101 (In)eligibility in the Life Sciences

SUZANNAH K. SUNDBY

Partner, Canady + Lortz LLP
1050 30th Street, NW
Washington, DC 20007

AIPLA Spring Meeting
Los Angeles, CA
April 30, 2015

Mayo/Myriad Guidance
(Superseded)

Ridiculous Factor-Based Analysis

3

- Ineligible factors weighed against eligible factors
- Ineligible factors are almost mirror images of eligible factors
- Eligible Factors (helps to still argue):
  - a) Claim to a non-naturally occurring product and markedly different in structure from naturally occurring products.
  - b) Claim recites elements/steps that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
  - c) Claim recites elements/steps that are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
  - d) Claim recites elements/steps that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
  - e) Claim recites elements/steps that include a particular machine or transformation of a particular article that implements or integrates the judicial exception(s) into a particular practical application.
  - f) Claim recites one or more elements/steps that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

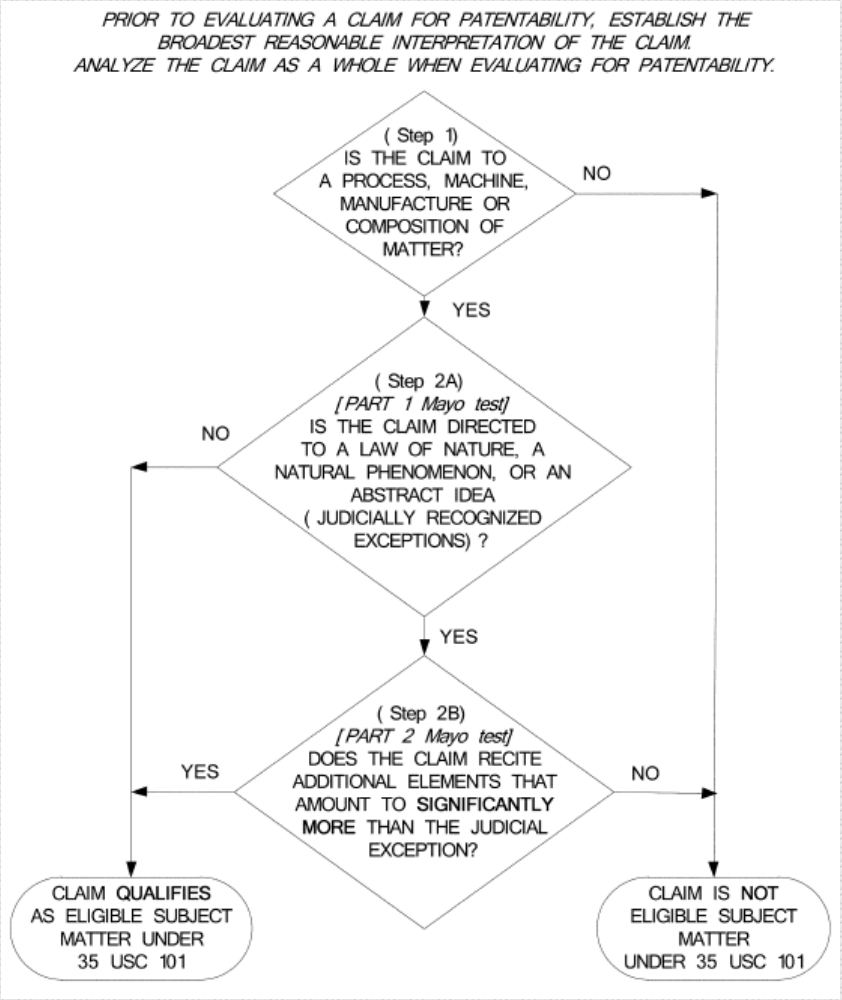
USPTO's Interim Guidance
(Current)

The Mayo Two-Part Test

- Citing Mayo, SCOTUS stated that the test is:
  - (1) Whether the claims are directed to a law of nature, natural phenomenon, or an abstract idea, then
  - (2) Whether the elements of the claim both individually and as an ordered combination transform the nature of the claim in to a patent-eligible application.

Two-Part Test

- Statutory Subject Matter
  - Processes, Machines, Articles of Manufacture, and Compositions of Matter
- Judicial Exceptions
  - Laws of Nature, Products of Nature, Natural Phenomena, and Abstract Ideas
- 1. Determine whether the claim is “directed to” a judicial exception.
  - “Directed to” means the judicial exception is recited in the claim.
  - If claim clearly doesn’t “tie up” the judicial exception, skip to streamlined analysis.
  - Identify the judicial exception.



Step 2A

- If the claim is directed to a nature-based product, use markedly different characteristics analysis to determine if the nature-based product is a "product of nature".
  - Compare the claimed nature-based product with the naturally occurring counterpart in its natural state to determine if it has a markedly different structure, function, and/or other property.
  - If there is no naturally occurring counterpart, compare the closest naturally occurring counterpart.
- If markedly different, the claim is not directed to a "product of nature" exception and determine whether other judicial exceptions apply.
  - If no other judicial exceptions, the claimed invention is eligible.
- If NOT markedly different, go to Step 2B - "significantly more"

Step 2B

- Does the claim recite additional elements that amount to significantly more than the judicial exception?
- This is where the eligibility factors (b)-(f) can be applied.
  - b) Claim recites elements/steps that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
  - c) Claim recites elements/steps that are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
  - d) Claim recites elements/steps that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
  - e) Claim recites elements/steps that include a particular machine or transformation of a particular article that implements or integrates the judicial exception(s) into a particular practical application.
  - f) Claim recites one or more elements/steps that add a feature that is more than well-understood, purely conventional, or routine in the relevant field.

Nature Based Product Examples

- A composition comprising pomelo juice and an effective amount of an added preservative. – Yes
- Purified amazonic acid. – No
- Purified Antibiotic L. – No
  - Purified Antibiotic L in a tetrahedral crystal form. – Yes
- An isolated nucleic acid comprising SEQ ID NO: 1. – No
- An isolated nucleic acid having a non-naturally occurring mutation. – Yes
- An isolated nucleic acid having a fluorescent label attached thereto. – Yes
- A pair of single-stranded DNA primers. – No

Nature Based Product Examples

- An antibody to Protein S. – No
- An isolated man-made human pacemaker cell. – No
- An isolated man-made human pacemaker cell expressing marker Z. – Yes
- A composition comprising a population of isolated man-made human pacemaker cells in a container. – No
- A kit for preparing goat milk yogurt comprising: Streptococcus thermophilus and Lactobacillus alexandrinus. – No
- A yogurt starter culture comprising: goat milk mixed with Streptococcus thermophilus and Lactobacillus alexandrinus. – Yes

Examples of 101 Rejections and Allowed Product Claims

- A kit for diagnosing cancer comprising reagents that consist essentially of primary monoclonal antibodies or antibody fragments that specifically detect biomarker proteins leptin, prolactin, osteopontin (OPN) and insulin-like growth factor II (IGF-II), and secondary antibodies that bind to the primary monoclonal antibodies or antibody fragments and are conjugated to a detectable label.
  - During an interview: The Examiner indicated that the rejection under Section 101 could be addressed by amending the claims to recite that (1) the primary antibodies are primary monoclonal antibodies and (2) the secondary antibodies are conjugated to a detectable label.
- A composition comprising a peptide having SEQ ID NO:1 and an aluminum adjuvant.
- An isolated cell population derived from Tissue T, wherein more than about 90% of the cells co-express biomarkers A and B.
  - Changed “substantially homologous” to “isolated”

A Few USPTO Method Examples

- A method comprising providing a pomelo fruit. – No
- 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. – Yes

No Assay Examples… yet

What Do Abstract Ideas Have to Do with Diagnostic Methods?

Mental and Mathematics

- 1. A method of diagnosing the likelihood of a subject as having a C Cancer, which comprises
  - contacting a sample obtained from the subject with antibodies to measure the amounts of at least three of the following protein biomarkers: A, B, C, D, and E, wherein said antibodies specifically bind the biomarkers;
  - calculating an index value using the following logistic regression model

    ALGORITHM (uses a weighted coefficient for each biomarker); and
  - diagnosing the subject as (1) not likely having the C Cancer where the index value is 0, (2) likely having the C Cancer where the index value is 1, or (3) having a N% likelihood of having the C Cancer where the index value is n and $0 < n > 1$ and $N = n \times 100$.

Apply the Microsoft Example (#3)

- 1. A computer-implemented method for halftoning a gray scale image, comprising the steps of:
  - generating, with a processor, a blue noise mask by encoding changes in pixel values across a plurality of blue noise filtered dot profiles at varying gray levels;
  - storing the blue noise mask in a first memory location;
  - receiving a gray scale image and storing the gray scale image in a second memory location;
  - comparing, with a processor on a pixel-by-pixel basis, each pixel of the gray scale image to a threshold number in the corresponding position of the blue noise mask to produce a binary image array; and
  - converting the binary image array to a halftoned image.

Apply the GPS Example (#4)

- 1. A system for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals comprising:
  - a mobile device comprising a GPS receiver, a display, a microprocessor and a wireless communication transceiver [ ], and
  - a server comprising a central processing unit [ ] programmed to:
    - estimate a position of the GPS receiver based on [ ],
    - calculate absolute time that the signals were sent from the GPS satellites using the pseudo-ranges [ ],
    - create a mathematical model to calculate absolute position of the GPS receiver based on the pseudo-ranges and calculated absolute time,
    - calculate the absolute position of the GPS receiver using the mathematical model, and
    - transmit the absolute position of the GPS receiver to the mobile device, via the server communication transceiver, for visual representation on the display.

Huh?

Further Guidance from the USPTO

- In a recent webinar on how to analyze diagnostic assays the USPTO pointed to
- Smartgene v. ABL - This 2014 opinion is NONPRECEDENTIAL
- Perkinelmer v. Intema - This 2012 opinion is NONPRECEDENTIAL
- UURF v. Ambry - 2014

Smartgene v. ABL

- 1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:
  - (a) providing patient information to a computing device comprising:
    - a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
    - a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
    - a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and
  - (b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and
  - (c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

Perkinelmer v. Intema

- 1. A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:
  - measuring the level of [a] screening marker from a first trimester of pregnancy by:
    - (i) assaying a sample . . . ; and/or
    - (ii) measuring at least one first ultrasound [ ] marker from an ultrasound scan . . . ."
  - measuring the level of [a] second screening marker from a second trimester of pregnancy, [ ], by:
    - (i) assaying a sample . . .; and/or
    - (ii) measuring at least one second ultrasound [ ] marker from an ultrasound scan . . .;
  - and determining the risk of Down's syndrome by comparing the measured levels of both [the first and] second screening [markers] with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies.

Myriad's Ineligible Method Claims

- 1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which
  - comprises analyzing a sequence of a BRCA1 gene [ ] from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184–4187 of SEQ ID NO: 1.
- 1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises [ ]
  - comparing a first sequence [from the tumor sample] with a second sequence [from a nontumor sample],
  - wherein a difference [ ] indicates a somatic alteration in the BRCA1 gene in said tumor sample.

Myriad's Ineligible Method Claims (Ambry)

- 7. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises
  - comparing germline sequence of a BRCA1 gene [from the subject with a] wild-type BRCA1 gene [ ], wherein a difference [ ] indicates an alteration in the BRCA1 gene [, and]
  - wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.
- 8. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises
  - comparing germline sequence of a BRCA1 gene [from the subject with a] wild-type BRCA1 gene [ ], wherein a difference [ ] indicates an alteration in the BRCA1 gene in said subject[, and]
  - wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.

Myriad's Eligible Method Claim 20

- 20. A method for screening potential cancer therapeutics which comprises:
  - growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic,
  - growing said transformed eukaryotic host cell in the absence of said compound,
  - determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells,
  - wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

Examples of 101 Rejections and Allowed Method Claims

- A method for detecting sepsis in canine subjects comprising the steps of:
  - obtaining a blood serum sample from a canine subject;
  - obtaining the concentration of c-reactive protein [ ] and assigning a first discrete value to said c-reactive protein concentration, wherein said first discrete value is assigned a value: zero (0) when the concentration of c-reactive protein is less than 40 mg/l, one (1) when the concentration of c-reactive protein is between 40.1 mg/l and 56.4 mg/l, or two (2) when the concentration of c-reactive protein is greater than 56.5 mg/l;
  - obtaining the concentration of C-type natriuretic peptide [ ] and assigning a second discrete value to said C-type natriuretic peptide concentration, wherein said second discrete value is assigned the value: zero (0) when said concentration of C-type natriuretic peptide is less than 3.8 picomole/l, one (1) when the concentration of C-type natriuretic peptide is between 3.9 picomole/l and 13.3 picomole/l, two (2) when the concentration of C-type natriuretic peptide is between 13.4 picomole/l and 20 picomole/l, or three (3) when the concentration of C-type natriuretic peptide is greater than 20.1 picomole/l;
  - computing an index value by adding: the first discrete value multiplied by a c-reactive protein weighing coefficient of value 1.43, and the second discrete value multiplied by a C-type natriuretic peptide weighing coefficient of value 1.17, and
  - determining that the canine subject is a carrier of sepsis if said index value is above a criterion value of 2.86.

- Argued
  - Narrow ranges
    - Prior art ranges of change are very broad and any assessment using only one or the other biomarker yields low-accuracy results because a large percentage of healthy subjects would be classified as sepsis affected (false positives) and also a large percentage of canine sepsis-affected subjects would be declared unaffected (false negatives).
  - The invention teaches and claims how to combine and use a set of biomarkers, specifying the manner in which the biomarkers levels are converted into discrete numbers that are used to obtain a unitless index. The latter index is then used to provide a cutoff threshold (e.g., a criterion) that enables a practitioner in the field of veterinary diagnostics to classify a canine subject as being affected by sepsis (e.g., above 85% accuracy).
  - The claims for the methods of diagnosing sepsis in canines are for neither a formula, nor for a mental process or for a natural phenomenon.
  - The method for detecting sepsis in canine is an instantiated application, and although it uses a formula to compute a result, the method affects actual subjects showing various symptoms, the claimed invention in the amended claims does not claim the formula for computing the results.

- 1. A diagnostic method to determine probability of an oral disease state comprising
  - (a) determining the levels of two or more biomarkers in a sample collected from a first individual, wherein a first biomarker is a bone-specific marker and a second biomarker is a plaque biofilm pathogen marker, said levels of said two or more biomarkers indicating the probability of said oral disease state, wherein the first biomarker is not type I collagen pyridinoline cross-linked telopeptide (ICTP); wherein elevated levels of said two or more biomarkers from said first individual compared to levels of identical biomarkers from a second, healthy individual, or compared to biomarker levels of said first individual measured at an earlier time point are indicative of occurrence of oral disease in said first individual with a probability of diagnosing the disease state equal to or greater than 70%; and
  - (b) treating said oral disease by administering an amount of a therapeutic or prophylactic composition sufficient to reduce activity of said two or more biomarkers.
- Argued – The "treating" limitation.

- A method for early stage detecting and treating a renal disease, which method comprises:
  - (i) determining a human megalin level in a urine sample;
  - (ii) screening for a patient who suffers from or is at high risk of the renal disease indicated by an increased level of human megalin in a urine sample in comparison to the human megalin level in a healthy subject; and
  - (iii) treating the patient identified by step (ii),
  - wherein the renal disease is selected from the group consisting of nephritis, nephropathy, and a renal tubular disorder.
- Argued meaningful limits (i.e., specific renal diseases) and real-world application (i.e., treating).

- A method for diagnosing depression using a biomarker, comprising the steps of:
  - measuring a level of phosphoethanolamine in a blood sample collected from a subject;
  - comparing the level of phosphoethanolamine in the blood sample with a predetermined threshold to diagnose that if the level of phosphoethanolamine in the blood sample is below the threshold, the subject is afflicted with depression, wherein the threshold is no greater than 2.41 µM; and
  - conducting an examination of the subject by interview or questionnaire to provide another diagnosis by a physician or psychologist of whether the subject is afflicted with depression.
- Argued
  - The combination of using both a diagnostic marker (measured level of phosphoethanolamine in the subject's blood) along with performing an analysis based upon an interview or questionnaire for the subject constitutes something significantly different or significantly more than simply a natural principle.
  - Pointed to other patents, US 8,628,979 and US 8,703,430.

- A method for treating impaired fluid homeostasis in a subject having symptoms of, being diagnosed with, or being at risk of developing heart failure, wherein the method comprises:
  - a) identifying the subject as in need of treatment for impaired fluid homeostasis by a method comprising:
    - (i) providing a sample from the subject;
    - (ii) measuring the quantity of circulating melanoma cell adhesion molecule (MCAM) in the sample from the subject;
    - (iii) comparing the quantity of circulating MCAM measured in (ii) with a reference value of the quantity of circulating MCAM, said reference value representing normal fluid homeostasis, and finding a deviation of the quantity of circulating MCAM measured in (ii) from said reference value so as to identify the subject as in need of the treatment,
    - wherein an increased quantity of circulating MCAM in the sample from the subject compared to a reference value representing normal fluid homeostasis identifies the subject as in need of treatment of impaired fluid homeostasis; and
  - b) treating the subject having the deviation, with a treatment or therapy that restores fluid homeostasis by decreasing the fluid content, selected from the group consisting of treatment with exogenous and/or endogenous diuretic agents, ultrafiltration, and treatment with exogenous and/or endogenous vasopressive antagonists.

- Argued – specific practical application
  - The claims are limited to a specific patient population (subjects having symptoms consistent with developing heart failure) and treating impaired fluid homeostasis in such patients by identifying the subjects in need of treatment for impaired fluid homeostasis (steps (a) i-iii of claim 1) and then treating the subject found to have the deviation with a specific treatment.
  - Accordingly, the present method steps encompass significantly more than merely applying an alleged law of nature and show a practical application.
  - The step of treating the patient having the deviation in quantity of MCAM compared to a reference value is integrated with the natural principle and limits the scope of the claim to do more than describe the alleged natural principle and apply it.
  - The present claims do not pre-empt the alleged natural principle as they are limited to a specific practical application.

- A method of screening for increased risk of developing fatal prostate cancer in a human male subject in need thereof, comprising:
  - providing a blood sample collected from said subject; and
  - detecting the presence or absence of an increased level of serum calcium in said sample, an increased level of serum calcium indicating said subject is at increased risk of fatal prostate cancer;
  - wherein said serum calcium is total serum calcium and said increased level is greater than 2.3 mmol/L, and said detecting step is carried out by absorption spectrometry.
- Argued
  - Active step of detecting serum calcium levels was not previously performed, and certainly not conventional, in the context of prostate cancer.
  - Use of particular machine for absorption spectrometry
  - Does not preempt all uses of a correlation between serum calcium levels and prostate cancer risk

- 1. An in vitro method for predicting the risk of heart failure in a human subject [ ], said method comprising the steps of:
  - (i) measuring the level of troponin T phosphorylated on serine 207 in the troponin T pool in a blood sample obtained from the subject by an ELISA immunoassay consisting of: providing a microtiter plate coated with a set of antibodies specific for troponin T phosporylated on serine 207 [ ],
  - (ii) comparing said measured level of troponin T phosphorylated on serine 207 to a control level of troponin T phosphorylated on serine 207 obtained from a healthy subject,
  - (iii) wherein when the level of troponin T phosphorylated on serine 207 determined at step i) is lower than the control level of troponin T phosphorylated on serine 207, it is indicative of a high risk of heart failure.
- Argued
  - ELISA immunoassay
  - Specific troponin T phosphorylation, i.e., serine 207
  - While the general concept of using antibodies to measure the level of a protein may be routine and conventional, there is nothing to demonstrate that it was at all conventional to use the particular antibody to troponin T phosphorylated on serine 207 for predicting heart failure.

- 1. A method of screening for interstitial cystitis in a patient, said method comprising the steps of:
  - (a) obtaining a fluid sample from a patient;
  - (b) applying the sample to a detector device, wherein the detector device is a dipstick device, wherein the detector device comprises at least one detection reagent, wherein the detection reagent is a fragment of CKAP4 which comprises a polyhistidine tag at the end of said fragment of CKAP4, and wherein the detection reagent specifically binds antiproliferative factor (APF), further wherein the detection reagent is detectably labeled, wherein the binding of APF to the detection reagent provides detection of a threshold level of APF in the sample in the form of a visual indication that provides correlation with the presence of interstitial cystitis, and wherein the threshold level is above about 10 fMolar; and,
  - (c) visualizing the dipstick device to ascertain a positive screen for interstitial cystitis.

- Argued:
  - The claimed method uses products which are significantly different than a judicial exception because the claimed method uses a protein which is a fragment of CKAP4 which binds APP used with a polyhistidine tag.
  - The claims are directed to methods using a product which is structurally distinct from any natural analogs.
  - While the claimed methods do utilize some naturally-occurring components, these components are structurally altered and together provide a synergistic effect absent from each of the individual components (i.e., efficacy as a method of screening for interstitial cystitis).
  - A truncated CKAP4 protein fused to a polyhistidine tag does not exist in nature.

- A method for determining if a subject has thyroid cancer, the method comprising
  - (a) contacting a thyroid aspirate derived from the subject comprising galectin-3 with trypsin to digest galectin-3 and produce one or more biomarkers selected from the group consisting of SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, and any combination thereof,
  - (b) adding a control biomarker to the thyroid aspirate, wherein the control biomarker is SEQ ID NO 5 or SEQ ID NO 6,
  - (c) quantifying the amount of the biomarker in the thyroid aspirate by multiple reaction monitoring, and
  - (d) comparing the amount of the biomarker in the thyroid aspirate to the amount of the same biomarker from a second thyroid aspirate from a subject that does not have thyroid cancer,
  - wherein an increase in the amount of the biomarker in the thyroid aspirate as compared to the amount of the same biomarker from the second thyroid aspirate from the subject that does not have thyroid cancer is an indication of the presence of thyroid cancer in the subject.
- Argued - Control biomarkers do not occur in nature.

- 1. A method of assessing the correlation of HPV infection to a variety of cancers and carcinomas in a clinical sample from a human subject, comprising:
  - obtaining a clinical sample from a source sample other than cervical sample; conducting one or more detection assays on the clinical sample from the human subject using a monoclonal antibody that specifically binds to two or more native HPV proteins from different HPV types, wherein the two or more native HPV proteins are native E7 proteins from different HPV types and/or native E6 proteins from different HPV types, and the monoclonal antibody is capable of binding in situ to the native HPV proteins in the clinical sample;
  - detecting a presence of an HPV protein in the clinical sample based at least in part upon a result of conducting the one or more detection assays on the clinical sample;
  - assigning a score based on the level of the presence of the HPV protein in the clinical sample; and
  - determining the correlation of HPV infection to a variety of cancers and carcinomas in the human subject based at least in part upon a result of detecting the presence of the HPV protein in the clinical sample.
- Argued - Claim 1 as amended is directed to a method with a significant contribution over the prior art, the recited monoclonal antibodies that specifically binds to two or more native HPV proteins from different HPV types are not routine or conventional.

- No 101 rejection
  - A method for estimating prognosis in a cancer patient having Cancer C comprising
    - determining the amount of Protein P in a cancer cell from the patient, and
    - comparing the amount of Protein P with a reference amount,
    - wherein an increase in the Protein P relative to the reference amount indicates a poor prognosis.
  - A method for diagnosing Disease D in a subject which comprises
    - obtaining a sample from the subject suspected of having Disease D,
    - providing a substrate having a first capture probe bound thereto,
    - contacting the substrate with the capture probe with the sample,
    - measuring the amount of the complex formed,
    - providing a normal reference,
    - comparing the amount of the complex with a normal reference, and
    - identifying the subject as having Disease D where the amount of the complex is more than that of the normal reference.

- No 101 rejection
  - An immunohistochemical method for typing a tumor as an X pathway tumor, a Y pathway tumor, or a Z tumor, which comprises
    - determining a protein expression profile of the tumor by detecting expression of at least two biomarker proteins, wherein the proteins comprise
      - A and B
      - A and C
      - A and D; or
      - C and D;
    - and typing said tumor as an X pathway tumor, a Y pathway tumor, or a Z tumor based on said protein expression profile.

- No 101 rejection
  - A method for evaluating [ ] status in a subject, comprising:
    - obtaining a [ ] sample from a subject selected for evaluation based on a determination that the subject is at risk of a [ ] injury;
    - performing one or more assays configured to detect a [ ] injury marker selected from the group consisting of A, B, C, D, and E by introducing the sample obtained from the subject into an assay instrument which (i) contacts the sample with one or more antibodies which specifically bind for detection the biomarker(s) which are assayed, and (ii) generates one or more assay results indicative of binding of each biomarker which is assayed to a respective antibody to provide one or more assay results; and
    - correlating the assay result(s) generated by the assay instrument to the [ ] status of the subject, wherein said correlation step comprises correlating the assay result(s) to one or more of risk stratification, staging, prognosis, classifying and monitoring of the [ ] status of the subject, wherein said correlating step comprises assigning a likelihood of one or more future changes in [ ] status to the subject based on the assay result(s).

- Support in Specification:
  - The assay devices and methods known in the art can utilize labeled molecules in various sandwich, competitive, or non-competitive assay formats, to generate a signal that is related to the presence or amount of the biomarker of interest. Suitable assay formats also include chromatographic, mass spectrographic, and protein "blotting" methods. Additionally, certain methods and devices, such as biosensors and optical immunoassays, may be employed to determine the presence or amount of analytes without the need for a labeled molecule. See, e.g., U.S. Pat. Nos. 5,631,171; and 5,955,377, each of which is hereby incorporated by reference in its entirety, including all tables, figures and claims. One skilled in the art also recognizes that robotic instrumentation including but not limited to Beckman ACCESS®, Abbott AXSYM®, Roche ELECSYS®, Dade Behring STRATUS® systems are among the immunoassay analyzers that are capable of performing immunoassays. But any suitable immunoassay may be utilized, for example, enzyme-linked immunoassays (ELISA), radioimmunoassays (RIAs), competitive binding assays, and the like.

Unduly Narrow Limitations Seem to Work

- Narrow ranges
- Treatment steps
- Specific subset of diseases/afflictions
- Particular type of assay format, e.g., ELISA
- Device/structure limitations
- Unconventional reagents

Simply giving up also works

Disclaimer

- Like everyone else, the author does not know with any degree of certainty what type of diagnostic assay claims are eligible.
- These materials and views expressed today reflect only the personal views of the author and do not necessarily represent the views of other members and clients of the author's organizations.
- These materials are public information and have been prepared solely for educational purposes to contribute to the understanding of U.S. intellectual property law. 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. These materials and views are not a source of legal advice and do not establish any form of attorney-client relationship with the author and Canady + Lortz LLP.

Thank You!

Suzannah K. Sundby, Esq.
Canady + Lortz LLP

1050 30th Street, NW
Washington, DC 20007

T: 202.486.8020
F: 202.540.8020
suzannah@canadylortz.com

Suzannah practices all aspects of intellectual property law including patent preparation, and prosecution, licensing, opinion work, strategic planning, and client counseling relating to diverse technologies including biochemistry, molecular biology, pharmaceuticals, microfluidics, diagnostics, medical devices, and nanotechnology.

Extra Slides

Mayo v. Prometheus

- 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 [the disorder]; and
  - (b) determining the level of 6-thioguanine in [the] subject [ ],
  - 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 [the drug administered to the 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 [the drug administered to the subject].

Mayo v. Prometheus

- "If a law of nature is not [eligible], then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."
- Simply appending conventional steps to laws of nature, natural phenomena, and abstract ideas does not confer patent eligibility
  - Pre-solution activity = post-solution activity

AMP v. Myriad

- 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
- 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.
- 1. An isolated DNA comprising an altered BRCA1 DNA having at least one of the alterations … with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.

AMP v. Myriad

- *Held*: 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.
- "Myriad did not create or alter either the genetic information encoded in the BRCA1 and BRCA2 genes or the genetic structure of the DNA."
- "The claims are not expressed in terms of chemical composition, nor do they rely on the chemical changes resulting from the isolation of a particular DNA section. Instead, they focus on the genetic information encoded in the BRCA1 and BRCA2 genes."
- "We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material."

Alice v. CLS Bank

- All about Abstract Ideas
- Claimed matter has nothing to do with biotech
- 33. A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of…
- We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention.