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October 15, 2021

Via Federal eRulemaking Portal: *www.regulations.gov*
Docket No. PTO-P-2021-0032
Attn: Andrew Hirshfeld
(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, VA 22213-1450

Re: Patent Eligibility Jurisprudence Study

Dear Mr. Hirshfeld:

The Boston Patent Law Association ("BPLA") wishes to thank the United States Patent and Trademark Office ("USPTO") for the opportunity to respond to the request for information ("RFI") on the current state of patent eligibility ("§101") jurisprudence in the United States, and how current jurisprudence has impacted investment and innovation, particularly in critical technologies such as quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments.

The BPLA is an association of more than 800 intellectual property ("IP") professionals, providing educational programs and a forum for the exchange of ideas and information concerning patent, trademark, and copyright laws in the First Circuit, focusing on the greater Boston area. The membership of the BPLA includes IP professionals working in all areas of science and technology, including pharmaceuticals, biotechnology, medical devices, chemistry, and computer technologies. Members include in-house counsel, as well as attorneys in private practice and academia. All are sensitive to developments in the law that affect American business.

The BPLA submits these comments solely as its consensus view. It should be noted that, in many cases, issues of confidentiality and privilege constrain the public identification of specific clients and examples. Accordingly, the following comments are based primarily on the anecdotal experiences of the BPLA's membership. They are not necessarily the views of any individual member, any firm, or any client.

I. Observations and Experiences

1. Background and Overview

The BPLA welcomes the inquiry by Senators Tillis, Hirono, Cotton, and Coons underlying this RFI. It is now widely acknowledged that recent judicial decisions in eligibility jurisprudence have substantially reduced the predictability of outcomes for inventors and investors seeking to acquire and enforce patent rights. Decisions in the *Mayo*[1], *Myriad*[2], *and Alice*[3] cases, along with subsequent holdings, have eroded previously established standards for determining the eligibility of subject matter for patent protection. In addition, the conflation of issues of anticipation and obviousness with eligibility has contributed to confusion, and preempted determination of these matters under §102 and §103 of the statute which already serve as high bars. Indeed, several of the objectives that appear to have been sought with the *Alice* and *Mayo* decisions are already being addressed by §102 and §103 without categorically excluding entire technical fields.

The resulting lack of certainty deprives inventors, investors, and innovators of a reliable basis for making investments in development and commercialization of technologies that are essential to bringing innovative products to market. It undercuts the innovation and commercialization on which we all depend and leaves us, as a nation, poorer and less competitive in an increasingly challenging world.

Private investment in research and development ("R&D") plays a crucial role in American innovation and, consequently, in the economy as a whole. Between 1976 and 2000, total federal research funding as a percent of GDP decreased by more than one third.[4] Private investment now accounts for approximately 60% of R&D funding in the United States and is essential to innovation.[5] It is axiomatic that business requires the balancing of risk and reward. Any loss of predictability corresponds to an increase in investment risk. An economic input that reduces predictability, and therefore increases risk, without a commensurate increase in potential reward, militates against future investment.

Recent changes in §101 jurisprudence have clearly diminished the rationality and reliability of processes for administrative and judicial evaluation of patent eligibility. Previously

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[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 132 S.Ct. 1289, 101 U.S.P.Q.2d 1961 (2012).

[2] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 133 S.Ct. 2107, 106 U.S.P.Q.2d 1972 (2013).

[3] *Alice Corp. Pty. Ltd. v. CLS Bank Intl.*, 573 U.S. 208, 134 S.Ct. 2347, 110 U.S.P.Q.2d 1976 (2014).

[4] https://www.aaas.org/programs/r-d-budget-and-policy/historical-trends-federal-rd; https://www.aaas.org/sites/default/files/2020-10/RDGDP.png; https://www.aaas.org/sites/default/files/2020-10/RDGDP_0.xlsx.

[5] Two sectors—business and the federal government—have together accounted for more than 90% of U.S. R&D funding since 1953, though their combined share has fallen from a high of 98% in 1956 to 92% in 2016. Federal R&D expenditures as a share of total U.S. R&D expenditures peaked in 1964 at 66.8%, the same year that business R&D expenditures reached a nadir of 30.8%. Between 1964 and 2000, the federal government's share fell and business's share rose. In 2000, business accounted for 69.4% of U.S. R&D expenditures and the federal government 25.1%. This shift in the composition of R&D funding resulted not from a reduction in federal government R&D expenditures, but rather from faster growth in business R&D expenditures. From 2000 to 2010, business R&D's share declined from 69.4% to 61.0%, and has risen each year since, reaching an all-time high of 69.7% in 2018; from 2010 to 2018, the federal share declined from 31.1% to 21.9%. *See* https://fas.org/sgp/crs/misc/R44307.pdf.

existing standards have been undercut and now-central concepts, such as "abstract idea" and "something more," have been left largely undefined. The BPLA membership has observed many anecdotal indicators suggesting that otherwise viable innovations are being abandoned by inventors and investing entities due to the resulting increase in patent eligibility uncertainty.

Related IP metrics provide direct context for evaluating the scope of the consequences. BPLA members have seen patent applications abandoned, or never filed, in connection with various technologies including but not limited to communications, medical diagnostics, and supply chain management. In light of the recent holdings in *American Axle*[6] and *Yu*[7], there is apparently no technical field in which an applicant for a patent can have reasonable certainty that their claimed invention will be deemed concrete and not abstract. In some instances, BPLA members have abandoned pending applications due to patent eligibility concerns. Companies are also postponing the disclosure of innovations that would otherwise be filed in patent applications and made public earlier, awaiting greater clarity with respect to the eligibility environment.

In sum, businesses across the American economy are negatively impacted by the new uncertainty as to how patent claims will be treated under §101. This uncertainty has led and will continue to lead to decisions reducing investment in R&D. The BPLA believes that the result will be fewer innovative technologies, a reduction in employment opportunities in STEM, and reduced global competitiveness for the United States in the future. Organizations of all sizes are being deprived of what has historically been considered the value of patent applications (and issued claims) in critical technology sectors.

The lower courts have responded to this new ambiguity in the law with broadly divergent holdings, which adds to rather than ameliorates uncertainty. There is little near-term prospect for substantial clarification from the judicial branch. As such, this is an appropriate moment for clarifying legislation providing clear and broadly inclusive criteria for the evaluation of patent subject matter eligibility.

2. Activity-Specific Impacts

The RFI identifies various specific areas of potential impact which are commented on here in turn.

a. Patent Prosecution Strategy and Portfolio Management

The potential for achieving patent protection is viewed as a substantial factor in terms of assessing the likelihood of recouping costs and/or generating profit. BPLA members have observed that companies are generally proceeding less aggressively with both new patent filings and with the prosecution of pending applications in the U.S. Some companies are not pursuing new filings at all while others are delaying new filings and/or prosecution of pending applications while awaiting a change in the law. Some companies are declining to convert U.S.

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6 *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019).

7 *Yu v. Apple Inc.*, 2020-1760, 2020-1803 (Fed. Cir. 2021).

provisional patent applications to U.S. non-provisional and/or international (PCT) applications. Other companies are declining to nationalize PCT applications in the U.S. or to file U.S. applications based on Paris Convention claims to foreign applications.

There is a sense of uncertainty as to how organizations should allocate funds towards the prosecution of patent applications, as well as towards the enforcement and maintenance of issued patents whose claims might face §101 challenges. A perceived potential for reduced value makes many anxious for a change in the law to provide greater clarity such that portfolio strategy can be informed and redirected.

In addition, the prosecution of individual applications has become more costly. Rather than rapidly traversing the question of eligibility and dealing with anticipation and obviousness, repeated cycles of office actions and responses that address substantially the same eligibility issues result in additional cost and delay. In some cases, separate applications are filed to carve out subject matter more likely to be found patent eligible (e.g., method claims) from that less likely to do so. Such consequences of current §101 jurisprudence run contrary to Congressional intent, as expressed in patent term adjustment (PTA) mechanisms, and to the USPTO policy of compact prosecution. Ultimately, these prosecution strategies result in unnecessary consumption of applicant, USPTO, and court resources.

i. Public Disclosure Considerations

The overall reduction in patent filings, and conversions of provisional applications, reduces disclosure of inventions that would otherwise benefit the public. These consequences are expressed directly by failing to teach how to make and use the inventions, which also inhibits the development of follow-on technology. Indeed, it is important to consider long-term effects. In light of the standard 20 year patent term, reduced disclosure of innovations in patents now may have downstream effects for decades.

ii. Trade Secret Considerations

The ambiguity around §101 jurisprudence has driven an increased reliance on trade secret protection. BPLA members have expressly indicated that companies (e.g. those in the bioinformatics space) actively consider trade secret protection in lieu of patent protection because of the uncertainty. While trade secrets can be very valuable under certain circumstances, they are often not an ideal solution and provide no disclosure benefit to the public.

Trade secrets typically provide a less robust basis for investment. Reverse engineering can be relatively trivial for some technologies, rendering trade secret protection less effective than patenting and reducing the potential value of corresponding commercial undertakings. Limited trade secret protection in some foreign jurisdictions can mean that relying on trade secrets reduces U.S. competitiveness in international trade. Moreover, in regulated industries, disclosures required for regulatory approval often render trade secret approaches moot.

b. Patent Counseling and Opinions

The current state of jurisprudence fosters uncertainty as to whether any given technology potentially covered by patents can be practiced. Competition in the marketplace and consumer choice are therefore affected. Advice and opinion letters, including white space and freedom to operate analyses, are necessarily less reliable and harder to prepare. Consequently, the rapidly changing §101 landscape results in reduced investor confidence.

c. R&D (and Innovation)

As noted above, private investment provides the resources for most domestic R&D. By increasing the risk of such investments, current §101 jurisprudence tends to reduce the resources available for corresponding R&D efforts.

d. Employment

Emerging companies are one of the largest generators of new jobs in the U.S.[8], and investment in such companies can have an outsized impact on immediate and future employment. Flows of venture capital and other early stage investment resources, on which such companies rely, are highly sensitive to the availability of patent protection. Consequently, the diminished patent protection afforded under current §101 jurisprudence may result in reduced hiring of those working in R&D and STEM, as well as the many ancillary occupations affected by startup activity.

e. Procurement

The territorial right to exclude others afforded by our patent system is protectionist in nature. Without the threat of potential patent assertion, businesses will have even less motivation to seek domestically sourced goods, which tend to be more expensive than imported goods due to various factors, including higher associated labor costs.

f. Marketing (and Sales)

Because of the increasing prevalence of method claims (e.g., over composition claims) as discussed above, secondary theories of infringement (e.g., inducement) may become more prevalent. Third-parties may therefore be more reticent and cautious in their product labeling and marketing to thwart potential liability that was not previously a risk factor.

[8] Startups and young businesses clearly play an important role in job creation. Between 1980 and 2010, the gross number of jobs created annually by all establishments averaged about 18 percent of the workforce—an average of 16.3 million jobs per year—according to our calculations from the [U.S. Census Bureau] Business Dynamics Statistics. Decker et al., *The Role of Entrepreneurship in US Job Creation and Economic Dynamism,* 28 Journal of Economic Perspectives, No. 3, 3, 6 (2014), pp 3–24; https://pubs.aeaweb.org/doi/pdfplus/10.1257/jep.28.3.3.

g. Ability to Obtain Financing from Investors or Financial Institutions

U.S. private investment in innovation is directly tied to the availability of IP rights in the resulting technologies. Absent those rights, U.S. companies simply do not invest to the same extent. An actual or perceived reduction in ability to secure patent protection due to patent eligibility jurisprudence makes it harder to secure grants and other investment. This is a particularly significant issue for startups and early stage companies, but important for entities at later life stages as well.

h. Investment Strategy

It has become increasingly difficult to obtain financing based on patent portfolios whose value is potentially reduced by the uncertainty concerning the applicability of §101. Investors are less likely to invest in companies developing technologies directed to subject matter that may run afoul of current patent eligibility jurisprudence due to an actual or perceived reduction in the value of related inventions.

i. Licensing of Patents and Patent Applications

Momentum around various transactions involving technology has diminished as well. The changes in jurisprudence at issue have created greater reluctance to enter into licensing arrangements for patented technologies that might implicate §101. Likewise, collaborations, mergers, and acquisitions between organizations where the relevant technology could fall within the ambit of present §101 jurisprudence have been complicated and dissuaded.

Because of an actual or perceived reduction in value of inventions directed to subject matter that may run afoul of current patent eligibility jurisprudence, licensing activities—and the value of licenses—related to patents in these technologies are reduced. Thus, companies that might otherwise bring such innovations to market will not do so. In particular, companies are less likely to seek licenses to patents in relevant technologies, even where there is a perceived risk of infringement, because there is increased potential for invalidating such patents under §101 at an early stage of the proceeding (e.g., via summary judgement).

j. Product Development

Product development extends from R&D efforts. Companies are allocating fewer resources to the development of products related to inventions that are subject to an actual or perceived reduction in value due to current patent eligibility jurisprudence. For example, companies that could develop diagnostic assays for early childhood treatment intervention have left the field. Similarly, investment in products related to, for example, advanced image processing, are not being pursued because of uncertainties regarding §101 eligibility. This will result in fewer improvements in diagnostic imaging in the future. Overall, there will be a reduced availability of goods and services because many are simply not created. U.S. companies are generally well-positioned to meet the regulatory and other requirements necessary to compete in the marketplace, but not if they are unmotivated to produce at the outset.

k. Competition

As discussed above, U.S. private investment in innovation is directly tied to the availability of IP rights in the resulting technologies. Absent those rights, U.S. companies do not invest, and U.S. competitiveness and technological superiority is diminished. Competitors based abroad (where patentability of such technologies is more certain) are positioned to gain an advantage.

Applicants for patents tend to seek protection in venues that are considered favorable to their interests. If the U.S. is not viewed as such a forum to an increasing number of applicants, both domestic and international, the result will be a reduced influx of cash into the U.S. economy. Current patent eligibility jurisprudence demotivates U.S. filing, leaving us at a competitive disadvantage, particularly relative to the rapidly growing Chinese patent system.[9] The global perception of the U.S. with respect to patent rights in connection with critical technologies is also an important consideration with respect to overall competitiveness.

3. Technology-Specific Impacts

The RFI also solicited input on any particular technological fields, including investment and innovation, and the BPLA wishes to offer the following observations.

Overall, a number of specific fields —in particular precision medicine, diagnostic methods, and pharmaceutical treatments—are often highly reliant on patent protection to motivate investment in R&D. By reducing predictability as to whether particular patent claims will pass muster under current §101 jurisprudence, companies are accordingly less likely to invest in the research, development, and marketing of these technologies. In the example fields noted above, such technologies can be crucial to patient health. All of this therefore reduces the value of inventions directed to these areas, as well as utility or benefit offered to the public in multiple other dimensions.

a. Diagnostics

Current §101 jurisprudence generally requires that claims to diagnostic tests be linked to affirmative steps reciting methods of treatment. As an initial matter, this is counterintuitive, as companies in the business of discovering and developing diagnostic tools are generally not in the business of treating patients. This dilutes the value of the IP these companies are able to secure by implicating divided infringement issues. In addition, the resulting "treatment" a medical professional might prescribe based on the results of a diagnostic test can be difficult to claim (e.g., a negative prescription like bedrest, etc.).

[9] *See* "China Becomes Top Filer of International Patents in 2019 Amid Robust Growth for WIPO's IP Services, Treaties and Finances" https://www.wipo.int/pressroom/en/articles/2020/article_0005.html.

b. Biotechnology

The blanket exclusion of isolated genes from patent eligible subject matter is technically misplaced. While the gene itself literally exists in nature (i.e., as part of DNA), it does not retain the same functioning when isolated that it would exhibit in nature as part of an overall genome. Exclusion of an identified gene sequence primarily responsible for a particular disorder denies the reward of patent protection to inventions that are otherwise useful, novel, and nonobvious, and also dissuades a public-benefitting disclosure.

While alternate, tangential claim strategies are available (e.g., seeking claims to a particular inhibitor/cDNA), these allow for relatively easy design-arounds (e.g., with miRNA), reducing the value of these inventions. The jurisprudence also further drives a tendency towards seeking patent protection for methods rather than compositions. Method claims are generally less valuable than composition claims because of complications in identifying infringers, divided infringement issues, and enforcement (e.g., when medical professionals are direct infringers).

As a result, companies in the critical business of isolating genetic components for treatment and diagnostic purposes are declining to file patent applications and sometimes keeping their innovations as trade secrets instead. The related policy implications should be closely examined and weighed.

c. Software

Software is pervasive and of significant public interest in our economy. The *Google*[10] decision cast significant doubt on, and undercut the value of, copyright for protecting software. There are more reasons now than ever to have an effective means of protecting IP rights in the software field. The scope of related patent ineligible subject matter, however, appears to continually expand, even encompassing mechanical devices (e.g., *American Axle* and *Yu*). Emerging companies based on software inventions have a particularly difficult time getting their patents through the patent eligibility filter.[11] There has been a significant downtick in related patent filings. While some software implementors may take the position that such trends result in fewer nuisance patents sapping their creative activity, the overall impact is harmful for early stage companies where IP often represents a significant portion of their value. Patents pertaining to standards essential technologies should be handled with particular care.

4. Impacts in the International Context

Many other jurisdictions appear to have more clear and well-established guidelines for the assessment of patentable subject matter. This disparity places the U.S. at risk for a relatively weakened IP position in connection with the critical technologies at issue, as was highlighted above with respect to competitiveness. For example, there seems to be more certainty about what is patent eligible and more consistency among examiners in Europe and abroad. In contrast, U.S.

[10] *Google LLC v. Oracle America, Inc.,* 140 S.Ct. 1261, __ U.S. __ (2020).

[11] *See* Lemley and Zyontza, *Does Alice target Patent Trolls?*, 18 Journal of Empirical Legal Studies 47 (2021) (discussing the effect of Alice on inventors and inventor-started companies in the software field).

prosecution is largely dependent on which examiner gets assigned to the matter and their thoughts on §101. The BPLA membership has experienced reduced or no difficulty in satisfying parallel requirements for patent eligibility in jurisdictions such as China, Japan, Korea, and Europe.

The treatment of patent claims in China and Europe currently has a broad impact on other patent offices which ascribe particular importance to their determinations. The result in the present context is that U.S. claims on a particular invention will often be narrower than what is granted elsewhere. For example, one BPLA member has seen broader claim scope obtained in Europe than in the U.S. for cases in the same patent family pertaining to bioinformatics. This puts U.S. patent holders at a disadvantage on the international stage.

II. Conclusion

As indicated above, current patent eligibility jurisprudence creates uncertainty as to the value of patents directed to critical technologies or directly diminishes their value, resulting in numerous downstream effects. A discounted likelihood of success pertaining to the ability to enforce issued patents reduces motivation to proceed with R&D, in addition to raising anxiety regarding the loss of market exclusivity and prospects for future cycles of investment. There is greater uncertainty as to whether and how funds should be allocated for IP-centric cost centers involving the preparation and prosecution of patent applications, enforcement and maintenance of issued patents whose claims might face §101 challenges, and general patent portfolio strategy. Less investment across the board in the short-term is sure to have adverse implications in the long-term. Ultimately, there is less benefit to society, as well as less investment in, and production by, U.S. companies and companies doing business in the U.S. The overall consequence is to discourage investment in domestic IP and the U.S. economy as a whole.

The BPLA appreciates the opportunity to respond to the RFI and looks forward to the USPTO emerging from its §101 jurisprudence study as a thought leader and model jurisdiction with respect to subject matter eligibility. Thank you in advance for your consideration of these comments.

Sincerely,

Boston Patent Law Association

By:

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