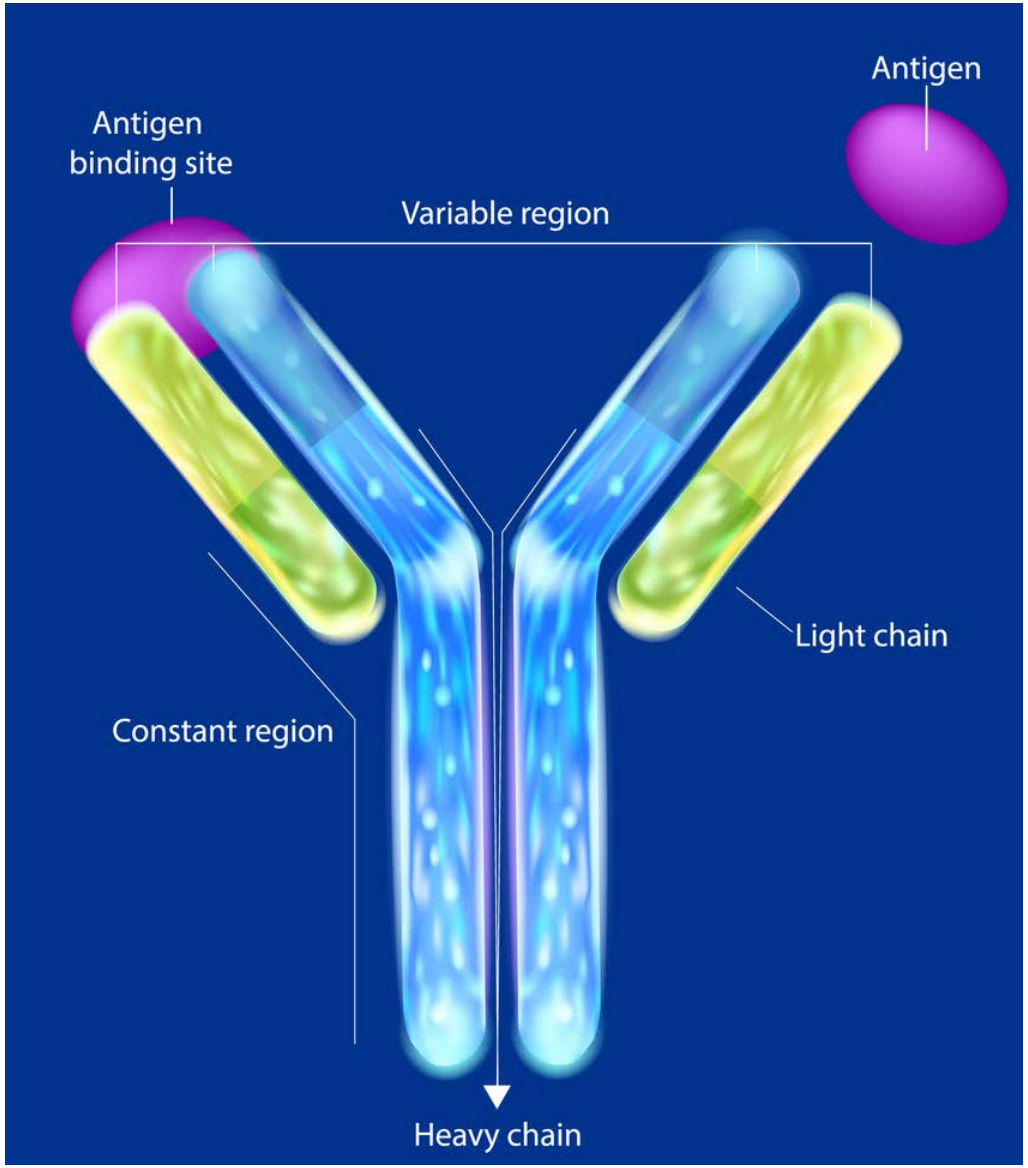
"Newly characterized antigen test" – claim to an antibody by its binding affinity to that antigen

Newly characterized antigen test

Functional characteristics when coupled with a known or disclosed correlation between function and structure

> a claim to an antibody satisfies the "function-structure test" where the antigen to which it binds has been fully characterized, and methods for making the antibody are routine“

quoting the Written Description Guidelines, 66 Fed. Reg. at 1106, n. 49, stating Id.



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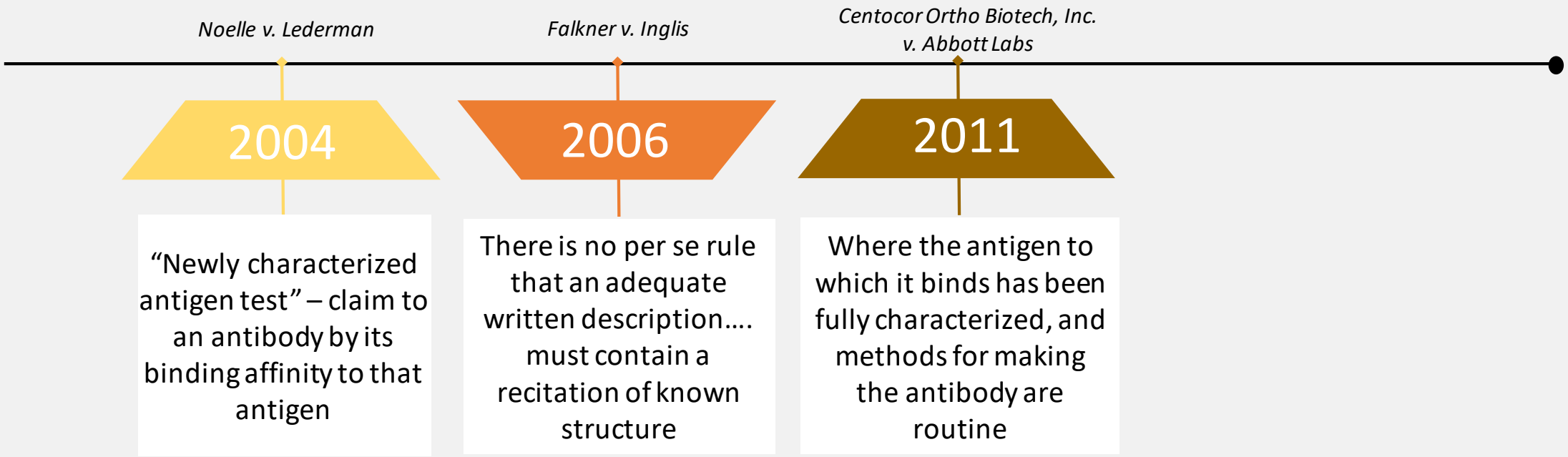

Newly characterized antigen test

Functional characteristics when coupled with a known or disclosed correlation between function and structure

- a claim to an antibody satisfies the "function-structure test" where the antigen to which it binds has been fully characterized, and methods for making the antibody are routine“

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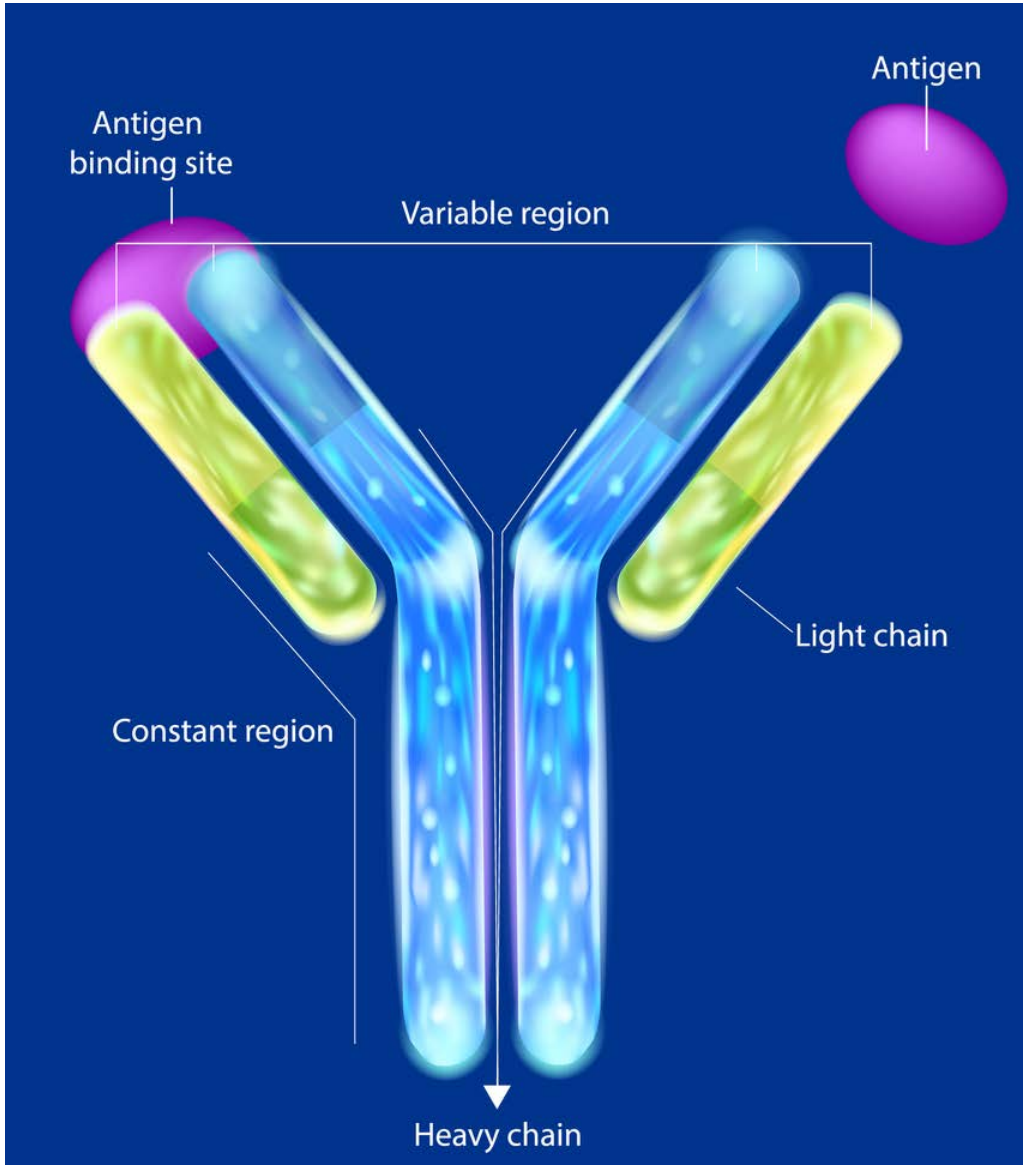

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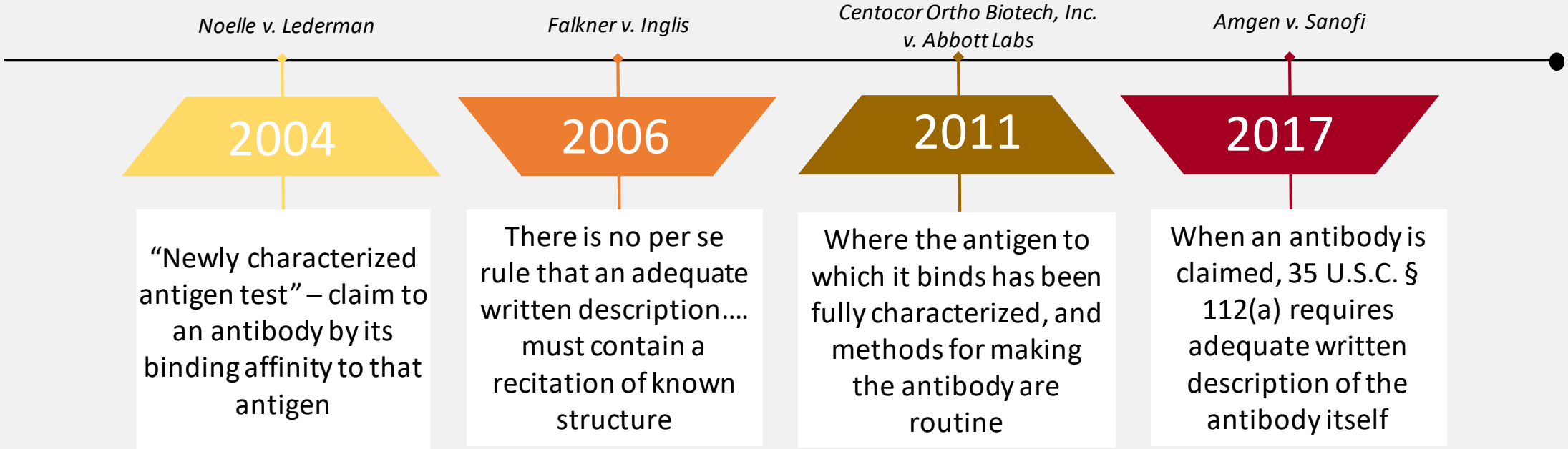


Amgen Inc.
Patent No. 8,829,165

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, 1369, 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.

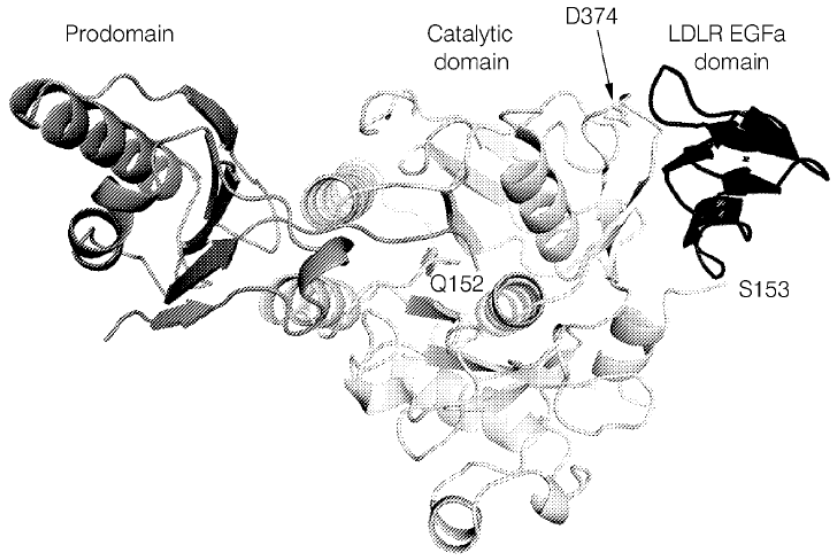


FIG. 17

Amgen v. Sanofi (2017)

Further, the "newly characterized antigen" test flouts basic legal principles of the written description requirement. Section 112 requires a "written description of the invention." But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen. The test thus contradicts the statutory "quid pro quo" of the patent system where "one describes an invention, and, if the law's other requirements are met, one obtains a patent."

Recent Clarification

…"adequate written description of a newly characterized antigen *alone* should not be considered adequate written description of a claimed antibody to that newly characterized antigen, even when preparation of such an antibody is routine and conventional."

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

DATE: February 22, 2018

TO: Patent Examining Corps

FROM: Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy

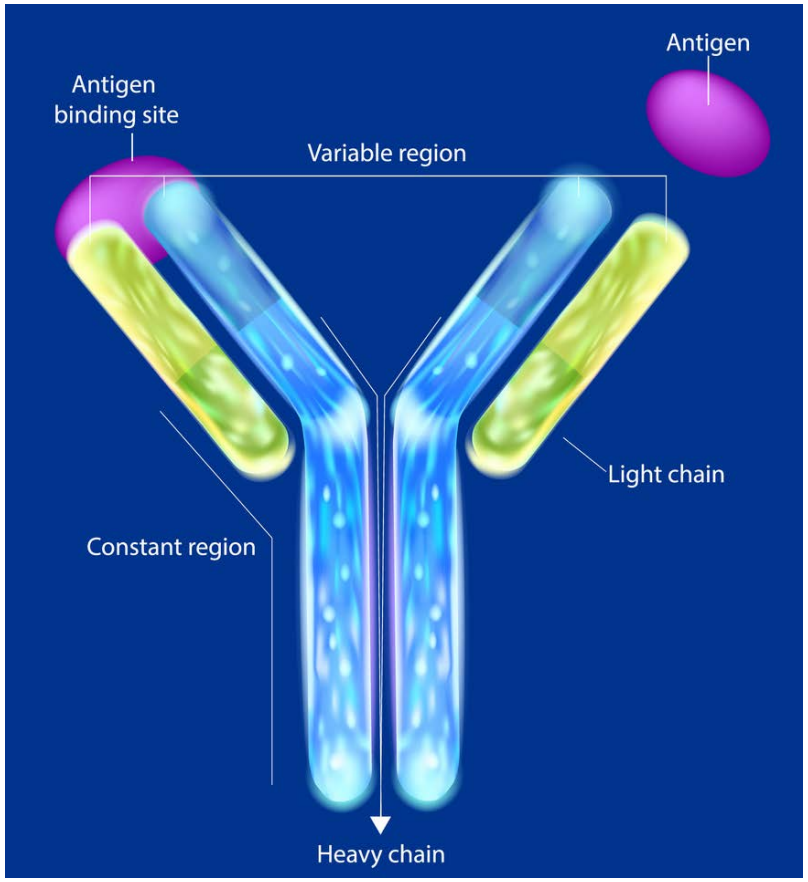
SUBJECT: **Clarification of Written Description Guidance For Claims Drawn to Antibodies and Status of 2008 Training Materials**

The purpose of this memorandum is to clarify the applicability of USPTO guidance regarding the written description requirement of 35 U.S.C. § 112(a), specifically concerning the written description requirement for claims drawn to antibodies.

I. Federal Circuit Clarification of the Law of Written Description As It Applies to Antibodies

Recently, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decided *Amgen v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), which concerned adequate written description for claims drawn to antibodies. These claims are usually handled in Technology Center 1600. The Federal Circuit explained in *Amgen* that when an antibody is claimed, 35 U.S.C. § 112(a) requires adequate written description of the antibody itself. *Amgen,* 872 F.3d at 1378-79. The *Amgen* court expressly stated that the so-called "newly characterized antigen" test, which had been based on an example in USPTO-issued training materials and was noted in dicta in several earlier Federal Circuit decisions, should not be used in determining whether there is adequate written description under 35 U.S.C. § 112(a) for a claim drawn to an antibody. Citing its

https://www.uspto.gov/patent/laws-and-regulations/examination-policy/memoranda-examining-corps



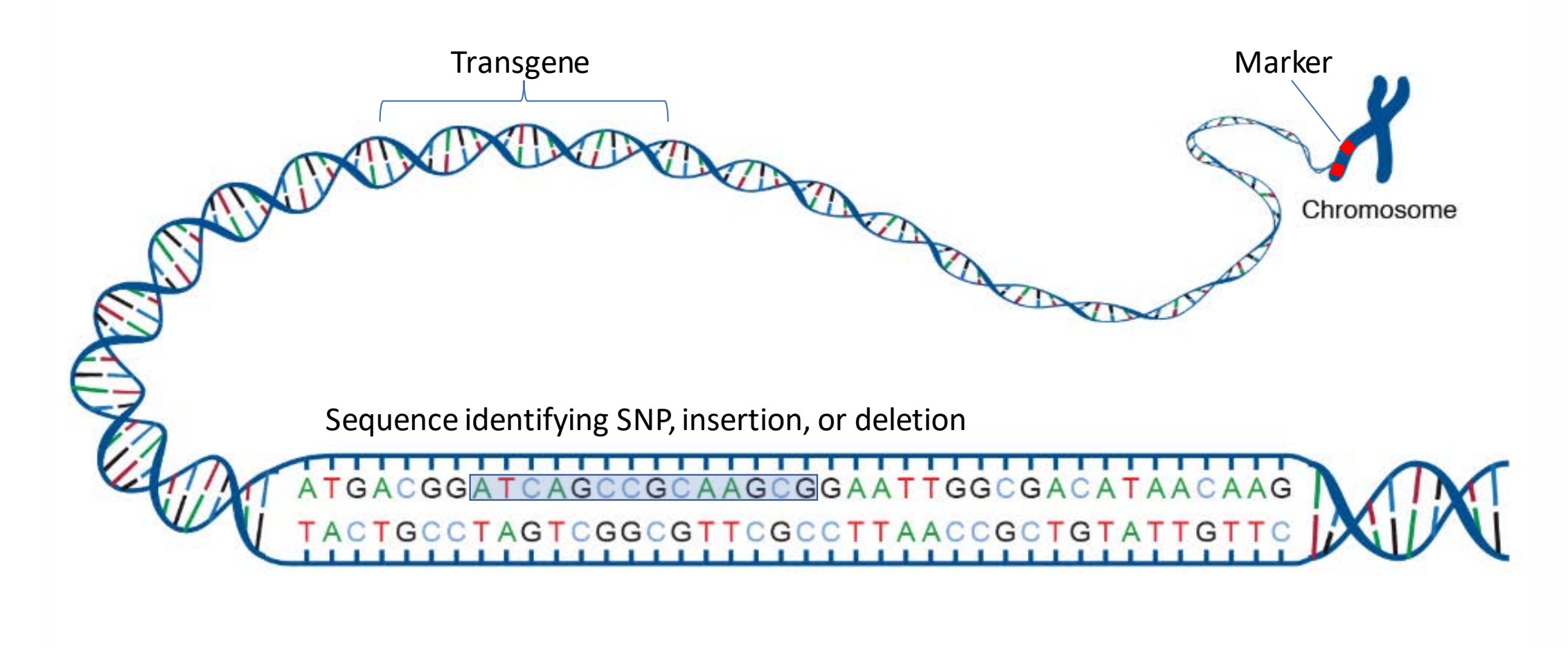
Protein
Amino Acids
X-ray crystallography, NMR
Static

Deoxyribonucleic Acid
Nucleotides
Structure is known*
Dynamic and degenerate

Binary code
Degenerate
Structure is the sequence*

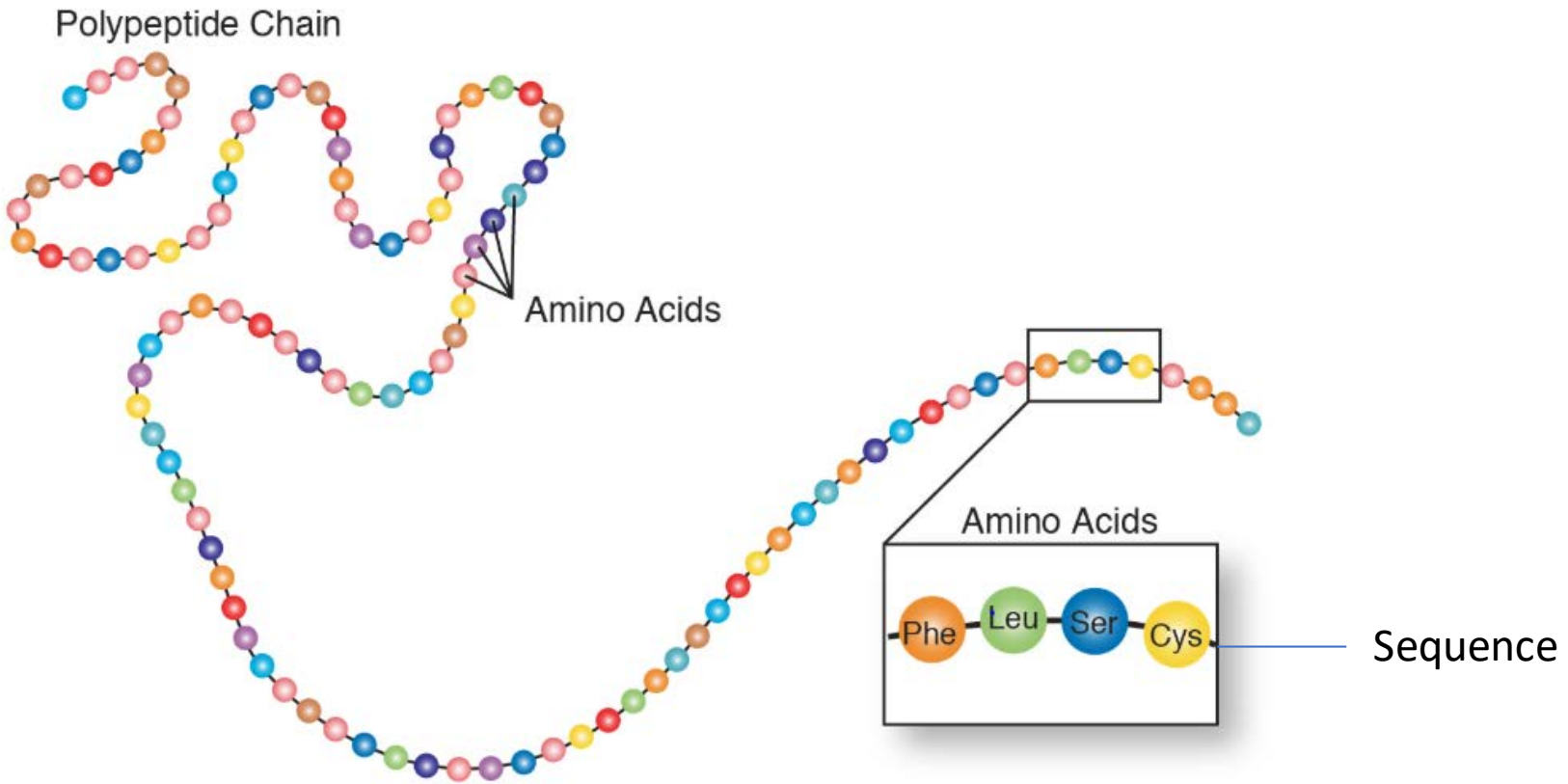
Analogous Art?

STRUCTURE AND FUNCTION FOR PATENTING PURPOSES



Courtesy: National Human Genome Research Institute (*with edits*)
https://www.genome.gov/

STRUCTURE AND FUNCTION FOR PATENTING PURPOSES



Courtesy: National Human Genome Research Institute
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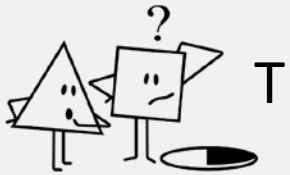
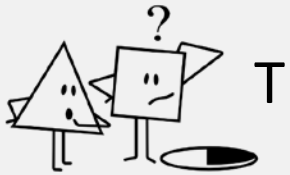
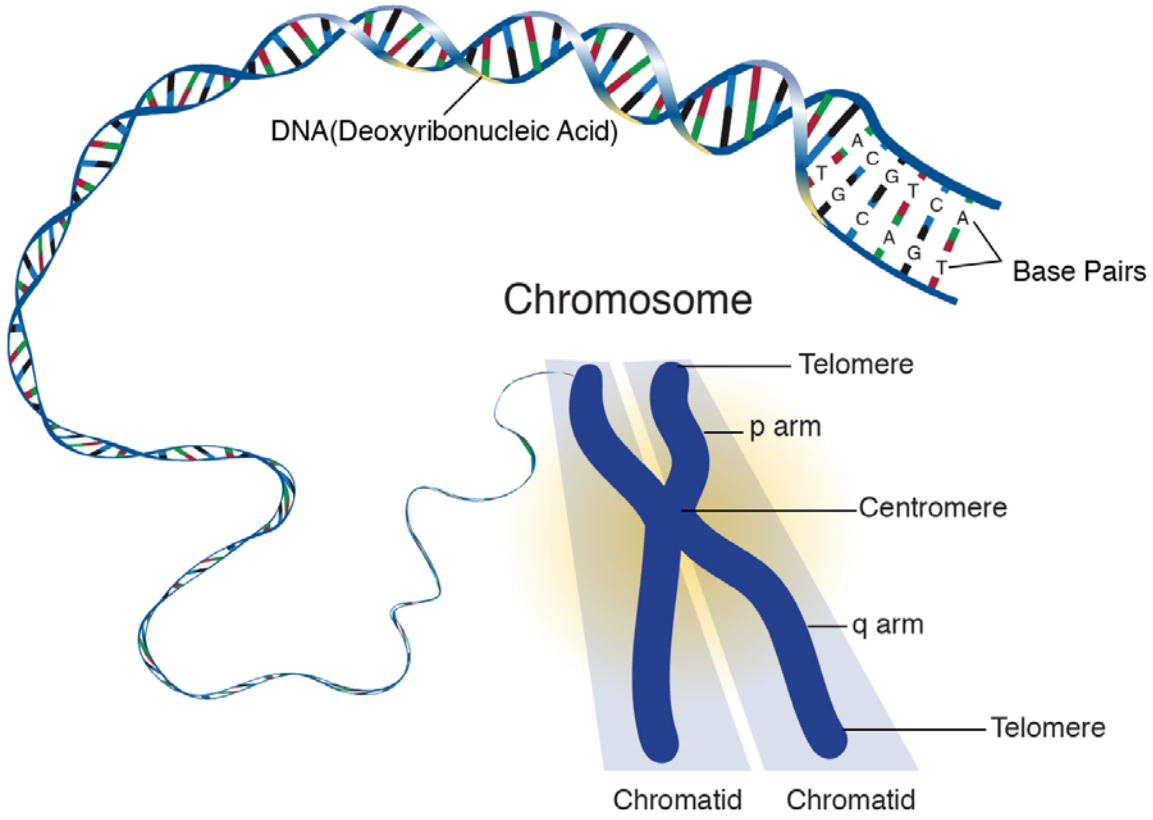


THE UNIQUE CHALLENGES OF TRAIT AND GENE BASED CLAIMS



THE UNIQUE CHALLENGES OF TRAIT AND GENE BASED CLAIMS

- Look to the literature first
- Establish chromosomal markers and map location



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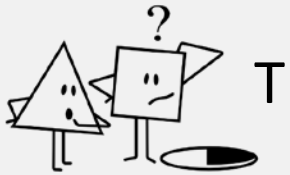

THE UNIQUE CHALLENGES OF TRAIT AND GENE BASED CLAIMS

- Look to the literature first
- Establish chromosomal markers and map location
- Sequence
- But where's the gene?

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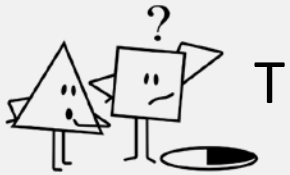

THE UNIQUE CHALLENGES OF TRAIT AND GENE BASED CLAIMS

- Look to the literature first
- Establish chromosomal markers and map location
- Sequence
- But where's the gene?
- Found a gene… is it the right one?

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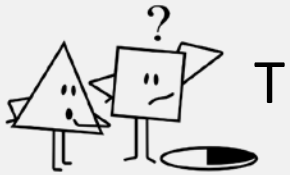

THE UNIQUE CHALLENGES OF TRAIT AND GENE BASED CLAIMS

- Look to the literature first
- Establish chromosomal markers and map location
- Sequence
- But where's the gene?
- Found a gene… is it the right one?
- Found the right one… which one is the causative mutation?

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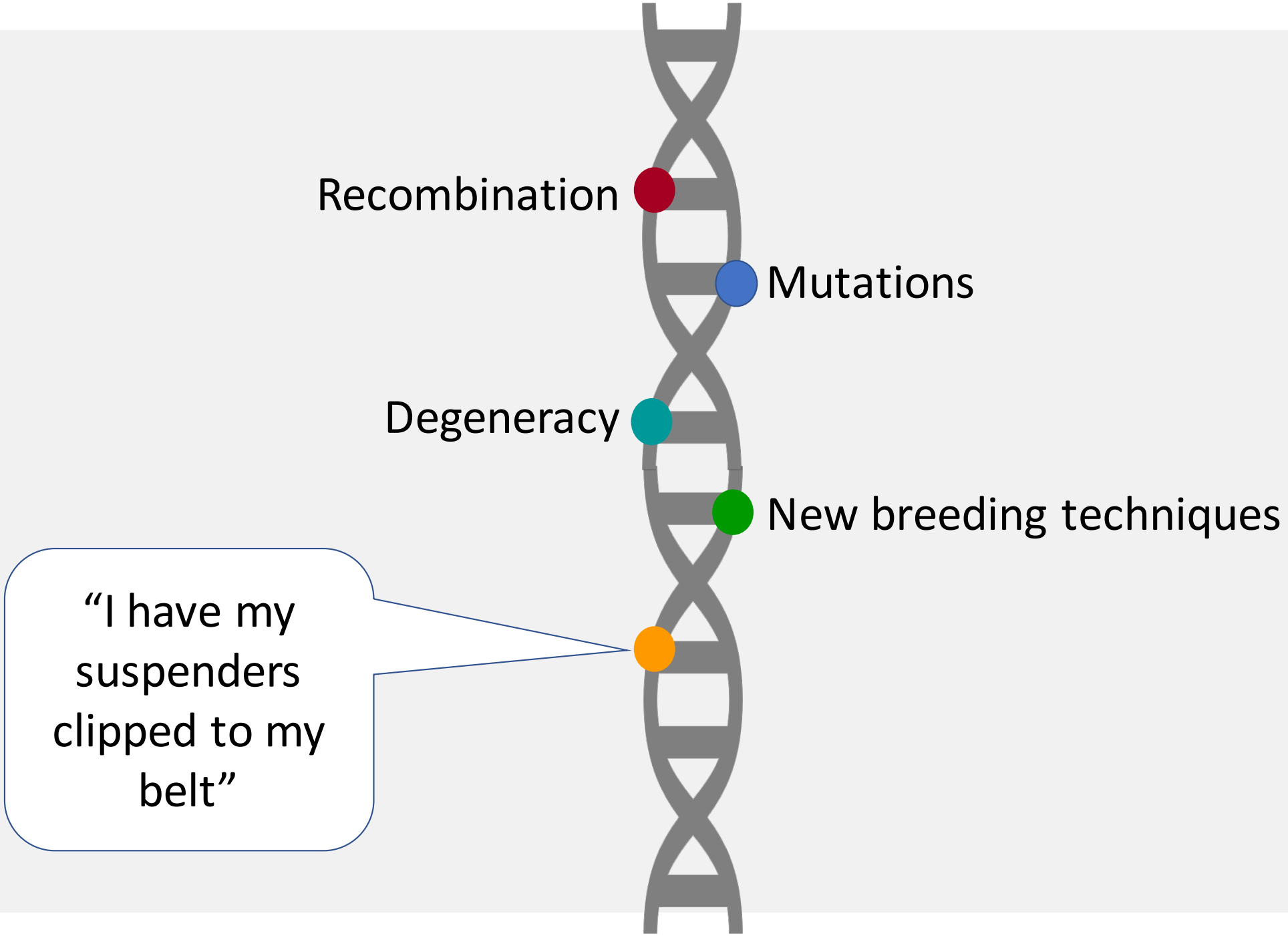
Recombination
Mutations
Degeneracy
New breeding techniques
“I have my suspenders clipped to my belt”

Other ways of establishing possession of a claimed invention may include unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity. *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966

- Clearly convey that an Applicant has invented that which is claimed
- Satisfy the obligation to disclose the technical knowledge upon which the patent is based
- To demonstrate that the patentee was in possession of the invention *as claimed*

What Satisfies the Written Description Requirement?

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem, 323 F.3d at 963, 63 USPQ2d at 1612*.

THANK YOU!

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SETTER ROCHE LLP