

No. 20-891

**In The
Supreme Court of the United States**

AMERICAN AXLE & MANUFACTURING, INC.,

Petitioner,

v.

NEAPCO HOLDINGS LLC, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

**BRIEF OF BIOTECHNOLOGY INNOVATION
ORGANIZATION AND AUTM AS *AMICI
CURIAE* IN SUPPORT OF PETITIONER**

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INTEREST OF THE *AMICI CURIAE*¹

The Biotechnology Innovation Organization (“BIO”) is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,000 members, ranging from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. The majority of BIO’s members are small companies that have yet to bring products to market or attain profitability. Approximately 90% of BIO’s corporate members have annual revenues of under \$25 million. These members rely heavily on venture capital and other private investment.

BIO’s members rely on the patent system to structure their businesses and protect their inventions. Strong patents, and an efficient, predictable, and objective patent system, are critical to ensuring a steady stream of capital investment that supports the massive development costs of new biotechnology products and services. BIO’s members are concerned that, here, the Federal Circuit misapplied this Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2021), introducing great uncertainty into the law of Sections 101 and 112.

AUTM is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession

¹ Rule 37 statement: The parties were notified and consented to the filing of this brief more than 10 days before its filing. See Sup. Ct. R. 37.2(a). No party’s counsel authored any of this brief; amicus alone funded its preparation and submission. See Sup. Ct. R. 37.6.

through education, professional development, partnering, and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions, and teaching hospitals around the world, as well as numerous businesses and government organizations.

Amici BIO and AUTM submit this brief in the hope that it will assist the Court in the orderly evaluation of the law in this important area. The *Amici* have no direct stake in the result of this appeal and take no position on the ultimate validity of the patents at issue. This brief reflects the consensus view of the *Amici's* members, but not necessarily the view of any individual member.

SUMMARY OF THE ARGUMENT

The Federal Circuit's *American Axle* decision misapplied the Court's two-step test for subject matter eligibility by converting it into a one-step test of judicial intuition, and mischaracterized the claims as directed to nothing more than a natural law. The decision is especially troubling given the technology at issue. Although the technology itself is new, it comes from a field of industrial manufacturing where issues of patent eligibility have been considered settled for more than one hundred years. And while the standards for such inventions under Section 101 are undeniably no less rigorous than those applied to inventions in biotechnology or computer science, they do not raise the complex policy considerations that sometimes underlie decisions in other fields. That the Federal Circuit so easily contorted this Court's

precedent to find a judicial exception (i.e., Hooke’s law) here illustrates how malleable and subjective the Court’s two-step framework has become in the lower courts. Under the reasoning set forth in *American Axle*, literally any invention could be reduced to a natural law or abstract idea, and thus, held ineligible for patenting. Patent eligibility is intended to be a threshold inquiry, not a “barricade” to patenting. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1305 (Fed. Cir. 2020) (Moore, J., dissenting).

Moreover, the Federal Circuit did not just misapply the Court’s two-step framework. It conflated the inquiry for subject matter eligibility with the enablement requirement of 35 U.S.C. § 112. Section 101 should not be used to do the work that other sections are intended to do and better equipped to handle. Such a result only further obscures the law. The *Amici’s* members work in a field with well-developed case law defining the scope and application of Section 112, and they expend great effort during patent prosecution to meet the written description and enablement requirements of the statute. Accordingly, the *Amici’s* members are concerned about the apparent ease with which a written description or enablement analysis can be misapplied under the guise of a Section 101 analysis, as happened in this case. Indeed, the decision at issue here illustrates the principal concern expressed by the Court in *Mayo* that Section 101 would be subsumed by the other statutory requirements for patentability, except that it is now Section 101 that subsumes the other sections. Clarification of the law is needed to prevent its further

degradation and to ensure consistency in its application.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION INJECTS SIGNIFICANT UNCERTAINTY INTO SECTION 101

Rather than apply the Court's prescribed analytical framework for evaluating subject matter eligibility, the Federal Circuit's *American Axle* decision revised the test, transforming it from an already-difficult-to-apply two-step analysis into a subjective one-step determination dependent on the intuition of judges. And, as noted by Judge Moore's dissent, the Federal Circuit's panel majority did so through a series of compounding errors. First, at step one, the court improperly reduced the substance of the claim, i.e., what the claim is "directed to," to its simplest and most basic form, which it found to be Hooke's law. Second, by defining the scope of the invention as a natural law and nothing more at step one, the court collapsed *Mayo's* two steps into a single inquiry that could, without this Court's intervention, be used to characterize any invention an ineligible law of nature, natural phenomenon, or abstract idea, including as happened here, methods of manufacturing that have been considered patent eligible since the beginning of the U.S. patent system.

A. The Federal Circuit Failed to Apply This Court’s Historical Guidance Limiting the Judicial Exceptions to Section 101

The current two-part analytical framework used to assess the subject-matter eligibility of a claimed invention developed from the Supreme Court’s decisions in *Mayo* and *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014). The two-part test first requires a determination of whether the claim as a whole is “directed to” a judicially-created exception such as a law of nature, a natural phenomenon, or an abstract idea. If so, the court must then determine whether the claim as a whole integrates the exception in a way that provides for a practical application of the law, phenomenon, or idea. *Alice Corp.*, 573 U.S. at 221-222.

These *judicial exceptions* were created by the Court to distinguish them from the affirmative definition of patentable subject matter in 35 U.S.C. § 101. But as the Court developed its current framework for evaluating subject matter eligibility, it included a warning about the consequences of expanding the reach of the judicial exceptions:

[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law At some level, “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”

Alice Corp., 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 71).

And the Court has historically trodden carefully in this area. Nearly 100 years ago, the Court considered and upheld claims directed to a paper-making machine that used gravity to increase the speed of the paper stock. *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923). Then in 1981, the Court addressed computer-based inventions that included certain algorithms and formulas. In *Diamond v. Diehr*, the Court explained that “a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.” 450 U.S. 175, 187 (1981). There, the Court upheld claims that covered physical and chemical processes for molding synthetic rubber products, even though those claimed methods included the use of a specific mathematical formula to do so. *Id.* at 184. The Court distinguished *Gottschalk v. Benson*, 409 U.S. 63 (1972) and *Parker v. Flook*, 437 U.S. 584 (1978), which each claimed ways of calculating a number using mathematical formulas. *Diehr*, 460 U.S. at 185-188. Unlike *Diehr*’s method of curing rubber, determining a number by using an equation was not patentable. And nearly 170 years ago, in *O’Reilly v. Morse*, the Court considered Samuel Morse’s patent related to the telegraph, and distinguished his patent eligible claims from a claim expressly directed to the concept of “electromagnetism.” 56 U.S. (15 How.) 62 (1853). There, the Court upheld the seven of Morse’s claims, which disclosed particular methods and machinery for printing at a distance, but invalidated the eighth. *Id.* at 112-113. Morse’s eighth claim, unlike the first seven, broadly reserved the exclusive rights to electromagnetism for the purpose of printing characters at a

distance. *Id.* The Court rejected that claim not because it was lacking in description of how to print at a distance, but because it literally claimed all uses of electro-magnetism without regard for method or machinery. *Id.*

This Court’s warning, however, has been treated inconsistently in the lower courts. As courts seek to determine the “focus of the claimed advance,” *Trading Technologies International, Inc. v. IBG LLC*, 921 F.3d 1378, 1384 (Fed. Cir. 2019), they necessarily struggle to properly analyze the claims as a whole, *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015). Focusing on the “claimed advance” forces courts to scour the elements of a claim separately for eligible subject matter, often leading to the conclusion that a claim is directed to nothing more than whatever law of nature, natural phenomenon, or an abstract idea happens to be incorporated into the invention—a form of cognitive bias that the Court cautioned against when it set forth the test. *Alice Corp.*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 71). The fractured Federal Circuit decision here exemplifies the lack of consistency achieved by this approach.

B. The Federal Circuit’s “Directed To” Analysis Improperly Reduces Claim 22 to a Natural Law

The first step of this Court’s subject matter eligibility analysis requires a court to consider the elements of a claim *both individually and as a whole* to determine whether the claim is “directed to” a judicially-created exception such as a law of nature, a

natural phenomenon, or an abstract idea. Here, the Federal Circuit reduced claim 22 to a single element, to the exclusion of its remaining parts and practical application, and incorrectly found that the method of manufacturing a driveshaft having a liner that attenuated specific vibrations was “directed to” a natural law and nothing more.

Claims 1 and 22 of U.S. Patent 7,774,911 (“the ’911 Patent”) are directed to methods of manufacturing a car part. The limitations include multiple components that are combined in a manner that improves the physical properties of the resulting drive shaft, but they are neither directed to a natural law nor do they preempt one. The specification of the ’911 patent explains that the structure of the liner materials, the number of liner(s), the positioning of the liner(s) within the shaft, and the characteristics of the liner(s) may be modified in order to tune the damping properties. *See, e.g.*, ’911 patent at Col. 6, ln. 49 – Col. 8, ln. 2. There should be no dispute that these types of methods are the processes that Section 101 affirmatively identifies as patentable subject matter. *Diehr*, 450 U.S. at 182-184.²

The Federal Circuit reached a contrary conclusion only by stripping away these elements to determine that the claims do not actually recite an industrial method, but instead recite only a natural

² The claim as a whole still must satisfy the other provisions of the Patent Act—the claimed subject matter must be fully described and enabled (35 U.S.C. § 112), and cannot be an obvious combination of known elements (35 U.S.C. § 103). But the claimed subject matter is certainly a “process” as that term is used in the patent laws.

law—Hooke’s law—and nothing more. The court came to this conclusion even though Hooke’s law was not mentioned in the patent, and it was undisputed that one could determine appropriate mass and stiffness by trial and error. *Am. Axle*, 967 F.3d at 1294. Stated differently, the court invalidated claim 22 despite acknowledging that the claims contain concrete limitations and have sufficient support in the specification to meet the enablement requirement. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (Enablement is ... not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive.”).

The Federal Circuit’s conclusion is particularly concerning applied to claims, like these, that do not recite a natural law. Any method of manufacture, from chemical synthesis to computer engineering, can be reduced to a natural law or abstract principle, and found ineligible for patenting. As Judge Moore recognized in her dissent, “[a]ll physical methods must comply with, and apply, the laws of physics and the laws of thermodynamics.” *Am. Axle*, 967 F.3d at 1308. Chemical reactions, for example, rely on the law of conservation of energy, i.e., the first law of thermodynamics. Applying the reasoning of *American Axle*, methods of manufacturing chemical compounds are all now at risk of being held patent ineligible. That cannot be the purpose of a statute containing only the words “[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.” 35 U.S.C. § 101 (emphasis added).³

The Federal Circuit’s misapplication of *Mayo*’s two-step framework is even clearer if one considers the majority’s erroneous distinction between claim 1 and claim 22. The Federal Circuit held that claim 22 is directed to Hooke’s law and nothing more. But it said it could not find that claim 1, which it determined to be “more general,” i.e., **broader** than claim 22, is directed to a natural law. *Am. Axle*, 967 F.3d at 1300. That cannot be correct. It is illogical that a claim with fewer limitations and less specificity can be found eligible, while a claim with specific limitations that do not encompass a natural law is found ineligible. Nevertheless, the court held “[t]he mere fact that any embodiment practicing claim 1 necessarily involves usage of one or more natural laws is by itself *insufficient to conclude the claim is directed to such natural laws.*” *Id.* at 1300.

In 1853, the Court recognized that the judicial exceptions are important to prevent overly broad claiming a natural law and preempting an entire field. *See O’Reilly*, 56 U.S. at 113.⁴ Now, the Court’s judicial

³ Of course, as Section 101 recognizes, the inventor must still satisfy the other “conditions and requirements of [the Patent Act].” If the patent’s specification does not disclose and enable the full scope of a broad claim, the claim would be invalid under 35 U.S.C. § 112. And if the claim covered subject matter that was already present in the prior art, or obvious in view of the prior art, the claim would be invalid under 35 U.S.C. §§ 102 or 103.

⁴ It appears the Court was equally concerned with the breadth of the claim in view of what the patent’s specification disclosed—an issue addressed by 35 U.S.C. § 112, not § 101.

exception analysis has become so unmoored from its original purpose that it can be applied in a manner such that one claim of a patent is ineligible for patenting because it is directed to a natural law and nothing more, while an even broader claim in the same patent is not. *Am. Axle*, 967 F.3d at 1300.

C. The Federal Circuit’s Analysis of Step One Eviscerates Step Two

The Federal Circuit further compounded its error at step one when it effectively eliminated the need for step two. Under *Mayo*, if a court determines that a claim is in fact “directed to” one of the judicial exceptions, the court must then determine whether the claim as a whole integrates the exception in a way that provides for a practical application of the law, phenomenon, or idea. *Alice Corp.*, 134 S. Ct. at 2357.

Here, the Federal Circuit’s analysis in step one predetermined the outcome without regard for step two. That is, because the court determined that claim 22 invoked a natural law *and nothing more* at step one, there was nothing left for the court to do. *Am. Axle*, 967 F.3d 1285. But that result was predicated on the Federal Circuit’s stripped down reading of the claim. It did not consider, as this Court requires, the claim as a whole—an inquiry that must be performed at step two. The Federal Circuit, in effect, discounted the entirety of the claimed invention and sidestepped the second half of the Section 101 analysis by declaring its job done at step one, despite having found the claim directed to a judicial exception. *Contra Vanda Pharms. Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018) (“If the claims are *not*

directed to a patent ineligible concept at step one, we need not address step two of the inquiry.”) (emphasis added). That analysis, if permitted to stand, could result in any invention being found ineligible for patenting.

The Federal Circuit’s decision leaves patentees awash in a sea of uncertainty; how can one avoid a finding of ineligibility if a court can subjectively rewrite the claims of a patent until all that remains is a natural law even where the natural law is not apparent on the face of the claim? And how can a patentee expect that—in light of the Federal Circuit’s decision here—a claim that has been redefined as directed to the natural law underlying the technology will possibly survive step two of the analysis if the court prejudges at step one that there is nothing more to the claim? The result of such an analysis is outcome determinative and leaving the Federal Circuit’s decision in place will lead to even greater use of Section 101 as a tool to attack all varieties of inventions. This Court should clarify the proper analysis for subject matter eligibility test.

II. THE FEDERAL CIRCUIT CONFLATED THE REQUIREMENTS FOR SECTION 101 WITH THE REQUIREMENTS FOR SECTION 112

The Federal Circuit exacerbated the flaws in its Section 101 analysis by inserting a new requirement into Section 101 that claims be self-enabling or risk being held ineligible for patenting. Specifically, the court incorrectly found that because claim 22 lacks sufficiently specific steps or structure for achieving its

method, it must be directed to a natural law and nothing more. In doing so, the Federal Circuit failed to account for the interplay that is intended to exist between the claims in a patent and the written description that precedes them. Section 101 does not, contrary to the Federal Circuit’s decision, require that claims alone demonstrate possession of the invention as well as how to make and use it—such a rule would render the written description in a patent superfluous and the enablement requirement of Section 112 a dead letter.

A. The Federal Circuit’s Analysis Conflates the Exceptions of Section 101 with Enablement Requirement of Section 112

In *Mayo*, this Court recognized that the patent eligibility inquiry may overlap with inquiries into other sections of the Patent Act, such as Section 102. 566 U.S. 66. There, the Court warned that shifting the inquiry under Section 101 entirely to other sections “risks creating greater legal uncertainty, while assuming that those sections can do the work that they are not equipped to do.” *Id.* at 90. But the reverse is also true—shifting the inquiry to be performed under Section 112 entirely to Section 101 creates significant uncertainty, redundancy, and asks Section 101 to do something that it is not equipped to do. That is exactly the situation this case presents. The Federal Circuit improperly shifted the Section 112 inquiry into Section 101, demanding that it perform a function that Section 112 is fully capable of and much better suited to perform.

The Federal Circuit’s primary criticism of claim 22 was that it does not specify *how* liners are tuned. *See, e.g., Am. Axle*, 967 F.3d at 1298-99. That is, by definition, the role of Section 112. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (“[T]he purposes of the specification are to teach and enable those of skill in the art to make and use the invention”). As Judge Moore discusses in her dissent, under the Federal Circuit’s treatment of *Mayo*’s two-step analysis in *American Axle*, claims that are fully enabled by the specification will still be held ineligible because the claims themselves do not include those teachings. 967 F.3d at 1316. But whether a skilled artisan would know *how* to tune a liner “is a question of enablement, not eligibility.” *Id.* at 1317. Eligibility is a threshold inquiry, described as performing a gatekeeper function. *Alice Corp.*, 573 U.S. at 216-17; *Mayo*, 566 U.S. at 75; *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Section 101 should not supplant the other Sections, especially where, as here, it is being forced to perform a function for which it was not intended. The only result of doing so will be to confuse parties and lower courts, introduce greater unpredictability in the law, and create new disputes that did not previously exist. *See Alice*, 573 U.S. at 217 (“[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law.”).

B. The Enablement Requirement is Better Suited to Address the Federal Circuit’s Concerns and Should be Developed to Do So

The law of enablement and written description is well developed in the biotechnology industry. Section

112 disputes arise as frequently, if not more, than disputes under Sections 101, 102, and 103 in litigation involving biotechnology-related patents. Likewise, Section 112 is frequently drawn upon by the Patent Office during examination of applications for biotechnology-related patents. During prosecution, patent applicants in the field of biotechnology go to great lengths to demonstrate enablement across the full scope of the claims through in-depth descriptions and working examples that cannot be realistically included in the text of the claims. Later, in litigation, parties draw on fact witnesses and experts to dispute the sufficiency of those description and examples. This analysis is necessarily fact intensive, but one that accounts for the entirety of the disclosures in the specification and is aided by the knowledge of persons of ordinary skill in the art. *See, e.g., Hybritech*, 802 F.2d at 1384 (“[A] patent need not teach, and preferably omits, what is well known in the art.”); *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (“[A] patent need not teach, and preferably omits, what is well known in the art.” (quoting *Spectra–Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987))); *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999) (“[I]t makes no sense to encumber the specification of a patent with all the knowledge of the past concerning how to make and use the claimed invention.”). And because the biotechnology industry deals with Section 112 disputes so regularly, a great deal of effort has been put into developing the law and practice in this field of technology.

Here, the Federal Circuit divorced the claims from the rest of the specification and replaced the fact-bound examination of Section 112 with judicial intuition under the guise of Section 101. This result is concerning—Section 112 should not be circumvented with such ease. Even in the Background section of its decision, when describing the '911 patent, the Federal Circuit expresses concerns that are relevant to an analysis under Section 112, but not Section 101. For example, the court states: “Neither the claims nor the specification describes how to achieve such tuning. The specification also discloses a solitary example describing the structure of a tuned liner, but does not discuss the process by which that liner was tuned.” *Am. Axle*, 939 F.3d at 1360.

The breadth and depth of these teachings may be relevant to the written description and enablement requirements of Section 112, but they have no place in a summary judgment determination under Section 101. Even worse, the result reached here suggests that even a claim for which every skilled person would agree there is legally sufficient description in the specification could fall under Section 101, not because it claims a natural law, but because it failed to provide sufficient detail in the body of the claims for how its method is achieved. In effect, the decision here attempts to solve a problem that does not exist and does so by invoking language from one section, Section 112, to reach a conclusion under another, Section 101.

And, as mentioned above, the technology here is a mechanical method where the requirements for drafting claims and enabling inventions are generally not controversial, but where perhaps additional

development in the relevant area of Section 112 law would be beneficial. Ultimately, the Federal Circuit's decision in *American Axle* does damage to Section 101 and raises new questions about long-standing jurisprudence governing the relationship between a patent's technical teachings and the scope of its claims.

CONCLUSION

This case represents a departure from this Court's jurisprudence in the area of patent eligibility that will likely create greater uncertainty and increased litigation. Such additional uncertainty and litigation will bring significant further harm to the nation's vital innovation ecosystem already reeling from the current level of uncertainty surrounding the Court's eligibility jurisprudence. As such, this case presents the Court with an appropriate and timely opportunity to clarify its two-step framework set forth in *Mayo*, and resolve the confusion that continues to develop around Section 101. The Petition for Writ of Certiorari should be granted.

Respectfully submitted.

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