No. 20-891

IN THE

Supreme Court of the United States

AMERICAN AXLE & MANUFACTURING, INC.

Petitioner,

v.

NEAPCO HOLDINGS LLC, *et al.*,

Respondents.

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

BRIEF OF UNITED STATES SENATOR THOM TILLIS, HONORABLE PAUL R. MICHEL, AND HONORABLE DAVID J. KAPPOS, AS *AMICI CURIAE* IN SUPPORT OF PETITION BY AMERICAN AXLE & MANUFACTURING, INC. FOR A WRIT OF CERTIORARI DIRECTED TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amicus Curiae Hon. Thom Tillis is a U.S. Senator and the ranking member of the Senate Committee on the Judiciary, Subcommittee on Intellectual Property.

Amicus Curiae Hon. David J. Kappos is a former Director of the U.S. Patent and Trademark Office (hereafter "USPTO").

Amicus Curiae Hon. Paul R. Michel is a former Chief Judge of the U.S. Court of Appeals for the Federal Circuit.

For many years, the *amici* have served the American people, each in his respective capacity as a member of the legislative, executive (administrative), and judicial branch of the federal government. In faithfully carrying out their duties and fulfilling their obligations as public servants, they have occupied positions within the government that have been directly relevant to and impactful upon, one of this nation's vitally important roles as prescribed by the founding fathers under Art. I, Sec. 8, cl. 8 of the U. S. Constitution, namely, the patent system. The a*mici's* interest in the present controversy lies primarily in the important ramifications of the instant case from the legislative, administrative policy, and judicial perspective. *Amici* therefore respectfully urge this Court to be mindful of these tripartite government perspectives in considering this brief in support of granting American Axle Manufacturing, Inc.'s petition for certiorari.[1,2]

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1. No party or its counsel authored this brief in whole or in part; and no party or its counsel nor any persons other than amici or their counsel have contributed or will contribute money intended to fund the preparation or submission of this brief. Sup.Ct.R.37.6.

2. Counsel for the parties were provided timely notice of, and have consented to, the filing of this brief. Sup.Ct.R. 37.2(a).

SUMMARY OF ARGUMENT

In 35 U.S.C. § 101 ("Section 101") the exclusive statutory categories of patent-eligible, inventive (new and useful) subject matter are set forth in the specific statutory text, namely, processes (methods), machines, (articles of) manufacture, compositions of matter, and improvements thereof. These categories are constrained by three judicially created exceptions that disqualify an invention from being eligible for the granting of a patent thereon: "laws of nature", "natural products and phenomena", and "abstract ideas."

These exceptions to patent eligibility have long been recognized as boundary conditions that limit the breadth of U.S. patent law. But there are significant disagreements among jurists that have resulted in harmful errors of law regarding the contours of threshold testing of claimed inventions under Section 101 against those exceptions, one of which in particular, "abstract ideas," is undefined. With respect to Section 101 and its antecedents, this Court's guidance has been vital to promoting its interpretation. In 2012 and 2014, in *Mayo Collab. Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014), this Court set forth a framework for resolution of Section 101 issues.

However, the test (collectively, "*Alice/Mayo*"), intended to filter out inventions deemed not eligible for patenting, has created a chaotic state of affairs that, from the standpoint of patent policy, threatens serious negative jurisprudential and real-world consequences to America's technological leadership. The undue confusion and uncertainty in outcome-predictability in patent

cases has become so ubiquitous as to render the U.S. patent system unstable and unreliable at its core across a spectrum of industries including those upon which the United States depends for the good health and well-being of the citizenry and its national security. The confusion is clearly manifested in the present case by the Federal Circuit's deeply divided denial of American Axle's petition for *en banc* re-hearing of the divided panel decision invalidating American Axle's patent claims.

Amici herein take no position in this case on the merits of American Axle's invention. Rather, we believe that patent policy and the public interest require us to alert this Court to the harm being done to the patent system and America's innovation economy. *American Axle* is just one example of the judicial confusion causing consternation among the stakeholders throughout the innovation economy since *Alice/Mayo* was enunciated.

The inconsistent application of *Alice/Mayo* is creating an unpredictable and unstable U.S. patent system. Since *Mayo* and *Alice* imposed a framework, *Alice/Mayo* has been applied differently and questions of its extent, scope, and rigidity have been common, and are at issue in *American Axle*. Questions about whether the additional information required by *Alice/Mayo* is a question of law or fact have also come to the forefront.

The "real world" adverse consequences of Section 101 uncertainty impact the incentive to innovate and to invest in new technology frontiers including life-saving treatments and diagnostics, artificial intelligence, and quantum computing.

There is clear empirical evidence demonstrating the devastating effect Section 101 uncertainty has on the U.S. patent system with respect to the incentive to innovate and the willingness to invest in advancing the cutting edge technologies and science necessary for the U.S. to compete and lead in the twenty-first century.[3]

Patent applications for innovations, routinely denied issuance in the United States on Section 101 grounds are granted under the patent regimes in China and Europe.

Failure to address and clarify Section 101 patent eligibility threatens America's ability to maintain its leadership role in innovation, defense, and economic superiority on the global stage.

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3. *See, e.g.*, Mark F. Schultz, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, ALLIANCE OF U.S. STARTUPS AND INVENTORS FOR JOBS (July 2020), at pp. 1-8, available at https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5f2829980ddf0c536e7132a4/1596467617939/USIJ+Full+Report_Final_2020.pdf (detailed study and statistical data analysis providing extensive evidence demonstrating the detrimental impact on the incentive to innovate, and the willingness to invest in "breakthrough technologies that change the world," due to Section 101 uncertainty); Taylor, David O., *Patent Eligibility and Investment* (February 24, 2019). Cardozo Law Review, Forthcoming, SMU Dedman School of Law Legal Studies Research Paper No. 414, available at SSRN: https://ssrn.com/abstract=3340937 or http://dx.doi.org/10.2139/ssrn.3340937 (same).

ARGUMENT

I. THE DISPARATE AND INCONSISTENT APPLICATION OF THE COURT'S JURISPRUDENCE HAS CREATED AN UNPREDICTABLE AND UNSTABLE U.S. PATENT SYSTEM CONTRARY TO THE ART. I, SEC. 8, CL. 8 CONSTITUTIONAL IMPERATIVE TO INCENTIVIZE INNOVATION

> The need for strong protection of intellectual property rights is greater now than it was at the dawn of our republic. Our Forefathers and the Framers of the U.S. Constitution recognized the need to secure those rights in Article 1, Section 8, Clause 8. James Madison provides insight for its significance in the Federalist Papers No. 43. … The clause recognizes the need for: ***uniformity*** of the protection of IP rights, s***ecuring those rights*** for the individual rather than the state; and ***incentivizing innovation and creative aspirations***.[4]

But in stark contrast to the Founders' intent, misinterpretation of Section 101 of our patent laws has created an unintelligible hash. The instability and uncertainty in Section 101 patent eligibility undermines the very foundation of the patent system as originally constructed by the Constitution's framers. Uniformity

4. Rando, Robert J., *America's Need For Strong, Stable and Sound Intellectual Property Protection and Policies: Why It Really Matters*, The Federal Lawyer, June 2016, at 12. Available at: http://www. randolawfirm.com/uploads/3/4/2/1/3421962/ip_insight.pdf. ("Rando Fed. Lawyer Article")

in securing patent rights to individuals to incentivize innovation was and is the fundamental purpose of the provision. Granting certiorari in this case will enable the Court to resolve our current Section 101 confusion and provide the clarity necessary to restore that fundamental purpose.

A. Statements From A Wide Array Of Judges, Legislators, And Policy Experts Attest To The Confused State Of The Law

Following is a sample of well-informed and knowledgeable individuals across the federal government, including federal agencies and related entities, recognizing the consequences of the current disarray of 35 U.S.C. § 101:

1. Judges of the U.S. Court of Appeals for the Federal Circuit

The Honorable Richard Linn, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, petition for reh'g *en banc* denied, 809 F.3d 1282 (Fed. Cir. 2015), opined:

> But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

788 F.3d at 1381 (Linn, J., concurring).

The Honorable S. Jay Plager, in *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335 (Fed. Cir. 2018), stated:

> Today we are called upon to decide the fate of some inventor's efforts, whether for good or ill, on the basis of criteria that provide no insight into whether the invention is good or ill. Given the current state of the law regarding what inventions are patent eligible, and in light of our governing precedents, I concur in the carefully reasoned opinion by my colleagues in the majority, even though the state of the law is such as to give little confidence that the outcome is necessarily correct. The law, . . . renders it near impossible to know with any certainty whether the invention is or is not patent eligible. Accordingly, I also respectfully dissent from our court's continued application of this incoherent body of doctrine.

896 F.3d at 1348 (Plager, J., concurring-in-part and dissenting-in-part).

The Honorable Alan D. Lourie, in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 915 F.3d 743, petition for reh'g *en banc* denied, 927 F.3d 1333 (Fed. Cir. 2019), declared:

> If I could write on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, *e.g.*, E=mc2, F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural laws. The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable. But we do not

> write here on a clean slate; we are bound by Supreme Court precedent. . . . Accordingly, as long as the Court's precedent stands, the only possible solution lies in the pens of claim drafters or legislators. We are neither.

927 F.3d at 1335-36 (Lourie, J., concurring).

The Honorable Todd M. Hughes, in *Athena*, observed:

> The multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is. . . .
>
> I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life-saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications. Such an explication might come from the Supreme Court. Or it might come from Congress, with its distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law.

927 F.3d at 1337 (Hughes, J., concurring).

The Honorable Paul R. Michel (ret.), in Congressional Testimony (2019), stated:

> It is important for me, as a retired judge, to acknowledge that the courts alone created this problem. In my view, recent cases are unclear, inconsistent with one another and confusing. I myself cannot reconcile the cases. That applies equally to Supreme Court and Federal Circuit cases. Nor can I predict outcomes in individual cases with any confidence since the law keeps changing year after year. If I, as a judge with 22 years of experience deciding patent cases on the Federal Circuit's bench, cannot predict outcomes based on case law, how can we expect patent examiners, trial judges, inventors and investors to do so?

The State Of Patent Eligibility In America: Hearing Before the United States Senate Subcomm. on Intellectual Property, Comm. on the Judiciary, 116th Cong. (2019) (hereafter "I.P. Subcomm., 2019 Patent Eligibility Hr'g") (June 4, 2019 Hearing Transcript of Oral Testimony of Judge Paul R. Michel (Ret.) United States Court of Appeals for the Federal Circuit (hereafter "*Michel Testimony*, Hr'g Tr."), at Hr'g Tr. p. 352).

2. Members of the U.S. Congress and the Congressional Research Service

"Why would anyone in their right mind risk millions if not billions of dollars to develop a product when they have no idea if they're eligible for protection? From a business perspective, it simply isn't worth the risk for many endeavors." – *Senator Thom Tillis.*

"Today, U.S. patent law discourages innovation in some of the most critical areas of technology, including artificial intelligence, medical diagnostics, and personalized medicine." – *Senator Chris Coons.*

"Upgrading the patent eligibility test is critical if we want American innovation to continue to lead worldwide." – *Representative Doug Collins.*

"In my home state of Ohio, leaders in the fields of biologics research and diagnostics will deliver the cures of tomorrow. This is only possible if we can protect those innovations with the patent protection that rewards the risks and investment necessary to discover the next great idea." – *Representative Steve Stivers.*

"Our current patent eligibility law truly is a mess. The Supreme Court, Federal Circuit, district courts, and USPTO are all spinning their wheels on decisions that are irreconcilable, incoherent, and against our national interest. . . . [U]nder current U.S. law governing patent eligibility, it is easier to secure patent protection for critical life sciences and information technology inventions in the People's Republic of China and in Europe, than in the U.S." – *Congressional Research Service* (2019).

3. U.S. Solicitor General

"The Court's recent Section 101 decisions have fostered substantial uncertainty." – *U.S. Solicitor General, Noel J. Francisco* (2019).

4. U.S. Chamber of Commerce

"There continues to be considerable uncertainty for innovators and the legal community, as well as an overly cautious and restrictive approach to determining eligibility for patentable subject matter in areas such as biotech, business methods, and computer-implemented inventions. This seriously undermines the long-standing world-class innovation environment and threatens the nation's global competitiveness." – *U.S. Chamber of Commerce* (2020).

5. U. S . Patent and Trademark Office

Honorable David Kappos, Former Director of the USPTO, in Congressional Testimony (2019), stated:

> Our current patent eligibility law truly is a mess. The Supreme Court, Federal Circuit, district courts, and USPTO are all spinning their wheels on decisions that are irreconcilable, incoherent, and against our national interest. . . . [U]nder current U.S. law governing patent eligibility, it is easier to secure patent protection for critical life sciences and information technology inventions in the People's Republic of China and in Europe, than in the U.S. I.P. Subcomm., 2019 Patent Eligibility Hr'g (June 4, 2019 Hearing Transcript of Oral Testimony of Honorable David Kappos, Former Director of the USPTO (hereafter "*Kappos Testimony*, Hr'g Tr."), at Hr'g Tr. pp. 366-367).

The USPTO, in a sensible effort to guide the work of its 8000 patent examiners in light of the present confusion in the courts, issued a series of administrative patent eligibility guidelines (PEG) for applying Section 101 in the examination of patent applications. The most recent set of guidelines begins by stating that "all USPTO personnel are expected to follow the [PEG]." The PEG has been disavowed by the Federal Circuit, leaving the agency with having to grant thousands of patents with claims to subject matter likely to be adjudged inconsistent with judicial case law, contrary to the Federal Circuit's interpretation of this Court's holdings. As recently as February 8, 2021, a Federal Circuit panel, in *cxLoyalty, Inc. v. Maritz Holdings, Inc.*, 986 F.3d 1367 (Fed. Cir. 2021), denigrated the USPTO guidelines. For example, the court stated:

> Throughout its Final Written Decision [on cxLoyalty's petition for post-patent-grant review under the America Invents Act of Maritz Holdings' business method patent], the [PTAB] repeatedly referred to the [USPTO's] 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019). We note that this guidance "is not, itself, the law of patent eligibility, does not carry the force of law, and is not binding on our patent eligibility analysis" (internal citation omitted). And to the extent the guidance "contradicts or does not fully accord with our caselaw, it is our caselaw, and the Supreme Court precedent it is based upon, that must control." (same).

cxLoyalty, Inc., 986 F.3d n.1.

It appears the USPTO itself, the agency tasked with examining patent applications and reviewing claims in issued patents, is, despite its own guidelines, deemed unqualified to determine what is or is not patent eligible under Section 101. If that is true, then the question remains: How can tribunals, and innovators and businesses allocating scarce funds to develop products and services from innovations, do so under this Court's almost 10-year-old *Alice/Mayo* test without further intervention by this Court?

6. National Security Commission on Artificial Intelligence

In a Draft Final Report of the National Security Commission on Artificial Intelligence (expected publication in final form on March 1, 2021) ("Dft. Fin. Rpt. NSCAI")[5], the Commission identifies "legal uncertainties created by current U.S. patent eligibility and patentability doctrine" as contributing to the United States failure to "[r]ecognize the importance of IP ***in securing its own national security, economic interests, and technology competitiveness***." *Id.* at p. 95 & n. 317 (emphasis added). While at the same time, "China is both leveraging and exploiting intellectual property (IP) policies as a critical tool within its national strategies for emerging technologies." *Id.* at p. 95.

The Commission finds further that "[C]hina is poised to 'fill the void' left by weakened U.S. IP protections, particularly for patents, as the U.S. has lost its

5. The Dft. Fin. Rpt. NSCAI is available at: https://www.nscai.gov/wp-content/uploads/2021/01/NSCAI-Draft-Final-Report-1.19.21.pdf

'comparative advantage in ***securing stable and effective property rights*** in new technological innovation.'" *Id.* at p. 95 & nn. 319 & 320 (emphasis added).

The Commission also found that the U.S. courts have "severely restricted" U.S. patent law protection on "computer-implemented and biotech-related inventions" and that "[c]ritical AI and biotech related inventions have been denied protection" over the past ten years. *Id.* at p. 95 & nn. 321 & 322. "Critically, China is now frequently identified as the current leader in domestic [U.S.] patent application filings for AI inventions." *Id.* at p. 96 & n. 327.

The Commission concluded that "[c]urrently, the U.S. government ***does not efficiently utilize IP policy as a tool to support national strategies for national security, economic interests, and technology competitiveness*** in AI and emerging technologies." *Id.* at p. 98 (emphasis added).

II. SECTION 101 UNCERTAINTY IS IMPACTING INCENTIVES TO INNOVATE AND INVEST IN CRITICAL TECHNOLOGIES INCLUDING HEALTHCARE, MEDICAL DIAGNOSTICS AND TREATMENTS, QUANTUM COMPUTING, ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING, AND BIOTECHNOLOGY

A. Rulings That Wrongly Curtail Patent Eligibility Destroy Innovator and Investor Confidence In The U.S. Patent System's Ability To Promote Innovation And U.S. Technological Leadership

Due to Section 101's constriction of patent-eligible subject matter, our key economic competitor – China – as

well as Europe, are, and are perceived by entrepreneurs and investors as being more hospitable and reliable concerning patent eligibility and hence more stable in predictability of outcomes of patent enforcement and licensing. These other major patent systems foster a sense among innovators that their technologies can be better protected by foreign patents than by U.S. patents. The inevitable effect of this perception is to encourage increased investment of risk capital in foreign locales to the detriment of innovation and its benefits to markets and employment in America.

When the worth of U.S. patents is viewed with skepticism by developers, implementers, licensors, and licensees due to the uncertainty of patents as industrial property, their attractiveness as assets and vehicles for technology transfer in the U.S. is adversely impacted. This disincentivizes U.S. business investment across the board – established, new, and developing – such as information technology including artificial intelligence, software generally, medical devices, medical diagnostics, therapeutics, and immunology, all of which play important roles in jobs growth, economic leadership, innovation leadership, healthcare outcomes, military superiority, and safeguarding the United States against national security vulnerabilities writ large. All of these concerns are broadly crushing to America's technological edge, calling for review of the case law that has led to our present predicament.

B. Preserving America's Competitiveness In The "Useful Arts" Requires Clear Direction That Preserves Patent Eligibility For Protection-Worthy Inventions.

For more than 100 years, before and after the 1952 Patent Act, and until the confusion created by the *Mayo* and *Alice* decisions, this Court has provided vital, stable guidance to promote the "progress of useful arts," in the words of our Constitution. In the late 1900s and the first decade of the twenty-first century, the proliferation of new technologies and an increasing number of patent applications and patents brought an increased focus on patent eligibility. In the process, the U.S. court system has grappled with "critical and emerging technologies" such as "precision medicine, quantum computing, artificial intelligence, 5G, and the internet of things." Letter of Hon. Thom Tillis to President Joseph R. Biden, February 16, 2021, at p. 2 (hereafter, "*Tillis Letter*"); *see also Kappos Testimony*, Hr'g Tr. at pp. 367-368. This Court's *Alice/Mayo* test has unfortunately proven to be an unsettling facet of that grappling.

As this Court and other tribunals have observed, *especially* with respect to patents and patent law, "clarity is essential to promote progress." *Bilski v. Kappos*, 561 U.S. 593, 655 (2010) (Stevens, J., concurring) (internal citation omitted).[6] As articulated in the *Tillis Letter*, this country needs "clear, predictable, and enforceable" patent rights. *Id.* at p. 1.

6. *Also* 561 U.S. at 613 (Stevens, J., concurring) ("In the area of patents, it is especially important that the law remain stable and clear").

Amici's concern is that Americans creating technological advances who must follow this Court's directives regarding patent eligibility are unable to do so because of the current confusion over the application of *Alice/Mayo*.[7] This is apparent at the USPTO (s*ee Kappos Testimony*, Hr'g Tr. at pp. 368-369) and district court levels (*id.*), tribunals of first instance, but particularly worrisome because there is also rampant confusion at the Federal Circuit. As Senator Tillis explained, Americans deserve a patent system that provides reliable incentives for innovators and inventors of America's "cutting edge technologies, therapeutics, and treatments that literally change the world for the better and save countless millions of lives." *Tillis Letter* at p. 1.

In short, in the absence of action by this Court providing much-needed guidance, our nation's most vital emerging technologies face death. *See Tillis Letter.*

C. The Stability And Vitality Of U.S. Patent Law Depends On The Reasonable, Consistent, And Settled Judicial Application Of Its Statutory Framework

Long before *Mayo* and *Alice*, in 1854, the Court laid down the principles underlying patent eligibility (as a prerequisite to patentability) in *O'Reilly v. Morse*, 56 U.S. 62 (1854) ("*O'Reilly*"), which excluded from eligibility "laws of nature." In the following 150 years, Section 101 (and its predecessors), with rulings of this Court,

7. "[T]he uncertainty surrounding the law of eligibility is the number one problem in our patent system today." *Michel Testimony*, Hr'g Tr. at p. 17.

operated hand in hand to provide stable foundational underpinnings for America's patent system. The USPTO (including examiners, tribunals, "stakeholder" applicants, and patent preparers), district courts, courts of appeals, and most importantly their stakeholders, have likewise relied on this Court to guide them in America's innovators maintaining clear and encompassing rules governing patent eligibility.

Concerns about proliferation of unworthy patents and reexamination of standards of eligibility led this Court to provide guidance in *Alice* and *Mayo*. At the same time, there was an increased focus on patent eligibility in new technologies, and patent claims at the intersection of several technologies implicating natural laws. In an effort to bring order to the process, this Court, in *Mayo* and *Alice*, established an analytical framework for assessing subject matter eligibility under Section 101.

But the lower courts and other tribunals have found *Alice/Mayo* impossible to apply consistently and reliably when determining patent eligibility of inventions touching on laws of nature, natural phenomena, and abstract ideas, and this Court has not taken up the issue since to continue its role in stabilizing the application of Section 101.

The confusion and unpredictability in applying *Alice/Mayo* is having widespread commercial ramifications at all levels: for innovators, those who fund innovators, those who turn innovations into products and services creating jobs and opportunity for Americans, and patients and consumers who benefit from those products and services, all to the great detriment of commerce and its motive force; innovation and competition.

D. The Proliferation Of Inconsistent And Deeply Divided Holdings Regarding Section 101 Eligibility Starkly Reflect Courts' Unsuccessful Struggles With The *Alice*/*Mayo* Test In Real Life Controversies

Between 1982 and 2012, Federal Circuit opinions (not cases) citing Section 101 averaged about 4-5 per year. But from 2011 to the present – after *Mayo* and *Alice* were handed down – that statistic skyrocketed to about 24 per year. At the same time, the proportion of Section 101 cases including separate opinions – concurrences and dissents – has also proliferated. The number of district court opinions devoted to Section 101 analysis – with the increasing likelihood of reversal on appeal – has mushroomed. The number of patent applications subject to review on appeal under Section 101 has also climbed dramatically. A sampling of decisions illustrates the confusion at the root of these statistics:

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, petition for reh'g *en banc* denied, 809 F.3d 1282 (Fed. Cir. 2015), provides an apt example of how chaotic the situation has become. In *Ariosa* the district court held under *Alice/Mayo* that a diagnostic method for detecting paternal nucleic acids, which "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care" (788 F.3d at 1379) was ineligible subject matter. The Federal Circuit affirmed. Judge Linn, concurred because the holding was compelled by *Mayo* and *Alice*, stating that this Court's "blanket dismissal of conventional post-solution steps leaves no room to distinguish …." 788 F.3d at 1380 (Linn, J., concurring). In dissent from denial of the petition for

rehearing *en banc* (while several members of the court concluded that they were bound by *Alice/Mayo)*, Judge Newman interpreted the caselaw very differently, finding the *Sequenom* facts distinguishable. 809 F.3d at 1293.

The claims in *Berkheimer v. HP Inc.*, 881 F.3d 1360, petition for reh'g *en banc denied*, 890 F.3d 1369 (Fed. Cir. 2018), covered a method for digitally processing and archiving files, where the district judge had ruled against eligibility on summary judgment. The claims in *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, petition for reh'g *en banc* denied, 890 F.3d 1354 (Fed. Cir. 2018) were for a system and method for designing, creating, and importing data into a viewable form, where the district court had ruled the claims ineligible at the pleadings stage.

On appeal, the cases and opinions raised the issue of whether the Section 101 issue raises factual questions. Numerous of the Federal Circuit judges perceived the holdings to stand for the "unremarkable proposition" that the second step of the *Alice/Mayo* test is a question of fact (890 F.3d at 1370 (Moore, Dyk, O'Malley, Taranto, and Stoll, J.J., concurring in denial of petition)), or that intervention by this Court was warranted (890 F.3d at 1374 (Lourie and Newman, J.J., concurring in denial of petition)). Judge Reyna considered the question to be of "exceptional importance" and divorces the second step of *Alice/Mayo* from the claims. 890 F.3d at 1377 (dissenting from denial of petition). He viewed this "profound change" (*id.*) to the analysis as exacerbating the expanding number of Section 101 cases addressed before necessary fact finding on summary judgement and at the USPTO (*id.*, n.3). These issues logically implicate and disrupt decisions at district court pleadings stage under Rule 12.

In *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 915 F.3d 743, petition for reh'g *en banc* denied, 927 F.3d 1333 (Fed. Cir. 2019), the court held the claims for a diagnostic technique ineligible under *Alice/Mayo*. On petition for rehearing *en banc*, eight separate opinions were filed. The four concurring opinions stated that the authors felt bound to the conclusion by the test and explicitly requested relief by this Court. 927 F.3d at 1335-52. The four dissents, spanning more than 20 pages, interpreted the *Athena* facts to be distinguishable from *Alice* which did not compel the instant result, and believed the test was simply too rigid to be appropriately applied. 927 F.3d at 1352-73. Judge Moore reflected, "Our fervor for clarity and consistency has resulted in a per se rule that excludes all diagnostics from eligibility. I do not agree with my colleagues that *Mayo* requires that all of these claims in all of these cases be held ineligible. But that is where we are." 927 F.3d 1354.

All of the foregoing hash has led to *American Axle v. Neapco Holdings LLC*, 939 F.3d 1355 amended in 967 F.3d 1285 (2019), petition for reh'g *en banc* denied, 966 F.3d 1347 (Fed. Cir. 2020). In *American Axle*, the court concluded under *Mayo* and *Alice* that since the method claims (related to dampening vibrations in ***motor vehicle drive train shafts***) invoked a natural law, Hooke's Law, and nothing more, they were patent ineligible under *Alice/Mayo*. The dissent emphatically disagreed.

On petition for rehearing *en banc*, three dissenting opinions asserted that the analysis did not comport with precedent, the holding had ignored the fact issue, there was insufficient evidence that there was "nothing more" than Hooke's Law in the claim, the opinion had developed

a new test and/or the decision created a heightened enablement provision, *inter alia*. 966 F.3d at 1357-67.

The law on patent eligibility has become plagued by disparate and conflicting applications of *Alice/Mayo*, and as demonstrated above, Federal Circuit opinions since have identified numerous situations that cannot be logically resolved, all of which deserve to be addressed. These concerns are simply crushing American innovation and technological leadership.

E. Respectfully, This Court Should Ameliorate The Chaos Which, If Allowed To Continue Longer, Will Further Undermine The Constitutional Underpinnings Of The Patent Law, "To Promote The Progress Of … [The] Useful Arts"

The Federal Circuit disagreements reflect serious flaws in the *Alice/Mayo* test, creating massive disincentive to innovation when our country needs it most, and represent an enormous waste of resources. As important as they are to the individual cases, the judges' internecine differences of opinion are illustrative of the widespread confusion caused by *Alice/Mayo*. Additionally illustrative are the number of split opinions in the court, not only in the original panel opinions, but also in the denials of petitions for rehearing en banc. In addition to *American Axle* with three dissenting opinions, *Sequenom*, *Aatrix*, *Berkheimer*, and *Athena*, citing *Alice* and/or *Mayo*, each had multiple opinions. This extent of disagreement on one legal issue reflects fundamental and incompatible differences on the critical, foundational *Alice/Mayo* analysis. The current state of affairs is untenable.

A decade has passed since this Court provided its analysis for Section 101 patent eligibility. It is clear now that those affected – in other words, all those in America's sophisticated technology fields, the USPTO, and the courts – have been unable to apply *Alice/Mayo* to resolve the questions that have arisen. This reality is reflected in the patent applications that have been rejected, the patents that have been invalidated, the courts of first instance that have been overturned on hotly disputed appeals, the many confused decisions of the Federal Circuit and accompanying array of dissenting and concurring opinions.

This Court has repeatedly refused to revisit Section 101 jurisprudence. While important innovations go unprotected, the Court has declined granting petitions for certiorari in dozens of cases that presented the opportunity to clarify patent eligibility law. The *American Axle* case should not suffer the same fate; it is an ideal vehicle for this Court to clarify the law.

Judge Newman articulated the problem well in her dissent in the *American Axle* petition for rehearing denial:

> The court's rulings on patent eligibility have become so random as to have a serious effect on the innovation incentive of the patent system in all fields of technology. The victim is not only the instant inventor of a now-copied improvement in driveshafts for automotive vehicles; the victims are the ***national interest in an innovative industrial economy***, and the ***public interest in the fruits of technological advance***.

966 F.3d at 1357 (emphasis added).

Amici also agree with Judge Reyna's observation (in *Berkheimer*, but which is equally applicable to many other cases), that the "consequences of this decision are staggering." 890 F.3d at 1380. Without renewed guidance from this Court, *Alice/Mayo* will continue to stifle American ingenuity.

Congress has held hearings in which dozens of witnesses have called the current system untenable. It is time for this Court to step in and advance the analysis.

CONCLUSION

Amici, representing the perspectives of the three branches of government, submit this brief supporting the grant of petitioner's writ of certiorari, all with an abiding passion for balancing the needs of our innovation economy, all convinced that section 101 is gravely damaging our country's ability to succeed in the race for global innovation leadership, and all convinced that the solution to the dilemma lies with the Court taking up the *American Axle* case.

This Court should begin its analysis of Section 101 and its jurisprudence with, and find its guidance in, the fundamental principle animating the Framers of Article I, Section 8, Clause 8 of the Constitution, by asking a basic question: whether the result or consequence of the Court's enterprise will "promote the progress of the sciences and useful arts" and, if so, whether it is directed to the purpose of maintaining the incentive to innovate, will achieve uniformity in its application and implementation and will remain in fidelity with securing for the individual intellectual property rights as unequivocally declared by

James Madison in Federalist Papers Number 43, as the self-evident purpose of the Patent and Copyright Clause.[8]

For the reasons and authorities set forth above, this Court should grant certiorari in order to resolve an ongoing and pervasive issue of exceptional importance to U.S. patent law and policy, and to all stakeholders in the U.S. patent system in view of its domestic and international real-world implications for U.S. leadership in innovation. In doing so, the Court at the merits stage could clarify its precedents for the benefit of lower courts and other tribunals, innovators, and those funding products and services development, who for years have been seeking guidance from the Court on how to test inventions for patent eligibility under Section 101.

Respectfully submitted,

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8. Rando Fed. Lawyer Article at 15.