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NYIPLA Responses to USPTO Notice re 101 Study

Identifying NYIPLA:

When responding to the questions, please identify yourself and your interest in the U.S. patent system. If applicable, please indicate whether you fall within one or more of the following categories: (1) Inventors, patent owners, or investors (*e.g.,* venture capital, investment bank, fund, etc.); (2) licensees or users of patented technology; (3) entities that represent inventors or patent owners (*e.g.,* law firms); (4) recipients of demand letters concerning alleged patent infringement or accused infringers in a patent lawsuit; (5) entities that represent accused infringers; (6) government agencies or officials; (7) academic or research institutions; (8) intellectual property organizations or associations; and (9) nonprofit organizations or advocacy groups. Additionally, if you are a patent owner or inventor, please include the number of U.S. and foreign patent applications you have filed; the number of U.S. and foreign patents you hold; the number of patents you have licensed or sold; and the number of patent cases you have been involved in since the Supreme Court's decision in *Bilski* in 2010.

The New York Intellectual Property Law Association (NYIPLA) is a ninety-nine-year-old professional association whose interests and practices lie in the area of patent, trademark, copyright, and other intellectual property ("IP") law. Traditionally, the NYIPLA has been one of the largest regional IP bar associations in the United States. The NYIPLA's members include a diverse array of attorneys specializing in patent law, including in-house counsel for businesses that own, enforce, and challenge patents, as well as attorneys in private practice who prepare and prosecute patents and represent entities in various proceedings before the U.S. Patent and Trademark Office (USPTO), the federal courts, and various arbitral fora.

Many of the NYIPLA's member attorneys actively participate in patent litigation, representing both patent owners and accused infringers. The NYIPLA's members also frequently engage in patent licensing matters on behalf of both licensors and licensees. The entities served by the NYIPLA's members include inventors, entrepreneurs, venture capitalists, businesses, universities, research institutions, and industry and trade associations.

NYIPLA's members regularly depend on Section 101 jurisprudence, including as implemented by the USPTO and the courts, in the conduct of their business, and seek a consistent and predictable application of Section 101. The NYIPLA thus brings the interested and informed perspective of stakeholders to the issues presented.

Commenters need not respond to every question and may provide relevant information even if not responsive to a particular question.

Section I—Observations and Experiences

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

The line between an unpatentable idea and a patentable invention still remains unclear under the current state of the patent eligibility (Section 101) jurisprudence in the United States across the many technologies in which our members operate. Members of the NYIPLA practice in multiple technologies where Section 101 issues arise in the prosecution context, for example – (1) avionics, (2) systems in nuclear power plants, (3) systems for steel manufacturing, (4) bioinformatics/data analytics, (5) AI, (6) Blockchain, and (7) biotechnology and medical diagnostics. Not only is unpredictability in the patent system harmful to the economy and the patent system as a whole, it is also problematic to inventors, business entities, investors, innovators attempting design around solutions, and other interested parties who need to understand what is, and is not, patentable. Such uncertainty hinders the ability to assess risks, evaluate investments, and make decisions based on a useful, understandable, and consistently applied patent eligibility jurisprudence. Significantly, this unpredictability exists with respect to seeking a patent grant, licensing patent rights, and enforcing patent rights.

Unpredictability results in more risk. There is therefore a need for determining whether to make the larger investment needed to mitigate this increased level of risk. Alternately, one can forego the investment and either accept the risk of not getting a patent of desired scope, or forego the innovation, perhaps in favor of pursuing a more protectable innovation. For example, the uncertainty has resulted in an increased burden, expense, and time to draft patent applications in anticipation of potential patent eligibility rejections, particularly in software based and biotechnology technologies. Some members estimate the cost of drafting an application has increased from 20% to 30% due to patent eligibility concerns. There also is a commensurate increased burden in prosecuting patent applications that are rejected for lack of patent eligibility, often multiple times. This leads to delays in obtaining a patent grant, and/or narrowing claims to establish eligibility more than needed to avoid the prior art, and increased costs to Applicants. Repeated rejections based on subject matter eligibility also increase the prospect of appeals to the PTAB and the Federal Circuit, consuming not only the inventor's, but also agency and judicial resources.

The Section 101 roadblock, when perceived as a potential problem, often discourages businesses from seeking patent protection or committing further resources to pursue innovative ideas, particularly when it remains uncertain that reasonable patent protection is available to recoup the investment cost. For many innovators, the publication of the patent application eighteen (18) months after filing is not sufficient to protect against global competition. While trade secret protection may be available for innovative processes and devices that cannot easily be reverse-engineered, without some form of exclusionary protection against competition, most innovators are left with little or no incentive to develop and publicly disclose their innovations that will simply become useable by others without any compensation. Thus, the uncertainty and difficulty in obtaining patent protection may disincentivize inventors from disclosing their innovations and instead, seek to protect their innovations as trade secrets for as long as possible. This obviously hinders the growth and progress of public knowledge that is encouraged by the patent system.

Further, unpredictability in patent eligibility for new innovations reduces the

ability of businesses to obtain outside investments necessary to further develop technological innovations Many private equity and venture capital investors doing their investment due diligence prefer to fund companies that have patent filings, which are considered more concrete and tangible assets to investors than trade secret protections. The harder it is to obtain investment, the more businesses are discouraged from enhancing and improving existing technologies or developing and disclosing innovative technologies in the first place. As President Abraham Lincoln stated, the patent system adds "the fuel of interest to the fire of genius." Thus, predictability is necessary to maintain incentives to invest in future technologies and discoveries.

Our members report the following anecdotal experiences.

For (1) avionics, (2) systems in nuclear power plants, and (3) systems for steel manufacturing, Section 101 rejections have not necessarily prevented members from obtaining patents, but they have impacted prosecution by increasing prosecution costs and narrowing the claims in a manner where the scope needed to overcome the rejections was not clear. Examiners are inconsistently setting the Section 101 goalposts with no consistent basis provided.

For (4) bioinformatics/data analytics, applications have been abandoned due to Section 101 issues, and the applications that are filed are extremely narrow and granted less frequently than before *Alice/Mayo*. Also, some Examiners in these art units have allowance rates as low as 10-15%. The lack of patent issuance is discouraging public disclosure of innovation.

For (5) AI, (6) Blockchain, and (7) biotechnology and medical diagnostics, many Applicants are going so far as to forego filing a patent application in the U.S., resulting in a relative increase in patent filings in China and the EU. Some members have reported a reduction in the number of patent filings in the U.S. for inventions relating to medical diagnostics.

On the other hand, with respect to patent enforcement and threats of infringement, some of our members have reported a benefit from the unpredictability in patent eligibility in a noted decrease in threatening letters from non-practicing entities asserting broad business method claims – in particular for a cosmetic company and for software companies. Specific examples include "Click to Chat" and "GPS" patents. In both cases the patent claims asserted were difficult to interpret and a prior art search would have been quite difficult, where the license fees demanded were set at values that made the cost of challenging the patent cost inefficient (not cost effective).

a. Patent prosecution strategy and portfolio management.

As noted above, members report filing fewer patent applications in view of the current state of patent eligibility because it is unpredictable how individual Examiners will apply Section 101. For example, our members in avionics report that patent attorneys often call Examiners and find out which additional features might be added to the claim to overcome a Section 101 rejection and obtain a patent. However, such narrowing limitations frequently are not at all directed to the main or essential features of the invention, but simply narrow the claim in a manner that makes it easier for a copycat to avoid infringing. While perhaps cost effective in the short term for prosecution, it yields patents of lower quality, less scope of protection, and less value. Rather than fostering innovation, it merely enables competitors who can avoid infringement by not using the narrowing limitation that is not necessary to practice the true innovation. This disincentivizes seeking patent protection in cases where Section 101 issues are likely to arise.

Other members working in computer-implemented inventions report that they have also dealt with Examiners that are unaware of or ignore recent patent eligibility jurisprudence and instead simply point to the language in *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016) that "collecting information, analyzing it, and displaying certain results of the collection and analysis" is not patent eligible. Taken to extremes and out of context, as experienced by some members, this statement has been applied to all varieties of software related inventions, and leads to uncertainty when seeking to protect such inventions, including questioning the benefits and advantages of publicly disclosing the innovations in patent applications.

Members working in medical diagnostics report that innovators currently have difficulties in securing protection for the full scope of their discoveries, patent claims to diagnostics are currently of very limited scope, and innovators resort to alternative strategies of protection, such as protecting tools to identify diagnostic markers. However, such alternative strategies also experience patent protection that is limited in scope and can be inadequate to attract the further investments needed to develop such discoveries. A member has reported one specific instance when an innovator for a diagnostic innovation was not able to secure financing to develop the diagnostic because patent protection could not be secured for a compound identifying the diagnostic marker.

Another member in the bioinformatics space reported that a patent could not be obtained for a tool that identifies disease causing genes that were determined to be novel and nonobvious over the prior art, but not patent eligible. Other members have reported that similar tools have been developed but patent applications have not been filed in view of the current state of Section 101 jurisprudence, leading to less public disclosure of these important and valuable innovations.

Our members who regularly litigate patents report a consensus view that unpredictability arising from *Mayo* and *Alice*, and thus Section 101 challenges, is likely to persist absent intervention from the Supreme Court or the Legislature. The current state of patent eligibility jurisprudence in the United States has the following impacts on U.S. patent litigation:

- Uncertainty/lack of predictability in the substantive application of Section 101 in district courts and the Federal Circuit. The absence of clear boundaries is exemplified by recent Federal Circuit cases, including *American Axle and Manufacturing, Inc. v. Neapco Holdings LLC*, 957 F.13 1285 (Fed. Cir. 2020), and *Yu v. Apple, Inc*., Nos. 2020-1760, 1803 (Fed. Cir., June 11, 2021).

- The current jurisprudence blurs the line between, and sometimes conflates, Section 101 patent eligibility, and Sections 102/103 relating to the separate issues of anticipation and obviousness.

- As pointed out by Judge Newman, in her dissent to the Federal Circuit's denial of rehearing in the *American Axle* case (939 F.3d 1355 *amended in* 967 F.3d 1285 (2019), *petition for reh'g en banc denied*, 96,6 F.3d 1347, 1357 (Fed. Cir. 2020)):

> The [Federal Circuit'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.

- Uncertainty caused by variations in the procedural handling of Section 101 challenges across different courts and judges, e.g., whether the issue is decided based on a motion to dismiss, a motion for summary judgment on the pleadings, a motion for summary judgment, or trial. This contributes to forum shopping and venue transfer motion practice by plaintiffs and defendants who believe certain courts are more favorable to their Section 101 positions.

- Increased costs and risks of litigation. This manifests itself in:

    - Pre-litigation patent/claim analysis – heightened scrutiny needed for patents in a growing number of technical areas;

    - Pleading requirements – many patent infringement complaints now address certain technical details in anticipation of mitigating the risk of a motion for dismissal on the pleadings based on Section 101 allegations;

    - Additional motion practice specific to Section 101 issues (including motions to dismiss, motions to bifurcate (or stay) certain discovery, and motions for summary judgment);

    - Additional expert costs attributable to Section 101 issues.

    - More focus on enforcement of foreign patents in areas where the U.S. counterpart patents are vulnerable to Section 101 challenges.

b. patent counseling and opinions;

The fluctuation of the USPTO's views on Section 101 issues has created uncertainty in the law. As a result, it is more challenging to counsel clients as to the patentability of certain technologies. Members report that there is a greater risk of forgoing the prospective procurement costs of the patent application if it faces an Examiner with a more liberal approach to issuing Section 101 rejections. Patent invalidity opinions based on Section 101 can be of limited value to clients because Federal Circuit opinions are inconsistent and often depend on the makeup of the particular panel, and as a result are constantly creating fluctuating standards.

It is also challenging for foreign practitioners to properly counsel clients on drafting cases that will eventually find themselves before the USPTO as well as other jurisdictions. This can leave U.S. practitioners with limited options to respond to U.S. Examiner rejections for lack of patent eligibility.

c. research and development;

d. employment;

e. procurement;

f. marketing;

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

As noted, the NYIPLA believes that the current state of patent eligibility jurisprudence generates significant uncertainty concerning the value of patents.

This raises obstacles to patent-related investments and other transactions. The current state of patent eligibility jurisprudence is the progeny of the Supreme Court's *Bilski, Alice* and *Mayo* decisions and the Federal Circuit's inconsistent and unpredictable implementation in its patent eligibility rulings. As a result, stakeholders can no longer rely upon past jurisprudence, or upon guidance from the USPTO (which the courts have indicated they need not follow), to ensure that patent protection for technologies previously presumed patentable will continue to exist (including those technologies listed in Question 3).

The NYIPLA does not seek to engage in a political debate over preserving the value of patents or serving public good. Rather, our members view the lack of predictability about patent eligibility as a roadblock to financing innovation development and deriving economic benefits from that innovation by burdening decision-making in the categories in Question 2. If the U.S. can provide a reasonably predictable indicator of patent eligibility, patent owners, licensees and other stakeholders will be able to make more informed decisions on resource allocation. For example, they will be able to assign a monetary value to licensed and assigned patents and anticipate a likelihood of patent enforceability, with improved confidence that their advice will accord with future patent eligibility law. Further, having a more clearly defined and efficient patent system would ensure that the U.S. remains the world innovation leader, especially in the cutting edge of AI, machine learning, precision medicines, and other valuable technological implementations.

The NYIPLA foresees that innovators may try to mitigate the effects of the uncertainty by shifting focus away from patents and toward trade secret protection and enforcement, and other forms of IP, in the "Question 3" technological areas. The NYIPLA, however, does not consider an increased reliance upon non-patent IP to be a viable long-term solution for the aforementioned problems. Nor is it a replacement for strong patent protection and its correlative public disclosure historically associated with investment in innovation.

h. investment strategy;

i. licensing of patents and patent applications;

j. product development;

k. sales, including downstream and upstream sales;

l. innovation; and

Some members have observed that start-up companies are experiencing a harder time obtaining funding. Investors typically look to a company's tangible IP assets prior to investing in a start-up. When they have choices for investment, lack of patent protection can be an impediment to securing financing. For example, our members report that a lack of ability to broadly protect software and medical diagnostics within the U.S. patent system limits accessibility to the capital investment needed to grow.

m. competition.

The shifting stance of the federal courts on Section 101 issues has made patents more vulnerable to attack. This increases competition from infringers for narrow solutions, and discourages development of new inventions previously generated by having to design around broader patents to compete.

2. 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;

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).

NYIPLA's responses above address many of these points in Question 2.

3. 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.

Several members indicated that the US is the only jurisdiction in the group of the above-mentioned countries where eligibility is often fatal, rather than a hurdle that can be overcome by working with the Examiner to narrow the claims. More specifically, the other jurisdictions also present eligibility issues, but unlike the U.S., stances in these jurisdictions have generally been more constant than in the U.S. and are now reasonably predictable at the time of filing. This predictability also offers more stability for patents granted outside the United States, where it is less likely that granted patents will be invalidated for lack of patent eligibility in post grant administrative proceedings or litigation.

Canada and the U.S. treat certain subject matter eligibility issues similarly. In practice, however, it remains easier to overcome a subject matter eligibility objection in Canada than in the U.S. Further, the resulting Canadian patent usually has a better (more expansive) scope of protection than the counterpart patent in the U.S. Further, the resulting Canadian patent usually has a better (more expansive) scope of protection than the counterpart patent in the U.S.

For Europe, members report that despite the jurisdiction having taken a stringent stance with regard to subject matter eligibility issues, European patent law provides a more predictable standard for determining patent eligibility than in the U.S. As such, there is more clarity as to how the EPO will react to certain subject matter issues pertaining to a particular application, and the application can be prepared to anticipate and mitigate eligibility issues.

Nature Biotechnology noted back in 2017 that while it had become very difficult to obtain patent coverage in the U.S. for medical diagnostic method-related inventions, the European Patent Office was starkly different in awarding patent coverage for these same innovations. *See* Amos, B., Miller, A. Differing diagnoses for European and US patents. *Nat Biotechnol* 35, 334–335 (2017) https://doi.org/10.1038/nbt.3839. Since then, NYIPLA members report that it has now become a recommended practice to pursue different protection in US and EPO, and in some cases not to pursue US protection.

In a more recent (2020) article in Diagnostics World News (https://www.diagnosticsworldnews.com/news/2020/01/20/assessing-patent-eligibility-uncertainty-for-diagnostics), an interviewee stated "some companies are deferring development of some diagnostic products until the protectability of diagnostic products is clarified. It is only reasonable to expect companies to react to an increased risk to their investments. While some companies continue development—perhaps adjusting how they exploit their diagnostic developments—some certainly will divert their resources to other, less risky endeavors."

Like the USPTO, the European Patent Office (EPO) considers that mere discovery of a natural phenomenon is not patent eligible. However, while courts in the U.S. have extended this exclusion to delimited, practical *uses* of the discovery, and effectively stopped many diagnostic methods from being patentable, the EPO takes the view that a patentable invention can derive from a practical use of that discovery. Thus, in Europe, use in a method of diagnosis (EPO Guidelines for Examination G-II, 3.1) is patentable. Although the EPO does prohibit methods directly performed on a human body, methods performed on *e.g.,* on a blood sample can be patent-eligible.

In view of recent rulings, it is expected that the divergence between U.S. and EPO subject matter eligibility will become wider still, with consequent effects on the competitive position of U.S. versus Europe when it comes to innovating technologies that benefit from IP protection.

In addition, some members have noted that Universities and Research Institutions, which have been monetizing their patent protection since the Bayh Dole Act and putting licensing fees back into funding research, have been hurt by this unpredictability. This is because a portion of their research is early-stage research, and early-stage research like this can lead to identification of disease diagnostic methods – even before treatments are developed. The Association of University Managers has specifically recognized that patent-eligibility of diagnostic methods is an issue they face (https://autm.net/about-tech-transfer/advocacy/autm-advocacy-update/august-14-autm-advocacy-update).

4. 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)

Members have identified the following specific instances:

- Diagnosis of inflammatory bowel disease by detecting bacteria. Claim in the U.S. were limited to a specific primer; broader and more valuable protection was obtained in Europe and Canada by simply tweaking the language.

- System for concussion treatment: Significant language had to be added to the U.S. claims to overcome a rejection that the subject matter was an abstract idea, despite including in the claim a vision tracker, presenting complementary images to both eyes. Claims without that narrowing limitation were deemed patentable in Canada.

5. 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.

Some members believe that the current state of patent eligibility jurisprudence weakens U.S. intellectual property and drives away investment. It also promotes what is referred to as "efficient infringement," as the changing stance of the courts on eligibility matters reduces the solidity of a granted patent as a bar to competition. Some members have noticed that funding for industries that have been particularly affected by Section 101 issues has been reduced.

6. 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.

Some members feel that the current state of patent eligibility jurisprudence makes it more difficult for start-up companies to obtain investment and grow. This results in strengthening large tech companies and encouraging monopolies, while limiting competition in the long run. On the other hand, other members suggest that it may help lessen the burden of some marginal patents on U.S. commerce.

Because patent prosecution has at least in some circumstances become more expensive and uncertain due to changes in patent eligibility jurisprudence, some members have the impression that individual inventors are increasingly incentivized to sell/assign their inventions to big companies which have a substantial market share in a particular industry. This is at the cost of those innovators building a competitive business, and can lessen competition and the growth of smaller companies. It also runs counter to the social policy initiatives aimed at increasing diversity among innovators, inventors, and entrepreneurs, particularly in industries negatively impacted by the current state of patent eligibility jurisprudence.

7. Please explain whether you have changed your behavior with regard to filing, purchasing, licensing, selling, or maintaining patent applications and patents 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.

Some members indicate that the current state of patent eligibility jurisprudence leads innovators to using trade secrecy to protect their IP. This leads to higher prices because knowledge is hoarded. Such "know how" becomes more expensive and is priced into licenses, diagnostic tests, etc. If everything were patented, some products likely would be more expensive in the short term, but in the long term as patent rights expire, there would be more free open-source software and generic diagnostic tests available.

Other members are concerned that changes in the current state of patent eligibility jurisprudence could result in a return to the days where non-practicing entities are asserting broad business method patents, which automate well known techniques, simply to extract settlements solely because settling is less expensive than litigation. This concern may also be impacted going forward because the Covered Business Methods post-issuance review was terminated for patents issued after September 30, 2020, and thus an accused infringer now has one less option to defend against such accusations.

8. 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 been involved as a party, as legal counsel, or as another participant (*e.g.,* an 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.

Section II—Impact of Subject Matter Eligibility on the General Marketplace

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

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

11. Please identify how the current state of subject matter eligibility 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).

In responding to this question, please provide concrete examples and supporting facts when possible.

12. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. 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?