March 8, 2019

The Hon. Andrei Iancu
Under Secretary and Director
U.S. Patent and Trademark Office
U.S. Department of Commerce
Washington, D.C.

Via Email: Eligibility2019@uspto.gov

COMMENTS OF USIJ re UNITED STATES PATENT AND TRADEMARK OFFICE REVISED GUIDANCE FOR SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. § 101 AND GUIDANCE ON THE APPLICATION OF 35 U.S.C. § 112 TO COMPUTER-IMPLEMENTED INVENTIONS.

(Docket No. PTO-P-2018-0053)

Dear Director Iancu:

The Alliance of U.S. Startups for Inventors and Jobs ("USIJ") respectfully responds herein to the request by the U.S Patent & Trademark Office ("USPTO") for comments regarding its recently revised guidance for examiners and patent judges to use in determining subject matter eligibility under 35 U.S.C. §101 (2019 Revised Patent Subject Matter Eligibility Guidance (Docket No. PTO-P-2019-0053)) ("Guidance"). USIJ supports the Guidance, which seeks to refine the approach taken by USPTO personnel to eligibility issues through a more careful and precise understanding of patent eligibility rulings by the U.S. Supreme Court than has been used previously. The current state of patent law regarding eligibility is poorly defined and is therefore applied erratically by both the USPTO and the federal judiciary.[1] District judges have been given little or no guidance as to what constitutes an "abstract idea" and therefore make uninformed rulings on that issue, often without even the benefit of an evidentiary hearing; many judges themselves complain about the lack of certainty. From the standpoint of the investors, entrepreneurs and inventors that comprise USIJ, in deciding whether to undertake the risks that attend the development of new technologies and new products, uncertainty as to the availability and enforceability of their patents is a serious deterrent. An uncertain patent is not much better than no patent at all and in fact, it may be an affirmative liability, because uncertainty induces opportunistic infringement that might not otherwise occur.

[1] Four Supreme Court cases decided since 2010 have created ambiguity and uncertainty among patent owners as to whether their new patents will be issued and their existing patents will be enforceable when needed. The four case are *Bilski v. Kappos*, 561 U. S. 593 (2010); *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S.Ct. 1289 (2012); *Association for Molecular Pathology v. Myriad Genetics, Inc*., 133 S.Ct. 2107 (2013) (2013); and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S.Ct. 2347 (2014). In two of the cases – *Bilski* and *Alice* – the Court rendered sweeping decisions that cast doubt on patents covering many forms of software. In *Myriad*, the Court held that naturally occurring DNA sequences are not patentable, even though isolated by human effort from the remainder of the genome. In *Mayo*, the Court held that a novel process for measuring the metabolites of a therapeutic drug to calibrate dosage was not patentable. The two latter decisions cast doubt on the patentability of numerous diagnostic procedures and treatments.

Although this problem of uncertainty arising from eligibility affects many industries, the problem has proven acute in of many parts of the healthcare industry and the development of new software, where reliable patents are essential to allow for the efficient transfer of technology by inventors to other entities that can commercialize it. The entire field of personalized medicine that targets a specific genetic trait or physical characteristic of a patient is at risk, as expensive research efforts are curtailed because reliable patent protection is no longer available. Software is an almost universal aspect of virtually every new technology. Artificial intelligence, robotics, cybersecurity, machine control, power grid management, telecommunications and many more technologies are dependent in whole or in part on software inventions that are perceived to be at risk. Moreover, knowledgeable people know that many computing devices and their associated hardware can be replicated in software that mimics the electronic inputs and outputs of the device.

In light of the many ambiguities in the Supreme Court's eligibility jurisprudence, the USPTO, the Federal Circuit and the lower courts have allowed eligibility challenges to nullify the protection of important inventions in these and many other critical areas, with the predictable results that (i) copyists have been emboldened to infringe and (ii) investment, innovation and invention in those areas has declined. By tailoring the examination process within the USPTO to precisely what is required by Supreme Court precedents, and no more, the revised guidance may help lower, at least to some extent, the current perception of uncertainty. We recognize that there is still much uncertainty within the Federal Circuit and that the lower courts that will not be affected directly by improving the guidance to USPTO personnel, but we believe that there mere fact that the agency has taken this positive step will provide greater comfort to the judiciary that any patent whose eligibility is in question has been vetted more carefully on that score. At the very least, the Guidance will improve the uniformity of decision making within the USPTO.

The Necessity for More Precise Guidance

Article I, Section 8, Clause 8 of the U.S. Constitution sets forth, among the full powers of Congress, the power:

> "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Pursuant to that power, Congress enacted Section 101 of the Patent Act, which is a broad grant of power for the Executive branch to issue patents:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Despite the absence of any constitutional or statutory authorization, the Supreme Court long ago engrafted certain "judicial exceptions" onto these otherwise broad grants of power: *i.e.*, mathematical formulas, laws of nature, and abstract ideas – standing alone – are not eligible for patent protection. This judicial exception is the basis for the four eligibility decisions referred to above, the Court finding in each case that the claimed invention or discovery failed to qualify for patent protection. Although many users of the patent system believe that the

power of the Supreme Court to create exceptions to unambiguous constitutional provisions and lawfully enacted statutes should be more limited, the USPTO and the federal judiciary are constrained, at the moment anyway, by the precedential effect of these Supreme Court rulings.

That said, there is no need for either the USPTO or the judiciary to read any of the precedents more broadly than the language used by the Supreme Court requires. Indeed, the Court's most recent eligibility decision – the *Alice* decision – specifically noted the need to

> "tread carefully in construing this exclusionary principle **lest it swallow all of patent law**. … **At some level, 'all inventions … embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'** Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. *See Diamond v. Diehr*, 450 U. S. 175, 187 (1981). '[A]pplication[s]' of such concepts 'to a new and useful end, we have said, remain eligible for patent protection. *Gottschalk v. Benson*, 409 U. S. 63, 67 (1972). Accordingly, in applying the §101 exception, we must distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more, thereby 'transform[ing]' them into a patent-eligible invention …. The former 'would risk disproportionately tying up the use of the underlying' ideas … and are therefore ineligible for patent protection. The latter pose no comparable risk of preemption, and therefore remain eligible for the monopoly granted under our patent laws." 134 S.Ct. at 2354-55.

This effort by the Supreme Court to articulate a proper balance between the incentive structure for invention and innovation established by the Constitution and the Patent Act with the Court's perceived need to avoid "preemption" of the "building blocks of human ingenuity" left far too much ambiguity in how the USPTO and the federal judiciary should approach eligibility challenges. The result has been widespread confusion, a striking lack of uniformity in decisions from both entities, and a strong proclivity to anticipate a broader judicial exception to the statutory language. Exemplary of the latter point is the decision of the Federal Circuit in *Ariosa Diagnostics, Inc. et al v. Sequenom, Inc., et al*, 788 F.3d 1371 (Fed. Cir. 2015), wherein the inventor had "discovered" that it is possible to detect fetal DNA (and therefore genetically caused birth defects) in the blood of the mother without need for the dangerous and invasive extraction of amniotic fluid. The Federal Circuit, while recognizing the enormous importance of the invention and the value of incentives to create such inventions, felt itself inhibited by the Supreme Court's eligibility decisions and held the patent was not eligible subject matter. A plaintive concurrence by Judge Richard Linn is informative:

> "The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish [*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012)] from this case, even though here no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be 'routinely discarded,' ('540 patent col.1 ll.50–53), because, as Dr. Evans testified, 'nobody thought that fetal cell-free DNA would be present.'"

USIJ does not believe that the Federal Circuit reached a justifiable outcome in that case or that the Ariosa patent should fall outside the ambit of the Patent Act.

Similarly, in *Athena Diagnostics v. Mayo Collaborative Services*, (Docket No. 2017-2508 decided February 6, 2019), the Federal Circuit again struck down a patent on a novel method of diagnosing myasthenia gravis, a dreadful autoimmune disease that destroys muscle function. The court once again took a tautological approach to its analysis, rejecting a common sense application of the patent statute to what the court acknowledged should be a protectable invention. A compelling dissent by Judge Pauline Newman stated the implications as follows:

> "This court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies and exacerbate the judge made disincentives to development of new diagnostic methods, with no public benefit. I respectfully dissent."

Her dissent notes further that when there is confusion as to whether an invention is patentable, the public loses the benefits of new technological advances. This legal uncertainty harms both the purveyors of technology and the potential downstream users, including and most importantly the public at-large.

In November 2018, Director Iancu succinctly summed up the challenge that a growing number of inventors and investors face today when considering whether to commit time and resources to their new and creative ideas:

> *Today … the law surrounding what subject matter is eligible for patenting, under 35 U.S.C. section 101, is anything but clear. There is a general consensus that something needs to be done. Several Federal Circuit judges, for example, have recently filed concurrences or dissents highlighting the uncertain nature of the law and calling for change.*

Although the Guidance from the USPTO to its own personnel may not be binding on the judiciary, by making certain that all patents emerging from the agency have been vetted in a way that reflects the need to balance the twin objectives set forth in the *Alice* decision, the revised Guidance is likely to improve confidence and reliability.

The Need for Legislation Still Exists

USIJ's support for the revised Guidance issued by the USPTO should not be taken to mean that we believe it will – by itself – correct the problems created by the Supreme Court. Because litigation is adversarial, and because advocates who serve their clients well must always try to win their cases, these eligibility challenges will continue to haunt the patent law until either the Court itself or Congress comes to grips with the disaster created by the current state of the law. The most likely path by which that could take place is for Congress to move forward with one of the several bills that have been or soon will be introduced to rein in the Supreme Court on this issue.

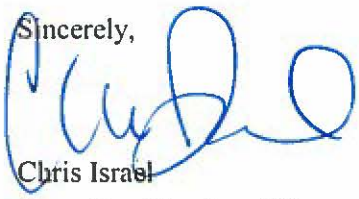
This would not be the first time in our history that Congress has been required to redirect the Supreme Court in its patent law jurisprudence. Section 103 became part of the Patent Act in 1952, after Supreme Court Justice Robert H. Jackson observed in dissent that "the only patent which is valid is one which this [Supreme] court not been able to get its hands on." *Jungersen v. Ostby*, 335 U.S. 560, 571 (1949). The majority in that case held that a patent lacked "invention" even though dozens of companies had taken licenses and acknowledged its value. Further, Sections 271 (b), (c) and (d) were adopted by Congress in the same 1952 revision to address the extreme views of Justice Douglas in *Mercoid Corporation v. Minneapolis Honeywell Regulator Co., 320 U.S.680, 684 (1946),* wherein the Supreme Court, with the stroke of a pen and on antitrust grounds, abolished 150 years of patent jurisprudence related to contributory infringement.

Makeup of USIJ

USIJ is a coalition of over 30 startup companies and their affiliated executives, inventors and investors that depend on stable and reliable patent protection as an essential foundation for their businesses. A list of USIJ members is attached as Appendix A. USIJ was formed in 2012 to address concerns that legislation, policies and practices adopted by the U.S. Congress, the U.S. Supreme Court and the USPTO were placing individual inventors and research-intensive startups ("the invention community") at an unsustainable disadvantage relative to their larger incumbent rivals, both domestic and foreign. USIJ's fundamental purpose is to assist and educate Members of Congress and leaders in the Executive branch regarding the critical role that patents play in our nation's economic system. In this endeavor, USIJ works closely with numerous other groups and coalitions within the invention community to ensure that protection of the creative role played by individual inventors, startups and small companies is recognized as one of the primary objectives of the U.S. patent system.

Please contact USIJ's Chris Israel at Israel@acg-consulants.com or 202-327-8100 if we can be of any further assistance.

Sincerely,



Chris Israel
Executive Director, Alliance of U.S. Startups for Inventors and Jobs

APPENDIX A

USIJ Member Companies

- Aegea Medical
- Arrinex, Inc
- Autonomic Technologies
- BioCardia
- Ceterix Orthopaedics
- CyberHeart
- Direct Flow Medical
- EarLens Corporation
- EnterVault
- ExploraMed
- Fogarty Institute for Innovation
- ForSight Labs
- Headwater Research
- Lauder Partners, LLC
- Materna
- MedicalCue
- MiramarLabs
- Moximed
- Pavey Investments
- Precision Biopsy
- Prescient Surgical
- Pulsar Vascular
- Puracath Medical
- Rearden Studios
- Roxwood Medical
- Siesta Medical
- Sippl Investments LLC
- Solar Junction
- Soraa
- Tallwood Venture Capital
- TiVo
- The Foundry
- WillowZipline Medical