Patentable subject matter and the frustrated inventor. A story by the United States federal courts.

March 19, 2021

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So you have an invention in the biotech area?

- ***Cornell inventor*: I just discovered a biomarker that is going to revolutionize the way we diagnose cancer!**
- ***Patent office: Good for you. Just don't send it here.***
- ***Cornell inventor*: Maybe you don't understand. This marker is novel, no one has ever even seen it, let alone connect it to cancer. And it is 100% predictive of cancer in thousands of samples that we already tested. It never seems to fail!**
- ***Patent office: Wait until we get our hands on it.***

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So you have an invention in the biotech area?

- ***Cornell inventor*: I just discovered a protein that interacts with another one and causes cancer. We inhibited that interaction using antibodies and it stopped the cancer in its tracks. Let's patent inhibiting that interaction using antibodies!**
- ***Patent office: What does your antibody look like, specifically?***
- ***Cornell inventor*: We've tested hundreds of them from our library – and they all work! Good, no?**
- ***Patent office: Pick <u>one</u> and tell me what it looks like, specifically.***

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We will come back to the previous two slides. In the meantime, let's discuss patentable subject matter

- 35 U.S.C. 101 (the source of what we call "101 rejections)

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
-

  - Not Patentable
    - Products of nature
    - Physical phenomenon

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Additional requirements for patentability

- The invention must be:
  - Useful (the easy one)
  - Novel
  - Non-obvious
- The description of the invention should be such that:
  - One skilled in the art can practice the invention from the description without undue experimentation
  - One skilled in the art would consider the inventor was in possession of the invention
  - A patent gives the rights discussed earlier only to what is covered in the **claims**. What are claims?

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What is a patent?

35 USCS Sects. 1 - 376

- What is a patent? (Or what is it not?)
- The right to ***exclude*** others from **making, using, and selling your invention,** as well as the **right** to prevent others from **importing** the invention into the **United States**
  - Not an affirmative right—obtaining a patent for your invention does not mean you have the right to practice it!
- Patents are issued in exchange for telling others how to practice your invention – the patent rights are defined by claims

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Example of a patent

US005443036A

United States Patent [19]

Amiss et al.

[11] **Patent Number: 5,443,036**

[45] **Date of Patent: Aug. 22, 1995**

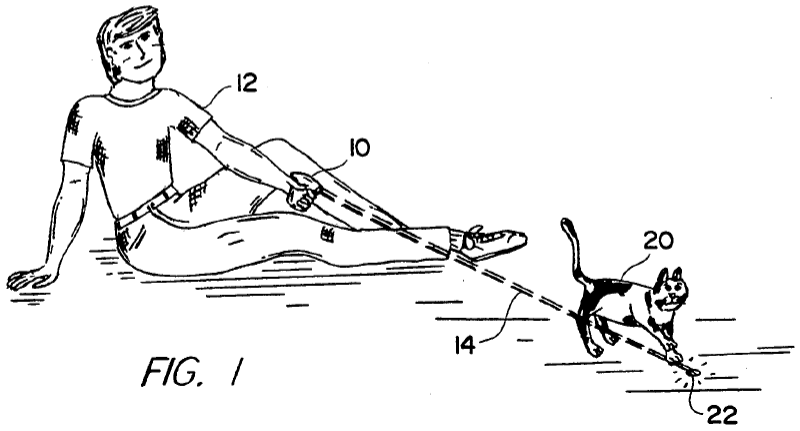

FIG. 1

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Exercise your cat

Claims:

- 1. A method of inducing aerobic exercise in an unrestrained cat comprising the steps of:(a) directing an intense coherent beam of invisible light produced by a hand-held laser apparatus to produce a bright highly-focused pattern of light at the intersection of the beam and an opaque surface, said pattern being of visual interest to a cat; and
- (b) selectively redirecting said beam out of the cat's immediate reach to induce said cat to run and chase said beam and pattern of light around an exercise area. [This is an **independent** claim.]

Exercise your cat

Claims:

- 2. The method of claim 1 wherein said bright pattern of light is small in area relative to a paw of the cat.

  3. The method of claim 1 wherein said beam remains invisible between said laser and said opaque surface until impinging on said opaque surface.

  4. The method of claim 1 wherein step (b) includes sweeping said beam at an angular speed to cause said pattern to move along said opaque surface at a speed in the range of five to twenty-five feet per second. [These are **dependent** claims.]

Exercise your cat

Exercising a cat used to be patent eligible… How have things changed?

Courts have created *Myriad* patentable subject matter issues

Association for Molecular Pathology et al. v. Myriad Genetics (569 U.S. 576) 2012

Myriad discovered the precise location and sequence of two human genes (*BRCA1* and *BRCA2*), mutations of which can substantially increase the risks of breast and ovarian cancer and obtained patents based upon this discovery.

The case required SCOTUS to resolve whether **a naturally occurring segment** of DNA is patent eligible under 35 U. S. C. §101 by virtue of its isolation from the rest of the human genome.

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Courts have created *Myriad* patentable subject matter issues

Association for Molecular Pathology et al. v. Myriad Genetics (569 U.S. 576) 2012

U.S. 5,747,282

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2. **[SEQ ID NO:2 is the protein sequence. This claim includes the gene in its native form.]**

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1. **[SEQ ID NO:1 is a cDNA sequence encoding the BRCA1 protein.]**

5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

6. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.

Courts have created *Myriad* patentable subject matter issues

Association for Molecular Pathology et al. v. Myriad Genetics (569 U.S. 576) 2012

What did SCOTUS say?

Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome.

Where they right?

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Courts have created *Myriad* patentable subject matter issues

Association for Molecular Pathology et al. v. Myriad Genetics (569 U.S. 576) 2012

What did SCOTUS say?

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.

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Courts have created *Myriad* patentable subject matter issues

Association for Molecular Pathology et al. v. Myriad Genetics (569 U.S. 576) 2012

What did SCOTUS say?

Court found that genes and the information they encode **are not patent eligible** under §101 simply because they have been isolated from the surrounding genetic material.

Myriad's claims are not saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule. The claims are simply not expressed in terms of chemical composition …. Instead, the claims focus on the **genetic information** encoded in the BRCA1 and BRCA2 genes.

But…cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. **As a result, cDNA is not a "product of nature"** and is **patent eligible** under §101.

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What does the *Myriad* decision mean?

Some USPTO examples:

1. A vaccine comprising live attenuated Pigeon flu virus. *Eligible? Yes.*

2. A vaccine comprising inactivated Pigeon flu virus. *Eligible? Yes.*

3. A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier.

Eligible? NO. Water is a pharmaceutically acceptable carrier. While the mixture of these two naturally occurring components is novel and does not occur in nature, there is no indication that mixing these components **changes the structure, function, or other properties of the peptide or water**.

4. A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier selected from the group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment. *Eligible? Yes.*

5. A vaccine comprising: Peptide F; and an immuno-effective amount of an aluminum salt adjuvant. *Eligible? Yes.*

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Do you want Mayo with your Titan god of fire?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

U. S. Patent No. 6,355,623

- A method of **optimizing therapeutic efficacy** for treatment of an immune-mediated gastrointestinal disorder, comprising:
- (a) **administering a drug** providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) **determining the level** of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
- wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells **indicates a need to increase the amount** of said drug subsequently administered to said subject and
- wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells **indicates a need to decrease the amount** of said drug subsequently administered to said subject.

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Do you want Mayo with your Titan god of fire?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, **do the patent claims add enough to their statements of the correlations** to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?

We believe that the answer to this question is no.

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Do you want Mayo with your Titan god of fire?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

Why was the answer “no”?

First, the “administering” step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims.

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Do you want Mayo with your Titan god of fire?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

Why was the answer “no”?

Second, the “wherein” clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient.

Do you want Mayo with your Titan god of fire?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)

Why was the answer “no”?

Third, the “determining” step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. …Thus, this step tells doctors to engage in **well-understood, routine, conventional activity previously engaged in by scientists who work in the field**.

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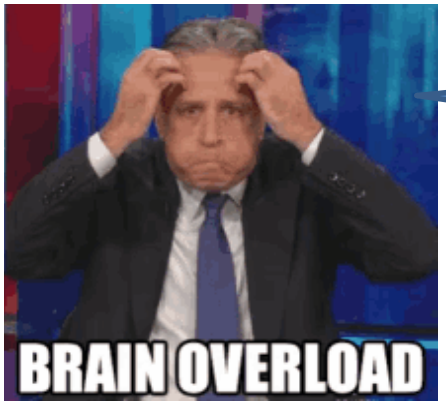
Do you want Mayo with your Titan god of fire?

Why was the answer “no”?

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist **of well-understood, routine, conventional activity already engaged in by the scientific community**; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.



What does this have to do with patentable subject matter!!!

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Alice in Wonderland

So far we have discussed composition of matter claims, what about processes?

- **Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014)**
- This is not a biotech case, but it expanded the holdings in *Myriad* and *Mayo* and provides a basis to reject many types of claims, including biotech claims as "abstract ideas" – which can be combined with "laws of nature"
- This and related cases established a "two part" test to determine whether or not a claim is patent eligible. This can be applied to processes and other types of claims.

Alice in Wonderland

The test has been refined somewhat, but the gist of it is this:

- **Step one**: Is the claim **directed to** one of the patent-ineligible concepts? If the answer is **no**, the inquiry is over.
- **Step two**: If the answer is **yes**, move to step two.
  - When considered both individually and as an ordered combination, do additional claim elements transform the nature of the claim into a patent-eligible application?
  - To move the claims along, they need to include more than well-understood, routine, conventional activity already engaged in by the scientific community, e.g., "significantly more" than a patent upon an ineligible concept itself.

Some recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042 (Fed. Cir. 2016)

- The patent at issue was U.S. Patent No. 7,604,929.

- 1. **A method of producing a desired preparation of multi-cryopreserved hepatocytes**, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

  (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,

  (B) recovering the separated viable hepatocytes, and

  (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

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Some (relatively) recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042

- The question the court answered relates to the two-part test we just saw.

- **The question for the court was**:

- Was patent invalid?

The answer was, no. (Courts love confusing double negatives!)

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Some recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042

- Why was this claim patentable?

- The **District Court** said it was not, because it was “directed to” a patent-ineligible concept. Specifically, the DC held the invention was an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles.

Some recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042

- The Fed. Cir. Found that the claimed laboratory technique for preserving hepatocytes was a constructive process, carried out by an artisan to achieve “a new and useful end,” and is precisely the type of claim that is eligible for patenting.

- **But why? What about the two part test?**

Some recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042

- **At step one**, it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is "**directed to**."

- The '929 patent does not simply claim hepatocytes' ability to survive multiple freeze-thaw cycles. The '929 patent instead claims a "**method of producing a desired preparation of multi-cryopreserved hepatocytes**."

- This new and improved technique, for producing a tangible and useful result, falls squarely outside those categories of inventions that are "directed to" patent-ineligible concepts.

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Some recent case law

Rapid Litig. Mgmt. v. CellzDirect, Inc. - 827 F.3d 1042

- Even if the defendant was correct that the '929 patent is "directed to" hepatocytes' natural ability to survive multiple freeze-thaw cycles, and **we must proceed to step two**, **we would find the claims patent-eligible at that point as well**.
- Under step two, claims that are "directed to" a patent-ineligible concept, *yet also improve an existing technological process, are sufficient to transform the process into an inventive application of the patent-ineligible concept*.
- It is the *process* of preservation that is patent eligible here, not necessarily the end product.

What is the take home message?

- It seems that a major influence on the court was the preamble…(the claim's introductory phrase):

- 1. ***A method of producing*** a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, *said method comprising*: (active steps only start here)

- **Tip**: For biotech method claims, think differently than just the process, think about how the steps transform one thing into something different. And frame the claim in a way that articulates something non-natural, e.g., multi-cryopreserved hepatocytes.

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Vanda Pharma v. West-Ward Pharma

U.S. Patent No. 8,586,610

- 1. **A method for treating** a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of: determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient **in an amount of 12 mg/day or less**, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient **in an amount that is greater than 12 mg/day,** up to 24 mg/day, **wherein a risk of QTc prolongation for a patient having a CYP2D6** poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

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Vanda Pharma v. West-Ward Pharma

U.S. Patent No. 8,586,610

- District Court concluded the claims depend upon **laws of nature**, namely, the relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation.

The Federal Circuit held that the claims **were not** directed to a patent-ineligible concepts. Therefore, no step two *Alice* inquiry is needed. The Federal Circuit explained, that "at step one, 'it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether the patent-ineligible concept is what the claim is 'directed to.'" *Id.* at 28 (quoting ***Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.***, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

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Vanda Pharma v. West-Ward Pharma

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Vanda Pharma v. West-Ward Pharma

U.S. Patent No. 8,586,610

- The Federal Circuit summarized that “the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses for a specific outcome.”

- **Tip**: For diagnostic claims that relate to treatment, link the treatment to the diagnosis. Not an ideal claim, but sometimes that may be all that’s available.

Illumina, Inc. v. Ariosa Diagnostics, Inc., No. 2019-1419 (Fed. Cir. March 17, 2020)

U.S. 9,580,751

1. A method for preparing a DNA fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising

- (a) ***extracting DNA from a cell-free sample of blood plasma*** or blood serum of **a pregnant human female** to obtain extracellular circulatory fetal and maternal DNA fragments;
- (b) **producing a fraction of the DNA** extracted in (a) by:
- (i) **size discrimination** of extracellular circulatory DNA fragments, and
- (ii) **selectively removing** the DNA fragments greater than approximately 500 base pairs, wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and
- (c) **analyzing a genetic locus** in the fraction of DNA produced in (b).

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Illumina, Inc. v. Ariosa Diagnostics, Inc., No. 2019-1419 (Fed. Cir. March 17, 2020)

Holding

We focus our *Alice/Mayo* step one analysis on what the inventors did purport to invent and what they claimed in their patents: **methods for preparing a fraction of cell-free DNA by the physical process of size discriminating** and selectively removing DNA fragments longer than a specified threshold. Those methods **are "directed to" more than merely the natural phenomenon that the inventors discovered**. Accordingly, we conclude at step one of the Alice/Mayo test that the claims are not directed to a patent-ineligible concept, and we need not reach step two of the test.

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In re Board of Trustees of the Leland Stanford Junior University (March 14, Fed. Cir. 2021)

Appeal from PTAB *ex parte* reexamination decision

- Application No. 13/445,925. The claim is excruciatingly long:

- 1. A method for **resolving haplotype** phase, comprising:
  receiving allele data describing allele information regarding genotypes for a family comprising at least a mother, a father, and at least two children of the mother and the father, where the genotypes for the family contain single nucleotide variants and storing the allele data on a computer system comprising a processor and a memory;
  receiving pedigree data for the family describing information regarding a pedigree for the family and storing the pedigree data on a computer system comprising a processor and a memory;
  determining an inheritance state for the allele information described in the allele data based on identity between single nucleotide variants contained in the genotypes for the family using a Hidden Markov Model having hidden states implemented on a computer system comprising a processor and a memory, **[*Bill, help me out here – is this a cold war thing*?]**
  wherein the hidden states comprise inheritance states, a compression fixed error state, and a[Mendelian inheritance error]- rich fixed error state,
  wherein the inheritance states are maternal identical, paternal identical, identical, and non-identical;
  receiving transition probability data describing transition probabilities for inheritance states and storing the transition probability data on a computer system comprising a processor and a memory;
  receiving population linkage disequilibrium data and storing the population disequilibrium data on a computer system comprising a processor and a memory;
  determining a haplotype phase for at least one member of the family based on the pedigree data for the family, the inheritance state for the information described in the allele data, the transition probability data, and the population linkage disequilibrium data using a computer system comprising a processor and a memory;
  storing the haplotype phase for at least one member of the family using a computer system comprising a processor and a memory; and
  providing the stored haplotype phase for at least one member of the family in response to a request using a computer system comprising a processor and a memory.

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In re Board of Trustees of the Leland Stanford Junior University (March 14, Fed. Cir. 2021)

Appeal from PTAB *ex parte* reexamination decision

- The Examiner, who's decision was affirmed by the PTAB, rejected the claims based on being directed to "abstract mathematical algorithms and mental processes."
- Federal Circuit held that the Board was correct in that the claim was patent-ineligible because Claim 1 recites **no concrete application for the haplotype phase** beyond storing it and providing it upon request. (Step 1).
- The Court turned to step 2, finding no error in the Board's determination regarding this step, because **Claim 1 recites no steps that practically apply** the claimed mathematical algorithm; instead, claim 1 ends at storing the haplotype phase and 'providing' it 'in response to a request.'

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And now for something completely different

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Amgen v. Sanofi (Fed. Cir. February 11, 2021)

Antibodies

- Amgen sued Sanofi and Regeneron over sales of alirocumab, sold under the trade name Praluent, which competes with Amgen's evolocumab, sold under the tradename Repatha.

- U.S. Patent Nos. 8,829,165 and 8,859,741 were involved.

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Amgen v. Sanofi (Fed. Cir. February 11, 2021)

The science

- Liver cells express receptors for LDL (LDL-R).
- Binding to the receptors reduces the amount of LDL cholesterol in blood.
- PCSK9 (proprotein convertase subtilisin kexin type 9) binds to and causes LDL-R to be destroyed. PCSK9 therefore impedes the ability of liver cells to reduce LDL-cholesterol in serum.

The patents:

- The claimed antibodies bind to PCSK9 and prevent PCSK9 from binding to LDL-R, protecting LDL-R and providing for lower serum cholesterol.

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Amgen v. Sanofi (Fed. Cir. February 11, 2021)

The specification and related evidence

- Sanofi challenged written description and enablement (Fed. Cir. 2021 case is mostly about enablement).
- The claimed antibodies were identified from 3,000 human monoclonal antibodies that were screened for binding PCSK9.
- From these, 85 antibodies that blocked the interaction between PCSK9 and LDLR with high efficiency were identified.
- Amgen's specification included three-dimensional binding arrangement and x-ray crystallography for two antibodies, one of which was Repatha. The specification also disclosed amino acid sequences for 22 human anti-PCSK9 antibodies able to compete for PCSK9 binding with these two more fully characterized antibodies. That's a lot of data! And took a lot of work to get there.

Amgen v. Sanofi (Fed. Cir. February 11, 2021)

A representative claim:

- Claims of the '165 patent:

- 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 LDL[-]R.

- 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.

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Amgen v. Sanofi (Fed. Cir. February 11, 2021)

The decision

- The Court determined Amgen's claims were composition claims defined, not by structure, but by functional limitations.
- "[t]he functional limitations here are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments.“
- The scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions.

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Amgen v. Sanofi (Fed. Cir. February 11, 2021)

The decision

- The Court found the claims invalid for lack of enablement. The claims were previously determined to lack an adequate written description. (This case bounced around between the District Court and the Federal Circuit.)

Summary

- ***Cornell inventor*: I just discovered a biomarker that is going to revolutionize the way we diagnose cancer!**

Ask:

1) Is there a treatment associated with it?
2) Is there something unique about the way the sample is prepared?
3) Is there a novel combination of reagents used in performance of the test? EXAMPLE:

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Cornell patent - Methods for diagnosing lyme disease

8,946,393 (February 2, 2015)

- 1. A composition comprising a combination of *Borrelia burgdorferi* (*B. burgdorferi*) outer surface proteins, wherein the proteins are the only B. burgdorferi proteins in the composition, wherein the proteins comprise the sequences of SEQ ID NO: 15, SEQ ID NO: 17, and SEQ ID NO: 19, wherein the proteins are covalently attached to a solid matrix, wherein the composition is suitable for use in determining vaccination against B*. burgdorferi* , early *B. burgdorferi* infection, intermediate *B. burgdorferi* infection and late *B. burgdorferi* infection, wherein the early infection is 2 to 6 weeks old, wherein the intermediate infection is from 6 weeks to 5 months old, and wherein the chronic infection is present for more than 5 months.

  2. The composition of claim 1, wherein the solid matrix comprises fluorescent beads.

  3. The composition of claim 1, wherein the solid matrix is present in a lateral flow device.

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Summary

Cornell inventor: I just discovered a protein that interacts with another one and causes cancer. We inhibited that interaction using antibodies and it stopped the cancer in its tracks. Let's patent inhibiting that interaction using antibodies! We've tested hundreds of them from our library – and they all work! Good, no?

Ask:

1) **How many of them are there?**
2) **Do any of them *not work*? (Don't forget your negative data!)**
3) **Do you have the variable light and heavy chain sequences? CDRs?**
4) **EXAMPLE (sometimes you get lucky):**

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Humanized anti-TF-antigen antibodies **US 10,023,651**

1. **A partially humanized monoclonal antibody (mAb) or fragment thereof that binds with specificity to TF-Ag**, the monoclonal antibody or fragment thereof comprising a **heavy chain and a light chain**, **wherein the heavy chain** comprises a sequence selected from the group consisting of: a) the sequence consisting of: a)

(H1) (SEQ ID NO: 7) EVQLVESGAEVKKPGASVKVSCKASGYTFTTYWMHWVRQAPGQGLEWMGF ISPNTDYTEYNQKFRDRVTMTADTSISTAYMELSRLRSDDTAVYYCARSF IGYNFDFWGQGTLVTVSS;

b) the sequence consisting of: **(H2)** (SEQ ID NO: 8) EVQLLESGAELKKPGASVKVSCKASGYTFTTYWMHWVRQAPGQGLEWMGF ISPNTDYTEYNQKFRDRVTLTADKSSSTAYMELSSLTSEDTAVYYCARSF IGYNFDFWGQGTTVTVSS;

c) the sequence consisting of: **(H3)** (SEQ ID NO: 9) EVQLVESGAEVKKPGASVKVSCKASGYTFTTYWMHWVKQAPGQGLEWIGF ISPNTDYTEYNQKFRDKATMTADTSISTAYMELSRLRSDDTAVYYCARSF IGYNFDFWGQGTTLTVSS,

d) the sequence consisting of: **(H2a)** (SEQ ID NO: 13) QVQLVQSGAEVKKPGSSVKVSCKASGYTFTTYWMHWVRQAPGQGLEWMGF ISPNTDYTEYNQKFRDRVTITADKSTSTAYMELSSLRSEDTAVYYCARSF IGYNFDFWGQGTTVTVS;

e) the sequence consisting of: **(H3a)** (SEQ ID NO: 14) EGQLLESGAELAKPGASVKMSCKASGYTFTTYWMHWVKKRPGQGLEWIGF ISPNTDYTEYNQKFRDKATLTADKSSTTAYMQLSSLTSDDSAVYYCARSF IGYNFDFWGQGTTLTVSS;

and combinations thereof;

and **wherein the light chain comprises a sequence selected from the group co**nsisting of: f) the sequence consisting of: **(L1)** (SEQ ID NO: 10) DVVMTQSPLSLPVTLGQPASISCRSSQTIVYSNGNTYLEWFQQRPGQSPR LLIYKVSNRFSGVPDRFSGSGSGTDFTLKISRVEAEDVGVYYCFQGSHVP FTFGSGTKLEIK;

g) the sequence consisting of: **(L2)** (SEQ ID NO: 11) DIVMTQTPLSLPVTLGQPASISCRSSQTIVYSNGNTYLEWFQQRPGQSPR LLIYKVSNRFSGVPDRFSGSGSGTDFTLKISRVEAEDVGVYYCFQGSHVP FTFGSGTKLEIK;

h) the sequence consisting of: **(L3)** (SEQ ID NO: 12) DVVMTQSPLSLPVTLGQPASISCRSSQTIVYSNGNTYLEWYLQRPGQSPR LLIYKVSNRFSGVPDRFSGSGSGTDFTLKISRVEAEDVGVYYCFQGSHVP FTFGSGTKLEIK;

i) the sequence consisting of: **(L2a**) (SEQ ID NO: 15) DIVMTQSPLSLPVTPGEPASISCRSSQTIVYSNGNTYLEWYLQKPGQSPQ LLIYKVSNRFSGVPDRFSGSGSGTDFTLKISRVEAEDVGVYYCFQGSHVP FTFGSGTKVDIK;

j) the sequence consisting of: **(L3a)** (SEQ ID NO: 16) ELVMTQTPLSLPVNLGDQASISCRSSQTIVYSNGNTYLEWYLQKPGQSPK LLIYKVSNRFSGVPDRFSGSGSGTDFTLKISRVEADDLGVYYCFQGSHVP FTFGSGTKLEIK; and combinations thereof.

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Summary

- There are significant challenges to patenting certain types of inventions in the biotech area. **But do not decide for yourself**. **Disclose it to the tech transfer office!**
- **Do not be discouraged** if a decision not to file is made. Those decisions are made based on experience, and do not have anything to do with the quality of the science. Remember what SCOTUS said: "***Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry*.**"

- **You will make groundbreaking and brilliant discoveries. You are at Cornell after all.**

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Summary

I hope this presentation helps explain some of the differences between “discoveries” and “inventions.” If not, ask questions!

Thank you!

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