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Akin Gump Strauss Hauer & Feld LLP

Executive Director
Jessica K. Landacre

October 15, 2021

Andrew Hirshfeld
Performing the functions and duties of the Under Secretary
of Commerce for Intellectual Property and Director of the USPTO
P.O. Box 1450
Alexandria VA 22313–1450

via https://www.regulations.gov (Docket Number PTO-P-2021-0032)

Re: IPO Comments on Patent Eligibility Jurisprudence Study

Dear Mr. Hirshfeld:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the USPTO's Federal Register notice titled "Patent Eligibility Jurisprudence Study," published in 86 Fed. Reg. 36257 (July 9, 2021) ("Notice"). As you know, IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers, and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO advocates for effective, affordable, and balanced IP rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of intellectual property.

IPO's mission is to promote high quality and enforceable IP rights and predictable legal systems for all industries and technologies. Our vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. IPO has a strategic objective to foster diverse engagement in the innovation ecosystem. Our members agree that the IP system is fundamental to the nation's economic growth and job creation and to our global competitiveness. They invest significant resources in their patent portfolios to protect their innovations. Certainty, consistency, and predictability in the patent system are of paramount importance to our members to support the massive investments in research and development required to bring new products to market. A vibrant, reliable patent system promotes innovation, investment, and job creation.

Making sound patent policy of course requires balancing competing, important interests that are not always uniform across industries and technologies. IPO member companies represent a range of perspectives on patent subject matter eligibility, which is unsurprising given the diversity of our membership. Our comments below attempt to capture their varied points of view—in furtherance of that objective, we invited each member of our Board of Directors to share their company's perspective. We have anonymized and synthesized them in our responses below.

The U.S. Supreme Court's opinions in *Bilski v. Kappos*, *Mayo Collaborative Servs. v. Prometheus Labs.*, *Ass'n for Molecular Pathology v. Myriad Genetics Inc.*, and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* changed the test for determining what inventions are patent-eligible under 35 U.S.C. § 101. The jurisprudence eliminated some undeserving patents, but some believe it also affected the ability to protect some deserving innovation. Some view the jurisprudence as

diverging from the historical interpretation of patent eligibility as being a relatively simple analysis intended to determine whether further, more complex, analysis concerning patentability is warranted, incorporating some or all the analysis that should be performed under sections 102, 103, and 112 into the eligibility analysis.

In 2017, IPO recommended a legislative solution to overturn the Supreme Court's jurisprudence. In 2018, we merged our thinking with the American Intellectual Property Law Association and adopted a joint legislative proposal that received a good deal of attention in the media and among policymakers. In 2019, we participated in an effort led by then Senate IP Subcommittee Chair Thom Tillis and Ranking Member Chris Coons to consider the need for legislation. Our objective remains to explore possibilities for legislative reform that balances the varying interests of IPO's members and that promotes innovation, investment, and job creation in the U.S.

We appreciate the opportunity to provide feedback on this important topic. In our assessment, the questions posed by the USPTO in Section 1 of the Notice are more appropriately answered by a single corporation rather than by a trade association representing numerous corporations operating in a variety of technology areas. Thus, the comments below respond only to Section 2, which begins at Question 10.

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

An important takeaway from our consideration of these issues is that we have widespread agreement about the negative impact our colleagues in bio/pharma have seen regarding precision medicine, pharmaceutical treatments, and diagnostic methods. In contrast, our membership is divided on the perceived impact to computer- and software-related inventions. We address these issues further in Question 12. In the present question, we focus on the global competitiveness of the U.S. patent system, recent progress in addressing the uncertainty of subject matter eligibility at the USPTO, and disagreement among our members concerning whether the doctrine is settling.

Uncertainty over the standard for determining patent subject matter eligibility has an impact on the global competitiveness of the U.S. patent system. In 2017, the U.S. tied for Hungary for 4th in the U.S. Chamber of Commerce Global Intellectual Property Center's ranking of the effectiveness of countries' patent systems, just barely making it into the top ten countries.[1] Previously the U.S. had consistently been in first place.[2] The 2017 *International IP Index* explained that the U.S.'s rank had dropped due in large part to "considerable uncertainty for innovators and the legal community, as well as an overly cautious and restrictive approach to determining eligibility for patentable subject matter in areas such as biotech, business method, and computer-implemented inventions" that "undermine[d] the longstanding world-class innovation environment in the U.S. and threaten[ed] the nation's global competitiveness." In 2018, the U.S. fell out of the top 10 for the

[1] U.S. Chamber of Commerce, Global Intellectual Property Center, *The Roots of Innovation: U.S. Chamber International IP Index* 117 (2017), https://www.theglobalipcenter.com/wp-content/uploads/2017/02/GIPC_IP_Index_2017_Report.pdf.
[2] *See* U.S. Chamber of Commerce, Global Intellectual Property Center, *Infinite Possibilities: U.S. Chamber International IP Index* 27 (2016), https://www.theglobalipcenter.com/wp-content/uploads/2017/04/GIPC_Index_Report_2016.pdf, and U.S. Chamber of Commerce, Global Intellectual Property Center, *Unlimited Potential: GIPC International IP Index* 29 (2015), https://www.theglobalipcenter.com/wp-content/uploads/2017/04/GIPC_Index_Report2015.pdf..

first time, with the *Index* noting that "the U.S. [wa]s no longer a global leader in this category of the *Index*…owing to uncertainty over patentability standards." [3]

The 2021 *IP Index* shows the U.S. in 2nd place, behind Singapore and tied with Japan, South Korea, and Switzerland.[4] It observes that "the patenting environment in the United States continues to be held back by uncertainty over what constitutes patentable subject matter," explaining that "[s]ince the Supreme Court decisions in the *Bilski*, *Myriad*, *Mayo*, and *Alice* cases, there has been a high and sustained level of uncertainty as to which inventions are patentable in the United States."[5] The *Index* notes that previous, evolving USPTO guidance, issued almost annually, and inconsistent court decisions, have left patent owners "without a clear sense of how decisions on patent eligibility will be made and, when granted patents are subsequently challenged or reviewed either through the courts or through the inter partes proceedings within the USPTO, which patent claims will be upheld."[6]

However, the USPTO has made important strides in addressing this uncertainty in recent years. The U.S.'s ranking in the IP Index began to improve in 2019, which the GIPC attributed in large part to changes made to the USPTO's inter partes review system.[7] Then in 2019, the USPTO issued Revised Patent Subject Matter Eligibility Guidance that the Chamber's report indicated "provides more of a principle-based analysis of how patentability will be judged and describes the stepwise approach examiners should follow to understand and apply the Supreme Court's *Alice/Mayo* test." As the guidance rightly points out, the key challenge for USPTO examiners and courts has been to "consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception… The new guidance … seeks, to the extent that is possible without further statutory changes, to clear this up with a revised procedure and process for examiners to follow."[8]

Consistent with GIPC's observations, many IPO members point to the 2019 revised examination guidance as a bright spot in helping stabilize patent prosecution outcomes. IPO applauded the overall intent of the 2019 Guidance to provide examiners with a way of finding eligible subject matter consistent with Supreme Court guidance, rather than articulating myriad ways to reject a claim as ineligible. But while some members view the guidance as bringing more consistency to examiner decisions and lowering the number of 101 rejections, other members note that the 2019 guidance could only go so far because of the existing Supreme Court precedent.

Some improvements in examination outcomes were documented in an April 2020 report by the USPTO's Office of the Chief Economist titled *Adjusting To Alice USPTO Patent Examination Outcomes After Alice Corp v. CLS Bank International*, which examines the effect of the 2019

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[3] U.S. Chamber of Commerce, Global Intellectual Property Center, *Create: U.S. Chamber International IP Index 35* (Feb. 2018), https://www.theglobalipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_2018.pdf.
[4] U.S. Chamber of Commerce, Global Intellectual Property Center, *International IP Index: Recovery through Ingenuity* 9 (2021), https://www.theglobalipcenter.com/wp-content/uploads/2021/03/GIPC_IPIndex2021_FullReport_v3.pdf.
[5] *Id.* at 310.
[6] *Id.* at 47.
[7] U.S. Chamber of Commerce, Global Intellectual Property Center, *Inspiring Tomorrow: U.S. Chamber International IP Index* vii (2019) https://www.theglobalipcenter.com/wp-content/uploads/2019/03/023593_GIPC_IP_Index_2019_Full_04.pdf.
[8] U.S. Chamber of Commerce, Global Intellectual Property Center, *Art of the Possible: U.S. Chamber International IP Index* 4 (2020), https://www.theglobalipcenter.com/wp-content/uploads/2020/02/GIPC_IP_Index_2020_FullReport.pdf.

guidance on rates of first office rejections for "Alice-affected technologies."[9] The report found that "[t]he evidence suggests that the 2019 PEG provided clarity and structure to the decision-making process," resulting in a statistically significant decreased in the issuance of first office rejections in Alice-affected technologies.[10] Specifically, the likelihood of receiving a first office rejection decreased by 25% in the 12 months following the introduction of the guidance.[11]

Some feel this suggests that the doctrine is settling. Especially in the computer-implemented or software related inventions, including AI, they say the guidance has allowed properly claimed inventions to avoid or overcome 101 rejections. Since its rollout, examiners have begun to stop asserting or holding fast to 101 rejections based on claims that have conventional elements if there is at least a practical application of what otherwise might be considered abstract. Those who note significant improvements in their patent prosecution practice say this has led to more uniform application of jurisprudence during prosecution of patent applications for AI and other computer-implemented inventions.

Some others are not as optimistic. They report inconsistencies in examination of applications for computer implemented inventions, even related applications assigned to the same examiner and supported by the same specification. They point to the need to rely on USPTO determinations when making strategic decisions about prosecution, which they say is still lacking.

Members in the life sciences lament that the USPTO has little latitude to change the landscape regarding life sciences inventions such as diagnostics, limited by existing Supreme Court precedent that has effectively rendered certain types of life sciences invention ineligible.

There is disagreement among our members about outcomes in the federal courts. Noting that the Federal Circuit affirms patent eligibility decisions appealed from district courts at high rates, some members argue that uncertainty has been largely eliminated. They believe the small number of highly controversial opinions are outliers and that the doctrine is, on balance, doing its job to bar protection for claims directed to broad implementations of abstract ideas using conventional technology, which inhibit innovation and are bad for the economy.

Other members are concerned that the courts continue to issue conflicting decisions on subject matter eligibility and will ultimately strike down patents issued under the 2019 Guidance. They argue that patentees need confidence that patents will stand up to court challenge. Because the examination guidance is not binding on the federal courts, patents granted by the USPTO under the revised guidance remain open to challenge and invalidation in the courts. Consequently, although some members believe that the USPTO and the courts are effectively determining subject matter eligibility and report not having trouble obtaining and maintaining patents on computer or software inventions or even AI related inventions, for others of our members this is of little comfort so long as the courts continue to operate under the current Supreme Court jurisprudence. Those members might be less likely to rely on patents for even the best of inventions in such an environment. Even when they discern that they will be able to obtain patents, some may not pursue patent protection because they perceive that their patents will be difficult to leverage. Moreover, they note that even if the doctrine were settling, this is only satisfactory if the Supreme Court's test strikes the correct balance and suggest that refinement is needed.

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[9] ANDREW A. TOOLE & NICHOLAS A. PAIROLERO, U.S. PAT. AND TRADEMARK OFFICE, OFFICE OF THE CHIEF ECONOMIST, IP DATA HIGHLIGHTS, ADJUSTING TO ALICE: USPTO PATENT EXAMINATION OUTCOMES AFTER *ALICE CORP. V. CLS BANK INTERNATIONAL* 2 (2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.
[10] *Id.* at 1.
[11] *Id.*

IPO previously has expressed concern about the expansion of the Supreme Court's jurisprudence into a wider range of technologies by Federal Circuit decisions such as *American Axle*, *Chamberlain Group*, and *Yu* that bind lower courts.[12] Some of our members fear that this creep will negatively affect the strength of U.S. patents and the U.S. economy because it will drag out the resulting uncertainty and begin to disincentivize investment in new areas of technology. They also fear controversial decisions finding straightforward innovations ineligible portend even harsher treatment of AI inventions, which could substantially impact future innovation in these areas. Other IPO members, including members with numerous patents covering AI-related innovations, have not observed any intrusion into AI or other emerging technologies such as quantum computing and do not share this concern.

Uncertainty about whether patents in key economic sectors may be invalid may undermine the ability of patent system to promote the progress of innovation. Court decisions since 2012 have disproportionately impacted newly emerging technologies overall, for example medical diagnostics. Some believe that rejections may have significantly contributed to abandonment of patent applications in those technologies, although at least one empirical study has concluded that this is not the case.[13]

On a related note, litigation costs concern all our members. Money spent on litigation means money not spent on R&D. But the concerns are varied. Uncertainty in patent eligibility has caused some companies undue litigation expenses due to fighting over the validity of patents, which ultimately increases the cost of products. Other companies have reported savings on litigation costs resulting from bad patents being invalidated during the early stages of litigation. Lack of legal certainty means that some companies need to defend themselves against patents that would not have been granted if the patentability rules were clearer and spend significant prosecution costs arguing over the patentability of certain inventions because the guidance is not sufficiently clear. This makes for a lot of litigation and litigation funding activities and higher prosecution costs.

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

It is challenging to find direct evidence concerning how patent policy affects the entire U.S. economy, which is enormously complex. Federal Reserve Economic Data (FRED) shows no decrease in U.S. GDP from Q2'14 to Q1'21, other than potentially due to the pandemic.[14] A Bureau of Economic Analysis report shows that digital economy accounted for 9.6% of US GDP in 2019, with 6.5% average annual growth from 2015-2019.[15]

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[12] Brief for Intellectual Property Owners Association as Amici Curiae Supporting Petitioner p. 8, *American Axle & Manufacturing, Inc., v. Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020), https://ipo.org/wp-content/uploads/2019/12/American-Axle-Amicus-Brief_FILED-1.pdf.

[13] Josh Landau, *The Alice Drizzle – Barely Even Noticeable*, PATENT PROGRESS, (Jan. 10, 2018), https://www.patentprogress.org/2018/01/10/alice-drizzle-barely-even-noticeable/.

[14] U.S. BUREAU OF ECONOMIC ANALYSIS, REAL GROSS DOMESTIC PRODUCT [A191RL1Q225SBEA], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A191RL1Q225SBEA, August 26, 2021.

[15] U.S. BUREAU OF ECONOMIC ANALYSIS, UPDATED DIGITAL ECONOMY ESTIMATES—JUNE 2021 P. 2, available at https://www.bea.gov/system/files/2021-06/DE%20June%202021%20update%20for%20web%20v3.pdf.

Patents are important for investment opportunities to varying degrees in most, if not all, technology fields. Patent eligibility affects investment by US venture capital and equity firms,[16] resulting in less investment into companies that develop technologies not protected by patents.

When patents are not granted, the loss of potential growth is not captured. Ultimately, the strength of the U.S. intellectual property depends on its value, which is ultimately driven by confidence. If the state of patent subject matter eligibility is perceived to be unresolved and a risk to investment in certain technologies, it may affect the distribution of money to the various technology sectors in the U.S. Intellectual property encompasses more than just patents, so areas that still can demand investment may turn to using trade secrets to protect their innovations, rather than patents.

Although the number of U.S. patents continues to grow, the share of U.S. innovators filing in the U.S. is decreasing. One report shows both the percentage of filed applications and granted patents to U.S. AI innovators has dropped since 2017.[17] Certainly, it cannot be concluded that loss of ground is related to patent eligibility concerns entirely, if at all. However, less investment in U.S. companies due to reduced confidence in patents could disproportionately hurt U.S.-based innovation and patent activity. U.S.-based applicants typically file in the U.S. first. If they are financially insecure, they are less likely to be able to invest in innovation, let alone file a patent application. In contrast, non-U.S. based applicants typically file in the U.S. only after filing in their own countries, having already overcome the economic hurdles necessary to innovate and apply for a patent. Other countries have not experienced the same changes in patent eligibility as in the U.S., and non-U.S. investments are less likely to be impeded by U.S. patent concerns.

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

As noted in our response to Question 10, IPO has widespread agreement about the negative impact our colleagues in bio/pharma have seen to precision medicine, pharmaceutical treatments, and diagnostic methods. In contrast, our membership is divided on the perceived impact to computer- and software-related inventions.

Our biopharmaceutical member companies are feeling the impact of uncertainty. Some say uncertain patent protection has led to decreased investment. Since 2012, biopharmaceutical companies have experienced regular rejections from the USPTO on section 101 grounds. The USPTO does not have much leeway in interpreting the Supreme Court's jurisprudence in this area. For all intents and purposes, advances in diagnostics testing are not considered to be eligible in the U.S. at present.

In addition, current case law has largely foreclosed patenting advances in bioinformatics and AI algorithms used in precision medicine. The current regime calls into question the eligibility of medicines that are closer to nature and replicate the body's own processes, which are striking

[16] Taylor, David O., *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2053 (2020), https://ssrn.com/abstract=3340937.
[17] Michael R. Casey, *AI Patent Trends in the U.S. Patent Office: Is the U.S. Losing Its Lead?*, OBLON.COM (Feb. 25, 2021), https://www.oblon.com/ai-patent-trends-in-the-us-patent-office-is-the-us-losing-its-lead.

technological advances that promise to revolutionize healthcare. This depends in part on whether these innovations will be patent-eligible in the U.S.

Personalized medicine/precision medicine is the future of medicine. Delivering more personalized therapies, as opposed to treating patients who suffer from a broad category of disease with the same "one-size-fits-all" medicines using a trial-and-error approach, can yield safer, more effective, and more cost-efficient outcomes. The unprecedented convergence of medical knowledge, technology and data science that is revolutionizing patient care has the potential to ensure the right treatment for the right patient at the right time. Yet personalized medicine and its various components, such as AI and bioinformatics, are precisely what section 101 jurisprudence calls into question.

Precision medicine is an area of biotechnology that is extremely difficult to achieve. It has taken scientists years to get to where we are today, and this is just the tip of the iceberg. We are at a pivotal juncture, much of which depends on whether such innovation is considered patent-eligible in the U.S. Companies need to know that when they develop precision medicine that is novel, non-obvious, and enabled that it will not be disqualified from patent protection based on an overly exclusionary judicial interpretation of section 101 that undermines America's reputation as the global leader in this critical area. Our global competitors are not waiting.

To wit, in the EU diagnostics, natural products, and bioinformatics are all patent-eligible. In China, natural products and bioinformatics are also generally patent-eligible. Moreover, China has committed to making "precision medicine" part of its five-year plan with an expected investment of over $9 billion for research—the largest investment in precision medicine of any country in the world.[18] Funding for biopharma companies in China from 2016 to 2020 increased exponentially, from $1 billion to over $200 billion.[19] In 2020 alone, China's life sciences sector investments reached $28 billion, doubling the previous year's amount.[20]

As previously noted, there is significant disagreement among our membership about the impact of the patent eligibility jurisprudence on computer-implemented/software-related inventions. Members report inconsistent experiences.

Some say the state of computer-related inventions, AI, and quantum computing has not been adversely affected by patent subject matter eligibility jurisprudence in the U.S. Those members report no difficulty securing appropriately scoped patents on computer or software inventions or even AI inventions, particularly following the USPTO's 2019 examination guidance. Some of our members argue that there has been a net positive impact with respect to certain ones of the enumerated areas; their view is that the current state of patent jurisprudence strikes an appropriate balance for promoting innovation.

Other members are concerned that alleged infringers now rely on patent eligibility defenses in virtually every patent dispute relating to computer-related inventions, no matter how strong and worthy the patented invention. They dispute that section 101 reduces expense, instead experiencing uncertainty and delays in resolving such disputes and the diminished value of the patents involved. They are particularly concerned about the prospect that the nature of artificial

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[18] *See* Genya Dana, *3 ways China is leading the way in precision medicine*, WORLD ECONOMIC FORUM (Nov. 2, 2017), https://www.weforum.org/agenda/2017/11/3-ways-china-is-leading-the-way-in-precision-medicine/.

[19] *See* Gaurav Gupta, *As Washington Ties Pharma's Hands, China is Leaping Ahead*, Barron's (June 11, 2021), www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808.

[20] *Id.*

intelligence as an abstraction of human intelligence may render it particularly vulnerable to such impact in the future.

A recent IEEE report details AI trends based on US patenting activity, which demonstrates U.S. leadership in AI patenting activity as well as the growth of that activity over time.[21] A recent USPTO report on AI inventions in the US also illustrates this growth.[22] The report lists the top AI patent holders, which include numerous IPO member companies.[23] As detailed in these reports, the USPTO grants more patents related for AI inventions than any other country, and the U.S. also leads in terms of country of origin of assignees. Several IPO members are among the companies who receive the most patents in AI.

Although the USPTO's 2019 patent examination guidance was well-received and generally helpful to applicants in these technology areas, some IPO members have noted inconsistency in examination of applications directed to computer implemented inventions, even among patent applications within the same family, supported by the same specification, and assigned to the same examiner. Some also note inconsistency regarding whether patent eligibility rejections are raised and how rejections are rationalized across different Technology Centers or even across art units within the same Technology Center. They note that harmonized, docketing-agnostic examining practices in patent-eligibility analysis would improve clarity, regardless of whether this consistency is inspired by additional USPTO examining guidance, case law, or legislation.

Some members note that examples concerning digital technologies published by the USPTO to help applicants navigate the 2019 examination guidance have proven to be of limited value, at least anecdotally. For instance, examiners have dismissed comparisons to the examples where not every limitation of an example claim is present in the examined claim. This seems to imply, if not require, that the example claims anticipate the examined claims under § 102 or render them obvious under § 103. In those cases, the examples seem to be used more as an analog under § 102 or under § 103 and less as framework to decide issues under § 101 as intended. These vagaries in patent examination increase these members' cost of obtaining patent protection.

Many of our members invest in and acquire companies as part of their overall business strategy. Much of the time, the primary value of such a business resides in its intellectual property, a significant part of which tends to be its patent portfolio. Uncertainty in particular fields such as software can make those investments or partnerships riskier. Unpredictability concerning what constitutes patentable subject matter means investments or partnerships come with heightened uncertainty, and thus risk. Some member companies say such heightened uncertainty and risk will disincentivize them from partnering with, investing in, or acquiring businesses operating in the digital space, which negatively impacts that entire industry, digital technology advancement, and the U.S. GDP.

Some global companies report that they are faced with the decision of whether to obtain a U.S. right that may or may not be valid and lose global trade secret protection or keep the innovation as a trade secret. A sub-optimal decision can lead to (1) concealment of information that could

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[21] Hamidreza Habibollahi Najaf Abadi and Michael Pecht, *Artificial Intelligence Trends Based on the Patents Granted by the United States Patent and Trademark Office* 3-4, IEEE ACCESS (May 14, 2020), https://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=9072177.

[22] ANDREW A. TOOLE ET AL, U.S. PAT. AND TRADEMARK OFFICE, OFFICE OF THE CHIEF ECONOMIST, IP DATA HIGHLIGHTS, INVENTING AI: TRACING THE DIFFUSION OF ARTIFICIAL INTELLIGENCE WITH U.S. PATENTS 2 (2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH-AI.pdf.

[23] *Id.* at 10

otherwise enrich the public domain by way of the patent process; or (2) disclosure of information that later prohibits or blocks trade secret protection, in cases in which trade secret protection would have been more appropriate.

Without clarity and consistency, companies lack important information necessary to make an informed decision about whether to pursue trade secret or patent protection. Trade secrets certainly are valuable. But because they are kept as secrets, they do not serve to educate others or advance science in the same way patents do. That is why patents are important contributions to society that we want to foster, allowing others to stand on the shoulders of those who have invented before them. A compelling and timely example is the COVID-19 vaccines, the rapid development of which was faster than any other vaccine in history due to the inventors' ability to rely on vaccine technology platforms and other groundbreaking medical advances previously disclosed by other inventors in patent applications. Absent those disclosures, it is worth considering whether we would have achieved such rapid development and clinical success.

Question 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?

Some fear the current state of patent eligibility jurisprudence at the U.S. Federal Circuit and U.S. Supreme Court will increasingly "chill" investment in patent protection in the U.S. Such companies say they will strive to maintain their IP under trade secret laws and potentially curtail R&D investment where trade secret law cannot prevent reverse engineering. The public will increasingly not have access to publicly available information on these inventions (that might otherwise have been disclosed in a patent application). The public in turn will not have access to the technology created either by the products or the publication of the patent.

In the biopharmaceutical space, the reduced ability to recover costs, along with reduced investment, is likely to have a long-term impact on whether new technologies are developed at all, leaving the public without access to new and important medicines, treatments, and diagnostics at any price. It is impossible to quantify the cost to society if medicines cannot be developed because the current section 101 jurisprudence is too restrictive. Moreover, if innovator companies cannot innovate, biosimilars/generics will be unable to come to market, creating less overall availability of medicines for patients.

In some cases, the high cost of manufacture may render some technologies too expensive to develop or produce without the ability to demand prices that patented technologies can. For example, some off-patent pharmaceuticals may become unavailable, have shortages, or increase in cost because competition can't be sustained while also maintaining reasonable profit margins.[24]

Software- and computer-implemented inventions may see little impact on consumer pricing due to the rapid nature of development. Patents on such inventions are often abandoned before expiration due to failure to pay maintenance fees, presumably because the technology has become outdated by the time the maintenance fee is due. However, the impact may be more significant on seminal technologies that are less ephemeral and form the basis for smaller innovations.

Patent protection spurs innovation because it provides a limited monopoly in return for full public disclosure, enabling the public to build on that innovation. However, it's no secret that neither

[24] *See Why Are Some Generic Drugs Getting So Expensive*, THE CONVERSATION (Jan. 21, 2015), https://theconversation.com/why-are-some-generic-drugs-getting-so-expensive-35603.

innovation nor patenting are cheap. The U.S. patent system is one of the most expensive in the world, which is justified by providing exclusionary rights in one of the richest markets in the world. But it doesn't matter how rich the market is if you cannot appropriately protect innovation.

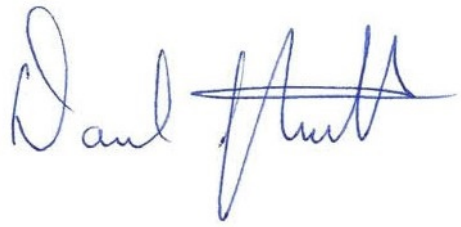
Absent the ability to protect innovations with patents, innovators may decide to prioritize commercialization of their inventions elsewhere, where they might be better able to protect their innovations to recover their costs and capitalize on their risk. Some members say they are investing in patent protection on important new technological advances with their fingers crossed that the courts or legislature will provide clarity and predictability before those patents eventually issue and must withstand challenge in the courts or at the USPTO. Depending on how those patents fare, they predict their companies might choose not to continue investing in U.S. patent protection.

Alternatively, innovators may increasingly rely on trade secrets to protect their investments. Some members that invest huge amounts in technologies that are often labeled "abstract ideas" under the Supreme Court's jurisprudence report that they are forced to make hard choices about whether to disclose the inventions or maintain them as trade secrets. Some members report that they are already counseling their business clients to protect computer-implemented or software-related inventions as trade secrets instead of seeking patent protection. Again, although trade secrets are important, legitimate, and often extremely valuable intellectual property rights, the risk of not being able to obtain a patent and increased reliance on trade secret protection is the accompanying disincentive to disclose. Reduced engagement in the patent system due to declining incentives to obtain patents might result in reduced or delayed public disclosure by way of the patent system, which eventually will deprive the public of the benefit of some innovation.

Finally, some companies not based in the U.S. report that extensive rulemaking and overly complicated conditions for establishing subject matter eligibility will cause them to reduce investment into research and development such that the public will be denied the benefit of their innovations in personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions.

Thank you for the opportunity to submit comments.

Sincerely,



Daniel J. Staudt
President