

CHRISTENSEN FONDER

PATENT & TRADEMARK LAW

PATENT ELIGIBLE SUBJECT MATTER:

Rethinking Biotech and Software Patents

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What Can Be Patented?

- **Statute: 35 U.S.C. 101 INVENTIONS PATENTABLE.**
 - 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.
 - Distinct from other requirements: new/novel and non-obvious
- **Case Law (Judge-Made)**
 - Long history of cases defining process, machine, manufacture and composition of matter
 - Recent history: judicial exceptions to four categories
- **Current Multi-Step Process for Determining Eligibility**
 - Does the claim fall into one of four statutory categories?
 - Does the claim “wholly embrace a judicially recognized exception”?
 - Abstract idea, natural phenomenon, or a law of nature?



What Can Be Patented

- **“Process, machine, method of manufacture, or composition of matter”**
 - Business methods (in the U.S.)
 - Mathematical algorithms, when used to achieve a concrete and useful result
 - Small improvements to or differences between prior technology is frequently patentable

What Cannot Be Patented

- i. Transitory forms of signal transmission
- ii. A naturally occurring organism,
- iii. A human *per se*
- iv. A legal contractual agreement between two parties,
- v. A game defined as a set of rules;
- vi. A computer program
- vii. A company,
- viii. A mere arrangement of printed matter
- Ix. Laws of nature
- X. Physical phenomenon
- Xi. Abstract ideas

LAB CORP. v. METABOLITE 548 U.S. ____ (2006)

MAYO V. PROMETHEUS, 566 U.S. ____ (2012)

**ASSOCIATION FOR MOLECULAR PATHOLOGY v.
MYRIAD GENETICS** 569 U.S. ____ (2013)

LAB CORP. v. METABOLITE 548 U.S. ___ (2006)

Scientists discover high levels of the amino acid homocysteine in the body are correlated with dangerously low levels of two B vitamins

1. A method of assaying for the amount of one or more sulfhydryl amino acid species present in a given sample, said method comprising:
 - a. **combining** said sample with an internal reference standard comprising a known amount of each sulfhydryl amino acid species to be assayed, labelled with a suitable marker;
 - b. **adding** sufficient reducing agent to insure randomization of the labelled and unlabelled sulfhydryl amino acids present;
 - c. **measuring** the relative amounts of labelled and unlabelled sulfhydryl amino acid present for each species with a mass spectrometer;
 - d. **calculating** the ratio of labelled to unlabelled sulfhydryl amino acid present for each species; and
 - e. **deriving** the amount of unlabelled sulfhydryl amino acid present for each species in said given sample.

Justice Stephen Breyer, joined by Justices Stevens and Souter, dissented from dismissing certiorari. The dissent argued that the Court should have taken the case in order to lend necessary clarity to an important issue in patent law. In the dissenters' view, a natural correlation between two substances in the body is a "natural phenomenon" that cannot be patented.

Mayo v. Prometheus, 566 U.S. ____ (2012),

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 8×10^8 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 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."

SCOTUS: “OPTIMIZING” When resulting from a correlation of a drug metabolite with efficacy was merely an unpatentable “natural law” for which the first two steps were not “genuine applications of those laws but merely drafting efforts designed to monopolize the correlations.”

“Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well understood, routine, conventional activity previously engaged in by scientists in the field. Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law”

Association for Molecular Pathology v. Myriad Genetics

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

"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."

Clarence Thomas

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA at the time of Myriad's patents "were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach," 702 F. Supp. 2d, at 202–203, and are not at issue in this case. C. Thomas

1. A method for the prediction or risk stratification for graft failure and/or mortality of a subject that has received an organ transplant and monitoring and therapy guidance of such a subject, comprising the determination of procalcitonin or fragments thereof with at least 12 amino acids in a sample taken from said subject, wherein the level of procalcitonin associated with an increased risk for graft failure and/or mortality is above a cut-off, which is below 0.1 ng/mL.

U.S. App. 12/995,772

1. A method for at least one of prediction or risk stratification for at least one of graft failure or mortality of a subject that has received an organ transplant, and monitoring and therapy guidance of such a subject, comprising
 - a. **detecting and quantitating**, in a sample taken from said subject, procalcitonin, wherein the level of procalcitonin is detected and quantitated with a diagnostic assay, and
 - b. **comparing** the result to a predetermined statistically significant cut-off value range of between 0.0127 ng/mL and 0.1 ng/mL which range is correlated with the prediction or risk stratification for at least one of graft failure or mortality in a subject that has received an organ transplant; with the proviso that the sample is taken from the subject at least one week after transplantation;

wherein when the level of procalcitonin in the sample is within the cut-off value range, the subject is predicted or stratified to have an increased risk for at least one of graft failure or mortality; and

when the level of procalcitonin in the sample is outside of the cut-off value range, the subject is predicted or stratified to not have an increased risk for at least one of graft failure or mortality; and

wherein, in each case, monitoring, therapy or both are indicated in accordance with the prediction or risk stratification or both of graft failure or mortality.

U.S. 8,889,366 – Issued 10/29/2014

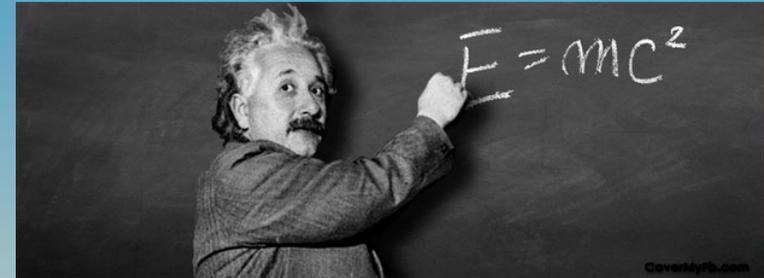
Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014)

- Claims to computer-implemented business method
 - Methods of exchanging financial obligations
- Question for US Supreme Court: Whether claims to computer-implemented inventions—including claims to systems and machines, processes, and items of manufacture—are directed to patent-eligible subject matter within the meaning of 35 U.S.C. §101 as interpreted by this Court?
- Decision: not patentable because this business method is an abstract idea implemented using a generic computer system and software
- 2-Step Mayo Test Defined



Step 1: law of nature, natural phenomenon or abstract idea?

“In *Mayo*... we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts.” (134 S. Ct. at 2355.)



Software claims likely to be considered an abstract idea by patent office and courts

Step 2: inventive concept sufficient to transform?

“At *Mayo* step two, we must examine the elements of the claim to **determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea** into a patent-eligible application. A claim that recites **an abstract idea must include ‘additional features’** to ensure that the claim is more than a drafting effort designed to monopolize the abstract idea. *Mayo* made clear that transformation into a patent-eligible application requires more than simply stating the abstract idea while adding the words ‘apply it.’” (134 S. Ct. at 2357.)



- Post Alice Examples:
- Ultramercial case: monetizing and distributing copyrighted products over the Internet-NO!
- DDR case: maintaining look and feel of a website by using computer technology to solve a problem arising in the realm of computer networks-YES!

Impact of Recent Case Law

- More difficult to get patents for some technologies and industries
 - Computer-implemented business methods (software)
 - Financial services
 - Recognizing medical conditions
- Potentially narrower claim scope for issued patents
- Increase in patents invalidated under §101
- Decreased valuation for computer-implemented business method patents?

Now What?

- **Thinking about filing for a computer-implemented business method patent?**
 - Take your best shot at determining subject matter eligibility
 - Consider whether to keep software a trade secret
- **Existing patent applications**
 - Amend current claims as much as possible to avoid judicial exceptions, e.g., abstract idea
 - Emphasize application of invention, include hardware, add implementation/application steps, e.g., “displaying”
 - File CIP applications to add new material to application
 - Hold tight and wait for law to develop (if you can)
- **Manage portfolio of issued patents**
 - Identify patents that could now be invalid
 - Particularly business method and software
 - Consider selling, donating or abandoning
- **Attack competitor’s patents**
 - Invalidate in court, e.g., file declaratory judgment action if being threatened
 - Commence Covered Business Method (CBM) or Post-Grant Review (PGR) to invalidate
 - Review licensing agreements and consider validity of licensed patents
 - Demand lower royalty

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