Section 101 Updates: Life Science

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U.S. Patent Eligibility: Statute and SCOTUS

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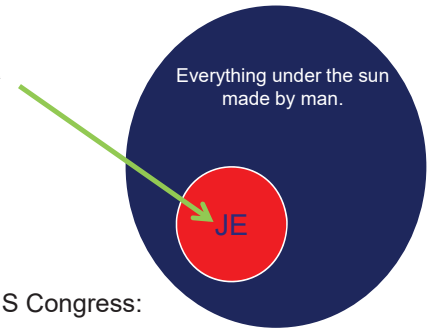
35 U.S.C. §101 – Four Categories of Eligible Subject Matter

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.

Judicial exceptions (JE) made by US courts: one cannot claim a **law of nature**, a **natural phenomena**, or an **abstract idea**.

Why: granting a monopoly over the basic tools of scientific and technological work would pre-empt use of these tools in all fields, thereby impeding innovation.



Article I, Section 8, Clause 8 of the constitution empowers the US Congress:

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

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Ass'n for Molecular Path. v. Myriad Genetics, 133 S. Ct. 2107 (2013)

- Holding: Isolated genomic DNA is a product of nature and not patent eligible, but cDNA is not a product of nature and is patent eligible.
- Why:
  - The Court understood the function of DNA as being a carrier of information.
    - The claimed gDNA does not have different information (function) from that which is found in nature.
    - The claimed gDNA does not have different sequence (structure) from that which is found in nature.

- Court was very careful to state that it "merely holds" that gDNA is not eligible for patenting simply because it has been isolated.
- **Should not be broadly applied to isolated natural products (natural phenomenon) other than DNA ... but USPTO *et al* disagree.**
- **As a result of this case, USPTO and courts typically ask whether a claimed composition has "markedly different characteristics" (MDC) from subject matter found in nature.**

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Mayo Collaborative Svcs. v. Prometheus Labs., Inc., 132 S.Ct. 1289 (2012)

A method of optimizing .. treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject; and

(b) determining the level of 6-thioguanine in the subject,

wherein a level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of the drug and wherein a level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of the drug.

- The claims do not add enough to the NL to describe an eligible process.
- administering - merely refers to a preexisting audience.
- determining - merely a routine activity.
- wherein - merely describes the natural law without instructing its **application.**
- **application** must be significant, not too preemptive of JE, and include elements beyond the JE that constitute an "inventive concept" that is significant and separate from the NL itself.
- "appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." (WURC)

The *Mayo* test is *the test* for claims under § 101*

(1) Is the claim directed to a JE (NP, AI, NL)?

(2) Does the claim contain an "'inventive concept'" sufficient to "transform" the claim into a patent-eligible application of the JE?

Analyze steps individually & as ordered combination (*Diehr* - claims cannot be deconstructed into their component steps but must be considered as a whole).

**Confirmed and crystalized in Alice Corp. v. CLS Bank International,* 573 U.S. 208, 134 S. Ct. 2347 (2014)

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