RESPONSE FROM THE ASSOCIATION OF AMICUS COUNSEL TO THE PTO's NOTICE IN 86 FED. REG. 36257-60 ("REQUEST FOR INFORMATION") – PTO -P-2021-0032

October 15, 2021

The Association of Amicus Counsel ("AAC") is an independent advocacy group of attorneys having diverse affiliations and law practices. They represent, *inter alia,* litigants, stakeholders in the patent system, and others across a spectrum of technologies, investment, and innovation, including not only traditional manufacturing enterprises, but also in quantum computing, artificial intelligence, precision medicine, diagnostic methods, pharmacology, and other computer-related activities.

By training, scholarship, experience, and discernment in their respective areas of the law, coupled with niche expertise in other disciplines pertinent to specific cases, members of the AAC possess the requisite abilities in preparing and submitting responses to requests for information by government agencies including the U. S. Patent and Trademark Office ("PTO" or "Agency"), as well as briefs on behalf of *amici* that merit the attention of courts and other tribunals as being helpful in avoiding errors of fact or law when deliberating and deciding cases of contention whose outcomes can impact intellectual property ("IP") jurisprudence. Submissions of the AAC seek to accomplish their purpose by calling attention to pertinent matters, including legitimate viewpoints and concerns, in addition to those previously recognized or likely to be addressed by decision-makers in tribunals, in government agencies such as the PTO, or by other responders to the present request.

In sum, the AAC's core mission is to advance the science of jurisprudence by responding to government requests for comment on legal matters, and through amicus briefs, for the purpose of advocating, promoting, and assisting in the development of the law in the time-

honored tradition of *amici agenciae et curiae.* Toward that end, the AAC, through its members, herewith submits its response to the PTO's present request for public comment in the hope that it will assist the Agency in its study of, and forthcoming report to the IP Subcommittee of the Senate Judiciary Committee on, the state of patent-eligibility jurisprudence and its impact on investment in innovation in the United States.

TOPICS FOR PUBLIC COMMENT

Section I – Observations and Experiences

Patent practitioners and others who dwell and toil in the realms of science, technology, engineering, and intellectual-property law have understood the term "technological invention" (hereinafter "invention") to mean the creative act or result of converting one or more ideas, theories, or discoveries, through ingenuity, experimentation, or luck, into things that are new and practicably useful in the real world. As so defined, an act of 'invention' can be motivated by a need or wish to improve the human condition in some tangible way, often coupled with a pecuniary interest in the venture.

In 1787, Article. I, Sec. 8, cl. 8 of the U.S. Constitution gave Congress the power to create a national patent system – a task embarked upon with legislation beginning in 1790 -- which is today largely embodied in title 35 of the United States Code ("the Patent Act"). Through it, inventors or their assigns may be granted exclusionary rights to their inventions by the issuance of letters patent by the government on applications vetted by examiners at the PTO in a federal administrative law process. Such patent rights are generally enforceable in the courts and in the U.S. International Trade Commission. The Founding Fathers' fundamental purpose in establishing our country's patent system – in and of itself a brilliant legislative invention -- was to add "the fuel of interest to the fire of genius" by incentivizing innovations that drive growth and change when the circumstances are ripe, thereby manifesting Congress's power to "promote the Progress of . . . useful Arts".

Within the Patent Act there resides a relatively short section, 35 U.S.C. 101 ("Section 101") titled "Inventions Patentable". It is a statutory gateway on the road to patenting inventions that sets forth five broad, distinct categories of inventions that qualify to be considered for possible patenting if they are "new and useful". Then, if the subsequent "conditions and requirements of [the Act]" are met, the PTO may properly issue a patent. But what are those "conditions and requirements"? And what does 'qualified to be considered for possible patenting' mean?

Patentability and Allowability

In answer to the first question, "the conditions … of the [Act]" signal an assessment of the intrinsic merits of the invention in order to decide its **patentability**. This is done by comparing a claim defining the invention in a patent or patent application against the standards of novelty and non-obviousness set forth respectively in Section 102 ("Conditions For Patentability: Novelty And Loss Of Right To Patent") and Section 103 ("Conditions For Patentability: Non-Obvious Subject Matter"). The "… requirements of the [Act]" pertain to the patent document itself against which the decision-maker applies the content, description, enablement, and claim-drafting criteria set forth in Section 111 ("Application") and Section 112 ("Specification") whereby the **allowability** of the patent document is determined.

If an invention that qualifies for consideration for possible patenting is presented as a claim in a patent application which fails to meet or comply with the aforesaid conditions and requirements, then the claim would be properly rejected. If such a claim were to somehow infiltrate an issued patent, then the claim ought to be judged invalid.

Patent Eligibility

In answer to the second question, the phrase 'qualified to be considered for possible patenting' means **patent-*eligible.*** In other words,

a patent-eligible invention is one that is suitable for substantive examination in a patent application, or adjudication of patentability following judicial claim construction, if any, in a contested proceeding. The term in that context doesn't appear in the Patent Act, but its meaning and usage are central to the present submission of the AAC's observations and experiences. Only inventions within the five textual categories of Section 101 that are new (not pre-existing) and useful (for achieving something demonstrably worthwhile or beneficial) can be patent-eligible. Then, if the subsequent "conditions and requirements" in Sections 102, 103, 111, 112, etc. are satisfied, the patent-eligible invention is patentable and the claim in a patent application defining it is allowable. Whether in the patenting process in the PTO or in claim validity determinations in contested proceedings, 'eligibility', 'patentability', and 'allowability' are distinct terms and none of them was ever meant to include the other two.

If a claim presented in a patent application defines subject matter which is not patent eligible because it does not qualify for possible patenting, then it should be rejected on that basis. In such cases the downstream conditions and requirements for patentability and allowability are irrelevant. Bells and whistles in the rest of the claim cannot redeem it. The claim should be amended, deleted, or or replaced. End of story. If such a claim were to somehow find its way into an issued patent, then the claim would properly be judged invalid.

Exceptions to Section 101 Patent Eligibility

Filtered from the five broadly-stated categories of patent-eligible subjects matter in Section 101 are several atextual (unstated, judicially implicit) types of exceptions that a priori cannot legitimately be patented, and indeed, are ineligible to even be considered for patenting. Three of these types of exceptions are: (i) laws of nature, (ii) natural products *in vivo*, and (iii) natural phenomena. As manifestations of the world of nature, they are not "new" because their existence predates any act of invention or discovery of them. In other words, one may not properly be granted a patent on something that person did not invent because it already

existed independently of human activity. Furthermore, in addition to being outside the universe of everything new under the sun that is made by man, the types of exceptions (i) to (iii) in and of themselves (except perhaps herbal medicines *au naturel*) have no practicable "use" in any "art" within the Art. I. Sec. 8. cl. 8 meaning of "useful Arts".

A fourth type of exception are (iv) so-called 'abstract ideas', for example, a computational algorithm that can be reduced to practice entirely in one's mind, and expressed on paper, on a blackboard, or on a computer. The term has been exemplified (as in the previous sentence) and discussed ad infinitum in the case law, but its contours and boundary conditions remain ill-defined in U.S. Supreme Court patent jurisprudence where it has become a controversial focus of attention and concern among members of the patent bar, patent applicants and the PTO, litigants and tribunals, and the commentariat. Among the four categories of exceptions, abstract ideas are outliers in that some of them may be new, beneficially useful, and can be called into existence through acts of invention. Because of this, some commentators question the across-the-board exclusion of abstract ideas from patent-eligibility. Instead, they have suggested that those which are "new under the sun", "useful", and made by man ought to be included among the categories of eligible inventions the patent system is meant to protect, and as such should be evaluated under the aforementioned conditions-subsequent for patentability. That said, q*uaere* whether a patent-eligible invention claimed in a so-called 'paper patent' is and remains an abstract idea unless and until the invention is actually reduced to practice.

A claim is patent-ineligible when, viewed as a whole by taking all recited limitations into account, it *monopolizes for all purposes* (i.e., preempts, appropriates, is directed to, reads upon, or covers) any of the exceptions (i) to (iv). In other words, the exception itself becomes the claimed invention. Such claims are rare, and when they pop up they are often easy to spot. On the other hand, a claim whose subject matter satisfies the stated requisites of Section 101 and which merely recites or implicates an exception as one of the claim's constituent elements *without*

monopolizing it for all purposes should not be deemed ipso facto patent-ineligible. In the universe of valid patents, such claims are ubiquitous.

The Mayo/Alice Test

Over the years the juxtaposition of the terms 'patentability' and 'eligibility' in the case law has become a puzzle many tribunals have sought to unravel, leading to constant widespread dissensus as to the relationship between the two terms. Beginning almost a decade ago, the Supreme Court sought to address the puzzle when it decided *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).

Mayo involved a patent on a method for monitoring the dosage level of a drug used to treat autoimmune disease. *Alice* involved a patent on a computer-implemented method for mitigating settlement risk in financial transactions. The Supreme Court judged both patents invalid for being "directed to", i.e., monopolizing, ideas that were abstract and hence patent-ineligible. In reaching its decisions, the Court devised a precedent-setting, two-part test for patent-eligibility (the "*Mayo/Alice* test") with the noble intention of promoting consistently correct and predictable decision-making on patent-eligibility questions. But alas, history shows that the *Mayo/Alice* test has fallen short of its intended purpose.

As conjured and formulated by the Court, the *Mayo/Alice* test begins with an inquiry at the get-go as to whether the subject matter of the claim as written falls within one of Section 101's textual categories of inventions. If it does, then part 1 of the test is applied to determine whether the claim recites or implicates an exception without monopolizing it. If the answer is yes, then the test is complete, the claim is patent-eligible, Section 101 has served its purpose, and the decision-maker can move on to determine the patentability of the invention under Sections 102 and 103, and the merits of the document that describes and claims it under Sections 111 and 112. If, on the other hand, the decision-maker finds that the claim appropriates or swallows an exception by

monopolizing or preempting it, then the test proceeds to part 2 to determine whether the claim includes a non-routine, non-conventional, so-called 'transformative inventive contribution' to the subject matter as a whole that can purportedly save the claim from ineligibility and hence invalidity.

The Problem

In practice, the *Mayo/Alice* test is troublesome. Indeed, it comes close to making no sense because the sequential invocations of parts 1 and 2 of the test are skewed, conflated, and as such are critically flawed to the extent that they are difficult to apply with any degree of confidence; together they present too many moving pieces for the test to work in all apposite cases. Take part 1: it addresses a threshold issue of law at the get-go of the examination stage of a patent application, or at the motion-to-dismiss, judgment on the pleadings, or summary judgement stage of litigation. Resolution of the issue is based on considerations intrinsic to the patent document without the need for extrinsic-fact-finding. If the claim recites or relies on an abstract idea as one of its constituent limitations but does not "read on it", then what need is there to invoke step 2? On the other hand, if the claim reads on or "covers" the abstract idea, then the claim is patent-ineligible and so performing step 2 of the test would be pointless. Moreover, the "transformative inventive concept" inquiry in part 2 of the test requires a comprehensive post factum resolution of fact-rich issues on a fully-developed record that requires pretrial discovery of relevant evidence extrinsic to the patent document.

Because of the two divergent inquiries – one grounded on an issue of law decided on intrinsic evidence (in part 1) vs. the other grounded at least in part on extrinsic fact evidence (in part 2) -- the *Mayo/Alice* test is unwieldy and unclear, and hence unworkable in practice. Although the test was intended to serve as a gateway on the road to determining patent-eligibility, it has proven itself to be a roadblock. As such, it has neither facilitated consistent and predicable decision-making nor satisfied the need of the IP community for certainty and stability in the patent system.

On the contrary, it has become an ill wind in the annals of contemporary patent law, leading courts and other tribunals into a Serbonian Bog of erroneous and, unfortunately, often incoherent precedent-setting administrative and judicial patent eligibility rulings and dissents across the board.

The simultaneous juxtaposition and conflation of 'patentability' and 'eligibility' in Section 101 cases that have used the *Mayo/Alice* test should be decided on the basis of patentability under Section 102, 103, and 112. Failure to do so has caused Section 101 to be overworked through egregious exploitation in far too many instances by patent challengers seeking to rid themselves quickly of meritorious litigations against them through early motion practice that conflates threshold eligibility with downstream patentability/allowability considerations. All too often this causes misapprehension of the issues on the part of decision-makers whose precedential rulings have resulted in the problem we now face, to the detriment of the entire U.S. patent system, including patent owners in particular.

The *stare decisis* created by the binding precedent of the *Mayo/Alice* test in its present form has led to a pervasive state of affairs in judicial and administrative patent policies and practices that harbor serious negative jurisprudential and real-world consequences to America's leadership in innovation on the world stage. The confusion and frustration following the inception and subsequent judicial applications of the *Mayo/Alice* test, and the uncertainty in outcome-predictability in cases where the test has been applied, have become ubiquitous to the point of undermining and destabilizing the U.S. patent system. These factors -- confusion, frustration, uncertainty, and instability – already are diminishing the reliability of the system at its very core across a spectrum of industries upon whose success depends the continued "Progress of the "useful Arts" in all areas of enterprise that America relies upon for the well-being of its citizenry, and the preservation of the nation's security. Enough is enough. It has to stop.

The situation is manifested in a number of contentious split-panel decisions that have sought to apply the *Mayo/Alice* test. Notable among these is the Federal Circuit's fractured decision in *American Axle & Manufacturing, Inc. 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), *cert. petition pending* (No. 21-891). In it, the appeals court affirmed the trial court's finding of patent-ineligibility of a claim in American Axle's patent on a method of manufacturing automotive drive shafts. In one of the steps of the claimed method, an unstated albeit well-known natural law of physics called Hooke's Law is relied upon to "tune" a liner in the shaft in order to prevent unwanted vibrations that might otherwise occur in it during the operation of the vehicle. Because the invention's reliance on Hooke's law figures into the process, the claim was judged ineligible for patenting since it supposedly covers an abstract idea based on a law of nature with no transformative contribution to save it. *Quaere* whether the judges would adhere to their notion that making the drive shaft is an abstract idea if an embodiment of the invention were to slide off the factory workbench and fall on their toes., As will be explained in the following paragraph, and without judging the subject matter of the patent, the issue facing the patent claim in *American Axle* and in other, similar post-*Alice* cases it is not one of patent-eligibility, but rather one of conflation of Section 101 with the requirements of Section 112.

The American Axle patent claim a*s a whole* (i.e., taking into consideration all the recited claim elements or steps of the method together in sequence) satisfies part 1 of the *Mayo/Alice* test inasmuch as it fits into not just one -- but two -- of the textual categories of patent-eligible subjects matter, i.e., a *process* resulting in an article of *manufacture*). Also, the claim does not appear to monopolize in any manner, way, shape, or form (or even mention) the operative natural law -- Hooke's Law – and it certainly doesn't implicate or inform its implementation in other settings. And yet, it was deemed appropriate to proceed to part 2 of the test and invalidate the claim on the ground that it

was directed to an abstract idea by monopolizing a law of nature while failing to redeem itself by not reciting an 'inventive concept'.

So what is the problem? Answer: the courts below, including a majority of the three-judge panel and a split (6-6) en banc panel of the Federal Circuit in *American Axle* misapprehended and misapplied the *Mayo/Alice* test. They judged the claim to be patent-ineligible for supposedly monopolizing a law of nature (which it does not) contra to part 1 of the test, while lacking any inventive, non-routine, non-conventional claim limitation contra to part 2 of the test that would avoid the issue of claiming an abstract idea. But why should a claim be judged under Section 101 when the real issue has to do with the lack of an enabling written description of, and the need for the claim in question to particularly point out and distinctly indicate, *how* to go about tuning the liner so as to elevate the subject matter of the claim above that of a wish or an abstraction. It appears the problem for the court lies not in the invention itself under Section 101, but rather, in the content and wording of the claim that is supposed to define it under Section 112. **And therein lies the rub.**

A Possible Solution:

If a claim is written in such a way that it defines a "new and useful" invention within the stated categories of Section 101 subjects matter without monopolizing any of the four exceptions to eligibility, then the claim passes the *Mayo/Alice* test. The adjudication of the patentability of claims should not depend on the one-size-fits-all *Mayo/Alice* test. Otherwise, it would swallow the entire patent system. Why? Because if the *Mayo/Alice* test as applied so far remains the law of the land, then one would be hard-pressed to write a patent-*eligible* claim to any invention that non-preemptively embodies, uses, reflects, rests upon, applies, implements, or exploits one or more exceptions to eligibility. If a claim to an invention that lies within one of the textual categories in Section 101 recites, alludes to, or depends upon, as one of the claim elements, a natural

phenomenon, on a natural product *in vivo*, on a natural law, or on an abstract idea *without monopolizing said exception*, then patent eligibility should not be negatived under the *Mayo/Alice* test. In such circumstances the Section 101 gateway inquiry is complete and the assessment of the claim should proceed to the patentability and allowability issues under Section 102, 103, 111, 112, etc. without conflating them with the issue of eligibility.

Conclusion

In sum, patent-eligibility under Section 101 is a condition precedent to an evaluation of the downstream "conditions and requirements" of patentability/allowability considerations of novelty, nonobviousness, description, and claiming requirements of Sections 102, 103, 111, and 112. These statutes involve extrinsic evidentiary, discovery-dependent fact issues that are not normally amenable to early disposition in the way that eligibility issues are under Section 101**.** Because of this, the time has come for either the Supreme Court or Congress to re-visit and further develop the law of Section 101 patent eligibility in order to resolve the impasse and thereby be a lighthouse that will guide courts and administrative tribunals in reestablishing one of the fundamental workings of the patent system aimed at correct determinations of patent-claim eligibility. Otherwise, decision-makers will continue languishing in the dark when applying the present *Mayo/Alice* test at the risk of saddling inventors with unjust results.

The following information includes comments attributable to the amici curiae in the AAC's "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" filed March 1, 2021.

1. **Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology areas(s). Please identify the technology area(s) in your response.**

2. **Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible.**

a.Patent prosecution strategy and portfolio management;

b.patent enforcement and litigation;

c.patent counseling and opinions;

d.research and development;

e.employment;

f.procurement;

g.marketing;

h.ability to obtain financing from investors or financial institutions;

i.investment strategy;

j.licensing of patents and patent applications;

k.product development;

l.sales, including downstream and upstream sales;

m.innovation; and

n.competition.

The AAC advocates the advancement of sound patent policy and the public interest by assisting the PTO in preparing its report to the IP

Subcommittee of the Senate Judiciary Committee, pointing to the harm being done to U.S. patent jurisprudence and America's innovation community by *American Axle.* The case is but one illustration of the confusion, frustration, uncertainty, instability, and mounting concern among stakeholders in the U.S. patent system that has been festering ever since the inception of the *Mayo/Alice* test.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:

a.Quantum computing;

b.artificial intelligence;

c.precision medicine;

d.diagnostic methods;

Federal Circuit Judge 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 [in diagnostics] should be deemed patent ineligible".

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

Federal Circuit judge, 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), said:

> 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).

Federal Circuit Judge, Todd M. Hughes in his concurring opinion 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).

e.pharmaceutical treatments; and

f.other computer-related inventions (*e.g.*, software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

It appears that the USPTO has been judicially deemed unqualified to put forth its own guidelines -- despite their entitlement to *Chevron* deference -- to determine what is or is not eligible for examination in a patent application under Section 101. If that is true, then the question remains: How can tribunals, innovators and businesses allocating scarce funds to develop products and services from innovations, do so with any confidence in *Mayo/Alice* without further intervention by the Supreme Court or legislative action by Congress?

4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions including China, Japan, Korea, and Europe, differ from your experiences in the United States.

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")[1], 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

[1] Available at: https://www.nscai.gov/wp-content/uploads/2021/01/NSCAI-Draft-Final-Report-1.19.21.pdf

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. under the *Mayo/Alice* test has lost its '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).

5.Please identify instances where you have been denied patent protection for an invention in the United States solely on the basis of patent subject matter ineligibility, but obtained protection for the same invention in a foreign jurisdiction, or vice versa. Please provide specific examples, such as the technology(ies) and jurisdiction(s) involved, and the reason the invention was held ineligible in the United States or other jurisdiction.

6.Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to modify or shift investment, research and development activities. or jobs from the United States to other jurisdictions, or to the United States from other jurisdictions. If so, please identify the relevant modifications and their associated impacts.

7.Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to change business strategies for protecting your intellectual property (*e.g.*, shifting from patents to trade secrets, or vice versa). If so, please identify the changes and their associated impacts.

8.Please explain whether you have changed your behavior with regard to filing, purchasing, licensing, selling, or maintaining patent applications in the United States as a result of the current state of patent eligibility jurisprudence in the United States. If so, please describe how you changed your behavior.

Federal Circuit Judge 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).

9. Please explain how, in your experience, the status of patent eligibility jurisprudence in the United States has affected any litigation for patent infringement in the United States in which you were involved as a party, as legal counsel, or as another participant (e.g., as expert witness). For example, please explain whether this jurisprudence has affected the cost or duration of such litigation, the ability to defend against claims of patent infringement, the certainty/uncertainty of litigation outcomes, or the likelihood of settlement.

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.

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* 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.

Section II – Impact of Subject Matter Eligibility on the General Market Place

Never has the need for meaningful protection of intellectual property rights in this country been greater it is today. The authors 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, ***securing those rights*** for the individual rather than the state; and ***incentivizing innovation and creative aspirations***."[2]

But in stark contrast to Madison's intent, the misapplication of Section 101 in the *Mayo/Alice* test has created instability and uncertainty in patent eligibility determinations which undermine the foundation of the U.S. patent system as envisaged by the framers. Uniformity in securing patent rights to individuals in order to incentivize innovation was and is central to the fundamental purpose of the provision. Granting American Axle's petition for certiorari will enable the Court to resolve the current

[2] 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: https://www.fedbar.org/wp-content/uploads/2016/06/IP-Insight-pdf1-1.pdf

problem of Section 101 confusion, and provide the clarity necessary to restore that fundamental purpose.

10. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property.

Because of the judicial constriction of patent-eligible subjects matter under the *Mayo/Alice* test, America's biggest economic competitor – China – along with Europe, are perceived by entrepreneurs and investors as being more hospitable to and reliable concerning patent eligibility, and hence more predictable in patent enforcement outcomes and licensing projects.. These other countries' patent systems also foster the perception among innovators and businesses that their technologies can be better protected by foreign patents than by U.S. patents. The inevitable effect of these perceptions is to encourage increased investment of risk capital in foreign locales to the detriment of innovation and its benefits to markets and employment in the United States.

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 intangible assets and vehicles for technology transfer in the U.S. is diminished. This disincentivizes U.S. business investment by companies 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 preparedness, and safeguarding the United States against national security vulnerabilities. Together, these concerns are causing America's technological edge to deteriorate, which calls for review of the eligibility jurisprudence that has led to the present situation.

Patent applications are routinely being denied issuance in the United States on Section 101 grounds whereas corresponding applications are granted under the patent regimes in China and Europe.

Failure to address and clarify Section 101 patent eligibility will continue to threaten America's ability to maintain its leadership role in innovation, defense, and economic development.

11. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the U.S. economy as a whole.

The disagreements within the Federal Circuit are evidence of serious flaws in the *Mayo/Alice* test, creating a disincentive to innovation when our country needs it most, and signals an enormous waste of resources. As important as they are in particular cases, judges' internecine differences of opinion illustrate the widespread confusion caused by the *Mayo/Alice* test. 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 in applying the critical, foundational *Mayo/Alice* analysis. The current state of affairs is untenable.

A decade has passed since the Supreme Court last addressed Section 101. It is clear now that those affected have been unable to rely on or apply the *Mayo*/Alice test. This reality is reflected in the patent applications that have been rejected in the PTO, the patents that have been invalidated in the courts of first instance whose decisions have been overturned on hotly disputed appeals, the many confused decisions of the Federal Circuit and the accompanying array of dissenting opinions.

The Supreme Court has repeatedly refused to revisit Section 101 jurisprudence since *Alice* was decided. While important innovations go unprotected, the Court has denied 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 en banc 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).

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

Congress has held hearings in which dozens of witnesses have called the current system untenable. If the *May/Alice* test is not clarified soon by the Supreme Court, then Congress will need to become involved legislatively.

12. Please identify how the current state of subject matter jurisprudence in the United States impacts the global strength of U.S.

intellectual property and the U. S. economy in any of the following areas:

a. Quantum computing;

b. artificial intelligence;

c. precision medicine;

d. diagnostic methods;

e. pharmaceutical treatments, and

f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

For more than 100 years, before and after the 1952 Patent Act, and until the *Mayo* and *Alice* decisions, the Supreme Court has provided vital, stable guidance "to promote the Progress of useful Arts," in the words of the 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." The *Mayo/Alice* test has proven itself to be an unsettling facet of that grappling. *See*, Letter dated February 6, 2021 from Senator Thom Tillis to President Biden, (hereafter, "*Tillis Letter*"), p.2; *see also The State Of Patent Eligibility In America*: Hearing Before the United States Senate Subcomm. on Intellectual Property, Comm. on the Judiciary, 116th Cong. (2019) (June 4th, 2019 Hearing Transcript of Oral Testimony of Judge Paul R. Michel (Ret.), United States Court of Appeals for the Federal Circuit at Hr'g Tr. p. 352; and June 4, 2019 Hearing Transcript of Oral Testimony of Honorable David Kappos, Former Director of the PTO at Hr'g. Tr. pp. 366-367).

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the pubic. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

The inconsistent application of the *Mayo/Alice* test is creating unpredictability and instability in the U.S. patent system. The test has imposed a framework that has been applied inconsistently, and questions regarding its extent, scope, and rigidity have become common, and are at issue in *American Axle*. Questions about whether the additional information is a question of law or fact have also arisen.

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

There is clear empirical evidence demonstrating the negative effect that Section 101 uncertainty has been having 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]

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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

As the Supreme 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).[4] As articulated in the *Tillis Letter*, our country needs "clear, predictable, and enforceable" patent rights. *Id*. at p. 1.

The AAC's concern is that Americans creating technological advances who must follow the Supreme Court's directives regarding patent eligibility are unable to do so because of the confusion over the application of the *Mayo/Alice* test.[5] 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."

In sum, unless the Supreme Court or Congress acts quickly and decisively in providing much-needed guidance in cases dealing with patent eligibility, our nation's technologies will continue to suffer.

Respectfully submitted,

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Paper No. 414, available at SSRN: https://ssrn.com/abstract=3340937 or http://dx.doi.org/10.2139/ssrn.3340937 (same).

[4] 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").

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

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