



Five requirements for a valid patent:

- Patentable subject matter
- Novelty
- Utility
- Nonobviousness
- Enablement



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 - Utility
 - Nonobviousness
 - Enablement



- easy, or
- hard



35 U.S.C. § 101

§ 101 - Inventions Patentable:

"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."

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These are the four categories of invention. They define patentable subject matter.

The four statutory categories

Process: "an act, or series of acts or steps" Machine: "a concrete thing, consisting of parts, or of certain devices and combination of devices" Manufacture: "an article produced from raw or

prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery"

Composition of Matter: "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids"

Problem: Show shoveling device

A **device** for shoveling snow, comprising: a metal scoop having a sharp edge and a wooden handle extending therefrom for manipulation by a person using said device.

Is this patentable subject matter?

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A **device** for shoveling snow, comprising: a metal scoop having a sharp edge and a wooden handle extending therefrom for manipulation by a person using said device.

Is this patentable subject matter?

Yes. Although a "device" isn't a word used in the categories of patentable subject matter, that's okay. Looking at this claim, the device is a machine (a concrete thing consisting of parts or devices), a manufacture (an article produced from raw or prepared materials), and a composition of matter (a composition of substances or composite article).

Problem: Marketing paradigm

A **paradigm** for marketing software, comprising: a marketing company that markets software from a plurality of different independent and autonomous software companies, and carries out and pays for operations associated with marketing of software for all of said different independent and autonomous software companies, in return for a contingent share of a total income stream from marketing of the software from all of said software companies, while allowing all of said software companies to retain their autonomy.

(In re Ferguson; claim 24)

Is this patentable subject matter?



Problem: Marketing paradigm

A **paradigm** for marketing software ... *Is this patentable subject matter?*

No. "Paradigm" is a business model for an intangible marketing company, not a process (series of steps), machine (a concrete thing consisting of parts or devices), manufacture (an article produced from raw or prepared materials), or composition of matter (a composition of substances or composite article).



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Excluded subject matter

Judicial exceptions:

 "Laws of nature, natural phenomena, and abstract ideas"

Diamond v. Diehr (1981)

Statutory exceptions, of which key examples are:

- tax strategies
- nuclear weapons inventions
- human organisms

Excluded subject matter – statutory

Statutory exceptions – three worth knowing:

- Tax strategies (post Sept. 16, 2011) "any strategy for reducing, avoiding, or deferring tax liability" Public Law 112-29, sec. 14 (2011)
- Nuclear weapons inventions "any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." 42 U.S.C. § 2181
- Human organisms "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." Public Law 112-29, sec. 33 (2011)

Excluded subject matter — judicial

Some easy examples of *excluded* matter:

- Laws of nature
 - E=mc²
- Natural phenomena
 - Newly discovered sap from a Amazon rainforest tree that reduces melanoma tumors
- Abstract ideas
 - The idea of using AI to scan a large set of medical records for unknown beneficial side effects of known, prescribed drugs.



Excluded subject matter — judicial

- We know these are excluded:
 - Laws of nature
 - Natural phenomena
 - Abstract ideas
- <u>But</u> many if not all inventions that are legitimately patentable subject matter make use of some or all of those things!
- So where do the off-limits judicial exceptions end and patentable inventions begin?
- In other words, how do we determine the scope of the judicial exceptions?

What is the scope of the judicial exceptions?

Mayo Collaborative v. Prometheus Labs (U.S. 2012) created a two-part test:

(1) Determine whether the claim is directed to a patent-ineligible concept.

(2) If so, then ask whether the claim's elements, considered both individually and as an ordered combination, transform the nature of the claim into a patent-eligible application.

Problem: Method for determining force required

A **method** for determining the force required to accelerate a mass of a given quantity at a desired rate of acceleration wherein a computer takes inputs for said desired rate of acceleration and said mass and produces a result for said force according to the formula F=ma, in which F is said force, m is said mass, and a is said desired rate of acceleration.

Is this patentable subject matter?

Problem: Method for determining force required

A **method** for determining the force required to accelerate a mass of a given quantity at a desired rate of acceleration wherein a computer takes inputs for said desired rate of acceleration and said mass and produces a result for said force according to the formula F=ma, in which F is said force, m is said mass, and a is said desired rate of acceleration.

Is this patentable subject matter?

No. Newton's Second Law expressed as F=ma is a law of nature. Adding that a computer will calculate a result according to the formula does not work to transform this law of nature into patentable subject matter.

Mayo v. Prometheus Labs (U.S. 2012)

The patent claims at issue covered "processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high." Inventors found "the precise correlations between metabolite levels and likely harm or ineffectiveness," which the court characterized as "natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects."

Mayo v. Prometheus Labs (U.S. 2012)

SCOTUS said: "[T]he steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. ... [U]pholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries. If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."

Mayo v. Prometheus Labs (U.S. 2012)

"Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws].' [citing *Flook*.] They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."



How the USPTO puts it ... (2/2)

"Accordingly, the Court has said that integration of an abstract idea, law of nature or natural phenomenon into a practical application may be eligible for patent protection. See, e.g., *Alice*, (explaining that 'in applying the § 101 exception, we must distinguish between patents that claim the "buildin[g] block[s]" of human ingenuity and those that integrate the building blocks into something more' ... "

Alice Corp. v. CLS Bank (U.S. 2014)

"The claims at issue relate to a computerized scheme for mitigating "settlement risk"—i.e., the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The intermediary creates "shadow" credit and debit records ... The intermediary updates the shadow records in real time ... At the end of the day, the intermediary instructs the relevant financial institutions to carry out the "permitted" transactions in accordance with the updated shadow records, thus mitigating the risk ... "

Alice Corp. v. CLS Bank (U.S. 2014)

"In sum, the patents in suit claim (1) the foregoing method for exchanging obligations (the method claims), (2) a computer system configured to carry out the method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well."

Alice Corp. v. CLS Bank (U.S. 2014)

"We must first determine whether the claims at issue are directed to a patent-ineligible concept. We conclude that they are: These claims are drawn to the abstract idea of intermediated settlement.

• • •

Because the claims at issue are directed to the abstract idea of intermediated settlement, we turn to the second step ... We conclude that the method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention."

Alice Corp. v. CLS Bank (U.S. 2014)

"[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea "while adding the words 'apply it'" is not enough for patent eligibility. ... [T]he relevant question is whether the claims here do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. They do not."

Problem: Optimizing therapeutic efficiency

A method of optimizing therapeutic efficacy for treatment of an immunemediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

(US6355623B2, claim 1)

Is this patentable subject matter?

Problem: Optimizing therapeutic efficiency

A method of optimizing therapeutic efficacy for treatment of an immunemediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

(US6355623B2, claim 1)

Is this patentable subject matter?

No. This is the claim from the *Mayo* case that SCOTUS rejected.