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September 2, 2021

The Honorable Andrew Hirshfeld
Commissioner for Patents, Performing the
Functions and Duties of the Under Secretary
of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22314

Re: USPTO Patent Eligibility Jurisprudence Study (PTO-P-2021-0032-0002)

Dear Acting Director Hirshfeld:

The American Bar Association Section of Intellectual Property Law ("Section") thanks the United States Patent and Trademark Office ("USPTO") for the opportunity to provide comments in response to the USPTO patent eligibility jurisprudence study set forth in the Federal Register Notice on July 9, 2021 ("Notice"). The views expressed herein are presented on behalf of the Section of Intellectual Property Law. They have not been reviewed or approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

Since 1894, the Section has advanced the development and improvement of intellectual property laws and their fair and just administration. As the forum for rich perspectives and balanced insight on the full spectrum of intellectual property law, the Section serves within the ABA as a highly respected voice in the intellectual property profession, before policy makers, and with the public. Section members include attorneys who represent patent owners and applicants, accused infringers, small to large corporations, universities, and research institutions across a wide range of industries. Our members are attorneys in private practice, in-house counsel, public sector attorneys, and others.

I. Observations and Experiences

We commend the USPTO for its initiative in undertaking the further study of these issues of fundamental importance not only to the patent bar but for the public in general. The interpretation of section 101 of the patent

statute (35 U.S.C. § 101) defines the types of inventions and discoveries that are eligible for patent protection and thereby the contours of our innovation ecosystem.

The Section appreciates the USPTO's continued efforts to implement examination guidance in light of the challenges posed by the current state of U.S. legal jurisprudence. We also commend the efforts of the USPTO over the past decade to improve patent quality, especially in technologies that have been the subject of patent eligibility questions in the USPTO as well as in the courts. We encourage the USPTO to continue those efforts in order to strengthen the validity of issued patents and reduce the uncertainty and unpredictability with respect to patent eligibility requirements. Today, patent subject matter eligibility is ever more uncertain, ambiguous, and unpredictable, as evidenced by recent federal court opinions that have effectively left the system "broken" in the eyes of many.[1]

The Section has provided comments to governmental inquiries following the decisions of the Supreme Court in *Bilski*, *Mayo*, *Myriad*, and *Alice*, as well as subsequent applications of that precedent by the Federal Circuit.[2] Of note is that we believe the summary of the status of the case law in the Supplementary Information of the Notice is a

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[1] *See generally*, the bipartisan and broad-ranging chorus of criticisms regarding the state of patent eligibility jurisprudence include no fewer than seven of the sitting Federal Circuit Judges, current Senators and Members of Congress, and executive branch officials, including U.S. Senator Chris Coons ("Today, U.S. patent law discourages innovation in some of the most critical areas of technology, including artificial intelligence, medical diagnostics, and personalized medicine") Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), https://www.coons.senate.gov/news/press-releases/; Chief Judge Kimberly A. Moore ("A disturbing amount of confusion will surely be caused by this opinion, which stands for the proposition that claims can be ineligible as directed to a natural law even though no actual natural law is articulated in the claim or even the specification") *Am. Axle & Mfg., Inc. v. Neapco Holdings*, LLC, 966 F.3d 1347, 1357 (Fed. Cir. 2020) (Moore, J., dissenting from denial of rehearing *en banc*); Senior Judge Todd M. Hughes ("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.") *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring in denial of rehearing *en banc*).; Judge Timothy B. Dyk ("I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in Mayo) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena"). *Id.* at 1287.

[2] ABA-IPL supplemental responses to questions for the record on the State of Patent Eligibility in America, U.S. Senate Committee on the Judiciary, Subcommittee on Intellectual Property Law (June 24, 2019); ABA-IPL letter to Senate IP Subcommittee providing supplemental views on the State of Patent Eligibility in America, following June 5 testimony of Scott Partridge before U.S. Senate Committee on the Judiciary, Subcommittee on Intellectual Property Law (June 18, 2019); ABA-IPL Immediate Past Chair Scott Partridge provides live testimony before U.S. Senate Committee on the Judiciary, Subcommittee on Intellectual Property Law on "The State of Patent Eligibility in America" (June 5, 2019); ABA-IPL Comments to the Chair and Ranking Member of the House Judiciary Committee on U.S. Patent and Trademark Office oversight; ABA-IPL letter addressed several issues including, *e.g.*, the need to amend 35 U.S.C. §101 to clarify patent eligibility requirements (May 16, 2018).

fair statement of the current law including the recent expansion of patent eligibility jurisprudence by the Federal Circuit into a broad range of technologies (*e.g.*, mechanical drive shafts in the case of *American Axle & Manufacturing, Inc., v. Neapco Holdings LLC, et al.*).

From a historical perspective, the U.S. Supreme Court's earlier precedent required the courts and the USPTO to assess eligibility of the claimed process as a whole—devoid of considerations of novelty, nonobviousness, written description, and definiteness—in order that they not render a claim patent ineligible by ignoring or discounting claim limitations. However, as many judges, commentators, and others have repeatedly pointed out, recent Supreme Court opinions on section 101 have injected ambiguity and unpredictability into the eligibility determination by requiring courts and the USPTO to apply criteria such as the existence of an "inventive concept," and questions such as whether claim elements are "well-known," "routine," or "conventional." As our Section recently testified before the U.S. Senate Subcommittee on Intellectual Property, such criteria were previously relevant only to substantive questions of patentability like novelty and obviousness under sections 102 and 103. The use of these criteria has led to court decisions ignoring limitations in a patent claim by finding one or more limitations individually routine or conventional, and then rendering the balance of that claim ineligible as a matter of law. As the Section's testimony explained, the gateway function of patent eligibility has been transformed into a patentability test better left to the other statutory provisions that specifically address patentability, like sections 102, 103, and 112 of the patent statute. We said then that this new patentability test has discouraged investment in new technologies, thereby risking U.S. leadership in many areas of innovation previously subject to patent protection. In fact, the Federal Circuit has observed that the Supreme Court's eligibility test *must* be applied so aggressively as to require lower courts to hold that "groundbreaking, innovative, or even brilliant discoveries" can be excluded from patent protection.[3]

As our Section has articulated in prior USPTO letters and its Senate testimony, uncertainty and unpredictability about what types of inventions qualify at the most fundamental level for patenting not only undermines the U.S. patent system but it creates unacceptable risks to investments American entrepreneurs choose to make in innovation. Indeed, because of this uncertainty and unpredictability, the strength of the U.S. patent system and the incentives for innovation as designed by Congress have been called into question. To regain its strength, our patent system must again be forward-looking, flexible enough to embrace entirely new, unimaginable fields of endeavor, and not restricted to historical conceptions of technology. Just as the new technologies of the past two decades were unknown and unpredictable in the '70s and '80s, the technologies of the future are unknown to us today.

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[3] *Supra* n. 2, Jun. 5, 2019 testimony (quoting *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring)), https://www.judiciary.senate.gov/imo/media/doc/Partridge Testimony.pdf.

For many years, our Section embraced the possibility that the Supreme Court would eventually address what many judges decried as the uncertainty and unpredictability created by Court's most recent series of patent eligibility cases (*Bilski*, *Myriad*, *Mayo* and *Alice*), and the application of those decisions by the Federal Circuit. However, the Supreme Court has consistently refused to review a number of Federal Circuit decisions since *Mayo* and *Alice* thereby making a judicial solution to this problem unlikely in the near future or within any reasonable time frame to avoid potentially significant, continuing harm to American innovation.

Our Section has voiced particular concern about the effect the current status of eligibility law has had and will likely continue to have in at least three primary areas:

- Negative effects on small businesses, midsize ones, and individual innovators, to whom patent protection of new technology is critical to their success and ability to secure investment;[4]
- Loss of global competitiveness as certain technologies are recognized as patent eligible in major competitor countries like China, but not in the U.S., which over time risks moving R&D overseas where these technologies may be more easily protected than in the U.S.;[5] and,
- Diminishment of licensing activity and loss of a U.S.-centric international licensing regime particularly with respect to SEPs and other technologies tied to large international portfolios.[6]

II. The Section's General Approach in Addressing the Specific Topics and Questions in the Notice

The Section notes that a number of the questions in the Notice are directed to specific technologies such as quantum computing, precision medicine and the like, and a number of other questions are directed toward specific examples in particular businesses. Since we are a bar association rather than one of these business enterprises, we determined that a useful approach to answering the questions in the Notice would be to

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[4] *See, e.g.*, the Statement of Adam Mossoff before the Senate Subcommittee on Intellectual Property on June 4, 2019 ("Mossoff Statement"). In the citations in footnote 7, Professor Mossoff describes an economic study that establishes that patents more than double a startup's chances of obtaining venture capital, and thus significantly increases a startup's chances of growing into a small business in the marketplace. And as that footnote also states, small businesses create nearly 70% of net new jobs in the United States. Indeed, recent USPTO data shows that over 20% of U.S. patent applications are filed by what it defines as "small entities" in the US. FY 2020 USPTO Performance and Accountability Report, Tab 11 at p. 210, https://www.uspto.gov/sites/default/files/documents/USPTOFY20PAR.pdf. Given that the report's definition of small entity is an entity with less than 500 people, it is not difficult to extrapolate from that percentage to a considerably higher number for all small businesses.

[5] *See, e.g.*, Mossoff Statement at pages 2-3 & n.9.

[6] *See, e.g.*, LES HIGH TECH SECTOR ROYALTY RATES & DEAL TERMS SURVEY REPORT 2017 at 38-41. While isolating the effects of 101 jurisprudence since Alice is difficult because of the additional effects of *eBay* and the America Invents Act, the decision in *Alice* continued the downward trend in licensing, patent sales and litigation.

first provide a short summary of actual real-world examples to demonstrate the experiences of lawyers representing clients as they seek to navigate the uncertainties in Section 101.[7] The following two real-world examples will first be shared as stories, and then will be referenced in our responses to multiple questions in the Notice. In pursuing this approach, the Section is not endeavoring to answer every question. Instead, as this process moves forward, and we expect to have the opportunity to further analyze the questions asked, we are hopeful to be able to avail the Section of further opportunities to address the issues raised by the USPTO.[8]

The real-world examples below are based on actual experiences, but are anonymized because they relate to pending matters.

Real-World Example No. 1

- Drug A, a small molecule, was developed by a small start-up company (StartupCo) as a "precision" or "personalized" medicine. A precision medicine in this context is the diagnosis of specific cancers at the genetic level, particularly protein mutations in the cancer cells, and the development of treatment options targeting those mutations. Drugs developed for precision medicine enable focused treatment options that (1) minimize patient exposure to side effects from drugs to which their cancer will not be fully responsive and (2) lower the overall costs of healthcare as medicines will not be used unproductively in patients whose tumor will not be responsive to the medicine. Precision medicine is therefore essential to better patient outcomes and cost-effective healthcare innovation.
- Drug A was developed to only treat patients with the specific cancers containing the specific protein amino acid mutations. Even in the early stages of development, the importance of a diagnostic test to identify patients suffering from the specific cancers with the specific mutations was appreciated as critical to positive patient outcomes. Consequently, the unpredictability surrounding the Supreme Court's patent eligibility decisions such as *Bilski*, *Mayo*, and *Myriad* and the potential consequences of patent subject matter eligibility issues for patents to methods for using Drug A and

[7] Numerous academic studies have provided useful data on impact at the USPTO by analyzing large data sets, including a recent University of Illinois study analyzing a data set of 4.8 million USPTO office actions and responses. Kesan and Wang, *Eligible Subject Matter at the Patent Office: an Empirical Study of the influence of Alice on Patent Examiners and Patent Applicants*, 105 Minnesota L. Rev., 2 (May 2020) Electronic copy available at: https://ssrn.com/abstract=3556216

[8] With respect to computer related inventions, *Alice* and its progeny, including the continued extension of *Alice's* dicta to other areas (*e.g.*, mechanical drive shafts and digital cameras), have been the subject of robust debate. As to computer related inventions, additional issues such as genericness, overbreadth, sufficiency of phrases such as "do it on a computer," eligibility standards such as potentially requiring a technical solution to a technical problem, business method eligibility, functional language under section 112(f) and the like have been a large part of the debate if not the center of the debate. Members of this Section have varying views on these issues. The scope of the current Notice is too narrow to address these issues. Accordingly, our response should not be read as addressing those issues.

diagnostic methods for identifying patients in need of Drug A were closely considered.

- More specifically, subject matter eligibility was considered across the entire patent portfolio in general, and specifically with respect to method-of-treatment claims and claims relating to diagnostic tests. A major concern was that method-of-treatment claims that include identifying the patient would be found to be ineligible because the correlation between the mutation and the cancer could be characterized as a "law of nature" and the class of drugs that includes Drug A as "conventional." Claims directed only to the diagnostic (*i.e.*, claims that do not include administration of Drug A) were not even pursued.
- After extensive pre-clinical and clinical testing of Drug A, a full New Drug Application (NDA) was filed, and an accelerated approval was granted by the FDA, but without a companion diagnostic. However, a companion diagnostic was included in the FDA's post-marketing requirements. StartupCo sought to engage several diagnostic partner companies to develop companion diagnostic products before the NDA was filed. There were very few interested partners, which StartupCo attributes to subject matter eligibility concerns. Large diagnostic companies can rely on size and presence/market share for a competitive advantage and investment return. In contrast, small companies cannot compete without strong IP. The result is a challenging dynamic to identify a diagnostic partner for critical innovation impacting a relatively limited patient population. Without robust patent protection, small-market players cannot compete effectively, and without the size of a diagnostic suitable for a broad population, the large-market players have little interest. Uncertainty around subject matter eligibility has thus resulted in, *inter alia*, challenges to bringing innovation and life-prolonging drugs to market.
- Throughout the development of Drug A, StartupCo continuously monitored and evaluated the level of investment committed to developing Drug A. Patent protection was critical to this investment. But for patent protection claiming Drug A as a "composition of matter," the investment to develop Drug A would not have been undertaken. The uncertainty in the subject matter eligibility jurisprudence as it applies to diagnostic method-of-treatment claims would have foreclosed the development of Drug A based on that uncertainty alone.
- StartupCo believes it has adopted sound strategies for complying with current subject matter eligibility requirements; it knows protecting its technological investments may be difficult because the rules keep changing. A more certain environment would allow StartupCo to focus on developing new drugs, new companion diagnostics, and treating patients, without the need to spend resources on assessing the impact a new court decision may have on its previously developed patent strategies. There should be no doubt that the

> innovation undertaken by StartupCo – both the diagnostic and the methods of treatment - should be patent eligible subject matter. Such innovation is the foundation for precision or personalized medicine and the next generation of healthcare innovation.

The above example sets out the following real-world impact of the patent eligibility jurisprudence and its negative impact on business.

1. The uncertainty in the law forecloses StartupCo from bringing forward a precision medicine based only on a diagnostic method-of-treatment patent claim. This contributes to a skew in pharmaceutical research – rather than seeking to discover the best precision medicine to treat a particular patient based on their tumor genetics, StartupCo has to discover the best medicine to treat a particular patient that ***also*** has composition-of-matter patent protection. This effectively removes known compounds and compounds that are potentially unpatentable as a composition of matter from being used in the development of a precision medicine therapy.

2. Patent eligibility jurisprudence has created a barrier to finding a suitable diagnostic partner. The jurisprudence practically forecloses a small company/new entrant to the diagnostic market, which makes it more difficult to find a diagnostic partner to develop Drug A as a precision medicine.

3. The patent eligibility jurisprudence thereby acted as a "tax" on the system by diverting resources. Money and time spent assessing the impact of evolving jurisprudence on Section 101 was money and time not spent on the development of Drug A.

Real-World Example No. 2

- Another example of the economic consequences of the interpretation of recent Supreme Court precedent on subject matter eligibility by the district courts and Federal Circuit is Sequenom. The company's technology provided non-invasive pregnancy testing (NIPT) that obviated the need for amniocentesis to diagnose, *inter alia*, Down's syndrome and cystic fibrosis; it was widely hailed as "groundbreaking" and had real world benefits to pregnant women due to the risks avoided by use of a simple blood test.
- The technology was invented by two Oxford University professors and initially commercialized by Isis Innovation Ltd., Oxford's technology transfer and commercialization entity. Sequenom, headquartered in Southern California, licensed the technology in 2008 and built its business based on the acknowledged benefits of NIPT.
- In January 2012, Sequenom brought suit against Ariosa and Natera over infringement of its licensed U.S. Patent No. 6,258,540. Sequenom was unsuccessful in attempting to obtain a preliminary injunction in July 2013;

immediately thereafter the company reduced its workforce by 13% (75 jobs). In October 2013, the district court invalidated the asserted claims on subject matter eligibility grounds, relying on a combination of the *AMP v Myriad Genetics* and *Parker v. Flook* decisions (Justice Breyer relied on *Flook* in his *Mayo* opinion). While awaiting the outcome of appeal to the Federal Circuit, Sequenom sold its bioscience division for almost $36 million and consolidated its testing services in North Carolina. The Federal Circuit affirmed the district court's invalidity determination in June 2015 and denied a petition for rehearing *en banc* in December 2015, despite several members of the Court acknowledging the wrongheadedness of this precedent but believing their hands to be tied. In January 2016, the company laid off 20% of its remaining workforce (110 jobs) and closed its North Carolina facility. During this time the company saw a marked diminution in sales of its NIPT products and services, despite having sold about half a million tests by then. In June 2016 the Supreme Court denied *certiorari*, and a month later LabCorp acquired the company for $371 million (a price acknowledged to be far lower than it would have been prior to the litigation outcome). The remnant of the company is now organized as a LabCorp Specialty Group under the name Integrated Genetics, providing NIPT and other genetic testing services based on detection of relevant DNA in blood as well as genetic counseling services.

- In contrast to the fate of Sequenom's U.S. patent, Sequenom's counterpart European Patent EP 994 963 (whose claims 1 and 18 are substantially identical to claims 1 and 21 of U.S. Patent No. 6,258,540) twice survived third-party challenges and the claims were upheld as patentable by the European Patent Office.[9] The German Federal Supreme Court expressly ruled that it would not follow the U.S. approach to subject matter eligibility: "unlike the US Supreme Court (in 566 U.S. (2012) – *Mayo v Prometheus*), … a teaching that involved performing a technical act which used a discovery to achieve a specific outcome was patentable, regardless of whether the teaching also contained 'inventive added value' above and beyond the use of the naturally occurring correlation discovered."[10]

This narrative illustrates four consequences of the current subject matter eligibility jurisprudence.

1. Significant real-world outcomes occur when company patents are invalidated on subject matter eligibility grounds, for the companies, their employees, innovation, and the economy.

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[9] Amicus Brief of the BioIndustry Association in Support of Certiorari, *Sequenom, Inc. v. Ariosa Diagnositics, Inc.*, No. 15-1182 (Apr. 19, 2016) (citing Decision of the Boards of Appeal of the EPO, Case No. T 0146/07 - 3.3.08 (Dec. 13, 2011).

[10] Official Journal of the EPO, supplementary publication 6 (2017), *available at* https://www.epo.org/law-practice/legal-texts/official-journal/2017/etc/se6/p12/2017-se6-p12.pdf (citing Federal Court of Justice, 19 Jan. 2016 (X ZR 141/13) – Receptor tyrosine kinase).

2. Despite widespread disagreement with both the outcome and legal rationale, the Federal Circuit acknowledged that it is incapable of challenging on any basis plenary application of the *Mayo/Myriad* precedent by district courts (even in cases such as these where the accused infringer's CEO bragged about expropriating Sequenom's patented technology).

3. Acquisition by LabCorp illustrates that only large, well-established and funded companies can prevail in an ecosystem where IP protection is practically unavailable to innovating startups, contradicting the experience over the last fifty years that it has primarily been just those companies (like Sequenom, based on university-developed technologies) that have driven innovation.[11]

4. The United States' restrictive approach to subject matter eligibility is out of step with the approach of other major patent jurisdictions in the world where patent protection is available for these inventions. This disparity creates an artificial incentive for global businesses to alter both where they conduct their R&D and where they offer their products for sale.

III. Conclusion

As USPTO studies have shown, intellectual property intensive industries support at least 45 million U.S. jobs and contribute over 38% to the U.S. GDP.[12] The above examples tell a compelling story of the impact of patent eligibility jurisprudence on jobs, the economy, and U.S. innovation. The stories feature precision medicine and

[11] Many young American companies that grew into large companies owe part of their success to patent protection. Examples include Amgen, Apple, General Motors, and Hewlett Packard.
[12] See U.S. Patent and Trademarks Office and Economics and Statistics Administration Joint Report, Intellectual Property and the U.S. Economy: 2016 Update (2016), https://www.uspto.gov/learning-and-resources/ip-motion/intellectual-property-and-us-economy; U.S. Patent and Trademarks Office and Economics and Statistics Administration Joint Report, Intellectual Property and the U.S. Economy: Industries in Focus (2012) https://www.uspto.gov/sites/default/files/news/publications/IP_Report_March_2012.pdf.

diagnostics, but the impact crosses technology lines with patent claims directed to axles and cameras falling to section 101.[13] Appendix A maps these stories to the specific questions in the Notice. If further opportunities arise in connection with the Notice or subsequent notices, the Section would be pleased to supplement its response. Should you have any questions or would like to discuss these issues further, please do not hesitate to contact me.

Sincerely,

Kim R. Jessum, Chair
ABA Section of Intellectual Property Law

[13] *American Axle & Mfg. v. Neapco Holdings*, 939 F.3d 1355 (Fed. Cir. 2019), *modified on panel rehearing*, 967 F.3d 1285 (Fed. Cir. 2020), *rehearing en banc denied*, 966 F.3d 1347; *Yanbin Yu v. Apple Inc.*, No. 2020-1760 (Fed. Cir. Jun. 11, 2021), http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/20-1760.OPINION.6-11-2021_1789244.pdf.

Appendix I

Specific responses - Section I

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.

Focusing just on the examples given in the body of our letter (and without exclusion of other technologies), the U.S. is the world leader in life sciences. The foremost edge of this leadership comprises gene therapy, mRNA vaccines and therapies, precision medicines tailored by a patient's genetics and other advancements that leverage endogenous biological mechanisms—alleged "laws of nature" or "products of nature"—into innovative medicines and treatments. As illustrated in the example of StartupCo's development of Drug A, the subject matter eligibility jurisprudence creates uncertainty and barriers, particularly in the diagnostic methods that support precision medicine. As illustrated in the Sequenom story, this uncertainty can lead to job loss and industry consolidation where the "small player," who relies exclusively on patent protection, cannot compete.

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 uncertainty in patent eligibility jurisprudence impacts all areas listed. As illustrated in the StartupCo example, the patent prosecution strategy and portfolio management focus on composition of matter protection to provide a hedge, given the

uncertainty of a diagnostic method of treatment claim, and diagnostic claims were not pursued.[14] The StartupCo example further illustrates the barriers presented to finding a licensee / diagnostic partner to support a precision medicine. The uncertainty has contributed to industry consolidation making the market less competitive and more challenging to find diagnostics directed to precision medicines with small patient populations.

The Sequenom example illustrates how the patent eligibility jurisprudence can have a catastrophic impact on a company during patent enforcement and litigation. Sequenom progressively cut jobs as an injunction was denied; then ultimately the patent claims were found invalid as being directed to ineligible subject matter. Counseling and opinions must necessarily reflect the stark reality -- all diagnostic claims that have reached a final decision at the Federal Circuit have been declared invalid.[15] Particularly in the life sciences, the societal cost of the uncertainty of subject matter eligibility jurisprudence is difficult to quantify or measure. A drug never discovered due to diverted resources, a medicine never developed because of the uncertainty of diagnostic method of treatment claims, or a precision medicine delayed because the small diagnostic companies are out of business are not easily quantified. Nevertheless, the impact on patients is unmistakable. It denies patients life-saving innovation.[16]

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;

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).

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[14] The inclusion of a treatment step does not necessarily solve the problem if the administration step is conventional or known (*e.g.*, step (a) of the claim at issue in *Mayo* provided administering a drug). Accordingly, relying on a diagnostic method of treatment claim (step (a) is diagnosis and step (b) is administering the precision medicine) is vulnerable if the precision medicine is known.

[15] "Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs*., LLC, 927 F.3d 1333, 1352 (J. Moore in dissent).

[16] The impact on Section 101 is not limited to life sciences. *See How Alice Affects Bioinformatics Patent Applications?*, Wang and Kesan, electronic copy available at: https://ssrn.com/abstract=36863642. ("Moreover, applicants gradually filed fewer patent applications, compared to the time period before *Alice*, with the greatest reduction in patent applications occurring in June 2014, when the *Alice* decision was delivered by the Supreme Court.").

As noted above in the body of our letter, the Section has repeatedly made the point in its testimony before Congress and in its previous letter submissions that, in general, patent eligibility jurisprudence has negatively affected investments in innovation in many technological fields. Not surprisingly, the impact from one field of technology to another varies as pointed out in a recent study by SMU Dedman School of Law professor David O. Taylor. Professor Taylor has frequently written and testified regarding the decreased level of investment across the spectrum of technological industry sectors, particularly in the life sciences sector, arising from the "crisis" in subject matter eligibility jurisprudence. As Professor Taylor explained in testimony before the Senate Judiciary Subcommittee:

> The second principal finding is that reduced patent eligibility correlates with particular investment behaviors in particular industries. Investors overwhelmingly indicated, for example, that the elimination of patents would either not impact their firm's decisions whether to invest in companies or only slightly decrease investments in companies developing technology in the construction (89%), software and Internet (80%), transportation (84%), energy (79%), and computer and electronic hardware (72%) industries. But investors, by contrast, overwhelmingly indicated almost the exact opposite that the elimination of patents would either somewhat decrease or strongly decrease their firm's investments in the biotechnology (77%), medical device (79%), and pharmaceutical industries (73%). Thus, according to these investors, on average each industry would see reduced investment, but the impact on particular industries would be different. And the life sciences industries are the ones most negatively affected.[17]

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 the body of our letter in response to this Notice, we reference prior responses of our Section as well as the Mossoff Statement with respect to this question. As noted by Professor Mossoff on pages 2-3 of his testimony and in the citations in footnote 9, other jurisdictions began taking advantage of the uncertainty and unpredictability in U.S. patent eligibility jurisprudence several years ago. As noted in footnote 9 of the Mossoff Statement, China, for example, relaxed rules on software patentability beginning in 2017, and in the biotech field of technology research and development dollars have been reported as shifting to China. Thus, the uncertainty and unpredictability in patent eligibility appears to be weakening U.S. leadership, and importantly signals to other countries that subject matter that was globally accepted as patent eligible subject matter now can be denied protection in the U.S. without violating Trade-Related Aspects of Intellectual Property Rights (TRIPS).[18] If Pandora's box on subject matter eligibility has been thrown open, the diminution of global rights in intellectual property may be inevitable.

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[17] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3399699.

[18] https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm ("patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application . . . patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced").

As a specific example of a significant difference in the treatment of substantially identical patent claims in corresponding patent applications in the U.S. and Europe, the second real world example laid out in the body of our letter is directly on point. In contrast to the fate of Sequenom's U.S. patent which was found to be subject matter ineligible, Sequenom's counterpart European Patent EP 994 963 (whose claims 1 and 18 are substantially identical to claims 1 and 21 of U.S. Patent No. 6,258,540) twice survived third-party challenges and were upheld as patentable by the European Patent Office. The German Federal Supreme Court expressly ruled that it would not follow the U.S. approach to subject matter eligibility: "unlike the U.S. Supreme Court (in 566 U.S. (2012) – *Mayo v Prometheus*), … a teaching that involved performing a technical act which used a discovery to achieve a specific outcome was patentable, regardless of whether the teaching also contained 'inventive added value' above and beyond the use of the naturally occurring correlation discovered."

As illustrated by the latter example and the broader explanation in the Mossoff Statement, the United States may now or soon stand as an outlier with no other competitive country finding similar, critical areas of research to be ineligible subject matter for patenting.[19] Thus, a risk exists that over time, this will erode the United States leadership in critical technologies.

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.

A specific instance of the denial of patent protection in the U.S. based on subject matter eligibility while protection was obtained in Europe for substantially identical patent claims is the real world example of Sequenom set forth in response to question 4 above. Sequenom was denied protection in the U.S. but granted protection in Europe. In the Mossoff Statement cited in response to question 4, Professor Mossoff points to other examples of other countries beginning to take advantage of the inability to protect innovations in the U.S. by expanding their eligibility requirements. However, at the present time the Section does not have any additional specific examples of the type of data requested by this question.

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.

Both real world examples set forth in the body of our letter present situations where business decisions were significantly altered as a consequence of patent eligibility determinations.

[19] The patent directed to non-invasive prenatal diagnostic tests that was found ineligible in the United States was found patentable in the United Kingdom (*Illumina, Inc v Premaitha Health Plc* [2017] EWHC 2930) and Australia (AU Patent No. 727,919, upheld by the Australian High Court, *Ariosa Diagnostics, Inc & Ors v Sequenom, Inc* [2021] FCAFC 101).

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.

As illustrated in both examples provided herein, patent eligibility jurisprudence has impacted business strategies. Research strategies for StartupCo were impacted – uncertainty of diagnostic methods of treatment focused the company on novel (and likely patentable) compounds only. It further created barriers to finding a suitable diagnostic partner. For Sequenom, the loss of patent protection led to job losses for employees and reduction in available funds for investment. These real-world impacts are undoubtedly multiplied by hundreds if not thousands of companies managing the uncertainty of patent eligibility jurisprudence. The question for policy-makers should not be whether U.S. innovation can be resilient enough to overcome this certainty – large companies likely can; rather, the question should be whether the current patent eligibility jurisprudence facilitates the engine of innovation across all technologies and inventive entities, small and large. It clearly does not.

8. 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.

At the present time, the Section does not have specific examples to offer in response to this question.

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 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.

While the Section has a large number of members who regularly litigate patent cases, including with respect to patent eligibility issues, the Section has not had sufficient time and opportunity to conduct a survey of its members to provide a response to this question.

Specific Responses Section II

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

As the Section replied in response to the U.S. Senate Judiciary Subcommittee 2019 Questions for the Record (QFR): “The effects of the current interpretation of section 101, however, are clear in one respect. Patents invalidated on the basis of eligibility in the U.S. are found to eligible in other countries. In a global economy, this puts at risk U.S. leadership in innovation. It is also problematic for the U.S. to be out of step with other industrialized countries. As Professor Timo Minseen notes, ‘Legal developments in patent law, while local

in immediate effect, migrate within an increasingly global economy and may destabilize the objective of harmonizing an efficient world patent system.'"[20]

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

American business craves certainty for economic activity. The uncertainty around patent subject matter eligibility has a real impact on the U.S. economy as a whole. This uncertainty is a frequent topic of discussion and legal scholarship. Such discussion for example has included Section meetings and CLE programs. In terms of legal scholarship, the most comprehensive and the only sophisticated empirical data of which we are aware is found in a recent analysis and report by Professor David Taylor who authored an article entitled "Patent Eligibility and Investment" to be published in the Cardozo Law Review.[21] Professor Taylor conducted a survey of 475 investors at firms investing in various industries and at various stages of funding. His survey establishes that patent eligibility has been an important consideration in investment decision making, and that the negative impact of the current patent eligibility jurisprudence is clear, albeit that the impact varies from industry to industry. The article reported, *inter alia*, "overall 62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable, while only 20% disagreed."[22] This study confirms our anecdotal evidence of the negative impact of the current state of jurisprudence on patent eligibility.

12. 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).

The Section has limited access to data necessary to fully respond to this question. However, the impact is clear in the areas of precision medicine, diagnostics and pharmaceutical treatments as illustrated in the two examples provided herein. Further, patent filings post-*Alice* on informatics have declined.[23] But perhaps the best summary of the

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[20] *See* n. 2.
[21] David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO LAW. REV. 5, http://cardozolawreview.com/patent-eligibility-and-investment/).
[22] *Id.*
[23] The impact on Section 101 is not limited to life sciences. *See* How *Alice* Affects Bioinformatics Patent Applications? *See supra*, n. 7, Kesan and Wang, electronic copy available at: https://ssrn.com/abstract=36863642.

negative effects of current patent eligibility jurisprudence across a range of technologies may be found in Section II, "The Closing of the U.S. Patent System to Innovation, pages 4-8 of the Mossoff Statement before the Senate Subcommittee on Intellectual Property on June 4, 2019. In his chart on the "Percent of Office Actions with Section 101 Rejections," Professor Mossoff identifies the effects of current jurisprudence on a range of technologies.[24]

13. 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?

In general, restoring patent eligibility to its gatekeeper role is likely to benefit U.S. consumers by encouraging investment in innovation in fields of endeavor that have been negatively impacted by the uncertainty and unpredictability of current eligibility jurisprudence.

We are not aware of any empirical data that addresses whether the restoration of traditional section 101 eligibility—that is, providing a more certain and predictable test for patent eligibility while enabling other sections of the patent statute to perform their roles in assessing patentability—would increase or decrease consumer prices. For example, it may be just as plausible that advances might reduce costs/prices incurred by consumers in seeking products or services in that field. Various examples of the potential for reduced costs/prices are not difficult to contemplate.

[24] *See* "Mossoff Statement," *supra* n. 4.