21C The Coalition for 21st Century Patent Reform

Why 21C Supports the Patent Eligibility Restoration Act (PERA) of 2023

PERA Reinstates the Legislative Definition of What Kinds of Inventions May Be Patented

35 U.S.C. § 101 defines "Inventions patentable" by stating:

> 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.

About a decade ago in its *Mayo* and *Myriad* decisions, the Supreme Court began substantially broadening the "laws of nature, natural phenomena, and abstract ideas" exceptions that its predecessor Courts had held should disqualify certain discoveries and inventions from patenting.[1] Even though the Court recognized in its *Alice* decision that it needed to "tread carefully in construing this exclusionary principle lest it swallow all of patent law,"[2] it failed to set any workable limits. As a result, the law interpreting 35 U.S.C. §101's definition of the subject matter that is eligible for patenting is now widely recognized as an unworkable "mess."[3] This is largely because in rendering its recent opinions, the Supreme Court failed to recognize that *all* inventions rely to some extent on laws of nature, natural phenomena, and/or abstract ideas—what sets patentable inventions apart from mere ideas is that they are practical implementations that provide useful results.[4]

Subsequent experience in the lower courts has demonstrated that the Supreme Court's expanded eligibility exceptions now routinely disqualify many different kinds of meritorious inventions from being patented even though in the past they were routinely patented. Examples include revolutionary advances in fields of diagnostics, therapeutics, information technology, and even classic mechanics.[5] In a recent opinion, the Chief Judge of the Federal Circuit—the court with exclusive appellate jurisdiction over all patent cases—lamented: "Our job, our mandate from Congress is to create a clear, uniform body of patent law. Our inability to do so in the § 101 space has not been a mess of our making."[6] The Chief Judge's view is widely shared, as the other Federal Circuit judges have repeatedly opined that aspects of this Supreme Court framework are "indeterminate,"[7] "arbitrary,"[8] "inconsisten[t],"[9] and "unpredictab[le]."[10] Not surprisingly, this state of uncertainty has led to the filing of several dozen petitions for writ of certiorari to the Supreme Court, all of which have been summarily denied.[11]

The ambiguity created by the Supreme Court has also been disruptive of the examination process in the U.S. Patent and Trademark Office (USPTO), which has attempted to conduct damage control in an unsuccessful attempt to give its examiners clear procedures for implementing these judicial exceptions.[12]

Although the law governing patentable subject matter is unclear, its effect on innovation in the U.S. is not. After the Supreme Court's patent law shakeup of the 2010s, many patents covering

cutting-edge inventions have been found unpatentable by the courts and the USPTO. Developments in computing and artificial intelligence, which often rely on calculations, simulations, models, and instruction sets, now fall into the rubric of abstract ideas despite novel practical physical applications.[13] Medical advances involving biologics, diagnostics, precision medicine, bioinformatics, and genes often take advantage of laws of nature and natural phenomena, rendering many of tthem ineligible for patenting under current precedent.[14] Indeed, the USPTO's Office of the Chief Economist has found that, from 2000 to 2020, the share of U.S. patents exposed to greater uncertainty due to subject matter jurisprudence increased by 50%.[15] The straw that broke the camel's back may well have been the case that prompted the Chief Judge of the Federal Circuit to call section 101 jurisprudence a "mess." In that decision, which "sent shock waves through the patent community," a splintered court deemed unpatentable a method of manufacturing an automotive drive shaft—the very type of invention that, as the Chief Judge put it, "has been eligible for patent protection since the invention of the car itself."[16]

The current uncertainty in the law of patent eligibility threatens the United States' competitive position for investment and innovation. Though foreign patent offices maintain exceptions to patent eligibility, international analogs are not as broad and ambiguous as the judicial exceptions of U.S. patent law.[17, 18] Inventors who are unable, or even merely uncertain of their ability, to secure patents over cutting-edge innovations may choose to seek patent protection and practice their inventions elsewhere, under more patentee-friendly regimes.

In view of the foregoing, it now falls to Congress to make sense of this body of law and restore confidence in the country's patent regime, encourage innovation, and foster U.S. competitiveness.

PERA Provides "Eligibility Exclusions" for Categories of Things Not Eligible For Patenting

The Patent Eligibility Restoration Act (PERA) seeks to clarify and reform the law on patentable subject matter.[19] Chiefly, the bill eliminates all judicial exceptions to patent eligibility while codifying five categories of things that are not patent eligible. These include (1) mathematical formulas other than those that are part of a useful invention or discovery; (2) certain non-technological processes;[20] (3) unmodified human genes as they exist in the human body; and (4) unmodified natural materials as they exist in nature.[21]

Arguably, the enumeration of these eligibility exceptions is unnecessary, as 35 U.S.C. § 101 already specifies that the patentability of all discoveries and inventions also further requires that to be patentable they must also comply with the other "conditions and requirements of this title." Principal among these are the requirements of 35 U.S.C. § 102 (requiring patentable inventions to be novel), 35 U.S.C. § 103 (requiring patented inventions to be non-obvious), and 35 U.S.C. § 112 (requiring patentable inventions to be fully described and to enable others how to make and use the invention claimed).

PERA Provides Procedural Guidelines for Determining Patent Eligibility

PERA also provides clear procedural rules for considering patentable subject matter challenges, and ensures that courts will have the ability to authorize and consider discovery relevant to

patent eligibility, and when there are no genuine issues of material fact, to rule on motions relating to eligibility at any time.[22]

Conclusion

The changes proposed in PERA are welcome steps toward enhancing administrability of patentable subject matter eligibility jurisprudence, increasing predictability and confidence in the U.S. patent system, and incentivizing technological innovations to solve the major problems of the modern world.

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[1] *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

[2] *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

[3] *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1319 (Fed. Cir. 2020) (Moore, J., dissenting).

[4] For decades before these decisions, the U.S. Patent and Trademark Office (USPTO) regarded § 101 as setting forth a "Utility Requirement," that the invention as described and claimed in a patent application must have a "specific and substantial utility." *See* USPTO Manual of Patent Examining Procedure (MPEP) § 2107.

[5] *See, e.g.*, *Ariosa Diagnostics v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *INO Therapeutics LLC v. Praxair Distrib. Inc.*, 782 F. App'x 1001 (Fed. Cir. 2019); *Int'l Bus. Machs. Corp. v. Zillow Grp., Inc.*, 50 F.4th 1371 (Fed. Cir. 2022); *American Axle*, 967 F.3d 1285 (Fed. Cir. 2020).

[6] *American Axle*, 967 F.3d at 1319 (Moore, J., dissenting).

[7] *Smart Sys. Innovations v. Chi. Transit Auth.*, 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part).

[8] *Id.*

[9] *Yu v. Apple Inc.*, 1 F.4th 1040, 1049 (Fed. Cir. 2021) (Newman, J., dissenting).

[10] *Id.*

[11] *See, e.g.*, Chart of Subject Matter Eligibility Court Decisions, U.S. Patent and Trademark Office, *available at* https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.uspto.gov%2Fsites%2Fdefault%2Ffiles%2Fdocuments%2Fieg_sme_crt_decisions.xlsx&wdOrigin=BROWSELINK (updated Oct. 17, 2019).

[12] *See, e.g.*, Subject Matter Eligibility, U.S. Patent and Trademark Office, *available at* https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility.

[13] Patent eligible subject matter: Public views on the current jurisprudence in the United States, U.S. Patent and Trademark Office, June 2022 ("USPTO Report to Congress") at 36, *available at* https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf.

[14] *Id.* at 31–32.

[15] *Id.* at 14–15.

[16] *American Axle*, 967 F.3d at 1306 (Moore, J., dissenting).

[17] *See, e.g.*, A Global Perspective on Patent Subject Matter Eligibility and Software-Related Inventions, Intellectual Property Owners Association, December 2019, *available at* https://ipo.org/wp-content/uploads/2019/12/IPO_elegibility_whitepaper11-20-19.pdf; Certain Aspects of National/Regional Patent

Laws, Exclusions from Patentable Subject Matter, World Intellectual Property Organization, June 2023, *available at* https://www.wipo.int/export/sites/www/scp/en/national_laws/exclusions.pdf.

[18] USPTO Report to Congress at 32–33.

[19] Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023) ("PERA").

[20] The excluded processes are any processes that are (i) non-technological, economic, financial, business, social, cultural, or artistic, (ii) a mental process performed solely in the human mind, and (iii) processes that occur in nature wholly independent of, and prior to, any human activity. PERA § 101(b)(1)(B)(i)-(iii).

[21] PERA includes further "Conditions" (A) to ensure that processes embodied in a machine or manufacture will remain patent eligible except in certain enumerated circumstances, and (B) that a human gene or 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. PERA § 101(b)(2)(A), (B).

[22] *See* PERA § 101(c)(1), (2).