



# Life Sciences Patent Eligibility: The US and Beyond

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# U.S. Patent Eligibility



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

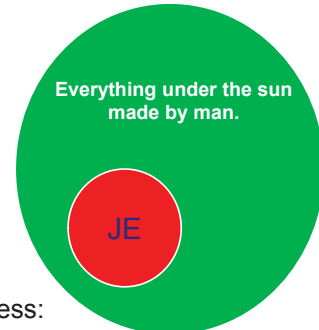
Whoever invents or discovers any new and useful **process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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

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, §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.



<sup>3</sup> L. Fischer/UT Conference/March 2017/VA

 **NOVARTIS**



## U.S. Patent Eligibility SCOTUS

 **NOVARTIS**

## Prometheus v. Mayo

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  $8 \times 10^8$  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  $8 \times 10^8$  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)

## Alice Corp. v. CLS Bank

- Confirms that the *Mayo* test is *the test* for claims under § 101.
- Analyze steps individually & as ordered combination (*Diehr* - claims cannot be deconstructed into their component steps but must be considered as a whole).
- *The Mayo/Alice two-step test*:
  - (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?

Dicta (*below*) supports the idea that a **solution to a technical problem** is not an AI, and a claim drawn to such a solution, even if broad, will satisfy the *Alice/Mayo* two-step.

According to SCOTUS, “the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.” In contrast, the *Alice* claims did not “improve the functioning of the computer itself” or “effect an improvement in any other technology or technical field.”

(1) method for exchanging financial obligations, (2) computer system; (3) computer-readable medium

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## Title search: Life Sciences Patent Eligibility: The US and Beyond

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12<sup>th</sup> Annual Advanced Patent Law Institute session

"Section 101 and Lifesciences: Current U.S. and International Perspectives"