

THE CONUNDRUM OF PATENTABLE SUBJECT MATTERBy [James R. Major, D.Phil.](#)**A) The Statutory Basis of Patentable Subject Matter**

Relating to “[i]nventions patentable,” 35 U.S.C. § 101 was enacted in 1952 and Congress has not amended the section since. The section provides that “[w]hoever 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,” a mere thirty-six words. Regarding the current language, the U.S. Supreme Court has noted that “[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)). Indeed, the language of the current statute has impressive historical roots because the comparable statute from 1790 provided that a patent could be granted:

[U]pon the petition of any person or persons to the Secretary of State, the Secretary for the department of war, and the Attorney General of the United States, setting forth, that he, she, or they, hath or have invented or discovered *any useful art, manufacture, engine, machine, or device*, or any improvement therein not before known and used

1 Stat. 109-10 (1790) (emphasis added).

The jurisprudence of the late Justice Antonin Scalia drastically changed the Court’s approach to statutory interpretation. Justice Scalia was famously dismissive of the value of

legislative history and professed to follow a textualist approach. *See, e.g., Zedner v. U.S.*, 547 U.S. 489, 511 (2006) (“Because the use of legislative history is illegitimate and ill advised in the interpretation of any statute—and especially a statute that is clear on its face—I do not join this portion of the Court’s opinion”) (Scalia, J., concurring in part and concurring in the judgment). Recent civil cases follow the late justice’s lead. For example, Justice Thomas, interpreting the Fair Debt Collection Practices Act, wrote that “[i]t is a fundamental principle of statutory interpretation that ‘absent provision[s] cannot be supplied by the courts.’” *Rotkiske v. Klemm*, 140 S. Ct. 355, 361-62 (2019) (Thomas, J.) (quoting ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 94 (2012)) (alteration in original). And in interpreting the Atomic Energy Act, Justice Gorsuch wrote that “[i]n this, as in any field of statutory interpretation, it is our duty to respect not only what Congress wrote but, as importantly, what it didn’t write.” *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1900 (2019) (Gorsuch, J.). “Nor does this Court usually read into statutes words that aren’t there.” *Romag Fasteners, Inc. v. Fossil Group, Inc.*, 140 S. Ct. 1492, 1495 (2020) (Gorsuch, J.). From these cases, we may draw a general rule that, under the Court’s modern jurisprudence, there are no implicit exceptions to the plain language of civil statutes. Indeed, at least Justice Alito seems to take the position that the general rule applies to patent statutes. *See Minerva Surgical, Inc. v. Hologic, Inc.*, No. 20-440, 2021 WL 2653265 at *11 (June 29, 2021) (Alito, J., dissenting) (citing *Romag*, 140 S. Ct. at 1495).

With the cited cases in mind, one might think that a claim reciting a process, machine, manufacture, or composition of matter—the very language of the current statute—would necessarily recite patentable subject matter. But this seemingly reasonable position is incorrect. Rather, “[t]he Court has long held that [35 U.S.C. § 101] contains an important implicit

exception: “[l]aws of nature, natural phenomena, and abstract ideas’ are not patentable.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (Breyer, J.). Moreover, the Court “ha[s] interpreted § 101 and its predecessors in light of this exception for more than 150 years.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216 (Thomas, J.). These exceptions have played out in four recent cases.

B) *Bilski, Mayo, Myriad, and Alice: The Four Horsemen of the Apocalypse?*

In *In re Bilski*, the U.S. Court of Appeals for the Federal Circuit held that “[a] claimed process is *surely* patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc) (emphasis added). The Court was not so sure and reversed, holding that “[t]he machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’” *Bilski v. Kappos*, 561 U.S. 593, 605 (2010). In *Mayo*, the Court held that “[l]aws of nature, natural phenomena, and abstract ideas’ are not patentable.” *Mayo*, 566 U.S. at 70 (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). In *Myriad*, the Court held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013). However, *Alice* sets forth the current approach to assessing patentable subject matter, namely that in step one “we determine whether the claims at issue are directed to one of those patent-ineligible concepts.” *Alice*, 573 U.S. at 217. “We have described step two of this analysis as a search for an “inventive concept”—*i.e.*, an element or combination of elements is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” *Id.* at 217-18 (citing *Mayo*, 566 U.S. at 72-73).

C) **Claims Drawn to Laws of Nature after *Alice***

In *Mayo*, “[t]he claims purport[ed] to apply 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*, 566 U.S. at 72. And in *Myriad*, the Association for Molecular Pathology (the “Association”) successfully challenged patents relating to genetic testing. One would imagine that invalidating patents covering medical testing might render the claimed tests cheaper. Indeed, the Association has found this to be true but not necessarily to the extent the Association desired. Specifically, in a survey of physicians and doctoral-level respondents involved in medical testing, the Association recently reported that “[a]ll types of respondents rated reimbursement for the analysis, interpretation, and reporting process to be *generally insufficient*” https://www.amp.org/AMP/assets/File/advocacy/AMP_MDx_Interpretation_Quant_Survey_Report.pdf?pass=24 at 32 (emphasis added).

Another recent dispute invoking the Court’s “laws of nature” jurisprudence is *American Axle & Manufacturing, Inc. v Neapco Holdings LLC*. Claim 22 recited “[a] method for manufacturing a shaft assembly of a driveline system . . . comprising: providing a hollow shaft member; *tuning a mass and a stiffness of at least one liner*, and inserting the at least one liner into the shaft member” *Am. Axle & Mfg., Inc. v Neapco Holdings LLC*, 939 F.3d 1355, 1359 (Fed. Cir. 2019) (emphasis added) (“*Axle I*”). “[B]oth parties’ witnesses agree[d] that Hooke’s law undergirds the design of a liner so that it exhibits a desired damping frequency pursuant to the claimed invention.” *Id.* at 1362. According to the majority, “Hooke’s law is a natural law that mathematically relates the mass and/or stiffness of an object to the frequency with which that object oscillates (vibrates).” *Id.* The majority held claim 22 invalid as reciting unpatentable subject matter. *Id.* at 1368. *Axle I* was controversial with the leading scholar Dennis Crouch

reporting the decision under the memorable title *Hey Mechanical Engineers: Your Patents are Also Ineligible*. <https://patentlyo.com/patent/2019/10/mechanical-engineers-ineligible.html>.

The original panel granted a petition for panel rehearing and withdrew *Axle I*. *Am. Axle & Mfg., Inc. v Neapco Holdings LLC*, 966 F.3d 1294, 1295 (Fed. Cir. 2020) (“*Axle II*”). On rehearing, the majority again held that claim 22 did not recite patentable subject matter. *Am. Axle & Mfg., Inc. v Neapco Holdings LLC*, 967 F.3d 1285, 1292 (Fed. Cir. 2020) (“*Axle III*”).

However, the majority in *Axle III* described Hooke’s law somewhat differently than in *Axle I*. *Id.* at 1291 (“Hooke’s law is an equation that describes the relationship between an object’s mass, its stiffness, and the frequency at which the object vibrates.”). However, the Federal Circuit denied a petition for rehearing en banc. *Am. Axle & Mfg., Inc. v Neapco Holdings LLC*, 966 F.3d 1347, 1348 (Fed. Cir. 2020) (“*Axle IV*”). Judge Newman, writing in dissent of the denial, saw Hooke’s law more directly. *Id.* at 1359 (“The panel majority does not explain how Hooke’s formula $F = kx$ for the compression of springs renders the . . . patent’s automotive driveshaft ineligible for access to the patent system.”) (Newman, J., dissenting). Arguably, the majority in *Axle I* and *Axle III* viewed Hooke’s Law as a law applying generally—the mass of an object is related *in some way* to the frequency at which the object oscillates—whereas Judge Newman in *Axle IV* viewed Hooke’s Law more specifically, namely that the force applied to an object directly correlates with the displacement of the object.

The patentee in *Axle III* submitted a petition for certiorari and various amici submitted briefs. Of note was that submitted by the New York City Bar Association (“NYCBA”). For example, *Axle I* stated that the patentee “may have discovered patentable refinements of this process, such as ‘us[ing] sophisticated FEA [finite element analysis] models during its design process’” *Axle I*, 939 F.3d at 1364 (citing patentee’s brief). In response, the NYCBA stated

that “[i]f the method of claim 22 is . . . a mere application of a natural law such as that in *Mayo*, one wonders why extensive computer modeling is needed.” Brief for New York City Bar Ass’n at 11, *Am. Axle & Mfg., Inc. v Neapco Holdings LLC*, No. 20-891 (Feb. 5, 2021). On May 3, 2021, the Court sought the views of the Acting Solicitor General as to whether to grant the petition. Statistically speaking, such a request means that the Court will likely grant the petition.

D) Claims Drawn to Natural Phenomena after *Alice*

While *Axle I-IV* have pushed the envelope of the Court’s jurisprudence regarding laws of nature, patents claiming natural phenomena have had less success. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), is an example. The patent at issue in *Ariosa* related to prenatal testing. Previously, physicians used techniques such as amniocentesis to sample fetal cells. However, such techniques are associated with risks such as loss of pregnancy. The patent discloses that fetal DNA is found in maternal blood free from cellular association. This DNA is known as cell-free fetal DNA (“cffDNA”) and is capable of amplification and detection clinically. *See id.* at 1373. However, “[i]t [was] undisputed that the existence of cffDNA in maternal blood is a natural phenomenon.” *Id.* at 1376. And “[b]ecause the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful.” *Id.* at 1377. Therefore, a method that was a significant step forward from the state of the art was nevertheless not patentable subject matter.

The Federal Circuit denied a petition for rehearing *Ariosa* en banc. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (per curiam). However, Judge Lourie wrote an interesting concurrence to the denial. He suggested that “[t]he claim to this invention, then, might have been better drafted as a so-called Jepson claim, which recites what is in the prior art and what is the improvement.” He continued: “Such a claim might read, perhaps

with more details added: ‘In a method of performing a prenatal diagnosis using techniques of fractionation and amplification, the improvement consisting of using the non-cellular fraction of a maternal blood sample.’” *Id.* at 1286 (Lourie, J., concurring). However, the preamble of a Jepson claim can be taken as an implied admission that the subject matter of the preamble is prior art. *See generally* MANUAL OF PATENT EXAMINING PROCEDURE § 2129(III) (2020). Because it is possible that such an implied admission can be damaging, U.S. practitioners have typically disfavored Jepson claims. That said, the recent changes in approach to patentable subject matter may make such claims more desirable.

E) Claims Drawn to Products of Nature after *Alice*

In *Myriad*, the Court held that claims drawn to an isolated natural product, without more, are not patent eligible merely because it has been isolated. *Myriad*, 569 U.S. at 580. However, it is well known that many common drugs such as aspirin and penicillin are natural products. Indeed, isolating penicillin in the 1940s was worthy of the Nobel Prize. While previously unknown natural products are disclosed regularly, the disclosing parties might not want to commercialize such products without patent protection.

There are options, though. In a recent Stradley case, claim 1 was drawn to a composition of bacterial proteins. The Examiner alleged that a composition of naturally-occurring bacterial proteins was not patentable subject matter, citing *Mayo*. We amended claim 1 to be drawn to a composition of bacterial proteins and an adjuvant. We argued that the presence of the adjuvant renders the bacterial proteins immunogenic, which is a marked difference from the composition of bacterial proteins without the adjuvant. We noted that the U.S. Patent and Trademark Office had taken the position that, while the components of gunpowder are naturally occurring but are not themselves explosive, the assembly of those components in a particular manner to form

gunpowder is also associated with a marked difference. Because the subject matter of amended claim 1 and gunpowder are both associated with a marked difference, we argued that amended claim 1 was on all fours with an example of subject matter that the Office has acknowledged is patent eligible. Therefore, amended claim 1 is drawn to patentable subject matter. While it remains to be seen whether our arguments persuade the Examiner, this is an example of how patentable subject matter rejections might be overcome.

F) Claims Drawn to Abstract Ideas after *Alice*

Alice led to the invalidation of many software-implemented patents. *In re TLI Communications LLC*, 823 F.3d 607 (Fed. Cir. 2016), is simply one example of many. There, the Federal Circuit held that “the patent-in-suit claims no more than the abstract idea of classifying and storing digital images in an organized manner”. *Id.* at 609. However, software-related claims associated with an improvement to computer functionality have a significantly higher chance of being found patent eligible. *See, e.g., Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016) (“In this case, however, the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity.”).

Yu v. Apple, Nos. 2020-1760 & 2020-1803, 2021 WL 2385520 (Fed. Cir. June 11, 2021), is an example of the extent to which litigants have pushed the principles of *Alice*. A simplified and emphasized version of claim 1 at issue in *Yu* is set forth below:

An improved digital camera comprising:
a first and a second image sensor, said first image sensor producing a first image and said second image sensor producing a second image;
two lenses . . . ;
an analog-to-digital converting circuitry . . . ;
an image memory . . . ; and
a digital image processor, coupled to said image memory and receiving said first digital image and said second digital image, producing a resultant

digital image from said first digital image enhanced with said second digital image.

Unlike the method claims at issue in *Mayo* and *Alice*, for example, the claim set forth above is drawn to a physical object. A person skilled in the art could easily remove the back from such a physical object and point to the italicized components. However, it is the underlined language that lead to the patent's demise.

In *Yu*, the Federal Circuit noted that “[t]he district court granted Defendants’ motion to dismiss on the basis that the asserted claims were invalid under 35 U.S.C. § 101.” *Yu*, 2021 WL 2385520 at *1. Unlike issues of lack of novelty and obviousness that typically require claim construction and expert testimony, a court can dismiss a claim reciting unpatentable subject matter very early in proceedings.

At step one of *Alice*, the court held that “claim 1 is directed to the abstract idea of taking two pictures (which may be at different exposures) and using one picture to enhance the other in some way.” The court also noted that “the idea and practice of using multiple pictures to enhance each other has been known by photographers for over a century.” “The claim’s remaining limitations undercut Yu’s contention” that “claim 1 is directed to a patent-eligible application of this idea as opposed to just the idea itself.” In this regard, the court was forthright: “Only conventional camera components are recited to effectuate the resulting ‘enhanced’ image—two image sensors, two lenses, an analog-to-digital converting circuitry, an image memory, and a digital image processor,” “it is undisputed that these components were well-known and conventional,” “as claimed, these conventional components perform only their basic functions,” and “[w]hat is claimed is simply a generic environment in which to carry out the abstract idea” *Id.*

“Turning to step two [of *Alice*], we conclude that claim 1 does not include an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible invention.” Moreover, “even if claim 1 recites novel subject matter, that fact is insufficient by itself to confer eligibility.” *Id.* at *4 (citing *Two-Way Media Ltd. v. Comcast Cable Commc ’ns, LLC*, 874 F.3d 1329, 1340 (Fed. Cir. 2017) (“Eligibility and novelty are separate inquiries.”)). Indeed, in step two of the *Alice* analysis, “[t]he main problem that [Yu] cannot overcome is that the *claim*—as opposed to something purportedly described in the specification—is missing an inventive concept.” *Id.* (alteration in original) (citing *Two-Way Media*, 874 F.3d at 1338). Therefore, the Federal Circuit affirmed the district court’s finding that claim 1 recited unpatentable subject matter. *Id.* at *5.

Judge Newman, in dissent, saw the claim at issue differently. “This camera is a mechanical and electronic device of defined structure and mechanism; it is not an ‘abstract idea.’” *Id.* (Newman, J., dissenting)). She took the position that “[a] device that uses known components does not thereby become an abstract idea, and is not on that ground ineligible for access to patenting.” *Id.* at *6. Judge Newman neatly summarized the issues arising from the current approach to patentable subject matter: “Although today’s Section 101 uncertainties have arisen primarily in the biological and computer-implemented technologies, all fields are affected.” *Id.* at *7.

Yu also illustrated an oddity that arises from the patentable subject matter jurisprudence. For example, it is elementary that if the subject matter of a claim is novel, the subject matter of any claim depending therefrom is also novel. However, this is not the case with patentable subject matter. It seems under *Yu* that if claim 1 set forth above *lacked* the language “producing a resultant digital image from said first digital image enhanced with said second digital image,” the

claim *would* recite patentable subject matter, although novelty and non-obviousness would be a different matter. However, if a dependent claim recited that language, such a dependent claim would not recite patentable subject matter.

G) Conclusion

The Court's recent forays into patentable subject matter have caused considerable uncertainty that seems to be increasing as time goes on. Perhaps the strangest aspect of the Court's approach is to read into a plain statute language that isn't there as this is seemingly impermissible in connection with other civil statutes. In this regard, one wonders whether patent law is *sui generis*. There are also serious concerns about investment strategies in some industries resulting from *Alice*-induced uncertainty. Perhaps Jepson claims, which have been disfavored in U.S. patent practice for years, may be a way forward in some cases. Additionally, there are some fundamental questions: What is a law of nature (*Axle I-IV*)? What is an abstract idea (*Yu*)? It will be interesting to see if the Court grants certiorari in connection with *Axle III* to resolve some of these important questions.

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