Life Sciences Patent Eligibility: The US and Beyond

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U.S. Patent Eligibility: Statute

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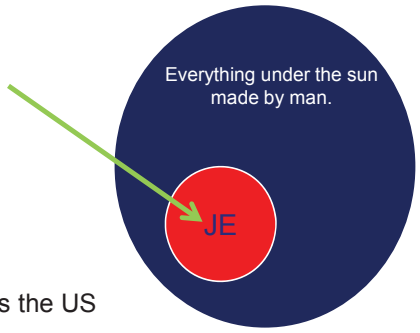
35 U.S.C. §101 – Four Categories of Eligible Subject Matter

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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U.S. Patent Eligibility: SCOTUS

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Prometheus v. Mayo (SCOTUS, March 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)

Alice Corp. v. CLS Bank (SCOTUS, June 2014)

- 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 a JE, 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

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

Also available as part of the eCourse
Patent Eligible Subject Matter: Significant Cases Impacting Software and Current Perspectives in Life Sciences

First appeared as part of the conference materials for the
13th Annual Advanced Patent Law Institute session
"Section 101: Life Sciences"