



Section 101 Updates: Life Science

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U.S. Patent Eligibility: Statute and SCOTUS



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

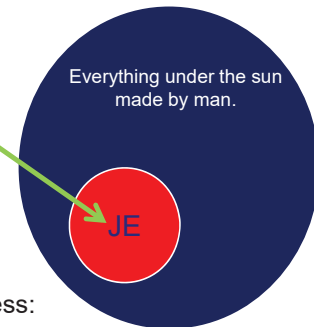
Whoever invents or discovers any new and useful **process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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.



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.**



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 8×10^8 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 8×10^8 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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