35 U.S.C. 101 AND THE PATENT ELIGIBILITY RESTORATION ACT OF 2022

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35 U.S.C. § 101

- 35 U.S.C. § 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.

35 U.S.C. § 101 Requirements

- Four requirements to § 101:
  - "A" patent – means only one patent granted for each invention.
  - "Useful" – the invention must have a specific, substantial, and credible utility.
  - "Process, Machine, Manufacture, Composition of Matter"
    - "Subject matter eligibility" – these categories, as interpreted by the courts, limit the subject matter that is eligible for patenting.
  - "Whoever invents or discovers"
    - A patent may only be obtained by the person who engages in the act of inventing.

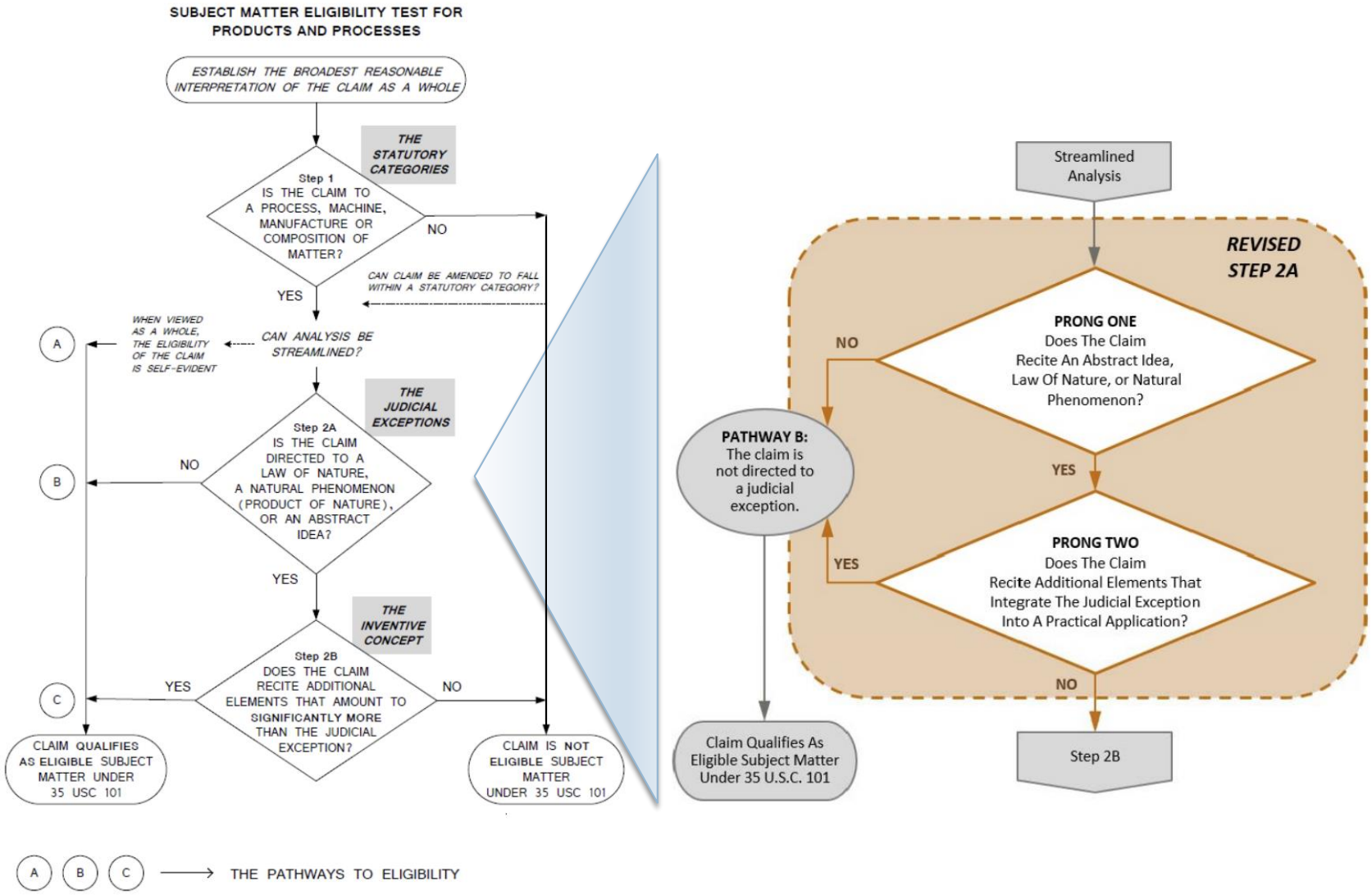
Subject Matter Eligibility

- Two criteria for subject matter eligibility:
  - Claimed invention must be to one of the four statutory categories:
    - Process, Machine, Manufacture, or Composition of Matter.
  - Claimed invention must qualify as patent-eligible subject matter – *i.e.*, the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.
    - Judicial exceptions are subject matter that the courts have found to be outside of, or exceptions to, the four statutory categories of invention, and are:
      - abstract ideas, laws of nature, and natural phenomena.

Subject Matter Eligibility

- Four statutory categories of statutory subject matter:
  - Process
    - "actions" – *i.e.*, "an act or step, or a series of acts or steps."
  - Machine
    - "concrete thing, consisting of parts, or of certain devices and combination of devices."
  - Manufacture
    - "a tangible article that is given a new form, quality, property, or combination through man-made or artificial means."
  - Composition of Matter
    - "combination of two or more substances and includes all composite articles."

Subject Matter Eligibility Test for Product and Process Claims



Related Supreme Court Cases

- *Bilski v. Kappos*, 561 U.S. 593 (2010).
- *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.CT. 1289 (2012).
- *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S.Ct. 1794 (2013).
- *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. CT. 2347 (2014).

Related Supreme Court Cases

- *Bilski v. Kappos*, 561 U.S. 593 (2010)
  - The Supreme Court rejected the Federal Circuit's holding in *In re Bilski* that the machine-or-transformation test is the sole test to determine whether a particular process constitutes patent-eligible subject mater. Instead the test should be viewed as "a clue" to this analysis.

Related Supreme Court Cases

- *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.CT. 1289 (2012)
  - The Supreme Court acknowledged that while laws of nature are not patentable, claims that contain a law of nature can be patentable as long as the claim applies the law of nature. The Court was guided by two principles: that it's important that the claim does not preempt the entire use of the natural law, and that the additional elements added to the claim beyond the natural law must be significant in that they cannot merely involve steps that are well-understood, routine, and conventional.

Related Supreme Court Cases

- *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S.Ct. 1794 (2013)
  - The Supreme Court found that isolating naturally occurring gene fragments did not result in the invention of anything that was not found in nature. But note, In contrast, the "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring." As a result, the cDNA sequence molecule was patent eligible subject matter.

Related Supreme Court Cases

- *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. CT. 2347 (2014)
  - The Supreme Court set forth a two-part test for analyzing whether or not a claim is unpatentable for claiming an abstract idea. First, the Court must determine "whether the claims at issue are directed to one of those patent-ineligible concepts." Second, if they are, then the Court must "search for an 'inventive concept' – i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon [the ineligible concept] itself.'"

Patent Eligibility Reform: How we Got Here

- In light of the numerous past Supreme Court decisions, patent eligibility law in the U.S. has become confused, constricted, and unclear.
- From the perspective of numerous practitioners/industry groups, the exceptions have swallowed the rule.
- In 2019, Senators Tillis, as IP Subcommittee Chairman, held numerous bipartisan and bicameral roundtables and extensive discussions with stakeholders on § 101 reform.
- On April 17, 2019, a bipartisan and bicameral framework for statutory § 101 reform was released by U.S. Senator Tillis and Representatives Collins, Johnson, and Stivers.

Patent Eligibility Reform: How we Got Here, Continued

- On May 22, 2019, following feedback on their draft framework, the same group of Congressional Members released a draft bill to reform § 101.
- In June 2022, Senator Tillis led a marathon series of 3 hearings featuring 45 witnesses on patent eligibility reform.
- On March 1, 2022 Senator Tillis, Honorable Paul Michel, and Honorable David Kappos filed an amicus brief with the Supreme Court in *American Axle & Manufacturing Inc. v. Neapco Holdings LLC*.
  - The brief provided the perspectives of three branches of government and called on the Court to take up this important case and clarify its patent eligibility jurisprudence.
  - On June 30, 2022, the U.S. Supreme Court refused to hear *American Axle*.

American Axle and its aftermath

- The U.S. Supreme Court's refusal to hear *American Axle* and to provide much needed clarity on patent eligibility jurisprudence was the catalyst for Senator Tillis to act and subsequently introduce the Patent Eligibility Restoration Act of 2022.
- The Patent Eligibility Restoration Act of 2022 restores clarity and provides patent eligibility to important inventions in fields such as diagnostics, gene-based medicine, artificial intelligence, quantum computing, and other software-based technologies.

The Patent Eligibility Restoration Act

- The Patent Eligibility Restoration Act of 2022 modifies § 101 as follows:
  - redefines "process:"
    - from: "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material"
    - to: "The term 'process' means process, art or method, and includes a use, application, or method of manufacture of a known or naturally-occurring process, machine, manufacture, composition of matter, or material"
  - defines "useful":"
    - "The term 'useful' means, with respect to an in invention or discovery, that the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains."

The Patent Eligibility Restoration Act

- The Patent Eligibility Restoration Act of 2022 maintains the existing statutory categories of eligible subject matter. A patent may not be obtained for the following claimed subject matter:
  - a mathematical formula, apart from a useful invention or discovery;
  - a process that:
    - is a non-technological economic, financial, business, social, cultural or artistic process;
      - *But*, a claimed invention that is a process, as previously described, embodied in a machine or manufacture shall be eligible unless the machine or manufacture is recited without integrating, beyond merely storing and executing, the process steps that are to be performed by the machine or manufacture thereon
    - is a mental process performed solely in the human mind; or
    - occurs in nature wholly independent of and prior to any human activity;
  - an unmodified human gene as it exists in the human body; or
    - *But*, a human gene that is isolated, purified, enriched, or otherwise altered by human activity, or that is otherwise employed in a useful invention or discovery, shall not be considered to be unmodified;
  - an unmodified natural material as it exists in nature
    - *But*, a natural material that is isolated, purified, enriched, or otherwise altered by human activity, or that is otherwise employed in a useful invention or discovery, shall not be considered to be unmodified

Myth vs. Fact

- **MYTH:** The Patent Eligibility Restoration Act would allow for patents on people's genes and on other materials that are part of nature.
  - **FACT:** The legislation expressly forbids patents on any "unmodified human gene, as that gene exists in the human body," as well as any "unmodified natural material, as that material exists in nature." The legislation only allows for patents on *useful inventions* made by humans. With regard to genes and natural materials, this means patents may only issue for inventions that result from human activities that *alter* or *apply* genes and other elements of nature in a useful way. It does not include such materials in their natural state.

Myth vs. Fact

- **MYTH:** Restoring patent eligibility for isolated genes, diagnostic methods, and similar subject matter would hinder science and technological progress and put the U.S. at a competitive disadvantage compared to other nations.
  - **FACT:** Precisely the opposite is true. When isolated genes, gene fragments, diagnostic tools, and similar technologies were patent-eligible, the U.S. led the world in both gene science and research, and in the private sector development of gene-based medicine and diagnostics. In that innovation friendly environment, the U.S., already the birthplace of the biotechnology industry, provided the conditions necessary to give rise to the modern genetic testing industry, built upon gene science and transformative US-developed technologies such as polymerase chain reaction (PCR), which was both patented and won a Nobel Prize. The U.S. was also home to the first successful sequencing of the human genome through parallel public and private efforts in the early 2000s, all while isolated genes, diagnostics, and similar technologies were patent eligible. Since these technologies became ineligible for protection in the U.S., numerous studies have documented substantial declines in US investment and innovative activity in these fields.

Myth vs. Fact

- **MYTH:** The legislation would lead to higher prices for diagnostic tests and prescription drugs.
  - **FACT:** The legislation would have no impact on existing products or their prices in any field. The bill is aimed at restoring incentives to invest in, invent and develop *new* products and technologies that do not currently exist, many of which will not otherwise be developed. Additionally, many of the technology areas that have been negatively impacted by current law, and which would benefit from the legislation, are those that would help *lower* healthcare costs. These include:
    - Personalized medicine and associated technologies, which help to tailor treatments to a particular patient, thereby reducing wasteful expenditures on treatments that are not likely to be effective for that patient;
    - Diagnostic tests, which help to diagnose and identify diseases earlier, often leading to more successful treatment and the avoidance of hospitalization and more expensive procedures and treatments later;
    - Novel diagnostic methods, which can eliminate the need for more invasive tests, and lower the risk of medical complications compared to older techniques, thereby substantially lowering healthcare costs (e.g. development of non-invasive blood tests to replace complicated surgical or medical procedures requiring anesthesia); and
    - Technologies related to cell and gene-based therapies, which hold the promise of curing diseases with a single one-time treatment, thereby saving the costs of a lifetime of conventional treatments.

Myth vs. Fact

- **MYTH:** By eliminating the Supreme Court's subject matter eligibility exclusions, the legislation would remove all meaningful restrictions on patenting, leading to low quality patents.
  - **FACT:** The legislation does not eliminate traditional restrictions on subject matter eligibility, but restores them to their original scope and intent, striking a common sense balance between sound innovation policy and legitimate concerns about patenting improper subject matter. The legislation prohibits the patenting of mathematical formulas, mental processes, non-technological processes, natural laws and processes as they occur in nature, and genes and natural materials as they exist in nature. In addition, the legislation codifies for the first time in US history the requirement that an invention demonstrate a specific and practical utility in order to earn a patent. Importantly, even where an invention qualifies as eligible subject matter under the legislation, it still must demonstrate such utility, in addition to novelty, non-obviousness, and full disclosure under law that itself has been strengthened by other Supreme Court decisions in recent years, in order for a patent to issue.

Myth vs. Fact

- **MYTH:** By eliminating the Supreme Court's subject matter eligibility exclusions, the legislation would remove an important tool to defend against abuse by patent trolls.
  - **FACT:** Abuses of the patent system have been addressed amply by numerous actions in Congress and the courts. Abuses of the patent system by patentees have been addressed so thoroughly that numerous studies now demonstrate a much larger problem of *actual* patent infringers raising meritless Section 101 defenses as a tactic to engage in so-called "efficient infringement" and to avoid or delay the fair and timely resolution of patent enforcement actions. Nevertheless, in recognition of legitimate concerns to resolve patent infringement cases efficiently where ineligible subject matter is claimed, in addition to codifying exclusions against the patenting of overbroad and vague subject matter, the legislation includes new tools that enable the efficient resolution of eligibility disputes early in litigation through motions, and with access to targeted discovery.

Myth vs. Fact

- **MYTH:** The Patent Eligibility Restoration Act would increase uncertainty regarding what constitutes patent eligible subject matter.
  - **FACT:** There is no question that uncertainty regarding what constitutes patent eligible subject matter hinders American innovation. The Patent Eligibility Restoration Act is necessitated by the extreme uncertainty that exists today regarding what constitutes patent eligible subject matter in the U.S. All twelve sitting Federal Circuit judges agreed the current law is uncertain when denying to revisit the question of patent eligibility in the most recent major case before them. Every PTO director since the Alice and Mayo decisions has agreed that the current law is uncertain. Numerous Senators have said the current law is uncertain. The CRS has said the current law is uncertain. Multiple solicitor generals have said the current law is uncertain. Simply put, there is no reasonable doubt that the law as it currently stands is very uncertain. A major objective of the Patent Eligibility Restoration Act is to make the law much more certain.

Questions?