U.S. Patent Eligibility: Update on the Status of Claims Reciting "Natural Phenomenon"

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U.S. Patent Eligibility: Statute and SCOTUS

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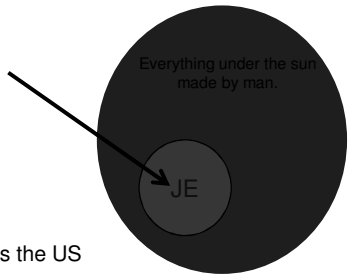
35 U.S.C. §101 – Four Categories of Eligible Subject Matter

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.

Judicial exceptions (JE) made by US courts: one cannot claim a **law of nature**, a **natural phenomena**, or an **abstract idea**.



Why: granting a monopoly over the basic tools of scientific and technological work would pre-empt use of these tools in all fields, thereby impeding innovation.

Article I, Section 8, Clause 8 of the constitution empowers the US Congress:

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

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Natural Phenomena?

I Claim:

- Vitamin E
- streptomycin
- viral genome
- Botulism toxin

I Claim:

- Vitamin E, isolated from nuts
- Purified streptomycin
- Isolated viral genome
- Purified botulism toxin

?

In the U.S., one can no longer rely on the words “isolated” or “purified” to differentiate between an ineligible natural phenomena and an eligible composition of matter or manufacture.

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Ass'n for Molecular Path. v. Myriad Genetics (SCOTUS 2013)

- Holding: Isolated gDNA is a product of nature and not patent eligible, but cDNA is not a product of nature and is patent eligible.
- Why:
  - The Court understood the function of DNA as being a carrier of information.
    - The claimed gDNA does not have different information (function) from that which is found in nature.
    - The claimed gDNA does not have different sequence (structure) from that which is found in nature.

- Court was very careful to state that it "merely holds" that gDNA is not eligible for patenting simply because it has been isolated.
- **Should not be broadly applied to NP other than DNA ... but USPTO *et al* disagree.**

Prometheus v. Mayo (SCOTUS 2012) Alice Corp. v. CLS Bank (SCOTUS 2014)

Alice/Mayo two-step test for all claims under § 101:

(1) Is the claim directed to a JE (NP, AI, NL)?

(2) Does the claim contain an "'inventive concept'" sufficient to "transform" the invention into a patent-eligible application of the JE?

Analyze steps/elements individually & as ordered combination (*Diehr* - claims cannot be deconstructed into their component steps; must be considered as a whole).

Mayo: "appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." (WURC)

Alice dicta supports the idea that a **solution to a technical problem** is not an AI, and a claim drawn to such a solution, even if broad, will satisfy the *Alice/Mayo* two-step.

U.S. Patent Eligibility: CAFC

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Ariosa v. Sequenom (CAFC 2015)

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.

21. A method of performing a prenatal diagnosis, which method comprises the steps of:

(i) providing a maternal blood sample;

(ii) separating the sample into a cellular and a non-cellular fraction;

(iii) detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction according to the method of claim 1;

(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid.

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Ariosa v. Sequenom (CAFC 2015)

- Claim starts with cffDNA taken from a sample of maternal plasma or serum … a natural phenomenon.
- Method ends with paternally inherited cffDNA, which is also a natural phenomenon.
- The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.
- The remaining claim steps are **WURC**.
- Fail *Alice* Step 2, including claim 21, which contains the additional step of "providing a diagnosis."

Rapid Litigation Management v. CellzDirect (CAFC 2016)

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 non-viable 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.

Rapid Litigation Management v. CellzDirect (CAFC 2016)

- End result of methods is not simply an observation or detection of a JE (i.e., the ability of hepatocytes to survive multiple freeze-thaw cycles).
- Claims are directed to a **new** and useful method of preserving hepatocytes. The invention achieves a **better way** of preserving hepatocytes.
- The claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease.
- *Alice* Step 1 win.

NB: Court notes claim would also have won at *Alice* Step 2 ("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" (citing *Alice*, quoting *Mayo*, discussing *Diehr*)).

U.S. Patent Eligibility: District Courts

Natural Alternatives Intl., Inc. v. Allmax Nutrition Inc., CA No. 16-cv-01764-H-AGS (SD CA, June 26, 2017)

Natural phenomenon? Yes. (grant MTD)

'084 Claim 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.

'947 Claim 34. A human dietary supplement for increasing human muscle tissue strength comprising a mixture of creatine, a carbohydrate and free amino acid beta-alanine that is not part of a dipeptide, polypeptide or an oligopeptide, wherein the human dietary supplement does not contain a free amino acid L-histidine, wherein the free amino acid beta-alanine is in an amount that is from 0.4 g to 16.0 g per daily dose, wherein the amount increases the muscle tissue strength in the human, and wherein the human dietary supplement is formulated for one or more doses per day for at least 14 days

'596 Claim 1: A method of regulating hydronium ion concentrations in a human tissue comprising:

providing an amount of beta-alanine to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in the human tissue; and

exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the human tissue.

Natural Alternatives Intl., Inc. v. Allmax Nutrition Inc., CA No. 16-cv-01764-H-AGS (SD CA, June 26, 2017)

Natural phenomenon? Yes. (grant MTD)

- Step 1 – beta-alanine, a natural amino acid that regulates [hydronium ion], is the only ingredient.
  - But, a "dietary supplement" containing b-alanine is not a NP. True, but the inquiry is whether the claim is *directed to* a NP. Here, the claim is directed to a NP, implemented via a supplement.
- Step 2 – the inventive concept is placing a specific dosage of beta-alanine into a dietary supplement. The spec. indicates that placing a natural substance in a supplement is **WURC**.
  - But, providing b-alanine in effective amounts doesn't preempt the natural law that b-alanine can regulate [hydronium ion] in tissues. True, but CAFC explains that absence of preemption does not demonstrate eligibility.

Mixtures including beta-alanine: **fail**. All mixed substances are natural products (Step 1); SCOTUS held (*Funk*) that mixing NP together is insufficient to impart eligibility (Step 2).

Methods of using beta-alanine to regulate [hydronium ion]: **fail**. Directed to a NL regulated by a NP with no further inventive concept (Step 2). Irrelevant that the method is new and useful.

Mimedix Group, Inc. v. Liventa Biosci., Inc., CA No. 14-cv-1178-MHC (N.D. GA, Aug. 11, 2017)

Natural phenomenon? No. (affirm advice of special master to deny SJ)

'494 Claim 1. A dehydrated, laminated tissue graft consisting essentially of one or more washed and/or substantially cleaned amnion layers and one or more washed and/or substantially cleaned chorion layers, wherein at least one of the amnion layers contains its fibroblast cell layer, and further wherein the amnion layer and the chorion layer are directly laminated to each other.

Mimedix Group, Inc. v. Liventa Biosci., Inc., CA No. 14-cv-1178-MHC (N.D. GA, Aug. 11, 2017)

Natural phenomenon? No. (affirm advice of special master to deny SJ)

- Special Master's recommendations are sealed. But, from the court decision on motion:
  - Separating and using amnion as graft is analogous to gDNA
  - Separating, cleaning and laminating chorion to amnion for use as graft is analogous to cDNA – the grafts are "something new"
- Δ argues that "something new" is not the standard; it is MDC. The laminated graft is similar to bacterial mix in *Funk* – no MDC (no improved function or utility, has same effect).
- Court: MDC is not a mandated analysis – sufficient, but not necessary. In fact, as noted by the special master:

"Myriad used the 'markedly different' language in finding a gene was not patentable, but used 'something new language" in determining that another gene was patentable"(emphasis in opinion).

- Court: special master uses "something new" in the manner used by SCOTUS in *Myriad*, not to mean "novel".

U.S. Patent Eligibility: PTAB

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Ex Parte McBride, Appeal 2015-6282 (PTAB, Dec. 5, 2016)

Natural phenomenon? No

1. (Previously presented) A composition comprising an isolated polypeptide that is from 24 to 75 amino acids in length, said polypeptide being selected from the group consisting of:

(a) an isolated polypeptide comprising SEQ ID NO:13; and

(b) an isolated polypeptide that is at least 95% identical to SEQ ID NO:13;

wherein the isolated polypeptide is bound to a solid support or a detectable label.

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Ex Parte McBride, Appeal 2015-6282 **(PTAB, Dec. 5, 2016)**

Natural phenomenon? No

- Examiner argues that the peptide is natural, as are solid supports (e.g., a rock) and detectable labels.
- PTAB: *Alice* Step 1 – claims recite a peptide *bound* to solid structure or label.
  - While both components may be NP, no evidence that they are *bound* together naturally.
  - Because they are *bound*, the invention is also distinguishable from *Funk* (a mere advance in packaging).
  - Under *Alice* step 1, the claim is not directed to a NP.
- *Alice* Step 2 (????) - When considered as an ordered combination, the claimed invention is not merely the routine or conventional use of technology.
- NB: No MDC analysis performed – just *Alice*.

Ex parte Gohla, Appeal 2017-003389 **(PTAB, July 19, 2017)**

Natural phenomenon? No

43. A topical cosmetic or dermatological preparation for protecting skin, wherein the preparation comprises from 0.0005 % to 20 % by weight of snow algae extract as well as one or more of (i) collagen, (ii) chitosan and/or acetylated chitosan having a degree of acetylation of about 50 %, (iii) a glycosaminoglycan, (iv) a peptide which promotes cell growth, and (v) a composition comprising glycoprotein 1, glycoprotein 2, ginseng extract, and horsetail extract.

Ex parte Gohla, Appeal 2017-003389 (PTAB, July 19, 2017)

Natural phenomenon? No

- Examiner alleges that the composition does not have MDC versus naturally-occurring counterparts.
- PTAB: in view of preamble (and Spec.), which require the composition to protect skin, we interpret the claim to require that the amounts of the substances, alone or together, must protect skin.
- The Examiner did not establish that the recited ingredients occur together in nature, nor did he adequately address the skin protective property of the substances when present together.
  - Refers to Example 1 of March 2014 guidance (likely meant Dec 2014 guidance, where Example 1 is to gunpowder, which has MDC vs individual components).

Ex parte Burgos, Appeal 2015-006760 (PTAB, Jan. 3, 2017) (appealed to CAFC Feb 20, 2017)

Natural phenomenon? Yes

61. A standardized extract comprising a plurality of anthocyanins and anthocyanidins, wherein at least about 35% of the composition, by weight, is a plurality of anthocyanins and anthocyanidins and wherein the anthocyanins and anthocyanidins are selected from the group consisting of delphinidin-3-0-sambubioside-5-0-glucoside, delphinidin-3,5-0-diglucoside, cyanidin-3-0-sambubioside-5-0-glucoside, cyanidin-3,5-0-diglucoside, delphinidin-3-0-sambubioside, delphinidin-3-0-glucoside, cyanidin-3-0-sambubioside, and cyanidin-3-0-glucoside; and at least about 15% of the anthocyanins or anthocyanidins or both, by weight, are sugar-free or sugar-containing delphinidins, and wherein the composition is nontoxic.

Ex parte Burgos, Appeal 2015-006760 **(PTAB, Jan. 3, 2017) (appealed to CAFC Feb 20, 2017)**

Natural phenomenon? Yes

- Examiner: Extract/concentrate = purify, which is not sufficient under *Myriad*. No evidence that extraction creates MDC v. compounds in maqui fruit.
- Appellant: providing compounds in a concentrated form allows claimed composition to acquire a different use when cf. to the amount of fruit one would have to consume daily.
- PTAB: *Alice* Step 1: analogous to *Funk* invention. No change in extracted compound structures.
- PTAB: *Alice* Step 2: No change in extracted compound's function v. nature, and as per *Myriad*, purification is not an inventive concept.
  - NB: Claim 65 and 69 – adds further components and data in spec. shows changed properties, but not across the breadth of claim.
  - NB: Feb 24, 2017 Examiner interview indicates case would be allowable if carrier elements of claim 81 (microcrystalline cellulose, lactose, silicon dioxide, etc.) incorporated.

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Conclusions

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Your Best Bets?

- MDC
- Unconventional Stuff (vs. WURC)
- Unconventional Combination
- Technological Improvement
  - US District Courts are applying this in final decisions and 12(b)(6) stage (typically for process claims);
  - CAFC mentions this "test", in some form, in *CellzDirect* (2016), as well as the computer trifecta: *Enfish* (May 2016), *Bascom* (June 2016), *Planet Blue* (Sept 2016), when considering both *Alice* Step 1 and Step 2.

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Thank you

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Additional Cases

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Oxford Immunotec Ltd. v. Qiagen, Inc., CA No. 15-cv-13124-NMG (D. Mass., Aug. 31, 2016)

Law of Nature? Yes/No. (suggest deny MTD method, grant MTD kit)

'646 claim 1: A method of diagnosing infection in a human host by, or exposure of a human host to, a mycobacterium that expresses ESAT-6, which method comprises the steps of:

(i) contacting a population of T cells from the host with a panel of eight peptides represented by SEQ ID NOS: 1 to 8, and

(ii) determining in vitro whether T cells of the T cell population show a recognition response to the panel by detecting IFN-γ secretion from the T cells.

Claim 7. A kit for diagnosing infection in a human host by, or exposure of a human host to, a mycobacterium that expresses ESAT-6, comprising a panel of eight peptides represented by SEQ ID NOS: 1 to 8

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Oxford Immunotec Ltd. v. Qiagen, Inc., **CA No. 15-cv-13124-NMG (D. Mass., Aug. 31, 2016)**

Law of Nature? Yes/No. (suggest deny MTD method, grant MTD kit)

- Step 1 – kit: peptides in panel based wholly on natural sequence of ESAT-6; method: T-cells previously exposed to *M. tuberculosis* will excrete IFN-γ.
- Step 2 – kit: only describe peptide panel of test and thus no inventive concept when divorced from the methods; method: **improve** existing methods for diagnosing TB (more convenient, less dependent on a physician's subjective interpretation of results, more accurate).

Court: Sept 30, 2016 denied MTD for both. Δ relied on *Myriad* re: peptides in kit claims, but *Myriad* was re: isolated DNA (no different information or chemical difference), and Π claims that the peptides in the kits are chemically different, which gives rise to "distinctive character and use".

Rutgers v Qiagen**, CA No. 3:15-cv-07187 (D. N.J., Feb. 29, 2016)**

Natural Phenomenon? Not sure (deny MTD)

'141 Claim 1. A method of *in vitro* diagnosis which discriminates between exposure of a subject to Mycobacterium tuberculosis and vaccination with the *Bacille Calmette Guerin* strain of *Mycobacterium bovis*, the method comprising

testing for the presence of CD4 T lymphocytes that respond to MTBN4,

wherein the presence of the CD4 T lymphocytes that respond to MTBN4 indicates that the subject has been exposed to Mycobacterium tuberculosis, and

wherein CD4 T lymphocytes from a subject vaccinated with the *Bacille Calmette Guerin* strain of *Mycobacterium bovis* but not exposed to Mycobacterium tuberculosis do not respond.

'800 Claim 1. A diagnostic composition that discriminates between infection by *Mycobacterium tuberculosis* and vaccination by *Bacille Calmette Guerin* (BCG) strain of *Mycobacterium bovis*, said composition comprising antigens, all antigens in said composition consisting of at least three different polypeptides of the *Mycobacterium tuberculosis* complex that are not encoded by BCG, and said polypeptides including at least one isolated polypeptide from the group consisting of

(i) a first amino acid sequence consisting of the sequence of MTBN4 (SEQ ID NO: 4),

(ii) a second amino acid sequence that is an antigenic segment of MTBN4 that has Mycobacterium tuberculosis specific antigenic or immunogenic properties and

(iii) a third amino acid sequence that is identical to said first or second amino acid sequence but has conservative substitutions and has Mycobacterium tuberculosis specific antigenic or immunogenic properties.

***Rutgers v Qiagen*, CA No. 3:15-cv-07187 (D. N.J., Feb. 29, 2016)**

Natural Phenomenon? Not sure (deny MTD)

- Step 1 (2A) –plausible that not all the materials used in the claimed methods and compositions are naturally-occurring
  - According to Plaintiff, neither the peptide or antigenic segments or its surroundings are naturally occurring and it is illogical that the methods are ineligible simply because they involve elements found in nature.
- Step 2(2B) –plausible that the special characteristics of proteins, as compared to those of DNA, may support patent-eligibility; plausible that the invention is not simply directed to isolating and identifying materials, but rather applies these materials in a new way to improve a process for detecting TB.
  - The only practical way to diagnose TB before the invention was the TB skin test. The invention is an *in vitro* test done in a single visit giving an objective measurement signifying TB infection.

***Ex parte Bhagat, Appeal 20156-004154* (PTAB, April 15, 2016) (appealed to CAFC Aug 16, 2016)**

Natural phenomenon? Yes

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4: 1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

(1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

Ex parte Bhagat, Appeal 20156-004154 (PTAB, April 15, 2016) (appealed to CAFC Aug 16, 2016)

Natural phenomenon? Yes

- Examiner: A 1 oz. serving of walnut oil is a lipid-containing formulation having the required ratio and % by weight of omega-6/-3. Thus, the claim reads on a JE.
- Appellant: claims contain several elements that add significantly more (intermixture, dosage, casings).
- PTAB: Claim interpretation: intermixture = p-b-p limit; casing = any orally accepted form; no dosage (only an amount of 40 g).
- PTAB: Processing (such as walnut oil refining) does not necessarily result in MDC (c.f., *Funk* invention of bacteria in powder base). *Funk* and *Myriad* teach that routine extraction and production does not produce MDC.
  - NB: Cannot rebut with long felt need or teaching away.
  - NB: Dependent claims with additional natural components (e.g., mixtures of proteins, carriers, starches, sugars, etc.), one-part dosages, steady delivery, different ratios of omegas, etc. re also not eligible. Board finds no evidence of MDC.

Status (as of Sept 2017)

- *Natural Alternatives Intl., Inc. v. Allmax Nutrition Inc*. - motion for reconsideration denied Aug 28, 2017. Case will proceed on trademark and civil conspiracy.
- *Mimedix Group, Inc. v. Liventa Biosci., Inc*. – no further activity.
- *Oxford Immunotec Ltd. v. Qiagen, Inc.* - Motions for SJ due by 10/31/2017, Jury Trial set for Jan. 16, 2018.
- *Rutgers v. Qiagen* – Settled. Case dismissed March 20, 2017.
- *Ex Parte McBride* – patented (US 9,605,032).
- *Ex parte Gohla* – request for rehearing filed September 15, 2017.
- *Ex parte Burgos* - appealed to **CAFC** Feb 20, 2017.
- *Ex parte Bhagat* - appealed to **CAFC** Aug 16, 2016.

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PATENT PROTECTION FOR HIGH TECHNOLOGY

Diagnostic Tests – Is There Anything Left to Patent?

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BIO IPDx Symposium
September 29, 2017

The "Big Question"

- Are "simple" diagnostic claims – "If A, then B" patent-eligible? (Elevated Hcys = low cobalamin.)
- PTO – "No" (2014 Guidelines)
- Justice Breyer, "No" ("Metabolite Labs. Dissent")(2006)
- Fed. Cir.: "No" –Even if claim is drafted with specificity as to both the marker measured and the condition identified.(Cleveland Clinic)

Genetic Technol. Ltd. v. Meriel, LLC

- (Appeal no. 1215-, -1202, -1203 (Fed. Cir. April 8, 2016))
- Claims were to the use of law of linkage disequilibrium to the problem of detecting specific coding sequences of DNA.
- Claim 1 was directed to a method of detection of at least one coding region allele of a multi-allelic genetic locus via an amplification step and a detection step.
- Claim 15 reads: "The method of claim 9 wherein said allele is associated with a monogenic disease" (e.g., cystic fibrosis).
- The panel characterized the term "to detect an allele in the coding region" as a mental process step – a routine comparison that can be performed by the human mind."(Emp. supplied)

Does Judge Dyk have a legal hangover post-Ariosa?

- "The inventive concept necessary at step 2…cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea itself. That is, under the Mayo/Alice framework, a claim directed to a newly discovered [PAIN] cannot rely on the novelty of that discovery for the inventive concept necessary for [PE]; instead the application must provide something inventive, beyond mere 'well-understood, routine conventional activity.'"[Citing Mayo, Myriad and Ariosa][Empasis supplied]

Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc.

- Appeal no. 2015-1570 (Fed. Cir., July 5, 2016)(U.S. Pat. No. 7,604,929). Judges Moore, Stoll and Prost, Prost writing.
- Method to isolate "hardy hepatocytes" by subjecting hepatocytes, including pooled ones, to two freeze-thaw cycles, resulting in cryopreserved "hardy" hepatocytes that could be used without further selection of viable from non-viable ones.
- D.C. held claim was to law of nature - reversed

Rationale: Claims are directed to new and useful preservation technique

- Panel distinguished the method steps of Genetic Techs., Ariosa and Myriad I and II as involving nothing more than observing or identifying the ineligible concept.
- Funk Bros. was distinguished as involving product claims and not methods of selecting and testing the strains.
- The method claimed in Mayo amounted to an old use of an old compound

Routine and Conventional Steps or Unobvious Advance?

- Panel carried out a full-blown obviousness analysis of the claimed method at Step 2 of the Mayo test, although method was PE under Step 1.
- "The benefits of the improved process over the prior art methods are significant."
- Prior art taught away from multiple freezing steps; art is unpredictable; crowded art did not suggest the multicryopreservation method.

Panel Relied on Diehr

- "Just as in Diehr, it is the particular 'combination of steps' that is patentable here. 450 U.S. at 188. The inventors discovered that some percentage of hepatocytes can survive multiple freeze-thaw cycles and applied that discovery to improve existing methods for preserving hepatocytes. To require something more would be to discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'" [citing Alice].

PTO Responds to CellzDirect

- Memo to Examiners from Robert Bahr of July 14, 2016.
- "The court determined that [the claims], like thousands of other claims that recite methods of producing things or methods of treating disease, were not directed to a judicial exception."
- Bad: Claims that "[amount] to nothing more that observing or identifying the patent ineligible concept itself."
- No mention of diagnostic claims
- PTO Guidelines are sufficient post-Ariosa and CellzDirect.
- May 2014 Guidelines state that simple diagnostic claims are not PE.

Are All "If (a) then (b)" claims doa?

- What is the "more" that is needed to get diagnostic claims into the Diehr safe harbor? Need "inventive concept" in the claim (A discovery of a natural correlation AND an invention apart from a practical application of the correlation to yield a diagnosis).
- The discovery of the effect or meaning of the in vivo correlation cannot provide the "inventive concept" (Dyk in Meriel).
- Can't be "what is well-understood, routine, conventional activity, previously engaged in by those in the field" pre- or post-solution. But need some "further act." Mayo 132 S.Ct. at 1298.
- BUT what if the assay techniques are not routine and/or the components are complex?

The Cleveland Clinic Foundation v. True Health Diagnostics

- Appeal No. 2016-1766 (Fed. Cir., June 16, 2017)
- Diagnostic test for cardiovascular disease based on determining MPO level in sample with levels in subjects diagnosed as not having CVD.
- "[After testing steps, the claimed] method then employs the natural relationship between those MPO values and predetermined or control values to predict a patient's risk of developing or having [CVD]….The presence of MPO in a bodily sample is correlated to its relationship to [CVD]. The claims are therefor directed to a natural law."

Practice of methods does not rise to the level of "inventive concept."

- "Cleveland Clinic does not purport to derive new statistical methods to arrive at the predetermined or control levels of MPO that would indicate a patient's risk of [CVD]. Known statistical methods can be employed, as described, for example, in the specification [quoting about 11 lines]."

Cleveland Clinic Should Have Purported More!

- This is not like discovering the correlation between high homocysteine and low cobalamin or measuring maternal cffDNA.
- The "hand of man" is required to weigh the importance of each of a myriad of variables to the presence or risk of CVD.
- The definition of the presence or risk of CVD depends on how CVD is defined, including exclusion/inclusion and diagnostic parameters.

A Conclusion that is based on Judgment is not a Natural Law or a "Bare Mental Process."

- U.S. Pat. No. 7,223,552; Cols. 22-24, Table 1.
- CVD is defined using many parameters, such as "greater than 50% stenosis in one or more coronary arteries."
- The exclusion criteria for controls is also complex, e.g., coronary stenosis of greater than or equal to 50%.
- At the least this is the application of known statistical methods to multiple parameters to achieve, "optimum specificity…and sensitivity."

Athena Diagnostics, Inc. v. Mayo Collab. Services, LLC

- Civ. Action No.: 15-cv-40075-IT (D. Mass., August 4, 2017)
- Claims 6-9 of U.S. Pat. No. 7,267,820 were directed to the diagnosis of MG by detecting autoantibodies that will bind to a receptor located on neuromuscular junctions ("MuSK").
- MuSK or MuSK was labeled with 125-I, was introduced into a sample and any complexes formed with the IgG autoantibodies were detected indirectly or directly.
- The court found that each assay "focusses on a natural occurrence, it is directed to a patent ineligible concept [a law of nature]".
- Predictably, the claims also failed Stage 2 of the Mayo/Alice test. Specification called the test techniques "standard."

What if claims were to novel compounds or complexes?

- The method of using a patentable compound is also patentable. In re Pleuddemann, 910 F2d 828 (Fed. Cir. 1990), even if the use is otherwise obvious.
- The judge conceded that I-125-MuSK and the Ab-MuSK complexes are not found in nature, but the judge noted that they were not claimed and fell back on "the focus of the claims…is the interaction of the I-125-MuSK and the bodily fluid, an interaction which is naturally occurring."

But what if the compositions had been patented?

- "An in vitro complex of an IgG antibody and a MuSK receptor protein comprising a detectable label."
- "Isolated, labelled MuSK receptor protein that binds in vivo to human IgG autoantibodies."
- "A tertiary complex comprising MuSK, a human IgG autoantibody bound to MuSK and an labelled anti-IgG autoantibody bound to said IgG autoantibody."
- Preparations of either antibody per se.
- Mayo claims did not comprise novel compounds; correlation was between metabolite conc. and efficacy or side effects.
- Old use of an old drug.

What about methods of medical treatment?

- The Prometheus claim could have easily been written as a "regimen" type method claim:
- "A method for treating an immune disorder comprising administering a 6-TP generating immunosuppressive drug to a human in need of such treatment so that the serum levels of 6-TP fall between concentrations x and y."
- "Unlike, say, a typical patent on a new drug or a new method of using an existing drug, the steps add nothing of significance to the natural laws themselves."(Mayo)
- Methods of treatment were assumed to be PE by Lourie and Moore in Myriad and by the panel in CellzDirect.

Watch this Space!

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PATENT PROTECTION FOR HIGH TECHNOLOGY

Thank you for your participation.

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Thank you for your consideration

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Legislative proposals

Current Statutory Law	IPO Proposal	AIPLA Proposal	ABA Proposal
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.	(a) Eligible Subject Matter.—Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention thereof, subject only to the exceptions, conditions, and requirements set forth in this Title.	(a) Eligible Subject Matter.—Whoever invents or discovers any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.	a) Eligible Subject Matter.- Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.
	(b) Sole Exceptions to Subject Matter Eligibility.—A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.	(b) Sole Exceptions to Subject Matter Eligibility.—A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.	(b) Exception.- A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored.
	(c) Sole Eligibility Standard.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112 of this Title, the manner in which the claimed invention was made or discovered, or the claimed invention's inventive concept.	(c) Sole Eligibility Standard.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.	(no (c) in this proposal) (b) continued: Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.

Legislative proposals (cont.)

- Longer; multiple subsections
- all permit (codify) exceptions
- IPO and AIPLA clarify: there are no other exceptions and no other eligibility standards
- “Sole exception:” ineligible if preexists in nature, or can be preformed solely in the human mind
- ABA-IPL not so exclusive: incorporates traditional exception for laws of nature, natural phenomena, abstract ideas, but only if preempt all practical applications
- All proposals emphasize “claims as a whole” and no-importation of 102,103 and 112.