Patentable Subject Matter in the U.S.
Anything Under the Sun?

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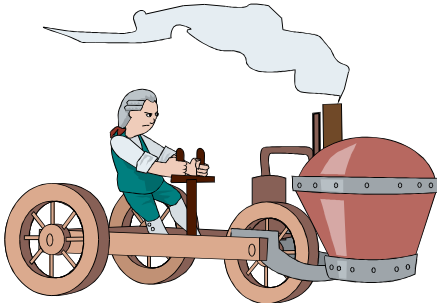
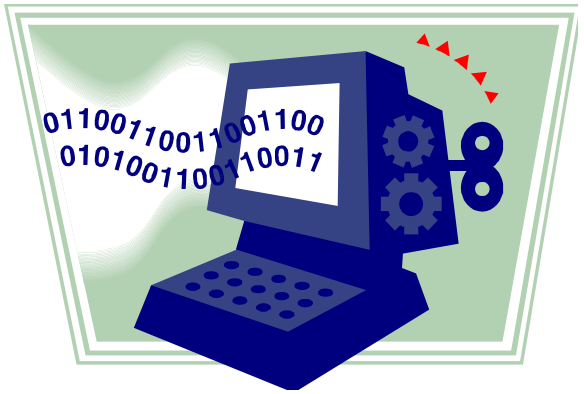
June 18, 2009

FINNEGAN

What can be patented?



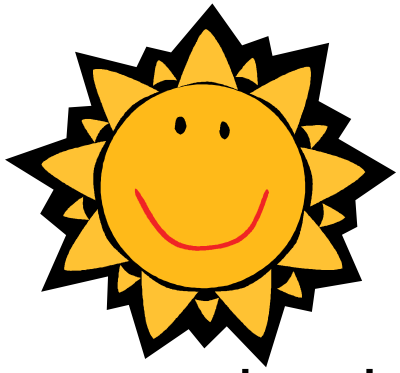
- 35 U.S.C. § 101 authorizes patents for:
  - Machines
  - Compositions of Matter
  - Articles of Manufacture
  - Processes



What can be patented?

- U.S. Supreme Court has held unpatentable:
  - Abstract ideas (*e.g.*, mathematical algorithms)
  - Natural phenomena
  - Laws of nature

That was then . . .



- "[A]nything under the sun that is made by man."
- Patentable subject matter is generally very broad
- *Diamond v. Chakrabarty*, Supreme Court (1980)
  - Human-made genetically engineered bacteria capable of breaking down multiple components of crude oil

. . . this is now.

- The Machine-or-Transformation test

  A process is patentable under § 101 only if:

  (1) it is tied to a particular machine or apparatus, or

  (2) it transforms a particular article into a different state or thing

  In re Bilski, Federal Circuit (2008)

- Supreme Court Argument held November 9, 2009
- Decision expected June 2010

Business Methods

- *Bilski v. Kappos*

1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

Business Methods

- *In re Bilski*: fails Machine-or-Transformation test
  - Transformation prong:
    - Must be central to the purpose of the invention
    - Must transform "physical objects or substances"
      - Not: legal obligations, organizational relationships, business risks
      - Maybe: electronic transformation of data representing physical objects
  - Machine prong:
    - Open question: whether reciting a computer sufficiently ties a process to a particular machine

Business Methods

- *In re Ferguson*

1. A method of marketing a product, comprising:

developing a shared marketing force, said shared marketing force including at least marketing channels, which enable marketing of a number of related products;

using said shared marketing force to market a plurality of different products that are made by a plurality of different autonomous producing company [sic], so that different autonomous companies, having different ownerships, respectively produce said related products;

obtaining a share of total profits from each of said plurality of different autonomous producing companies in return for said using; and

obtaining an exclusive right to market each of said plurality of products in return for said using.

Business Methods

- *In re Ferguson*
  - Federal Circuit: “Marketing paradigm for bringing products to market” non-statutory abstract idea
  - Petition to Supreme Court filed June 2, 2009
  - Awaiting decision on petition

Business Methods

- *Fort Properties, Inc. v. American Master Lease, LLC,* (C.D. Cal. Jan. 22, 2009)

  1. A method of creating a real estate investment instrument adapted for performing tax-deferred exchanges comprising:

     aggregating real property to form a real estate portfolio;

     encumbering the property in the real estate portfolio with a master agreement; and

     creating a plurality of deedshares by dividing title in the real estate portfolio into a plurality of tenant-in-common deeds of at least one predetermined denomination, each of the plurality of deedshares subject to a provision in the master agreement for reaggregating the plurality of tenant-in-common deeds after a specified interval.

Business Methods

- *Fort Properties* (cont.)
- District Court granted summary judgment of invalidity under § 101 in light of *Bilski*
  - Claims involve only transformation or manipulation of legal obligations and relationships
  - Patentee admitted during prosecution that claimed method need not be performed by a computer
  - Even if "creation" of deedshares is transformative, the deedshares are not physical objects or substances
- Appealed to Federal Circuit; stayed pending Supreme Court decision in *Bilski*

Treatment Methods

- *Classen Immunotherapies, Inc. v. Biogen IDEC*

1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises:

immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and

comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Treatment Methods

- *Classen Immunotherapies, Inc. v. Biogen IDEC*
  - Federal Circuit: No machine-or-transformation so unpatentable after *Bilski*
  - Petition to Supreme Court filed May 11, 2009
  - Awaiting decision on petition

Treatment Methods

- *Prometheus Labs., Inc. v. Mayo Collaborative Servs.* (Fed. Cir. 2009)

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Treatment Methods

- *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*
  - Federal Circuit: Patentable transformation
    - "When administering a drug such as [those here], the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it."
    - Determining the levels of [metabolites] in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection.
  - Petition to Supreme Court filed Oct. 22, 2009
  - Awaiting decision on petition

Isolated Genes and Genetic Methods

- Ass'n for Molecular Pathology, ACLU, et al. v. USPTO, Myriad Genetics, et al. (S.D.N.Y. 2008)
  - 7 Myriad patents on methods to detect a gene that predisposes people to breast and ovarian cancer (BRCA1) and related isolated DNA or RNA molecules
  - Sample patent claim:

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 or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA 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.

Isolated Genes and Genetic Methods

- Lawsuit challenging validity of patents
  - Filed by ACLU, doctors, researchers, cancer patients, breast cancer research advocacy groups
  - Challenged Myriad patents based on:
    - Non-patentable subject matter under § 101
      - Natural phenomena, abstract ideas
    - Violation of 1st Amendment
      - Patents cover basic genetic information, thought processes
- Defendants are Myriad Genetics, USPTO, University of Utah Research Foundation (where inventions were made)
- 10 Amicus curiae briefs filed to the District Court

Isolated Genes and Genetic Methods

- Do isolated DNA/RNA sequences satisfy § 101?
  - ACLU parties argue NO
    - BRCA gene sequences are products of nature and manifestations of laws of nature
    - Isolated genes are not simply chemical compounds—the critical aspect of a gene is the information it contains
  - Patent owners argue YES
    - Myriad's claims cover isolated DNA/RNA molecules different in kind from any found in nature, and not native human genes
    - Isolated DNA/RNA molecules are chemical compositions of matter, not merely information or manifestations of laws of nature

Isolated Genes and Genetic Methods

- Do methods of analyzing BRCA gene for alterations satisfy § 101?
  - ACLU parties argue NO
    - Methods of comparing two genes monopolize laws of nature/abstract ideas
    - Claims fail under *Bilski* because they are not tied to a particular machine or apparatus for analyzing or comparing and do not transform a gene into a different state or thing
  - Patent owners argue YES
    - Analyzing a BRCA1 gene requires transforming a tissue or blood sample in order to sequence the gene in the sample, the same sort of transformation found to meet *Bilski* "machine-or-transformation" test in *Prometheus*

Isolated Genes and Genetic Methods

- District Court: composition claims are invalid under § 101
  - "Purification of a natural product, without more, cannot transform it into patentable subject matter."
  - The purified product must possess "markedly different characteristics" in order to satisfy § 101
  - Isolated DNA is **not** markedly different from native DNA, so it is not patent-eligible under § 101

Isolated Genes and Genetic Methods

- District Court: method claims are invalid under § 101
  - "Analyzing" and "comparing" BRCA genes is different from "determining" metabolite levels in *Prometheus*
    - "Analyzing" does **not** inherently require isolating and sequencing DNA
  - The claims do not cover any physical transformations associated with isolating and sequencing DNA
    - Doesn't matter that claims cover analyzing a sequence "from a human sample"
  - Even if the claims covered physical transformations associated with isolating and sequencing DNA, this would be merely a data gathering step

Computer-Implemented Inventions

- *CyberSource Corp. v. Retail Decisions, Inc.* (N.D. Cal. March 27, 2009)

  2. A computer readable medium containing program instructions for detecting fraud in a credit card transaction between a consumer and a merchant over the Internet, wherein execution of the program instructions by one or more processors of a computer system causes the one or more processors to carry out the steps of:

  obtaining credit card information relating to the transactions from the consumer;

  verifying the credit card information based upon . . . ;

  obtaining information about other transactions that have utilized an Internet address that is identified with the credit card transaction;

  constructing a map of credit card numbers based upon the other transactions; and

  utilizing the map of credit card numbers to determine if the credit card transaction is valid.

Computer-Implemented Inventions

- *CyberSource* cont.
- District Court granted summary judgment of invalidity under § 101 in light of *Bilski*
  - Both "computer readable medium" claim 2 and method claim 3 fail machine-or-transformation test
  - "Manipulation" is not the same as "transformation" required by *Bilski* test
  - Reciting "over the Internet" is not a tie to a specific machine
  - Dismissed argument that *In re Beauregard* creates a special "computer readable medium" claim exempt from machine-or-transformation test
- Appealed to the Federal Circuit; stayed pending Supreme Court decision in *Bilski*

Computer-Implemented Inventions

- *Every Penny Counts, Inc. v. Bank of America Corp. et al.* (M.D. FL. May 27, 2009)

  A system, comprising:

  a network;

  entry means … for entering into the network an amount being paid in a transaction by a payor;

  identification entering means …for entering an identification of the payor;

  said network including computing means having data concerning the payor including an excess determinant established by the payor for the accounts;

  said computing means … for determining an excess payment on the basis of the determinant established by the payor, and

  said computing means … for apportioning, at least a part of the excess payment amount . . . .

Computer-Implemented Inventions

- *Every Penny Counts* (cont.)
- District Court granted summary judgment of invalidity under § 101 in light of *Bilski*
  - EPC did not argue transformation
  - Claim is not tied to a particular machine
    - "[I]t is beyond question that the patented process is not tied to a particular computer or other device."
    - Machines for data input, output, calculations do not impose any limit on the process itself
    - Use of machine is "insignificant extra solution activity"
- Appealed to the Federal Circuit; stayed pending Supreme Court decision in *Bilski*

Computer-Implemented Inventions

- *DealerTrack v. Huber et al.* (C.D. Cal. July 7, 2009)

1. A computer aided method of managing a credit application, the method comprising the steps of:

receiving credit application data from a remote application entry and display device;

selectively forwarding the credit application data to remote funding source terminal devices;

forwarding funding decision data from at least one of the remote funding source terminal devices to the remote application entry and display device . . . ;

sending at least a portion of a credit application to more than one of said remote funding sources sequentially until a finding source returns a positive funding decision . . . .

Computer-Implemented Inventions

- *DealerTrack* (cont.)
- District Court granted summary judgment of invalidity under § 101 in light of *Bilski*
  - DealerTrack did not argue transformation
  - Claim is not tied to a particular machine
    - Claimed devices were construed to cover "any device, e.g., personal computer or dumb terminal"
    - These are not particular machines; the patent does not specify how the devices are specially programmed

Computer-Implemented Inventions

- *Research Corp. Technologies v. Microsoft* (D. Ariz. July 28, 2009)

  1. A method for the halftoning of gray scale images by utilizing a pixel-by-pixel comparison of the image against a blue noise mask in which the blue noise mask is comprised of a random non-deterministic, non-white noise single valued function which is designed to produce visually pleasing dot profiles when thresholded at any level of said gray scale images.

- District Court: invalid under § 101 in light of *Bilski*
  - Claims do not recite a particular machine; "comparison" could be done with pencil and paper
  - No transformation – no visual depiction or display required by claim
- Appealed to the Federal Circuit; argued June 9, 2010

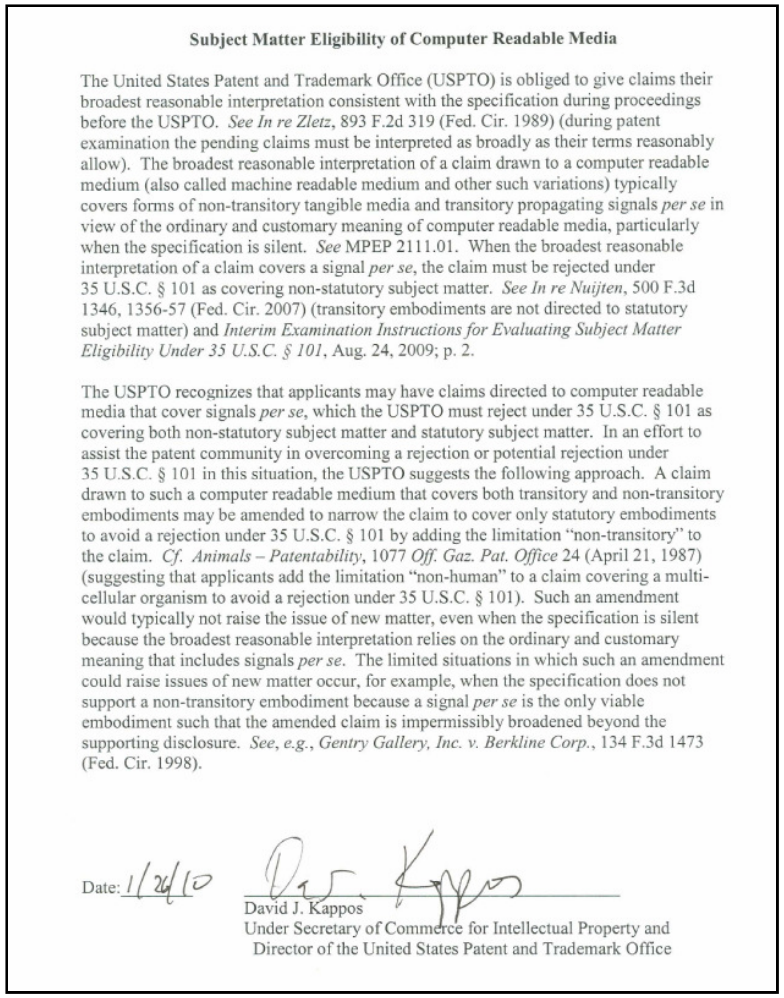
Computer-Implemented Inventions

- *RCT v. Microsoft* (cont.)

  29. Apparatus for the halftoning of color images comprising a comparator for comparing, on a pixel-by-pixel basis, a plurality of color planes of said color image against a blue noise mask in which the blue noise mask is comprised of a random non-deterministic, non-white noise single valued function which is designed to provide visually pleasing dot profiles when thresholded at any level of said color images, wherein an output of said comparator is used to produce a halftoned image.

- District Court: **valid** under § 101 in light of *Bilski*
  - Claims do not recite a particular machine; "apparatus" and "comparator" do not require particular machines
  - But claims recite patent-eligible transformation of data – the color image is processed to produce a "halftoned image"

Computer-Implemented Inventions



Subject Matter Eligibility of Computer Readable Media

The United States Patent and Trademark Office (USPTO) is obliged to give claims their broadest reasonable interpretation consistent with the specification during proceedings before the USPTO. *See In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989) (during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow). The broadest reasonable interpretation of a claim drawn to a computer readable medium (also called machine readable medium and other such variations) typically covers forms of non-transitory tangible media and transitory propagating signals *per se* in view of the ordinary and customary meaning of computer readable media, particularly when the specification is silent. *See* MPEP 2111.01. When the broadest reasonable interpretation of a claim covers a signal *per se*, the claim must be rejected under 35 U.S.C. § 101 as covering non-statutory subject matter. *See In re Nuijten*, 500 F.3d 1346, 1356-57 (Fed. Cir. 2007) (transitory embodiments are not directed to statutory subject matter) and *Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101*, Aug. 24, 2009; p. 2.

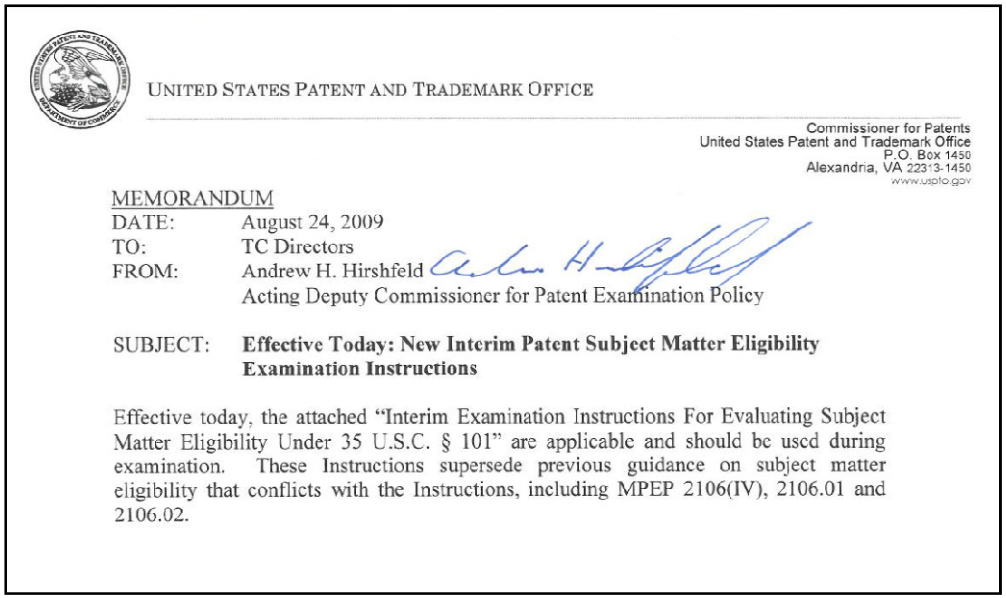
The USPTO recognizes that applicants may have claims directed to computer readable media that cover signals *per se*, which the USPTO must reject under 35 U.S.C. § 101 as covering both non-statutory subject matter and statutory subject matter. In an effort to assist the patent community in overcoming a rejection or potential rejection under 35 U.S.C. § 101 in this situation, the USPTO suggests the following approach. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments may be amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. § 101 by adding the limitation "non-transitory" to the claim. *Cf. Animals – Patentability*, 1077 *Off. Gaz. Pat. Office* 24 (April 21, 1987) (suggesting that applicants add the limitation "non-human" to a claim covering a multi-cellular organism to avoid a rejection under 35 U.S.C. § 101). Such an amendment would typically not raise the issue of new matter, even when the specification is silent because the broadest reasonable interpretation relies on the ordinary and customary meaning that includes signals *per se*. The limited situations in which such an amendment could raise issues of new matter occur, for example, when the specification does not support a non-transitory embodiment because a signal *per se* is the only viable embodiment such that the amended claim is impermissibly broadened beyond the supporting disclosure. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

Date: 1/26/10

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

- **USPTO Guidance: Subject Matter Eligibility of Computer Readable Media**
  - Issued January 26, 2010
  - CRM claim that covers both tangible media and non-transitory signals must be rejected under § 101
  - Adding "non-transitory" to claim is suggested approach
    - Typically will not be new matter

USPTO Interim Guidance



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

DATE: August 24, 2009
TO: TC Directors
FROM: Andrew H. Hirshfeld
Acting Deputy Commissioner for Patent Examination Policy

SUBJECT: **Effective Today: New Interim Patent Subject Matter Eligibility Examination Instructions**

Effective today, the attached "Interim Examination Instructions For Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101" are applicable and should be used during examination. These Instructions supersede previous guidance on subject matter eligibility that conflicts with the Instructions, including MPEP 2106(IV), 2106.01 and 2106.02.

- **Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101**
  - Issued August 24, 2009
  - Replace conflicting sections of MPEP
    - MPEP 2106(IV) – Useful, concrete and tangible result
    - MPEP 2106.01 – Computer-related nonstatutory subject matter
    - MPEP 2106.02 – Mathematical algorithms

USPTO Interim Guidance

- Patentable subject matter does not include:
  - Transitory signals
  - Naturally occurring organism
  - Human being
  - Legal contractual agreement between two parties
  - Game defined as a set of rules
  - Computer program *per se*
  - A company

USPTO Interim Guidance

- Claim must not be wholly directed to:
  - Abstract ideas, mental processes, systems that depend on human intelligence alone
  - Laws of nature, natural phenomena, physical phenomena, scientific principles
  - Disembodied mathematical algorithms and formulas, disembodied concepts
- A product including an abstract idea must recite a "practical application"

USPTO Interim Guidance

- Practical application = Man-made tangible embodiment with a real world use"
  - Patentable: machine comprised of gears, pulleys, and belts that interact based on a mathematical relationship
  - Patentable: non-transitory, tangible computer readable storage medium with executable instructions or stored data
  - Non-patentable: "a machine" that operates in accordance with mathematical principles with no tangible structural elements recited

USPTO Interim Guidance

- Method claims must satisfy the machine-or-transformation test
  - "Particular machine"
    - Concrete thing consisting or parts or devices
    - Not enough to recite a "machine implemented process"
    - General purpose computer may be a particular machine when programmed to perform the process steps
  - Transformation
    - Transform physical object or substance, including data representing a physical object or substance
    - Article must be changed to a different state or thing
      - More than using or moving the article

Thank you.

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Hypothetical # 1: On-screen program guide

- On-screen menu of television programs
- Program titles organized in folders or hierarchy
- Claimed three different ways – are any of them patentable subject matter?
- Method claim?

1. A method for identifying one or more mean items for a plurality of items, J, each of the items having a symbolic value of a symbolic attribute, the method comprising:

   computing a variance of the symbolic values of the plurality of items relative to the symbolic value of each of the items; and

   selecting at least one mean item that has the symbolic value the minimizes the variance.

Hypothetical # 1: On-screen program guide

- System claim?

14. A system for identifying one or more mean items for a plurality of items, J, each of the items having at least one symbolic attribute having a symbolic value, the system comprising:

a memory for storing computer readable code; and

a processor operatively coupled to the memory, the processor configured to:

compute a variance of the symbolic values of the plurality of items relative to each of the items; and

select the at least one mean item having a symbolic value that minimizes the variance.

Hypothetical # 1: On-screen program guide

- Article of manufacture claim?

19. An article of manufacture for identifying one or more mean items for a plurality of items, J, each of the items having at least one symbolic attribute having a symbolic value, comprising:

a computer readable medium having computer readable [program] code embodied thereon, the computer readable program code comprising:

a step to compute a variance of the symbolic values of the plurality of items relative to the symbolic value of each of the items; and

a step to select at least one item that has the symbolic value that minimizes the variance.

Hypothetical # 2: Diagnostic method

- Diagnosing a vitamin B deficiency based on elevated amino acid levels: patentable subject matter?

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

assaying a body fluid for an elevated level of total homocysteine; and

correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Hypothetical # 3: Systems analysis

- Monitoring useful life cycle of components in a computer system: patentable subject matter?

1. A system that facilitates managing product life cycle, comprising:

   a data-receiving component that receives data on availability of components to a product and suitable substitution components and determines relevance of the components to the product;

   an analyzing component that evaluates the received data, and determines, infers or predicts obsolescence and/or risk to end-of-life (EOL) of a subset of the components to a product by scoring each component on a numerical EOL scale; and

   a notification component that provides notification to at least one of individuals, computers and systems regarding obsolescence and/or risk to end-of-life of the subset of the components to a product, and provides recommendations in accordance therewith.

Hypothetical # 4: Electronic signals

- Signal with embedded data to provide a digital watermark: patentable subject matter?

A signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process.

Hypothetical # 5: Surgical methods

- Improving technique in laser eye surgery: patentable subject matter?

A method for improving refractive ophthalmic treatment comprising:
obtaining a first, pre-operative diagnostic measurement of an individual cornea of an eye;
determining a first operative corneal ablation specification . . . ;
obtaining non-tissue removing perturbation data from the individual cornea before ablation . . .;
obtaining a second, post-perturbation, preoperative diagnostic measurement of the individual cornea;
correlating said non-tissue removing perturbation data with the biodynamic response data . . . ; and
establishing an individual customized laser ablation specification for corneal ablation for that individual cornea . . . .