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Patent **Eligible** Subject Matter
Half Empty or Half Full

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Agenda

- Motives
- PTO Guidelines
- 101 Rejections
- Laws of Nature/Natural Phenomena
- Abstract Ideas
- Significantly More/Markedly Different

Motives

- Complaints regarding PTO Guidelines issued March 4, 2014 (based on Myriad and Mayo decisions)
- Pending Myriad case(s) (vs. Ambry Genetics Corp)
- Ultramercial under review, again
- Drastic reductions in allowances in TC 3600 (Business-method Art Units)
- Substantial Increase in Section 101 rejections by examiners and the Board, often as the sole basis for denying a patent
- Reconsidering patent **eligibility** post-Alice

PTO Guidelines

March 4, 2014 Guidelines, following Myriad Genetics (2013) and Mayo v. Prometheus (2012)

"2014 Procedure For Subject Matter Eligibility Analysis of Claims Reciting Or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products"

Public Comments on Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products (Revised Guidance due out later this month)

PTO Guidelines

June 25, 2014 Guidelines, following Alice (2014)

"Preliminary Examination Instructions in view of the Supreme Court Decision in Alice Corporation…"

In the Guidelines: "The Supreme Court made clear in Alice Corp. that it applies the framework set forth in Mayo …to analyze all claims"

Thus, these preliminary examination instructions may change based on revisions to the March 4, 2014 Guidelines.

Examiner's Rejection (Business Methods Art)

When considering subject matter eligibility under 35 USC 101, it must be determined whether

the claim is directed to one of the four statutory categories of invention, ie, process, machine, manufacture, or composition of matter.

If the claim does fall within one of the statutory categories, it must then be determined whether the claim is directed to a judicial exception (ie, law of nature, natural phenomenon, and abstract idea), and if so,

it must additionally be determined whether the claim is a patent-eligible application of the exception. If an abstract idea is present in the claim, any element or combination of elements in the claim must be sufficient to ensure that the claim amounts to **<u>significantly more</u>** than the abstract idea itself.

Examiner's Rejection

Examples of abstract ideas include
fundamental economic practices;
certain methods of organizing human activities;
an idea itself; and
mathematical relationships/formulas.

Alice Corporation Pty. Ltd. v. CLS Bank International,
et al., 573 U.S.   (2014).

Examiner's Rejection (General)

Form Paragraph 7.05.01 Rejection, 35 U.S.C. 101, Non-Statutory [Mayo, Alice]

the claimed invention is directed to non-statutory subject matter because [1]

Examiner Note:

1. In bracket 1, explain why the claimed invention is not patent eligible subject matter, e.g.,

(a) why the claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter), e.g., the claim is directed to a signal per se, a contract between two parties, or a human being; or

(b) why the claimed invention, although nominally falling within at least one of the four eligible categories, is directed to a judicial exception to 35 U.S.C. 101 (i.e., an abstract idea, natural phenomenon, or law of nature); or

(c) why the claimed invention would impermissibly cover every substantial practical application of, and thereby preempt all use of, an abstract idea, natural phenomenon, or law of nature; or

(d) why the claimed invention is directed to a naturally-occurring nucleic acid or fragment thereof, whether isolated or not, that is not patent-eligible pursuant to the Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, -- U.S. -- (June 13, 2013).

2. For a claim that is directed to an abstract idea and is non-statutory, use form paragraph 7.05.011.

Examiner's Rejection (Law of Nature)

Form Paragraph 7.05.013 Rejection, 35 U.S.C. 101, Non-Statutory <u>Method</u> (Law of Nature)

-The claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) [1] is/are determined to be directed to a law of nature/natural principle. The rationale for this determination is explained below: [2]

Examiner's Rejection (Law of Nature)

Form Paragraph 7.05.013 Rejection, 35 U.S.C. 101, Non-Statutory Method (Law of Nature) [Mayo]

- [2] identify the natural principle that is the limiting feature in the claim, and explain why the additional elements or steps in the claim do not integrate the natural principle into the method and/or why the additional elements or steps in the claim are not sufficient to ensure that the claim amounts to **significantly more** than the natural principle itself. For instance, the additional elements or steps can be shown to be extrasolution activity or mere field of use that impose **no meaningful limit** on the performance of the method or can be shown to be no more than well-understood, purely conventional, and routinely taken by others in order to apply the natural principle.

Examiner's Rejection

Thus, even if a claimed invention is within a statutory category (e.g., machine, process, composition of matter), an examiner may still allege that the claimed invention (machine, process) is <u>not significantly more</u> than an application of an abstract idea using some unspecified, generic computer; or (composition of matter) does <u>not have markedly different characteristics</u> from any found in nature.

Laws of Nature or Natural Phenomena

- What are Laws of Nature or Natural Phenomena?
  - Theory of Relativity
  - Law of Gravity
  - Naturally occurring product (not markedly different in structure from naturally occurring products)
  - Genes and the information they encode
  - Sequence for a primer?

Laws of Nature or Natural Phenomena

- What are Laws of Nature or Natural Phenomena?
  - 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 (2013))

  - Correlation between total homocysteine and deficiencies in cobalamin and folate (i.e., B vitamin deficiency) (Metabolite Labs (2006))

Abstract Ideas

- What are Abstract Ideas?
  - Pre-emption: (Bilski) upholding the patent "would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."
  - Monopolization: (Mayo) of those tools [exceptions] through grant of a patent might tend to impede innovation more than it would tend to promote it," thereby thwarting the primary object of the patent laws.
  - High level of generality (covers all practical applications)

Abstract Ideas

- What are Abstract Ideas? (from Alice)
  - An idea itself (*Rubber-Tip Pencil Co.* 1874)
  - <u>Fundamental economic practice</u> (Bilski: "hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.") (Alice: concept of intermediated settlement)
  - Organizing human activity (Sotomayor, et al., concurring)
  - Mathematical formula (Diehr, Flook, Benson)

Significantly More? General Definitions

- "statistically significant" – (mathematical) has a particular meaning to a statistician, related to hypothesis testing; basically answers whether the sample was large enough.

- "**practical significance**" – (subjective) an estimate, where the actual difference being estimated will affect a decision to be made (i.e., *relevance to an inventive concept*).

Markedly Different – Court Definition

- Chakrabarty (1980) – modified bacterium

- Held that the modified bacterium was new "with <u>markedly different</u> characteristics from any found in nature," due to additional plasmids and resultant "capacity for degrading oil."

- [Marked :having a distinctive or emphasized character – Webster's online Dictionary]

Markedly Different – Court Definition

- Creation of a unique molecule (specific chemical composition of a particular molecule) – isolated DNA sequence that includes a gene and one <u>additional nucleotide pair</u> (Myriad)

- Innovative method of manipulating [DNA] while searching for a gene(s)

- DNA in which the order of the naturally occurring nucleotides has been altered

Markedly Different – Court Definition

- A novel and useful structure created with the aid of knowledge of scientific truth might be patentable. (Benson, quoting Mackay Radio)

- Adding something specific to the law of nature other than what is well-understood, routine, conventional activity, previously engaged by those in the field. (<u>adding inventive/unconventional step(s)</u> to the law of nature, that confine the claims to a particular, useful application of the principle)

Significantly More – Court Definition

- (Mayo) Additional feature that provides any "practical assurance that the process is more than a drafting effort designed to monopolize the abstract idea itself."
- (Alice) Improve the functioning of the computer itself
- (Alice) Improvement in any other technology or technical field
- (Alice/Bilski) Hardware recited by claims that "offers a <u>meaningful limitation</u> beyond generally linking the use of the method to a particular technological environment, that is, implementation via computers."

Significantly More – Court Definition

- (Diehr) <u>thermocouple</u> used to record constant temperature measurements inside the rubber mold – something the industry had not been able to obtain (i.e., an improvement to an existing technological process)

Eligible Claims

- Factors that weigh <u>toward</u> eligibility (significantly different):

    a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and <u>markedly different in structure</u> from naturally occurring products.

    b) Claim recites elements/steps in addition to the judicial exception(s) 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 in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).

Eligible Claims

- Factors that weigh <u>toward </u>eligibility (significantly different):

  d) Claim recites elements/steps in addition to the judicial exception(s) 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 in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the <u>particular machine/transformation </u>implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular <u>practical application</u>. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).

  f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

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Ineligible Claims

- Factors that weigh <u>against</u> eligibility (not significantly different):

    g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.

    h) Claim recites elements/steps in addition to the judicial exception(s) at a <u>high level of generality</u> such that substantially all practical applications of the judicial exception(s) are covered.

    i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).

Ineligible Claims

- Factors that weigh <u>against</u> eligibility (not significantly different):

    j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.

    k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra- solution activity, e.g., are merely appended to the judicial exception(s).

    l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.

Allowable Claims (AU 3691)

A computer system for matching enterprises with investors, comprising:

(a) an enterprise characterization module resident on a server system comprising at least one server and configured to receive from an enterprise-user terminal information concerning an enterprise characterization, wherein said server system and said enterprise-user terminal are connected through a computer network;

(b) an investor requirements module resident on said server system and configured to receive from an investor-user terminal information concerning investor requirements, wherein said server system and said investor-user terminal are connected through a computer network; and

(c) an analysis module resident on said server system and configured to receive information from said enterprise characterization module and said investor requirements module, and further configured to generate an investor output comprising private enterprises matching the investor requirements information, and generate a multi-factor private enterprise scoring value associated with each private enterprise.

Allowable Claims (Chakrabarty)

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

- Purified 5-methyl amazonic acid.
- Applicant has discovered that amazonic acid is useful to treat colon cancer as well as breast cancer, and applicant has also created a derivative of amazonic acid in the laboratory (called 5-methyl amazonic acid), which is structurally different from amazonic acid and is functionally different, because it stimulates the growth of hair in addition to treating cancer.

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Claims at issue (Myriad)

- Claim 1. A pair of primers, the first primer having the sequence of SEQ ID NO: 1 and the second primer having the sequence of SEQ ID NO: 2.

Claims at issue (Myriad)

Claim 2. A method of amplifying a target DNA sequence comprising:

- providing a reaction mixture comprising a double-stranded target DNA, the pair of primers of claim 1 wherein the first primer is complementary to a sequence on the first strand of the target DNA and the second primer is complementary to a sequence on the second strand of the target DNA, Taq polymerase, and a plurality of free nucleotides comprising adenine, thymine, cytosine and guanine;

- heating the reaction mixture to a first predetermined temperature for a first predetermined time to separate the strands of the target DNA from each other;

- cooling the reaction mixture to a second predetermined temperature for a second predetermined time under conditions to allow the first and second primers to hybridize with their complementary sequences on the first and second strands of the target DNA, and to allow the Taq polymerase to extend the primers; and

- repeating steps (b) and (c) at least 20 times.

Approach to Addressing Rejection (Composition)

Consider casting claim as not reciting a law of nature or natural phenomena (e.g., cDNA; unobvious homolog; product-by-process)

Otherwise, consider applications to another technology or technical field (e.g., treatment of other diseases)

Approach to Addressing Rejection (Abstract Idea)

<u>Perspective</u>: not a claim to an abstract idea, but to features of processing by a processing apparatus; machine that facilitates the abstract idea, but not a claim to the abstract idea.

Approach to Addressing Rejection (Abstract Idea)

Consider **improvements to the functioning of the computer itself**; in particular, consider details as to how processing is implemented to facilitate the abstract idea (i.e., features such as improved memory usage, faster processing speed; e.g., an algorithm that takes less time to perform and/or requires fewer resources)

Consider ways in which the computer implementation is integral to the abstract idea (e.g., benefit of performing certain functions on a server)

Approach to Addressing Rejection (Abstract Idea)

Otherwise, may have to consider improvements to another technology or technical field

e.g., Diehr, where it was not known to use a thermocouple in a molding process; hence in control processing – location and types of sensors

Comments!

Handout