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Patent-eligibility under section 101  
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Intellectual Property Law

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### Lots of decisions, lots of uncertainties

- Diagnostic methods
  - Prometheus (S. Ct. 3/2012)
- Genetic materials
  - Myriad (Fed. Cir. 8/2012)
- Computer-implemented methods
  - Progeny of Bilski v. Kappos (S. Ct. 2010)
  - Research Corp., Cybersource, Ultramercial, Dealertrack, CLS Bank...

### 35 U.S.C. 101

- 101: 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.

### Traditional exceptions

- Abstract ideas
- Natural laws
- Products of nature

### 35 U.S.C. 100

- 100(b) definition of "**process**":
- "**Process**, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

[Summary of previous episode]

## Bilski v. Kappos (S. Ct. 2010)

### Pre-Bilski test: machine-or-transformation

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- An invention is a “process” if
    - (1) it is tied to a **particular machine** or apparatus, or
    - (2) it **transforms a particular article** into a different state or thing
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### Bilski v. Kappos (2010)

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- Business methods not categorically excluded
    - Section 101 defines four categories: process, machine, manufacture, composition of matter
  - Abstract ideas not patentable
    - Machine-or-transformation test (M-or-T) useful, but not the exclusive test, especially for new technologies
  - Balance securing patents for valuable inventions vs. protecting public domain
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### Pre-Bilski Supreme Court decisions

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- Benson: algorithm to convert binary-coded decimal numerals into pure binary code
    - Not a process but an abstract idea, would preempt the algorithm itself
  - Flook: monitoring catalytic conversion
    - Post-solution activity, limitation of algorithm to particular technological environment is insufficient
  - Diehr: molding synthetic rubber using mathematical formula
    - “Application” of law of nature or formula deserves patent protection, consider invention as a whole
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### Supreme Court conclusion in Bilski

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- “The court, therefore, **need not define further** what constitutes a patentable ‘process,’ beyond pointing to the definition of that term provided in §100(b) and looking to the guideposts in Benson, Flook, and Diehr.”
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### Bilski patent claim

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- 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 commodities provider and consumers of said commodities at a fixed rate..
    - (b) **identifying market participants** for said commodity having a counter-risk position...
    - (c) **initiating a series of transactions** between said commodities provider and said market participants at a second fixed rates...
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### Mayo v. Prometheus (S. Ct. 3/2012)

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## Mayo v. Prometheus (S. Ct. 3/2012)

- Summary of technology:
  - Thiopurine drug affect different patients differently, correlation with metabolites levels was suspected
  - Invention provides specific correlation with drug effectiveness
  - Invention makes it possible to improve therapeutic treatment

## Prometheus patent claim

- 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  $8 \times 10^8$  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  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

## Prior proceedings in Federal courts

- District Court: unpatentable abstract idea
- Federal Circuit (pre-Bilski): “administering” step meets M-or-T test
- Supreme Court: vacated and remanded
  - For consideration in view of Bilski
- Federal Circuit (post-Bilski): does not encompass laws of nature or preempt natural correlations
- Second petition for certiorari granted

## S. Ct. decision in Mayo

- Issue is whether method does “significantly more” than simply describe natural correlations.
- “Administering” step:
  - Defines relevant audience (doctors/patients)
  - Cf. Flook (technological environment )
- “Wherein” clauses:
  - Define relevant natural laws
  - Cf. Benson (natural law should not be preempted)

## S. Ct. decision in Mayo (cont.)

- “Determining” step:
  - Well-understood, routine, conventional activity
  - Extra-solution activity
  - 101 patent-eligibility and 102 novelty inquiries may overlap
- Not patent-eligible

## Assoc. Mol. Pathology v. Myriad (Fed. Cir. 8/2012)

### Myriad product claim

- 1. An **isolated DNA** coding for BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2
- District Court: DNA is product of nature

### Fed. Cir. decision in Myriad

- Yes, patent-eligible
- Plurality opinion (1): markedly different chemical structure => patent-eligible
- Concurrence (1): avoid disrupting established property rights
- Dissent (1): isolated DNA not different from a kidney extracted from the body or a leaf plucked from a tree

### Myriad method claim

- 1. A method for detecting a germline alteration in a BRCA1 gene... which comprises **analyzing** a sequence of a BRCA1 gene... from a human sample...

### Fed. Cir. decision in Myriad

- Abstract mental process
  - Limitation to BRCA1 gene is "particular technological environment"
  - Claim does not recite extracting or sequencing DNA sequence
- Not patent-eligible

### Other Myriad method claim

- 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... BRCA1 gene from said tumor sample... with a BRCA1 gene... from a nontumor sample of said subject,
- **wherein** a difference in the sequence of the BRCA1 gene... from said tumor sample from the sequence of the BRCA1 gene... from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample

### Fed. Cir. decision in Myriad

- Abstract idea
  - Similar to the "administering" and "determining" claims in Mayo
- Not patent-eligible

### Still another Myriad patent claim

- 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[s] of growth... and comparing the growth rate of said host cells,
- **wherein** a slower rate of growth... in the presence of said compound is indicative of a cancer therapeutic.

### Fed. Cir. decision in Myriad

- Does not simply apply a natural law
- Transformed cells are not products of nature
- Yes, patent-eligible

### Federal Circuit on computer-implemented methods

### Research Corp. v. Microsoft (12/2010)

- 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 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.

### Fed. Cir. decision in Research Corp.

- Includes mathematical formula and algorithm
- But specific application to halftoning
- Not “manifestly abstract”
- Yes, patent-eligible under 101
  - Might still be invalid under 112-1 as lacking written description

### Cybersource v. Retail Decision (8/2011)

- 3. A method for verifying the validity of a credit card transaction over the Internet comprising the steps of:
- a) **obtaining information** about other transactions that have utilized an Internet address that it identified with the... credit card transaction
- b) **constructing a map of credit card numbers** based upon the other transactions and;
- c) **utilizing the map of credit card numbers** to determine if the credit card transaction is valid

### Cybersource (cont.)

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- 2. A **computer readable medium** containing program instructions for detecting fraud... wherein execution of the program instructions by one or more processors of a computer system causes the one of more processors to carry out the steps of...
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### Fed. Cir. decision in Cybersource

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- Fails the M-or-T test
    - Mental process is a subcategory of abstract ideas
    - Method can be performed entirely in the human mind, even if it is performed by a computer
  - Beauregard claim is not “truly drawn to a specific” computer readable medium
  - Not patent-eligible
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### Ultramercial v. Hulu (9/2011)

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- 1. A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:
    - **Receiving**, from a content provider, media products.. covered by intellectual property rights...
    - **Selecting** a sponsor message to be associated with the media product...
    - **Offering** to a consumer access to the media product without charge to the consumer on the precondition that the consumer views the sponsor message...
    - **Receiving payment** from the sponsor...
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### Fed. Cir. decision in Ultramercial

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- Abstract idea to use advertising as a form of currency
  - “Application” of the idea to monetize copyrighted products
  - Particular method for collecting revenue from the distribution of media products over the Internet
  - Yes, patent-eligible
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### Dealertrack v. Huber (1/2012)

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- 7. **Computer-based** method of operating a credit application and routing system... including a **central processor** coupled to a communications medium for communicating with remote application **entry and display device**, remote credit bureau **terminal devices**, and remote funding source **terminal devices**, the method comprising:
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### Dealertrack (cont.)

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- **Selectively receiving credit application data** from a remote application entry and display device;
  - **Selectively obtaining** credit report data from at least one remote credit bureau terminal device;
  - **Selectively forwarding** the credit application data... to at least one funding source terminal device; and
  - **Forwarding funding decision data** from the at least one remote funding source terminal device...
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### Fed. Cir. decision in Dealertrack

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- Wholly preempts the clearinghouse concept for auto dealership loans
  - Computer-aided limitation is no less abstract than the idea of the clearinghouse itself
  - Different from Ultramercial, which required an extensive computer interface (for ads associated with copyrighted products delivered via the Internet)
  - Not patent-eligible
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### CLS Bank v. Alice Corp. (7/2012)

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- 33. A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution..., the method comprising the steps of:
    - (a) **creating a shadow credit record** and a shadow debit record for each stakeholder party...
    - (b) **obtaining** from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
    - (c) for every transaction... the institution **adjusting** each respective party's shadow credit record and shadow debit record...
    - (d) at the end-of-day, the supervisory institution **instructing** one of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties...
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### CLS Bank (cont.)

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- 1. A **data processing system** to enable the exchange of an obligation between parties, the system comprising:
    - A **data storage unit** having stored therein **information about a shadow credit record** and shadow debit record for a party...
    - A **computer**, coupled to said storage unit, that is **configured to (a) receive a transaction**; (b) electronically **adjust** said shadow credit record and/or said shadow debit record... and (c) **generate an instruction** to said exchange institution at the end of a period of time...
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### CLS Bank (cont.)

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- 39. A **computer program product** comprising a computer readable storage medium having computer readable program code embodied in the medium... comprising:
    - Program code for causing a computer to **send a transaction**...
    - Program code for causing a computer to **allow viewing of information** relating to processing, by a supervisory institution...
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### Fed. Cir. panel decision in CLS Bank

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- District court: abstract concept of using a neutral intermediary between parties to a transaction
    - System and medium claims: no meaningful additional limitation
  - Federal Circuit: shadow credit/debit records implicitly require computer-implementation, based on description and expert testimony
  - Patent-ineligibility must be "manifestly evident"
  - Yes, method is patent-eligible
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### Dissent in CLS Bank

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- Translation of method claims into "plain English" shows that it is an abstract idea
  - System claims recite (1) computer memory and (2) computer that can track the account balance.
  - No implementation described in specification
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## Update Oct 9, 2012

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- Federal Circuit will reconsider CLS Bank v. Alice “en banc”:
    - What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible “abstract idea”; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?
    - In assessing patent eligibility under 35 U.S.C. §101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium and should such claims at times be considered equivalent for §101 purposes?
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## Questions, comments?

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