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Patent Eligibility

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Patent Eligibility: Rule

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- Ineligible
  - Laws of nature, natural phenomena
  - Abstract ideas, mental processes
  - Products of nature
- Eligible
  - Useful *applications* of ideas
  - Products of *human ingenuity*
- *Cf.* Copyright Law: idea/expression dichotomy

Invention: Involves Laws of Nature

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G. Curtis, *A Treatise on the Law of Patents* (1873)

An invention subsists in a:

- New arrangements of particles of matter in new relations;
- Calling into activity some latent law, or natural force, or property; and
- Producing some new effect or result in application.

See In re Alappat, 33 F.3d 1526, 1551-68 (Fed. Cir. 1994) (Archer, C.J., dissenting)

Patent Eligibility: Basic Principles

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- Two related themes running through decisions
  - Preemption
    - Presence of claim structure generally addresses this problem
  - The subject of patent law
    - Patent law does not reward the discovery of new ideas, natural laws or products of nature
    - Need subject matter that can be meaningfully examined under patent law standards
      - Grey area for litigation

Mayo v. Prometheus Labs., 132 S. Ct. 1289 (2011)

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- Method claim
  - Method of *optimizing therapeutic efficacy* for treatment of an immune-mediated [GI] disorder, comprising:
    - *Administering* a drug providing 6-thioguanine to a subject having said [GI] disorder; and
    - *Determining* the level of 6-thioguanine in said subject having said [GI] disorder;
    - *Wherein* the level of 6-thioguanine less than about [x] *indicates a need* to increase the amount of drug subsequently administered to said subject and
    - *Wherein* the level of 6-thioguanine greater than about [y] *indicates a need* to decrease the amount of said drug subequently administered to said subject.

Supreme Court Book-End Cases

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- *Parker v. Flook*, 437 U.S. 584 (1978): Ineligible
  - Method of updating an "alarm limit" in a known chemical process using a computer programmed according to a particular formula

- *Diamond v. Diehr*, 450 U.S. 175 (1981): Eligible
  - Process for operating a rubber-molding press to achieve precision rubber curing, including a thermocouple measuring temperature inside the press, feeding signals to a computer to repeatedly calculate cure time (according to a particular algorithm), and then enabling press to open at the right moment

Mayo v. Prometheus Labs., 132 S. Ct. 1289 (2011)

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- Ineligible
  - The invention:
    - discovery of the correlation between concentrations of certain blood metabolites and likelihood that a dosage of a thiopurine drug will be ineffective or harmful
  - What else is there in addition to the correlation?
    - "Administering" step: defines a preexisting audience and at most a technical environment
    - "Wherein" clause: discloses the natural laws and tells the relevant audience to consider them where relevant to decision-making
    - "Determining" step: tells relevant audience to take a measurement, which is a well-understood, routine, and conventional activity
    - Totality of claim: combination is an instruction to doctors to consider the natural law when treating patients / gather data from which an inference may be drawn in light of natural law
- Eligible (dicta): "Unlike" a "typical patent on a new drug or a new way of using an existing drug"

PerkinElmer v. Intema, 2012 WL 5861658 (Fed. Cir. Nov. 20, 2012)

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- Method claim: Ineligible
  - A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome comprising the steps of:
    - Measuring the level of at least one screening marker from a first trimester of pregnancy by assaying a sample or from an ultrasound scan
    - Measuring the level of at least one different screening marker from a second trimester of pregnancy [the same possible ways]; and
    - Determining the risk by comparing the levels of the two markers with observed relative frequency distribution of marker levels in Down's Syndrome pregnancies and unaffected pregnancies

AMP v. Myriad, 2012 WL 3518509 (Fed. Cir. Aug. 16, 2012)

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- Claims:
  - Method claim covering the process of "screening" potential cancer therapeutics by growing cells, detecting their growth rate, and making comparisons in the presence or absence of the alteration;
    - All three judges agree **eligible** as a process involving a transformed host cell product
  - Method claim covering "analyzing" or "comparing" a patient's gene sequence to a normal sequence to identify predisposition to certain cancers
    - All three judges agree **ineligible** under *Prometheus*
  - Composition claims covering isolated human BRCA genes and mutations correlating to a predisposition to certain cancers
    - Synthetic DNAs (cDNAs)
    - Isolated human DNA

Supreme Court Book-End Cases

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- *Funk Bros. v. Kalo Inoculant*, 333 U.S. 127 (1948): Ineligible
  - Discovery that certain nitrogen fixing bacteria associated in nature with certain plants did not mutually inhibit each other
  - Claim was to mixed cultures of nitrogen-fixing species of bacteria, capable of inoculating a broader range of plants than individual single-species cultures

- *Diamond v. Chakrabarty*, 447 U.S. 303 (1980): Eligible
  - Man-made bacteria genetically engineered with four naturally occurring DNA plasmids, each of which enabled the breakdown of a different component of crude oil
  - Bacterium was unlike any existing in nature either in structure of function, a product of human ingenuity having a distinctive name, character and use

AMP v. Myriad, 2012 WL 3518509 (Fed. Cir. Aug. 16, 2012)

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- DNA Composition Claims
  - Synthetic DNAs (cDNAs)
    - All three judges agree **eligible**
  - Isolated DNA: Split
    - Judge Lourie: Eligible
      - Covalent bonds are broken in isolating the gene from the human DNA molecule, transforming it into a product that does not exist in nature
    - Judge Bryson: Ineligible
      - There is no "magic" to a covalent bond
      - Isolated gene is an invention of nothing more than the human DNA
    - Judge Moore: Eligible (barely)
      - Short isolated sequences: eligible because utilities markedly different from human DNA, including use as probes and primers
      - Long sequences: Close call. Probably ineligible, but eligible to maintain *status quo*

AMP v. Myriad, Petition for Certiorari Granted Friday, November 30, 2012

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- Issue: Are human genes patentable?
  - Loaded question, but not the one technically at issue
- Broader issues
  - Does *Prometheus* apply to product claims or is it limited just to method claims?
    - Federal Circuit says *Prometheus* is instructive but not controlling of claims other than method claims (but see GVR)
  - Is an *isolated* human DNA sequence patent-eligible?
    - What is the invention?
    - How is the invention different from a product of nature?
    - Is the difference sufficient to allow for patentability?
      - Synthetic DNAs
      - "Short" sequence DNAs
      - Longer sequence DNAs
  - How do "settled expectations" impact the analysis in close cases, if at all?
  - Deference to PTO

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- **Bruce M. Wexler** is a trial lawyer with extensive experience litigating patent cases, representing clients as lead counsel in cases involving multi-million and multi-billion dollar products. Recent representations include:
  - *Boehringer v. Mylan*: Argued and won a Federal Circuit appeal for client Boehringer Ingelheim. Mr. Wexler was hired to handle the appeal and obtained a complete reversal of a district court judgment of patent invalidity.
  - *Eisai v. Teva*: Obtained a preliminary injunction against Teva's threatened launch of a generic version of the market leading Alzheimer's disease drug, Aricept®, having U.S. sales of almost $2 billion per year.
  - *Boehringer v. Sandoz*: Argued and won a preliminary injunction preventing Sandoz from launching a generic version of Mirapex®, a leading drug for the treatment of Parkinson's disease.
  - *Pfizer v. Teva*: Successfully tried a case defending Pfizer's patent on Accupril®, an ACE inhibitor.
  - *Eisai v. Teva, Dr. Reddy's, Mylan*: Successfully tried a case for Eisai covering its patent for Aciphex®, an acid reflux drug with annual US sales in excess of $1 billion. Mr. Wexler previously won summary judgment for Eisai of patent validity.
  - *Teva and Apotex v. Eisai*: Won dismissals of declaratory judgment actions asserting noninfringement of several patents owned by client Eisai.
- *IAM Magazine* refers to him as an "awesomely effective trial lawyer." *Chambers USA* calls Mr. Wexler a "litigation and trial expert at the firm," noting his ability to "explain complex situations clearly to enable informed decision-making," and "exceptional writing skills and strong technical ability." *The Financial Times* awarded his successful defense of the Aricept® drug franchise "standout" notice for innovative lawyering.
- Mr. Wexler is a former judicial law clerk of the U.S. Court of Appeals for the Federal Circuit, where he served under Chief Judge Glenn L. Archer, Jr. He assisted in the preparation of influential Federal Circuit opinions including *Markman v. Westview.*
- Mr. Wexler received his J.D. *magna cum laude* from New York University (Order of the Coif) and his B.S., *summa cum laude*, in physics from Rensselaer Polytechnic Institute, where he was a member of Sigma Pi Sigma honor society.

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