Strafford

Presenting a live 90-minute webinar with interactive Q&A

Patent Eligibility and Engineered Natural Products: Overcoming 101 Challenges, Leveraging Options for IP Protection

THURSDAY, APRIL 28, 2022

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Megan L. Meyers, Attorney, **Finnegan Henderson Farabow Garrett & Dunner, LLP**, Atlanta, GA

Jeffrey D. Smyth, Partner, **Finnegan Henderson Farabow Garrett & Dunner, LLP**, Palo Alto, CA

The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 1**.

Tips for Optimal Quality

FOR LIVE EVENT ONLY

Sound Quality

If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial **1-877-447-0294** and enter your **Conference ID and PIN** when prompted. Otherwise, please **send us a chat** or e-mail **sound@straffordpub.com** immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

Viewing Quality

To maximize your screen, press the 'Full Screen' symbol located on the bottom right of the slides. To exit full screen, press the Esc button.

Continuing Education Credits

FOR LIVE EVENT ONLY

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about continuing education, call us at 1-800-926-7926 ext. 2.

Program Materials

FOR LIVE EVENT ONLY

If you have not printed the conference materials for this program, please complete the following steps:

- Click on the link to the PDF of the slides for today's program, which is located to the right of the slides, just above the Q&A box.
- The PDF will open a separate tab/window. Print the slides by clicking on the printer icon.

Recording our programs is not permitted. However, today's participants can order a recorded version of this event at a special attendee price. Please call Customer Service at 800-926-7926 ext.1 or visit Strafford's website at www.straffordpub.com.

Disclaimer

These materials have been prepared solely for educational and informational purposes to contribute to the understanding of U.S. and European intellectual property law. These materials reflect only the personal views of the authors and are not individualized legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm), cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.

Recent Trends in the Industry

- Plant Based Diets
  - Plant Based Milk Market is expected to grow at a CAGR of 8.62% up to 2026
  - Almond milk is widely consumed in North America
- Consumer Interest in Mushrooms
  - Global functional mushroom market generated $7.98 billion in 2020
  - Market is expected to amount to $19.33 billion by 2030
- Natural Products Expo West Trade Show
  - Natural and Organic Industry grew 7.7% to $274 billion in 2021
  - Forecasted to surpass $300 billion in sales by 2024 and $400 billion by 2030

Recent Trends in the Industry

- Consumers are prioritizing their health and wellness
  - Vitamins and supplements saw a 43% year over year growth on Amazon
  - Stress relief and sleep support products saw a 30% growth
- Global probiotics market estimated at $54.77 billion in 2020
  - Continuing to grow at a compound annual growth rate of 7.2% from 2021 to 2028
  - Products include yogurt, kimchi, and carbonated beverages
- Regenerative Agriculture
  - Promotes biodiversity, sequesters carbon, and allows living systems to work in harmony
  - Increase in labels touting the benefits of food products sourced from farms utilizing this method
- Packaging
  - 23% increase in recyclable pod/cup systems, 9% increase in aseptic cartons, and 2% increase in using glass

35 U.S.C Section 101

"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." 35 U.S.C. § 101

Judicial Exceptions: "laws of nature, physical [natural] phenomena, and abstract ideas" *Bilski*; citing *Diamond v. Chakrabarty*

Historic Case Law

Isolated and Purified Exception

- *Ex parte Latimer*
  - 1889 Dec. Comm'r Pat. 123 (1889)
  - Not patent eligible
  - Natural products are "common stock"

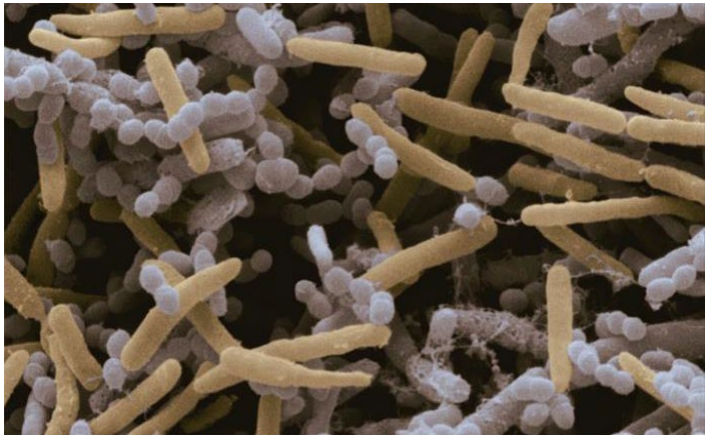
- *Parke-Davis & Co. v. H.K. Mulford Co.*
  - 189 F. 95 (C.C.S.D.N.Y. 1911)
  - Patent eligible
  - Extraordinary utility of isolated and purified product overcame the exclusion

Historic Case Law

Made by Man or Nature?

Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)

- Not patent eligible
- "[W]ork of nature"; no species acquired a different property or use

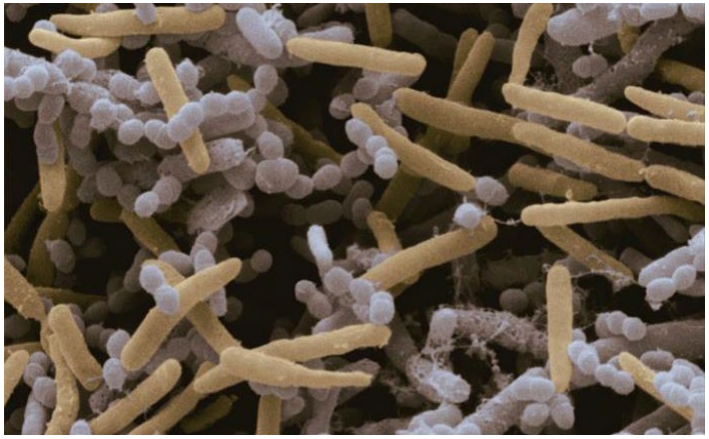


Historic Case Law

Made by Man or Nature?

Diamond v. Chakrabarty, 447 U.S. 303 (1980)

- Patent eligible
- "[A]nything under the sun that is **made by man**"



Section 101
Mayo/Alice Two-Step Test

Step One: Are the claims **directed to patent ineligible subject matter**? (law of nature, natural phenomena, abstract idea)

- No → End of analysis
- Yes → Move to Step Two

Step Two: Search for an **inventive concept**

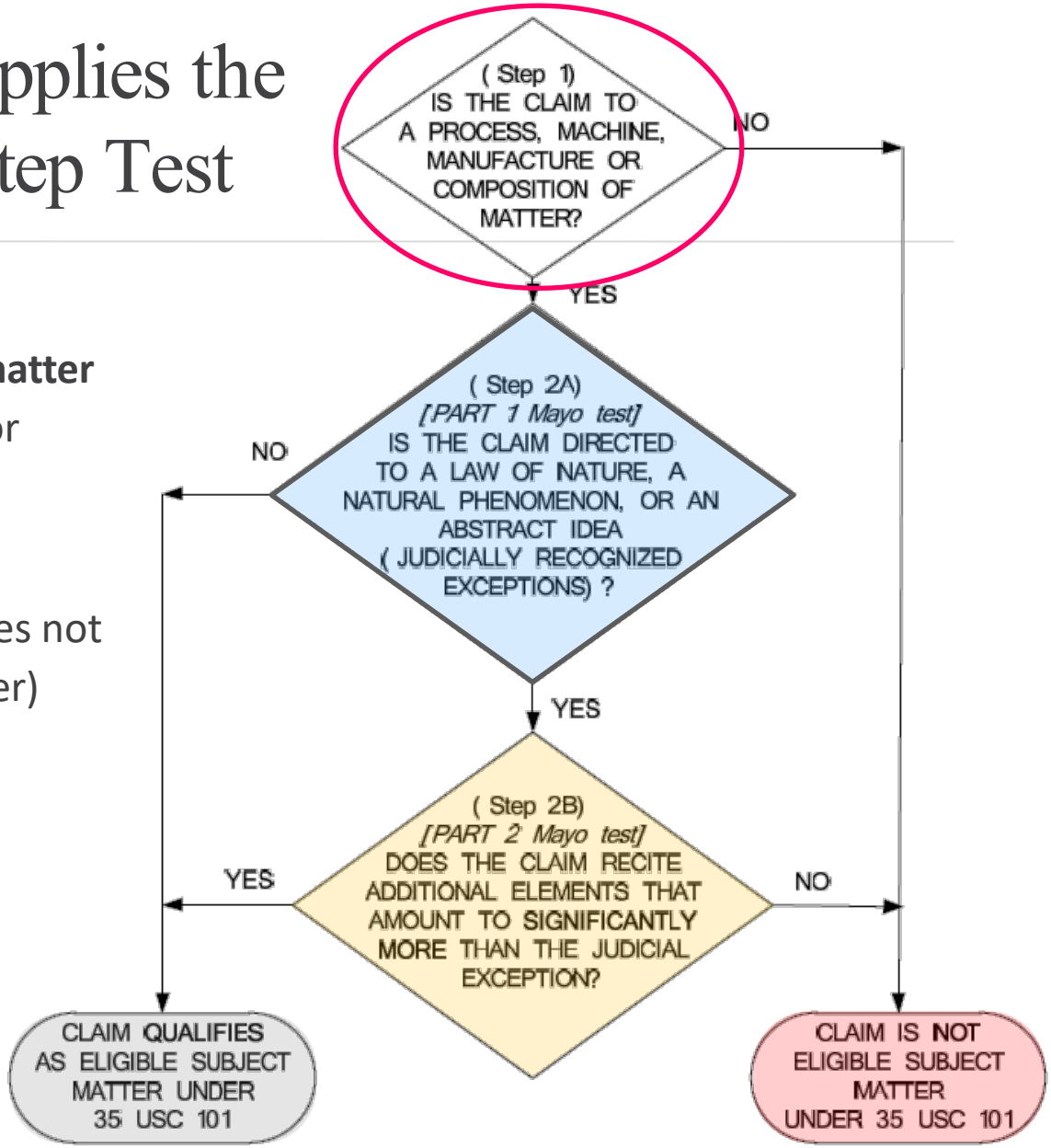
- Identify non-patent-ineligible elements of the claim.
- Consider these elements both individually and as an ordered combination.
- Do the additional elements "transform the nature of the claim" into a patent-eligible application?

How the USPTO Applies the *Mayo/Alice* Two-Step Test

<u>Step 1</u>: Is the claim directed to **statutory patent eligible subject matter** (process, machine, manufacture, or composition of matter)?

Yes → Move to Step 2A

No → End of analysis (claim does not recite patent-eligible subject matter)



How the USPTO Applies the *Mayo/Alice* Two-Step Test

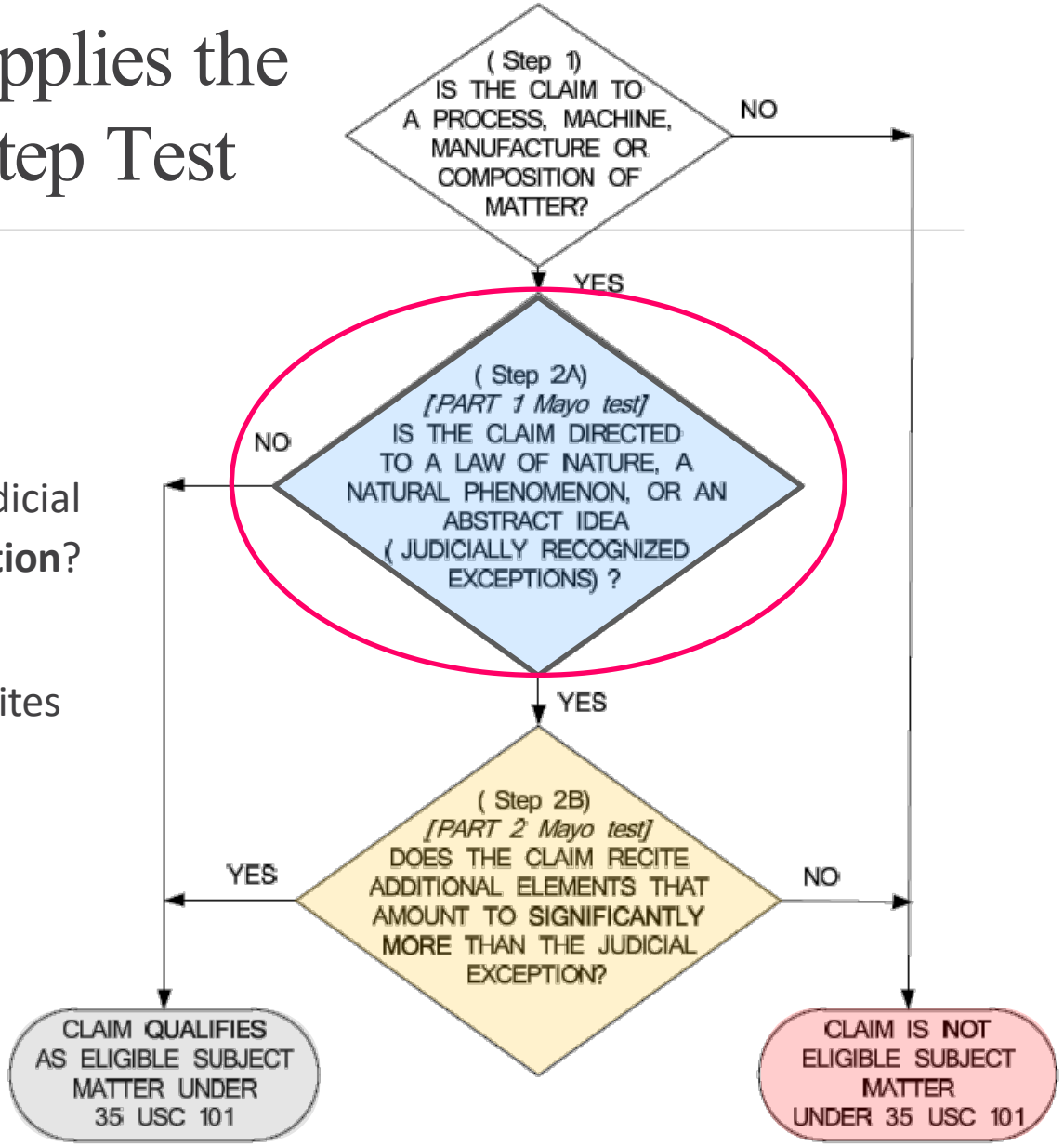
<u>Step 2A</u>:

1.Does the claim recite a **judicial exception**?

2.Does the claim **integrate** the judicial exception into a **practical application**?

Yes → Move to Step 2B

No → End of analysis (claim recites patent-eligible subject matter)



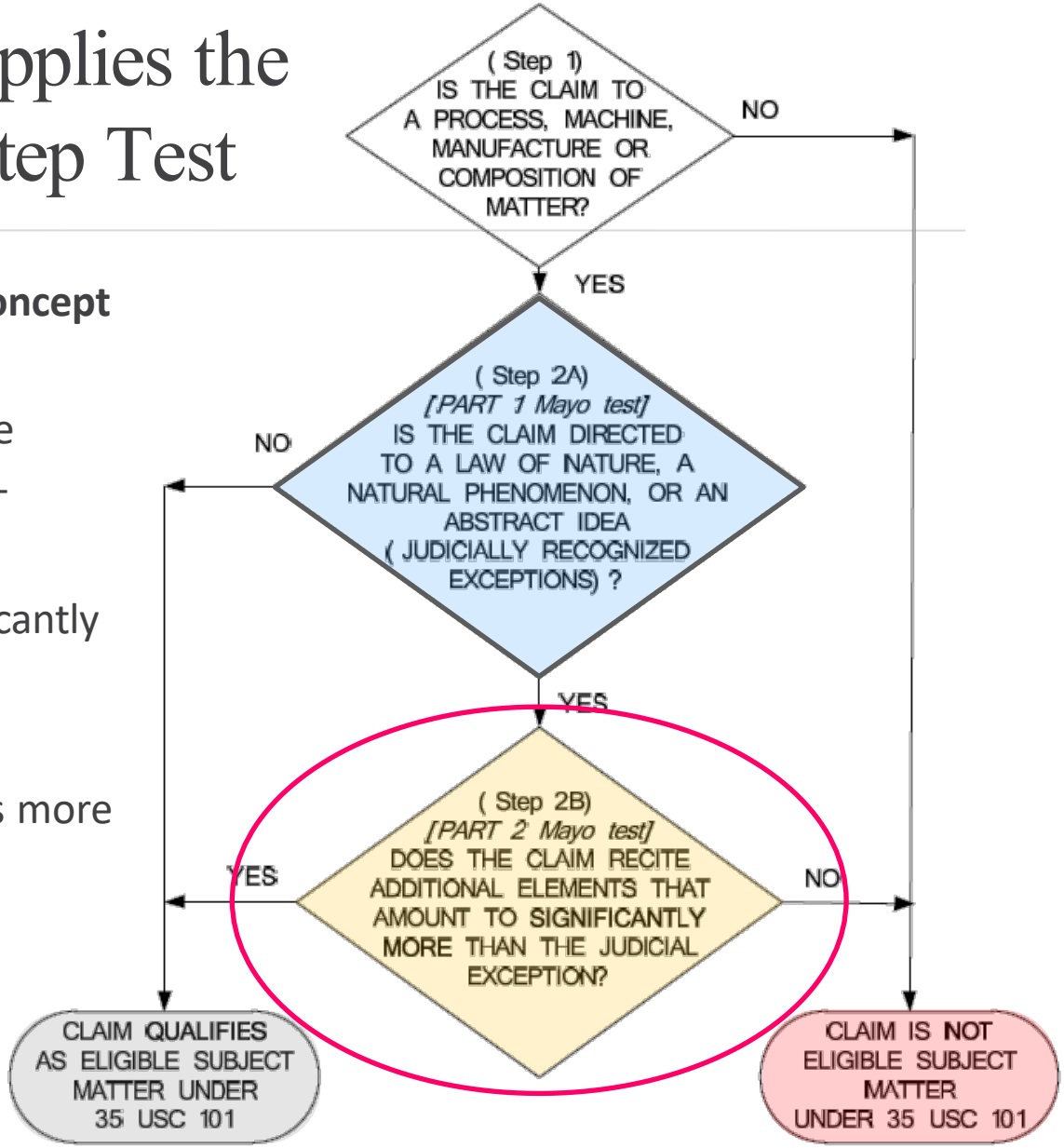
How the USPTO Applies the *Mayo/Alice* Two-Step Test

<u>Step 2B</u>: Search for an **inventive concept**

- Do the additional elements "transform the nature of the claim" into a patent eligible-application?
- Do the claims recite "significantly more" than the judicial exception?
- Are the additional elements more than "well-understood, conventional, or routine"?

Yes → patent-eligible

No → patent-ineligible



Life Sciences: Categories of Method Claims

Diagnostic Methods

"Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.,* LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing *en banc*).

Methods of Treatment

"In contrast, we have held that method of treatment claims are patent-eligible." *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 952 F.3d 1367, 1371 (Fed. Cir. 2020).

Methods of Preparation

"[E]ligible subject matter that exploits the discovery of the natural phenomenon." *Illumina*, 952 F.3d. at 1372.

Engineered Natural Products

Myriad: Challenged Claims

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2. (Isolated gene)

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO: 1. (cDNA)

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

- DNA encoding SEQ ID NO: 2 may include exons and introns of *BRCA1.* →genomic DNA
- SEQ ID NO: 1 includes only exons of *BRCA1.* → cDNA

Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

Myriad: Analysis

"It is undisputed that **Myriad did not create or alter** any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides **existed in nature before Myriad found them**."

"Myriad's claims are simply not expressed in terms of chemical composition, **nor do they rely in any way on the chemical changes that result** from the isolation of a particular section of DNA."

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

Myriad Genetics, 569 U.S. at 590–91, 593.

Myriad: Holding and Caveats

Holding: *"*A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."

Caveat 1: "cDNA is not a 'product of nature' and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA."

Caveat 2: The holding does not extend to *methods applying* Myriad's BRCA gene discovery or to altered BRCA genes

Myriad Genetics, 569 U.S. at 579, 595.

Post-*Myriad* Decisions

In re: BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litigation: Challenged Claims

1. A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

In re BRCA1- and BRCA2 Based Hereditary Cancer Test Pat. Litig., 774 F.3d 755 (Fed. Cir. 2014).

BRCA1- and BRCA2: Analysis and Holding

"Primers necessarily contain the identical sequence of the BRCA sequence directly opposite to the strand to which they are designed to bind. They are **structurally identical** to the ends of DNA strands found in nature."

In re BRCA1- and BRCA2, 774 F.3d at 760.

Ex parte Sheau Yu Hsu: Challenged Claims

1. An isolated polypeptide consisting essentially of the amino acid sequence set forth in SEQ ID NO: 1 or SEQ ID NO:2.

2. An isolated polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 1.

Ex parte Sheau Yu Hsu, 2016 WL 7474845 (PTAB Dec. 19, 2016).

Ex parte Sheau Yu Hsu

- Not patent eligible
- "[N]either naturally occurring compositions of matter, nor synthetically created compositions that **are structurally identical to the naturally occurring compositions**, are patent eligible."

Ex parte Sheau Yu Hsu, 2016 WL 7474845, at *3.

Exergen Corp. v. Kaz USA, Inc.: Challenged Claims

48. A body temperature detector comprising:
a radiation detector; and
electronics that measure radiation from at least three readings per second of the radiation detector as a target skin surface over an artery is viewed, the artery having a relatively constant blood flow, and that process the measured radiation to provide a body temperature approximation, distinct from skin surface temperature, based on detected radiation.

49. The body temperature detector of claim 48 wherein the artery is a temporal artery.

Exergen Corp. v. Kaz USA, Inc., 725 F. App'x 959 (Fed. Cir. 2018).

Exergen Corp. v. Kaz USA, Inc.: Challenged Claims

14. A method of detecting human body temperature comprising making at least three radiation readings per second while moving a radiation detector to scan across a region of skin over an artery to electronically determine a body temperature approximation, distinct from skin surface temperature.

24. The method of claim 14 wherein the artery is a temporal artery.

Exergen Corp., 725 F. App'x at 959.

Exergen Corp.: Analysis and Holding

- "[T]he patent is directed to the measurement of a natural phenomenon (core body temperature)."
- "Even if the concept of such measurement is directed to a natural phenomenon and is abstract at step one, **the measurement method here was not conventional, routine, and well-understood**."

Exergen Corp., 725 F. App'x at 967.

Roche Molecular Systems, Inc. v. Cepheid: Challenged Claim

1. A method for detecting Mycobacterium tuberculosis in a biological sample suspected of containing M. tuberculosis comprising:
   a) subjecting DNA from the biological sample to PCR using a plurality of primers under reaction conditions sufficient to simplify a portion of a M. tuberculosis rpoB [gene] to produce an amplification product, wherein the plurality of primers comprises at least one primer that hybridizes under hybridizing conditions to the amplified portion of the [gene] at a site comprising at least one position-specific M. tuberculosis signature nucleotide selected, from the group consisting . . . .

Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363 (Fed. Cir. 2018).

Roche Molecular Systems: Challenged Claim

1. A method for detecting Mycobacterium tuberculosis in a biological sample suspected of containing M. tuberculosis comprising:
   b) detecting the presence or absence of an amplification product, wherein the presence of an amplification product is indicative of the presence of M. tuberculosis in the biological sample and wherein the absence of the amplification product is indicative of the absence of M. tuberculosis in the biological sample.

Roche Molecular Sys., 905 F.3d at 1363.

Roche Molecular Systems, Inc. v. Cepheid: Analysis and Holding

- District Court granted Cepheid's Motion for Summary Judgment that all of the asserted claims claim patent-ineligible subject matter
- Federal Circuit relied on its prior opinion, *BRCA1*, to affirm the District Court

- "It is undisputed that the primers before us have the identical nucleotide sequences as naturally occurring DNA, just like the primers found subject matter ineligible in *BRCA1*."

- "We hold that **the primers before us are indistinguishable from their corresponding nucleotide sequences on the naturally occurring DNA**, and that the primer claims, therefore, are patent-ineligible. . . ."

Roche Molecular Sys., 905 F.3d at 1369.

Natural Alternatives: Challenged Claims

1. A human **dietary supplement**, comprising a beta-alanine in a unit dosage of between about 0.4 grams to 16 grams, wherein the supplement provides a unit dosage of beta-alanine.

1. A composition, comprising: glycine; and

a). . . a beta-alanine, an ester of a beta-alanine, [or] an amide of a beta-alanine, or

b) . . . a beta-alanine di-peptide [or] a beta-alanylhistidine di-peptide.

5.The composition of claim 1, wherein the composition is a dietary supplement or a sports drink.

6. The composition of claim 5, wherein the **dietary supplement** or sports drink is a supplement for humans.

Nat. Alts. Int'l, Inc. v. Creative Compounds, LCC, 918 F.3d 1388 (Fed. Cir. 2019).

Natural Alternatives: Analysis and Holding

Procedural posture: Motion for judgment on the pleadings

Adopted Natural Alternative's claim constructions

- Dietary supplement = a **non-natural**, **non-conventional** addition to the human diet, which effectively **increases athletic performance**

"the specification does not contain language supporting the idea that this limitation was well-understood, routine, and conventional"

"a determination may not be made on a motion for judgment on the pleadings"

Nat. Alts., 918 F.3d at 1349.

Genetic Veterinary Sciences: Challenged Claims

1. An **in vitro method for genotyping** a Labrador retriever comprising:

a) obtaining a biological sample from the Labrador Retriever;

b) genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO:1; and

c) detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of SEQ ID:NO2.

Genetic Veterinary Scis., Inc. v. LABOKlin GmbH & Co. KG, 933 F.3d 1302 (Fed. Cir. 2019).

Genetic Veterinary Sciences: Analysis and Holding

- Claim directed to ineligible subject matter
- Reciting the specific sequence did not save the claim
- Not mentioning the correlation between the mutation and the disease did not save the claim

Genetic Veterinary Scis., 933 F.3d at 1302.

Ino Therapeutics: Challenged Claims

1. A **method of treating patients who are candidates for inhaled nitric oxide treatment**, which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:

a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;

b) determining that a first patient of the plurality does not have left ventricular dysfunction;

c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide;

d) administering 20 ppm inhaled nitric oxide treatment to the first patient; and

e) excluding the second patient from treatment with inhaled nitric oxide, **based on the determination that the second patient has left ventricular dysfunction**, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.

INO Therapeutics LLC v. Praxair Distrib. Inc., 782 F. App'x 1001 (Fed. Cir. 2019).

Ino Therapeutics: Analysis and Holding

- DC: Ineligible; Fed. Cir.: Affirmed
- Step 1: "The claimed invention is focused on screening for a natural law." "The patent claim does no more than add an instruction to withhold iNO treatment from the identified patients; **it does not recite giving any affirmative treatment** for the iNO-excluded group, and so it covers a method in which, for the iNO-excluded patients, **the body's natural processes are simply allowed to take place**."
- Step 2: All but the exclusion step are "well understood, routine, and conventional steps."

Ino Therapeutics, 782 F. App'x at 1005, 1009.

Illumina, Inc. v. Ariosa Diagnostics, Inc.: Challenged Claims

1. A method for preparing a deoxyribonucleic acid (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 substantially 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:

. . .

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).

Illumina, Inc. v. Ariosa Diagnostics, Inc., 952 F.3d 1367, 1368 (Fed. Cir. 2020)

Illumina, Inc.: Analysis and Holding

- "[T]he inventors discovered that, not only does the fetal DNA exist in the bloodstream of a pregnant mother, but it has **characteristics that make it distinguishable**, and therefore separable, from the maternal DNA."

- "Again, regardless how groundbreaking this additional discovery may have been, **the inventors were not entitled to patent the natural phenomenon that cell-free fetal DNA tends to be shorter than cell-free maternal DNA**."

- "Thus, they could not claim a method directed to the natural phenomenon, e.g., a method for determining whether a fragment of cell-free DNA is fetal or maternal based on its length. And they did not attempt to patent such a method."

Illumina, Inc., 952 F.3d at 1375.

Illumina, Inc.: Analysis and Holding

- "The inventors here patented methods of preparing a DNA fraction."
- "The claimed methods utilize the natural phenomenon that the inventors discovered by **employing physical process steps and human-engineered size parameters to selectively remove larger fragments of cell-free DNA** and thus enrich a mixture in cell-free fetal DNA."
- "[U]nder § 101 the claimed methods are patent-eligible subject matter."

Illumina, Inc., 952 F.3d at 1375.

Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.: Challenged Claims

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

Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).

Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.: Challenged Claims

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.

Vanda Pharms., 887 F.3d at 1117.

Vanda Memorandum

- Addresses the limited question of how to evaluate the patent eligibility of "method of treatment claims" in light of the Federal Circuit decision in *Vanda*
  - "method of treatment" **claims that practically apply natural relationships** should be considered patent eligible under Step 2A of the USPTO's subject matter eligibility guidance; and
  - it is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered patent eligible under 35 U.S.C. § 101.

Vanda Pharms., 887 F.3d at 1117.

Boehringer Ingelheim Pharms. Inc. v. Mylan Pharms. Inc.: Challenged Claims

1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance.

2. The method according to claim 1 wherein the metabolic disorder is type 2 diabetes mellitus and wherein the contraindication is renal disease, renal impairment or renal dysfunction, and wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function.

Boehringer Ingelheim Pharms. Inc. v. Mylan Pharms. Inc., 803 F. App'x 397 (Fed. Cir. 2020).

Boehringer Ingelheim Pharms. Inc.: Analysis and Holding

- "We hold that, consistent with this court's decision in *Vanda*, the claims are directed to a particular method of treatment under step one and are therefore patent eligible."
- "[T]he claims were directed to a patent-eligible method of using iloperidone to treat schizophrenia, 'a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.'"

Boehringer Ingelheim Pharms., 803 F. App'x at 400.

Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC: En Banc Rehearing Petition Denial

- The ’820 patent covered a method of diagnosing *myasthenia gravis* based on the presence of muscle-specific tyrosine kinase autoantibodies

- Federal Circuit, in a split-panel decision, affirmed a district court that the patent claims covering a diagnostic test for MG were patent ineligible

Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333 (Fed. Cir. 2019).

Athena Diagnostics: Judge Dyk's Concurrence

- Joined by Judge Hughes, and, in part, by Judge Chen
- "The *Mayo/Alice* framework has . . . proven to be both valuable and effective at invalidating overly broad, non-inventive claims that would effectively 'grant a monopoly over an abstract idea.'"
- **"[I]t is the Supreme Court, not this court, that must reconsider the breadth of *Mayo*."**
- As a result, "*Mayo* left no room for us to find typical diagnostic claims patent eligible, absent some inventive concept at *Mayo* step two."

Athena Diagnostics, 927 F.3d at 1339.

Athena Diagnostics: Judge Chen's Concurrence

- "Through it all, there is a serious question today in patent law as to what extent *Diehr* remains good law in light of *Mayo*. **We are not in a position to resolve that question, but the Supreme Court can**. Resolution of the present confusion is important because if *Mayo* in fact overruled the principles in *Diehr* (as reiterated in *Bilski*), then that would be a significant incursion on the settled expectations that had existed for 30 years since *Diehr*."
- "New methods for diagnosing medical conditions, as a general matter, intuitively seem to be the kind of subject matter the patent system is designed for . . . ."
- "Even though Athena's claims likely would be found patent-eligible under *Diehr*'s framework, it is not an inferior court's role to dodge the clear, recent direction of the Supreme Court."

Athena Diagnostics, 927 F.3d at 1352.

Athena Diagnostics: Judge Moore's Dissent

- "This is not a case in which the judges of this court disagree over whether diagnostic claims, like those at issue in *Athena*, should be eligible for patent protection. They should."
- "We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible."
- "The math is simple, you need not be an economist to get it: Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline. **To put it simply, this is bad. It is bad for the health of the American people and the health of the American economy.** And it is avoidable depending on our interpretation of the Supreme Court's holding in *Mayo*."

Athena Diagnostics, 927 F.3d at 1358.

Athena Diagnostics: Judge Newman's Dissent

- Joined by Judge Wallach
- "I write again in dissent because of the importance of medical diagnosis and the critical role of the patent system in achieving new diagnostic methods."
- "This case presents an opportunity for judicial review and judicial remedy. Although diagnostic methods are not the only area in which section 101 jurisprudence warrants attention, **Federal Circuit precedent is ripe for reconsideration specific to diagnostic methods, to correct our application of the *Mayo* decision and to restore the necessary economic incentive**."

Athena Diagnostics, 927 F.3d at 1370.

USPTO Guidance

Examples with 2014 Interim Eligibility Guidance

Nature-Based Products

The following examples should be used in conjunction with the 2014 Interim Eligibility Guidance. They replace the examples issued with the March 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products and related training. As the examples are intended to be illustrative only, they should be interpreted based on fact patterns set forth below. Other fact patterns may have different eligibility outcomes.

1. Gunpowder and fireworks
2. Pomelo Juice
3. Amazonic Acid, Pharmaceutical Compositions, & Methods of Treatment
4. Purified Proteins
5. Genetically Modified Bacterium
6. Bacterial Mixtures
7. Nucleic Acids
8. Antibodies
9. Cells
10. Food

https://www.uspto.gov/sites/default/files/documents/mdc_examples_nature-based_products.pdf

Pomelo Juice Example

Pomelo Juice: Process Claim That Is Directed To An Exception And Product Claim That Is Not Directed To An Exception

Claim 1: A method comprising providing a pomelo fruit. 

-No difference in substance from a product claim to the pomelo fruit itself; No markedly different characteristics

Claim 2: A beverage composition comprising pomelo juice and an effective amount of an added preservative. 

- Slower spoiling property is markedly different from properties of the juice by itself in nature; Not a "product by nature"

Amazonic Acid Example

Claim 1: Purified amazonic acid. 

Claim 2: Purified 5-methyl amazonic acid. 

Claim 3: Deoxyamazonic acid. 

Claim 4: A composition comprising an acid produced by a process which comprises: providing amazonic acid; and replacing the hydroxyl group of the amazonic acid with a hydrogen. 

Claim 5: A pharmaceutical composition comprising: a core comprising amazonic acid; and a layer of natural polymeric material enveloping the core. 

Claim 8: A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer. 

Purified Proteins Example

Claim 1: Antibiotic L. 

Claim 2: Purified Antibiotic L. 

Claim 3: The Antibiotic L of claim 1, which is in a tetrahedral crystal form. 

Claim 4: The Antibiotic L of claim 1, which is expressed by recombinant yeast. 

Claim 5: A purified antibiotic comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one substitution modification relative to SEQ ID NO: 2. 

Genetically Modified Bacterium Example

Claim 1: A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway. 

Claim 2: A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway. 

Bacterial Mixtures Example

Claim 1: An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.

Claim 2: An inoculant for leguminous plants comprising a mixture of *Rhizobium californiana* and *Rhizobium phaseoli*.

Nucleic Acid Example

Claim 1: Isolated nucleic acid comprising SEQ ID NO: 1. 

Claim 2: Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1. 

Claim 3: The isolated nucleic acid of claim 1, further comprising a fluorescent label attached to the nucleic acid. 

Claim 4: A vector comprising the nucleic acid of claim 1 and a heterologous nucleic acid sequence. 

Antibodies Example

Claim 1: An antibody to Protein S. 

Claim 2: The antibody of claim 1, wherein the antibody is a human antibody. 

Claim 3: The antibody of claim 1, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12. 

Claim 4: The antibody of claim 1, wherein the antibody is a chimeric or humanized antibody. 

Claim 5: The antibody of claim 1, wherein the antibody comprises a variant Fc domain. 

Cells Example

Claim 1: An isolated man-made human pacemaker cell. 

Claim 2: An isolated man-made human pacemaker cell expressing marker Z. 

Claim 3: A population of human pacemaker cells, wherein the population is about 10-15% positive for marker Z, and 85-90% positive for marker P. 

Claim 4: A composition comprising a population of isolated man-made human pacemaker cells in a container. 

Claim 5: A composition comprising a population of isolated man-made human pacemaker cells in a biocompatible three-dimensional scaffold. 

Food Example

Claim 1: A kit for preparing goat milk yogurt comprising: *Streptococcus thermophilus* and *Lactobacillus alexandrinus*.

Claim 2: A yogurt starter culture comprising: goat milk mixed with *Streptococcus thermophilus* and *Lactobacillus alexandrinus*.

2016 USPTO Subject Matter Eligibility Guidance

Subject Matter Eligibility Examples: Life Sciences

The following examples should be used in conjunction with the *2014 Interim Guidance on Subject Matter Eligibility* (2014 IEG). As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth below. Other fact patterns may have different eligibility outcomes. While some of the fact patterns draw from U.S. Supreme Court or U.S. Court of Appeals for the Federal Circuit decisions, each of the examples shows how claims should be analyzed under the 2014 IEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

28. Vaccines
29. Diagnosing and Treating Julitis
30. Dietary Sweeteners
31. Screening For Gene Alterations

Others

https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf

Vaccines Example

Claim 1: A vaccine comprising live attenuated Pigeon flu virus.

Claim 2: A vaccine comprising inactivated Pigeon flu virus.

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

Claim 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.

Claim 5: A vaccine comprising Peptide F; and an immuno-effective amount of an aluminum salt adjuvant.

Claim 7: A vaccine delivery device comprising a microneedle array that is coated with a vaccine comprising Peptide F.

Dietary Sweeteners Example

Claim 1: A dietary sweetener comprising texiol; and water. 

Claim 2: A dietary sweetener comprising 1-5 percent texiol; and at least 90 percent water. 

Claim 3: A dietary sweetener comprising 1-5 percent texiol; at least 90 percent water; and 1-2 percent Compound N. 

Claim 4: A dietary sweetener comprising 5 percent texiol; water, fruit juice, or a combination of water and fruit juice; and sufficient amounts of pectin to provide a solid gel. 

Claim 5: A dietary sweetener comprising granular particles of texiol having a particle diameter of X10 of microns and X90 of 300 microns. 

Claim 6: A dietary sweetener comprising texiol in a controlled release formulation. 

2019 USPTO Subject Matter Eligibility Guidance

Appendix 1 to the October 2019 Update: Subject Matter Eligibility
Life Sciences & Data Processing Examples

The following examples should be used in conjunction with the 2019 Revised Patent Subject Matter Eligibility Guidance ("2019 PEG") and the October 2019 Update: Subject Matter Eligibility ("October 2019 Update"). The examples below are hypothetical and only intended to be illustrative of the claim analysis under the 2019 PEG, and of the particular issues noted below in the Issue Spotting Chart. These examples should be interpreted based on the fact patterns set forth below as other fact patterns may have different eligibility outcomes. That is, it is not necessary for a claim under examination to mirror an example claim to be subject matter eligible under the 2019 PEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

43. Treating Kidney Disease
44. Denveric Acid
Others

https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_app1.pdf

Treating Kidney Disease Example

Claim 1: A treatment method comprising (a) calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype; (b) administering a treatment to the patient having a non-responder phenotype.

Claim 2: The method of claim 1, wherein the treatment is a non-steroidal agent capable of treating NAS-3.

Claim 3: The method of claim 1, wherein the treatment is rapamycin.

Claim 4: The method of claim 1, wherein the treatment is a course of plasmapheresis.

Claim 5: A treatment method comprising administering rapamycin to a patient identified as having Nephritic Autoimmune Syndrome Type 3 (NAS-3).

Denveric Acid Example

Claim 1: A dosage unit comprising denveric acid in a container. 

Claim 2: The dosage unit of claim 1, wherein the container is a wearable delivery device having a flexible patch-shaped housing, a needle assembly mounted on one side of the housing, a reservoir located inside the housing in which the denveric acid is stored, a dosage control button mounted on the opposite side of the housing from the needle assembly, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly. 

Claim 3: The dosage unit of claim 1, wherein the denveric acid is an intermediate-acting denveric acid. 

Claim 4: The dosage unit of claim 1, further comprising protamine that is mixed with the denveric acid in the container in an amount of 0.75 mg to 1.5 mg protamine per every mg of denveric acid. 

2019 USPTO Subject Matter Eligibility Guidance

- January 2019 new guidance on Abstract Ideas

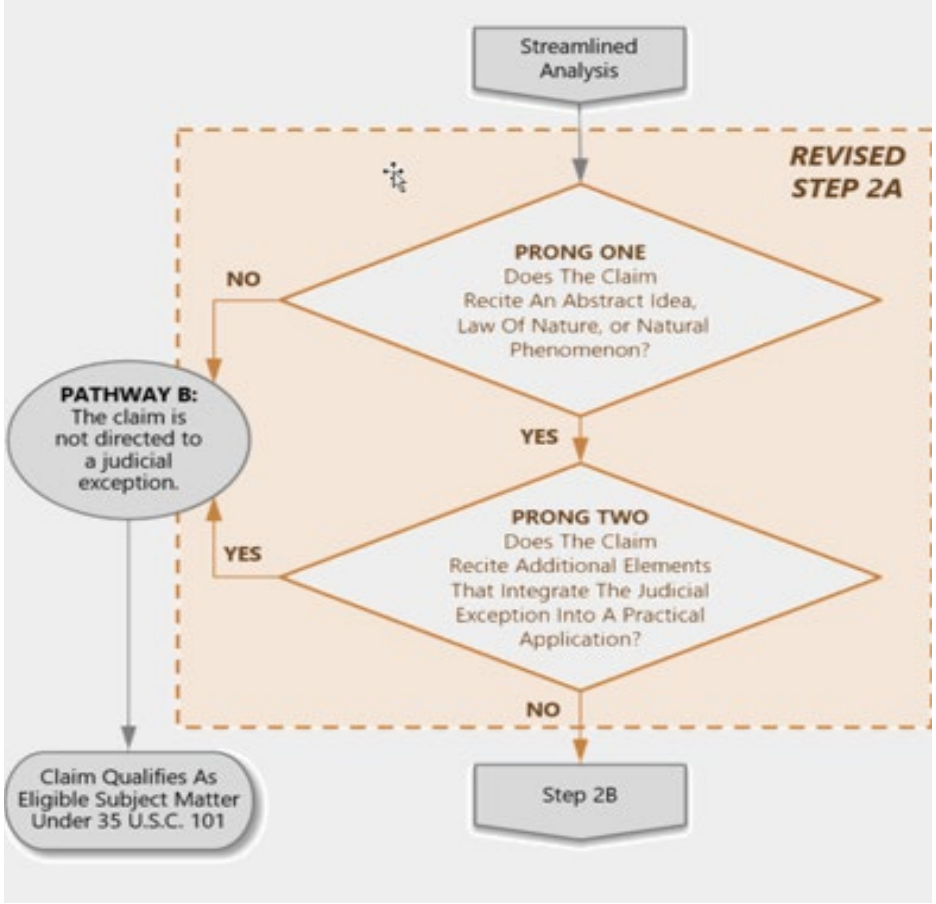
- Revised Step 2(a):
  - Whether the claim recites a judicial exception; and
  - Whether a recited judicial exception is integrated into a practical application

https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf

2019 USPTO Subject Matter Eligibility Guidance

Revised Step 2A

- Prong 1 → Abstract idea?
  - No → Not Directed to Judicial Exception (Eligible)
  - Yes → Go to Prong 2
- Prong 2 → Additional elements?
  - No → Step 2B
  - Yes → Not Directed to Judicial Exception (Eligible)



Future of Section 101

- No substantial changes since October 2019 PTO guidance
- Supreme Court continues to deny *cert.* in Section 101 cases
- No news regarding proposed legislation since the Tillis-Coons draft bill introduced in 2019

Avoiding and Overcoming § 101 Rejections and Challenges

Avoiding/Overcoming a § 101 Rejection: General Tips

- Draft the specification to avoid/overcome §101 issues
- Support and claim a variety of invention categories
- Be strategic as to choosing which claims to prosecute first
- Balance § 101 and § 112 requirements
- In prosecution, be prepared to explain:
  - How the claims compare those found allowable
  - How the combination of elements transforms the natural phenomena
  - Why the elements cited are not routine
  - How the invention is an improvement over the prior art

Other Considerations

- Product claims
- Other claim types
- Trade Secrets

Thank you!

Jeffrey D. Smyth, Partner
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Palo Alto, CA 94304
650.849.6618
jeffrey.smyth@finnegan.com

Megan L. Meyers
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Atlanta, GA 30363
404.653.6565
megan.meyers@finnegan.com