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Biotech Patents and Section 101 Rejections: Meeting Patent Eligibility Requirements

Leveraging Recent Decisions and USPTO Guidance to Overcome Rejections

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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*

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**

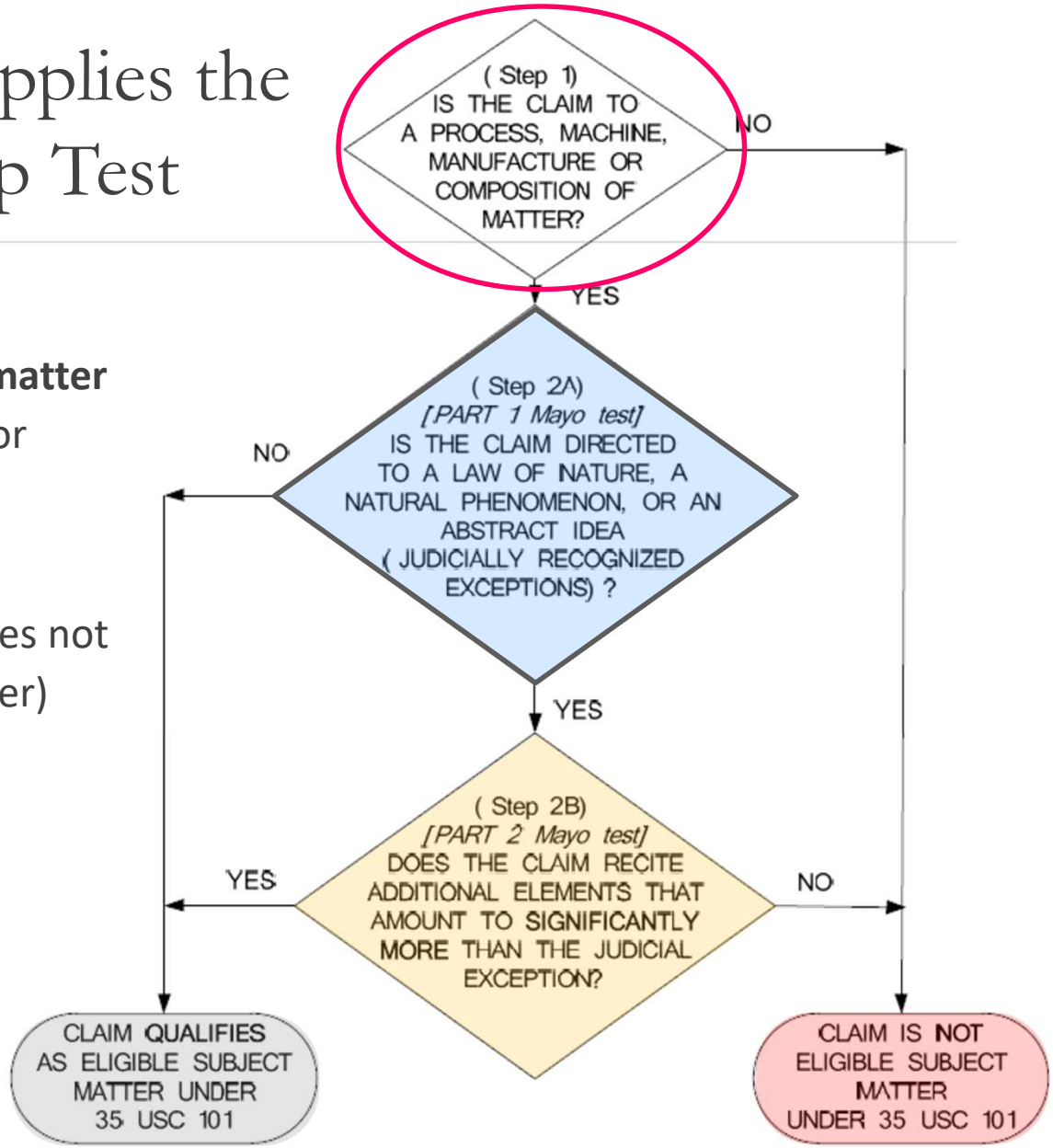
- Identify non-patent-ineligible elements of the claim.
- Consider these elements both individually and as an ordered combination.
- Do the additional elements "transform the nature of the claim" into a patent-eligible application?

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

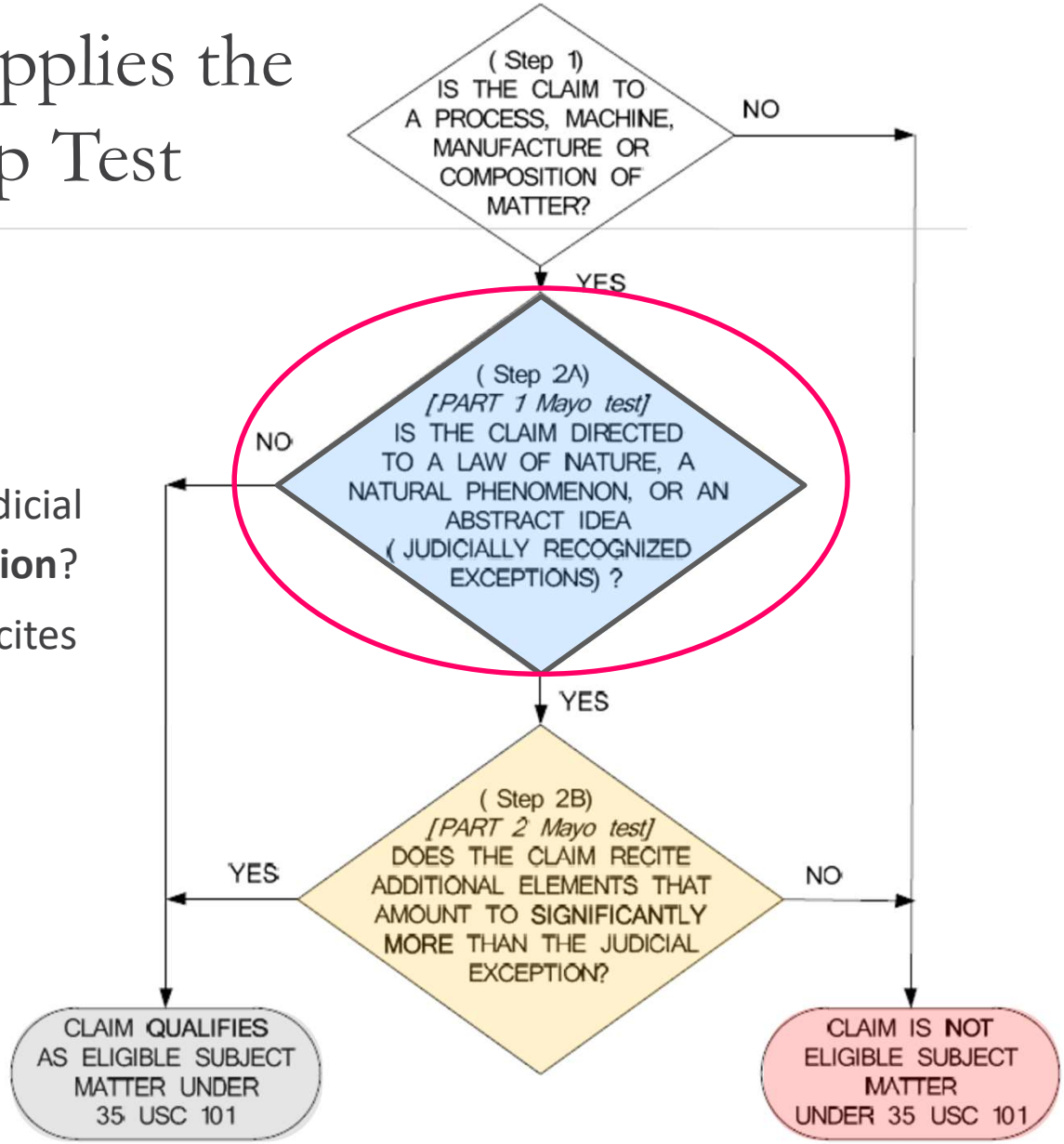
<u>Step 2A</u>:

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

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

Yes → End of analysis (claim recites patent-eligible subject matter)

No → Move to Step 2B



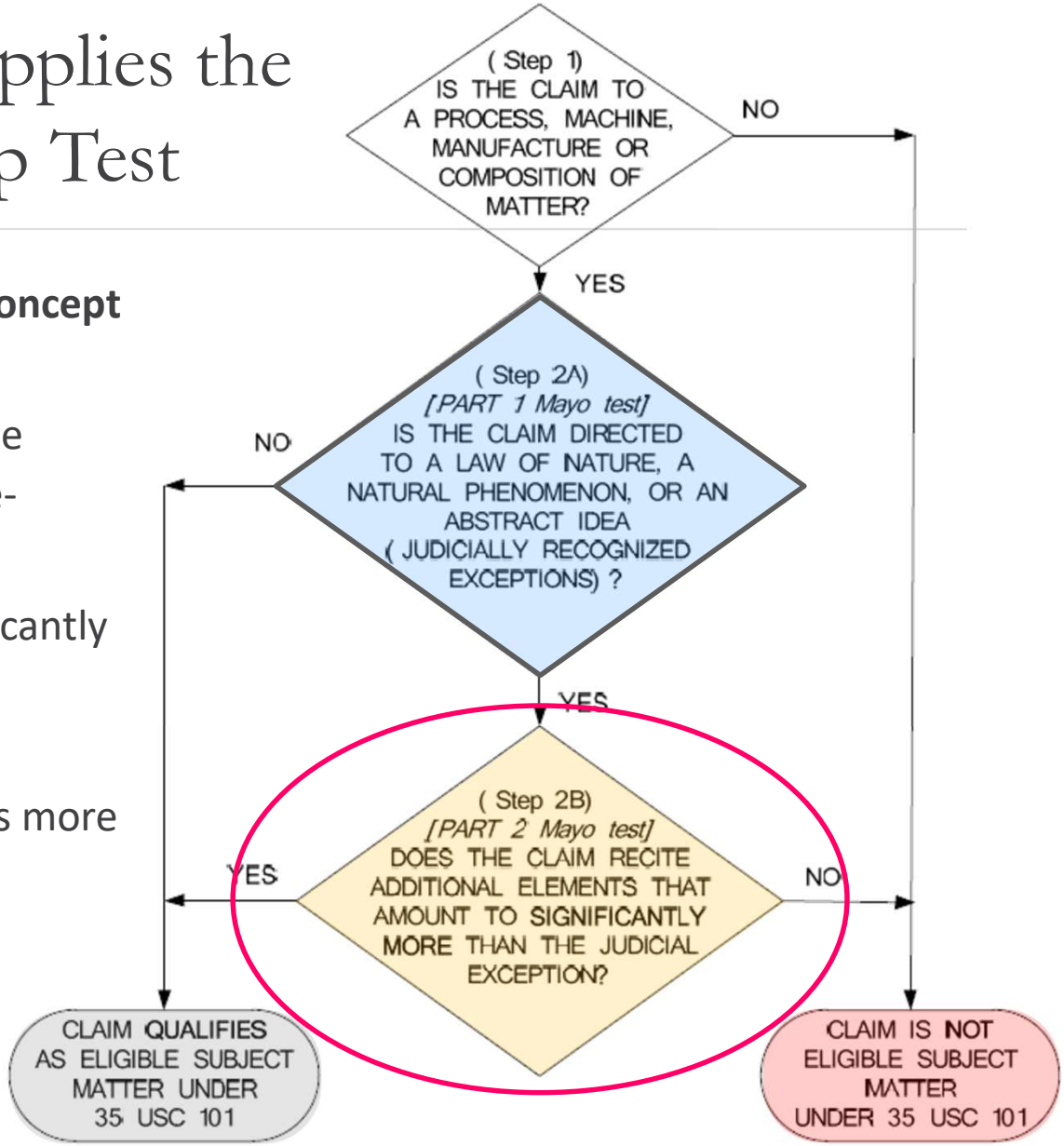
How the USPTO Applies the *Mayo/Alice* Two-Step Test

<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



Mayo: Challenged Claims

1. 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 $8x10^8$ 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 $8x10^8$ red blood cells **indicates a need to decrease** the amount of said drug subsequently administered to said subject."

Mayo: Analysis and Holding

The "administering" step tells doctors to treat a pre-existing patient population with a thiopurine drug (already used to treat such patients).

The "determining" step tells doctors to determine the level of a relevant metabolite (using techniques known in the art).

The "wherein" clauses tell doctors about a natural correlation and, at most, *suggest* they apply that correlation in the future.

"[T]he steps [of the claims] are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."

Held Prometheus' claims patent-ineligible.

Mayo: Implications

Patentees cannot preempt others' use of a natural law

- Even if the patent claims apply the natural law to a narrow context

Must include "significantly more" than natural law

- "Inventive concept" must go further than merely applying the natural law
- Blurs eligibility with obviousness

Routine, conventional, well-understood steps cannot make a "natural law" patent-eligible

Substance, not form, of claims is key

Methods of Diagnosis

Since *Mayo*, US courts have consistently found diagnostic claims patent-ineligible.

Athena: Challenged Claims

1. A **method for diagnosing** neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of **detecting** in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).

7. A method according to claim 1, comprising **contacting** MuSK or an epitope or antigenic determinant thereof having a suitable **label** thereon, with said bodily fluid, **immunoprecipitating** any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid, **monitoring for said label** . . ., wherein the presence of said **label is indicative of [a MuSK-related disorder]**."

Athena: Analysis and Holding

Claims directed to "the correlation between the presence of naturally-occurring MuSK autoantibodies in the bodily fluid and MuSK related neurological diseases like MG. **This correlation exists in nature apart from any human action**."

"[U]se of a man-made molecule [a label] in a method claim employing standard techniques to detect or observe may still leave the claim directed to a natural law."

Use of standard techniques (labeling, detecting) do not transform a claim into patentable subject matter under Step 2 of *Mayo/Alice* Test

Held Athena's claims patent-ineligible.

Athena: Petition for rehearsing *en banc* Denied

Four Concurrences: **Claims should be patent-eligible** but must be found ineligible under precedent set in *Mayo*. Need solution from Supreme Court or Congress.

J. Lourie – "If I could write on a clean slate . . . I would not exclude uses or detection of natural laws."

J. Dyk – "I share the concerns expressed by my dissenting colleagues that the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents."

J. Hughes – "I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life-saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications."

J. Chen – SCOTUS should clarify that *Mayo* wasn't meant to abrogate *Diehr.* "In any meaningful sense, [Athena's claimed diagnostic method] represents a practical application of the discovered law of nature, that is, it is applied science in every sense of that term. And it should be patentable subject matter in a well-functioning patent system."

Athena: Petition for rehearsing *en banc* Denied

Four Dissents: **Claims should be patent-eligible** and are **distinguishable over *Mayo***.

J. Newman – "The Court did not hold that methods of diagnosis are subject to unique patent-eligibility rules. We have mistakenly enlarged the Court's holding, in substance and in application."

J. Moore – "The majority of my colleagues believe that our hands are tied and that *Mayo* requires this outcome. I believe *Mayo* does not . . . the claims in *Athena*, unlike the claims in *Mayo*, contain specific, concrete steps applying the law of nature."

J. Stoll – "because this court's bright-line rule is based on an over-reaching and flawed test for eligibility, a test that undermines the constitutional rationale for having a patent system . . . the court should take this opportunity to correct its erroneous rule ."

J. O'Malley – "I believe that confusion and disagreements over patent eligibility have been engendered by the fact that the Supreme Court has ignored Congress's direction to the courts to apply [Section 101] as written. Specifically, the Supreme Court has instructed federal courts to read into Section 101 an "inventive concept" requirement—a baffling standard that Congress removed when it amended the Patent Act in 1952."

Athena: Petition for *cert.* Denied

Solicitor General encouraged Supreme Court them to grant *cert.* in *Athena*:

Mayo has had particularly significant practical effects with respect to medical-diagnostic methods. . . . the Federal Circuit's recent order denying rehearing en banc in *Athena* was accompanied by multiple separate opinions articulating different understandings of *Mayo* and seeking clarification from this Court. . . . Those various opinions provide substantial grounds for inferring that, if the Federal Circuit were not bound by the current Section 101 framework, that court might have reached different outcomes in *Athena* itself and in other diagnostic-method cases. Whether in *Athena* or in another such case, further guidance from this Court is amply warranted.

2016 USPTO Subject Matter Eligibility Guidance

Example 29: Diagnosing and Treating Julitis

2. A **method of diagnosing julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Methods of Detection

2016 USPTO Subject Matter Eligibility Guidance Example 29, Detection v. Diagnosis

1. A **method of detecting JUL-1** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

2. A **method of diagnosing julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Conflict between USPTO Guidance and Case Law

Example 29

1. A **method of detecting JUL-1** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

Ariosa Diagnostics v. Sequenom

1. A **method for detecting a paternally inherited nucleic acid of fetal origin** performed on a **maternal serum or plasma sample** from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

CAFC follows its precedent, not USPTO Guidance

Example 29

1. A **method of detecting JUL-1** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by **contacting** the plasma sample with an anti-JUL-1 antibody and **detecting binding** between JUL-1 and the antibody.

Cleveland Clinic v. True Health Diagnostics

1. **A method of detecting** elevated MPO mass in a patient sample comprising:

a. **obtaining** a plasma sample from a human patient having atherosclerotic cardiovascular disease (CVD); and

b. **detecting** elevated MPO mass in said plasma sample, as compared to a control MPO mass level from the general population or apparently healthy subjects, **by contacting** said plasma sample with anti-MPO antibodies and **detecting binding** between MPO in said plasma sample and said anti-MPO antibodies.

Nonprecedential Opinion

Cleveland Clinic: Analysis and Holding

"While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially . . . we are mindful of the need for consistent application of our case law."

"[W]e decline to follow the PTO's Example 29."

Claims directed to methods for observing a law of nature, that MPO correlates to cardiovascular disease and methods employ routine techniques.

Held Cleveland Clinic's claims patent-ineligible.

Cleveland Clinic: Implications

Detection method claims, like diagnostic method claims, are not patent-eligible (if using routine techniques).

- But this subject matter is often patent-eligible in other jurisdictions

Carefully consider whether and when to characterize a method/technique as "routine" or "conventional."

- "the specification and prosecution history plainly concede that each of the process steps was well-known in the art."

View USPTO guidance with caution

- A good starting point, and USPTO often adjusts guidance to align with case law (though guidance on Example 29, claim 1 has not been changed)
- Where discrepancies remain, defer to case law

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.

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

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

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: 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

Nat. 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. 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"

2016 USPTO Subject Matter Eligibility Guidance

Example 30: Dietary Sweeteners

Texiol is produced in the sap of the Texas mint plant.
Sap contains 10% texiol.
Compound N reduces bitterness of texiol.

A dietary sweetener comprising:

a) 1-5% texiol, and

b) at least 90% water.

A dietary sweetener comprising:

a) 1-5% texiol,

b) at least 90% water; and

c) 1-2% compound N.

2019 USPTO Subject Matter Eligibility Guidance

Example 44: Denveric Acid

Denveric acid is a tree bark protein with "short-acting" glycemic control properties. Administering denveric acid to diabetic patients reduces their need for insulin. Longer-acting glycemic control is desired, particularly when patients sleep. Denveric acid and protamine do not occur together in nature. Combined, they yield longer glycemic control compared to either product alone.

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

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

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.

Methods of Treatment

Vanda: 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

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: Analysis and Holding

Claims directed to a "**specific** method of treatment for **specific** patients using a **specific** compound at **specific** doses to achieve a **specific** outcome."

Claims not directed to a law of nature, but to a specific application of that law of nature.

Held Vanda's claims patent-eligible.

Vanda: Implications and Aftermath

Courts and examiners should evaluate claims **as a whole** to determine what they are "directed to."

Courts have since evaluated claims for subject matter eligibility by comparing them to the patent eligible claims in *Vanda.*

- In doing so, however, courts appear to take a generous/flexible approach when assessing the "specificity" of claim elements and how closely claims mirror Vanda's (*Natural Alternatives* and *Endo*)

USPTO issued a Subject Matter Eligibility Memo on June 7, 2018, conforming to the analysis and holding in *Vanda* ("*Vanda* Memo").

USPTO's *Vanda* Memo

"'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"

"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. For example, claims 5 and 6 of USPTO Example 29 (Diagnosing and Treating Julitis) should be considered patent eligible under Step 2A of the USPTO's subject matter eligibility guidance in light of the Federal Circuit decision in *Vanda*."

2016 USPTO Subject Matter Eligibility Guidance Example 29: Diagnosing and Treating Julitis

Applicant found that the presence of a particular protein "JUL-1" is indicative of a particular skin disease (julitis).

Julitis patients were sometimes misdiagnosed as having rosacea.

Misdiagnosis can result in julitis patients receiving rosacea treatments, which are ineffective against julitis.

Julitis traditionally treated with anti-TNF antibodies.

Example 29, Diagnostics v. Treatment Pre-*Vanda*

2. A **method of diagnosing julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

6. A **method of diagnosing and treating julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample;

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and

d. **administering** an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.

Example 29, Diagnostics v. Treatment Post-*Vanda*

2. A **method of diagnosing julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

6. A **method of diagnosing and treating julitis** in a patient, said method comprising:

a. **obtaining** a plasma sample from a human patient;

b. **detecting** whether JUL-1 is present in the plasma sample;

c. **diagnosing** the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and

d. **administering** an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.

Endo: Challenged Claims

1. A method of treating pain in a renally impaired patient, comprising the steps of:

(a) providing a solid oral controlled release dosage form, comprising:

(i) about 5 mg to about 80 mg of oxymorphone . . . and (ii) a controlled release matrix;

(b) measuring a creatinine clearance rate of the patient and determining it to be

(a) less than about 30 mL/min,

(b) about 30 mL/min to about 50 mL/min,

(c) about 51 mL/min to about 80 mL/min, or

(d) above about 80 mL/min; and

(c) orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief; wherein after said administration to the patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL.

Endo: Analysis and Holding

Vanda	***Endo***
A **method for treating** a patient with iloperidone, wherein . . . **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** . . .	A **method of treating** pain in a renally impaired patient, comprising . . . orally administering to said patient, **in dependence on which creatinine clearance rate is found**, a **lower dosage** of the dosage form to provide pain relief; wherein after said administration to the patient, the **average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL**.

"The claims at issue here are legally indistinguishable from the representative claim in *Vanda*"

Held Endo's claims patent-eligible

Endo: Implications

Claims are more likely to be held patent-eligible if they recite an active drug administration step, in which the drug alters the recipient's physiology (as in *Vanda*)

Courts look for "specific" claim elements (as in *Vanda*) **but may do so generously**

- Claims reciting administering **"a lower dosage"** satisfied the element of a **"specific dose"**
- "any differences in specificity are not of a sufficient degree to convince us to conclude that the claims here should be ineligible as compared to the claims in *Vanda*."

Vanda did not make all "method of treatment" claims patent-eligible . . .

As the Supreme Court explained in *Mayo*, substance, not form, of the claims is key.

INO: Challenged Claims

1. A method of treating patients who are candidates for inhaled nitric oxide treatment . . . 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 . . . ;

(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 . . . pulmonary edema upon treatment with inhaled nitric oxide.

INO: Analysis and Holding

"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**. Consequently, the claim here is directed to the natural phenomenon. The claim, apart from the natural phenomenon itself, involves **only well-understood, routine, and conventional steps**. For the reasons below, claim 1 of the '741 patent **fails to recite eligible subject matter**."

INO: Implications

A specific treatment step may not be enough if it was already known/used in the field (*but see Vanda*)

To be patent-eligible, a method of diagnosis + treatment claim must treat (or otherwise alter than natural state of) **all** "diagnosed" patients

Would the claims have been eligible if the patients without left ventricular function were treated with a non-conventional dosing regimen? Or if the patients with left ventricular dysfunction were given a sub-therapeutic dose of iNO or a different known drug?

What if the claim never mentioned the patients who were not candidates for iNO?

In re *Zunshine*

1. A **process** wherein, on day one, you--which stands for a user of the process--**cut your food intake** during all three regular meals, breakfast, lunch, and dinner, **by 1/3 and keep it that way for 3 months**, and **follow the how-to-eat rules**: (1) no food unless you are hungry, or it is your regular mealtime, breakfast, lunch, or dinner, (2) if you are hungry and it is not your regular mealtime, you drink a glass of water, first, and wait 10-15 minutes; if you are still hungry, then you eat a snack, and (3) the amount of the snack is determined by your BMI (body mass index) and the time left before the next regular meal or bedtime, whichever comes first.

Inventor argued the claim is directed to a method of treating obesity and related diseases.

CAFC disagreed, clarifying that not all methods of treatment claims are patent-eligible. They must recite specific elements, as Vanda did.

In re *Stanford*

Claim 1 recites a method for **resolving haplotype phase**, comprising **receiving and storing on a computer system:**

- **allele data** describing allele information regarding **genotypes for a family**
- **pedigree data** for the family
- **transition probability data** describing transition probabilities for inheritance states, wherein the inheritance states are determined based on the allele data using a Hidden Markov Model having specified hidden states
- **population linkage disequilibrium data**

and further comprising **determining and storing on a computer system a haplotype phase** for at least one member of the family based on the pedigree data, inheritance state, transition probability data, and the population linkage disequilibrium data using a computer system; and **providing the stored haplotype phase** for at least one member of the family in response to a request using a computer system.

Claim 9 depends from claim 1 and further recites **determining whether at least one genetic variant associated with disease is within the stored haplotype phase** by utilizing the haplotype phase to query a disease associated-single nucleotide polymorphism database using a computer system; **determining a drug for treatment** of at least one member of the family **based on information regarding drug-variant-phenotype associations** using a computer system; and **providing the determined drug** in response to a request using a computer system.

Held that making a "non-specific determination" of a drug treatment does no more than instruct a user to "apply" an abstract idea (the haplotype phase mathematical algorithm). Claims lack the specificity of the claims in *Vanda*.

Methods of Preparation/Manufacture

Illumina: 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:
(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).

Illumina: Analysis and Holding

"the claimed methods achieve **more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon**. The claims include **physical process steps** that **change the composition** of the mixture, **resulting in a DNA fraction that is different from the naturally occurring fraction** in the mother's blood.

"We thus turn to the crucial question on which this case depends: whether the claims are 'directed to' that natural phenomenon. We conclude that **the claims are *not* directed to that natural phenomenon but rather to a patent-eligible method that utilizes it**."

American Axle: Challenged Claims

1. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:
providing a hollow shaft member;
tuning at least one liner to attenuate at least two types of vibration transmitted through the shaft member; and
positioning the at least one liner within the shaft member such that the at least one liner is **configured to damp shell mode vibrations** in the shaft member **by an amount that is greater than or equal to about 2%**, and the at least one liner is also **configured to damp bending mode vibrations** in the shaft member, the at least one liner being **tuned to within about ±20% of a bending mode natural frequency** of the shaft assembly as installed in the driveline system.

22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:
providing a hollow shaft member;
tuning a mass and a stiffness of at least one liner, and **inserting the at least one liner** into the shaft member;
wherein the at least one liner is a tuned resistive absorber for **attenuating shell mode vibrations** and
wherein the at least one liner is a tuned reactive absorber for **attenuating bending mode vibrations**.

American Axle: Analysis and Holding

Analysis of claim 22 (directed to a natural law):

- "Claim 22 requires use of a natural law of relating frequency to mass and stiffness—i.e., Hooke's law."
- "Both claim 8 in *O'Reilly* and claim 22 here recite a natural law (electromagnetism in *O'Reilly* and Hooke's law here) and a result to be achieved (printing characters at a distance in *O'Reilly* and producing a liner to dampen specific vibrations). And just as claim 8 in O'Reilly did not recite any engineering or techniques to achieve this result, claim 22 likewise provides no details. Thus, claim 22, like claim 8 in O'Reilly, is directed to a natural law because it clearly invokes a natural law and nothing more, to accomplish a desired result."
- "What is missing is any physical structure or steps for achieving the claimed result of damping two different types of vibrations."

American Axle: Analysis and Holding

Analysis of claim 1 (not directed to a natural law):

- "While both claims [1 and 22] require 'tuning,' claim 1 is more general."
- "The specification indicates or may suggest that the 'characteristics' that can be 'tuned' in claim 1 include variable other than mass and stiffness."
- Claim 1 also "has an additional limitation of 'positioning the at least one liner.'"
- "The mere fact that any embodiment practicing claim 1 necessarily involves usage of one or more natural laws is by itself insufficient to conclude the claim is directed to such natural laws."

American Axle: Petition for rehearsing *en banc* – Denied

Two Concurrences: A claim reciting nothing more than a natural law to achieve a result is not patent eligible.

J. Dyk: "Claim 22 and related claims instruct only the use of mass and stiffness to match relevant frequencies to tune a propshaft liner so that the liner, when used, will produce certain results (reducing two modes of vibration from the propshaft) . . . these claims in no way 'recite the process and machinery necessary to produce the desired effect of reducing vibrations in a shaft assembly.'"

J. Chen: "The narrow scope of the majority's holding is illustrated by the differences in the outcomes between claims 1 and 22. If claim 22 had omitted any reference to mass and stiffness, such that the claim simply recited 'tuning to match the relevant frequency or frequencies,' there would be no basis to say that the claim invokes Hooke's law."

American Axle: Petition for rehearing *en banc* – Denied

Four Dissents: The claims are directed to an automotive driveshaft, which is patent-eligible, and the majority has conflated patent eligibility with enablement.

J. Newman: "The court's new spin on Section 101 holds that when technological advance is claimed too broadly, and the claims draw on scientific principles, the subject matter is barred 'at the threshold' from access to patenting as a matter of law." . . . "Yet it is apparent that [claims 1 and 22] are for an automotive driveshaft, not for an abstract idea or law of nature or mathematical formula."

J. Stoll: "[T]he majority's decision extends § 101 to place in doubt the patent eligibility of historically eligible mechanical inventions, and thus presents 'a question of exceptional importance' that warrants consideration by the full court."

"The majority's reasoning also introduces further uncertainty by blurring the line between patent eligibility and enablement. While the eligibility inquiry may take into account whether a claim has 'the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it,' . . . the majority's 'how to' analysis seems to go further, potentially incorporating a heightened enablment requirement into § 101."

Opportunities for Section 101 Reform

Supreme Court could grant *cert*. in *American Axle*

- However, last year denied *cert.* in three other Section 101 cases

Congress could reform Section 101

- However, no news since the Tillis-Coons draft bill was introduced in 2019
- In light of the COVID-19 pandemic, Congress may feel further pressure to incentivize certain types of medical inventions, like diagnostic methods, historically held to be patent-ineligible. However, it is unclear whether this pressure might result in Section 101 reform or an incentive structure outside of patent law (if it materializes at all)

Avoiding and Overcoming § 101 Rejections and Challenges

Avoiding/Overcoming a § 101 Rejection: General Tips

Support and claim a variety of invention categories

Prosecute narrow or "easy" claims first

- "Easy":
  - A method of treatment
  - A method of diagnosis + treatment
- Pursue more challenging subject matter in a divisional

Avoid language indicating a mental step or other judicial exception, and instead focus on concrete physical steps and specific claim elements

Avoid referring to a claim element or technique as "routine" or "conventional" unless that status is undisputed

- Need to balance § 101 and § 112 requirements

Drafting the Specification to Avoid/Overcome a § 101 Rejection

Disclose practical applications (e.g., implementation beyond "mental step" diagnosis, such as diagnosis + treatment)

Disclose concrete examples of broadly-claimed methods (e.g., suitable technologies for carrying out the method)

Disclose why recited elements (e.g., compositions, steps in a method) are non-routine

Disclose why the invention is an improvement over the prior art

Drafting or Amending Method Claims to Avoid/Overcome a § 101 Rejection

- Recite a practical application and/or tangible result
- Recite at least one concrete/physical step
- Recite how the natural law is applied (not just the desired result)
- If possible, recite a *series* of steps
- If possible, recite at least one non-routine element
- Model claims using claims held eligible by courts

Choose a clear preamble, and continue with language consistent with that preamble:

- A method of treatment . . .
- A method of preventing . . .
- A method of [achieving X tangible/measurable result] . . .

If claiming a method of diagnosis, include a non-routine element or a specific treatment step

Arguments during Prosecution to Overcome a § 101 Rejection

Argue that the claims recite physical/tangible elements (point to support from specification)

Argue that the claims are similar to claims found eligible by courts

Argue the *specificity* of the claim terms

Argue the claim elements *combined* transform the nature of the claim

Argue that the invention is an improvement to specific technology in the prior art

Argue that the claims recite elements other than the exception (e.g., other than the abstract idea or natural law) that are not routine

Argue that the prior art teaches away from the invention, thus indicating the steps are not routine

Thank you.

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