Questions for Section 101 Roundtable Participants

Response of AAU, APLU, & COGR
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The Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), and the Council on Governmental Relations appreciate this opportunity to provide answers to questions posed in advance of the upcoming Section 101 Roundtable.

A robust patent system is essential to a successful university technology transfer ecosystem. Unfortunately, recent court decisions have introduced non-statutory concepts – such as "abstract ideas" and "natural phenomena" – into the patent law, thereby generating confusion and inconsistency that have had a destabilizing effect on university technology transfer processes and planning. We hope that any congressional work in this area will take steps towards ensuring greater clarity around patent eligibility by strengthening current criteria for patenting by reinforcing terminology made explicit in existing statutes and not by appending unclear court terminology to the language of the statutes.

1. Broadly, what is the purpose of Section 101 in our patent system?

(a) If Section 101 should serve a gatekeeping function, how narrow or broad should it be?

Section 101 should serve a gatekeeping function in our patent system and amenable to a straightforward "yes" or "no" answer to the question of whether or not human ingenuity was used to generate a *useful* invention. Once an invention is initially deemed useful under Section 101, then patentability should be determined by operation of the criteria set forth in Sections 102 (novelty), 103 (non-obviousness), and 112 (written description). In addition, the test for Section 101 should not be one that directly or

indirectly gets into comparing the claims with what was known prior to the applications; that should be done in a straightforward Section 102/Section 103 analysis. In other words, Sections 102, 103, and 112 provide sufficient limits on unpatentable inventions, thus Section 101 should provide a broad aperture that is narrowed appropriately by those subsequent requirements.

(b) What role does—or should— Section 101 play in preventing the issuance of patents which fail to meet the requirements of Sections 102, 103, and 112?

As noted above, once an invention has been found useful pursuant to Section 101, the criteria of Sections 102, 103, and 112 should be applied in order to further narrow that first determination.

2. Assuming Section 101 should be reformed, which ***current*** legislative proposal—including, but not limited to, the ABA, IPO and AIPLA proposals— best encompasses the spirit and purpose of Section 101? Please explain your answer in detail.

Although we agree that some action is likely warranted to correct judicial misapplications of patent eligibility criteria to innovations in areas such as computing and biotechnology, we believe that further discussions are desirable before concluding that amending Section 101 is the optimal course of action. That said, in our view, the joint IPO/AIPLA proposal best encapsulates the spirit and purpose of Section 101. The joint IPO/AIPLA proposal has the virtue of being simple and concise. The proposal's elegant structure and language would help to avoid future judicial misconstructions of congressional intent vis-à-vis Section 101. Consequently, IPO/AIPLA proposal hopefully would give rise to fewer broad interpretations and unanticipated consequences. In no event should any legislative emendations add the confused/confusing, unscientific language of legal interpretations to the clear language of the existing patent statute. On the contrary: current criteria for patenting should be bolstered by reinforcing terminology already rendered explicit in the existing statutes.

3. If you have a new legislative proposal to reform Section 101 please provide a description of that proposal in detail and explain why you believe it is the best path forward.

We do not have an alternative legislative proposal to offer at this time.

(a) If you believe Section 101 should not be reformed, please explain why you think the status quo is acceptable?

Any hesitation regarding amending Section 101 should not be mistaken for our acceptance of the status quo, which is marked by a cloud of confusion, uncertainty, and lowered confidence among both patent applicants and potential investors in innovative technologies.

4. Many foreign jurisdictions expressly exclude certain subject matter from patent eligibility (e.g., "diagnostic methods practiced on the human or animal body"). What subject matter, if any, should be ineligible for patent protection in the United States? Why?

The patent law must remain technologically neutral to ensure that innovation – particularly future innovation we cannot yet anticipate – can continue unimpeded. Accordingly, delineating (or, more precisely, delimiting) specific inventions in the law would be a mistake.

(a) Should the categories of "abstractions, laws of nature, and natural phenomena" be the basis for excluding broad classes of innovations from statutory subject matter eligibility?

Extant terminology defined by Sections 101, 102, 103, and 112 are preferable and should be reinforced rather than replaced.

(b) If so, how should abstractions, laws of nature, and natural phenomena be defined?

These should not be defined statutorily.

(c) What is the relationship between laws of nature and natural phenomena?

This is not a legal question, but rather a scientific question.

(d) With respect to life science inventions, has the Supreme Court confused the terms "law of nature" and "natural phenomenon" sufficiently that subject matter that should be eligible is held ineligible? Have the courts misinterpreted those terms so often that no test can reference either term? Is it possible to redefine "laws of nature" to avoid the Federal Circuit being forced to find inventions ineligible, even though judges on the Court clearly believe that those inventions should be eligible?

The terms "law of nature" and "natural phenomenon" should not have been introduced as a matter of law. Consequently, subject matter that should have been deemed eligible has been held ineligible whether by courts or by patent examiners struggling to interpret these courts' rulings.

(e) Should any of the following be per se patent eligible or per se patent ineligible: a) a software program

running on a computer, b) an artificial intelligence program run on a computer, or c) a business method run as software on a computer?

Not *per se* – patent applications should be assessed case by case within the context of current scientific understanding.

5. Many have criticized the "abstract idea" exception to Section 101 as more appropriately handled under Section 112. Is this a valid criticism? As currently applied by the PTO and the courts, does Section 112 provide an adequate filter to ensure that patent claims across all industries are sufficiently definite? If not, should Section 112 be amended and, if so, how?

This is a non-statutory term and should not be introduced into the law. Statutory criteria under Sections 101, 102, 103, and 112 are sufficient to address any problems addressed by the problematic "abstract idea" exception.

6. If an invention contains subject matter that itself cannot be patented (e.g., an abstract idea, law of nature, or natural phenomena under current Supreme Court precedent), what should the test be to transform an otherwise ineligible invention into a patent-eligible invention? Please describe your proposed test with detail and specificity.

Instead of introducing new exceptions – particularly ones that rest on categories such as "abstract" and natural" – any new legislative language should clarify that exceptions are unnecessary given the robust implementable criteria in extant statutory language.

7. If Section 101 is reformed, which Supreme Court cases should be ***expressly*** overruled? If you believe that a 101 reform proposal should "re-set" patent eligibility to a point in time, what point in time should that be?

Any reform to Section 101 should contend with the quartet of Supreme Court decisions that have created an environment of confusion and uncertainty for universities striving to patent certain cutting-edge technologies for society's benefit, particularly with respect to software-embodied inventions and medical diagnostics. These troublesome decisions are: *Alice Corporation v. CLS Bank* (2014); *Association for Molecular Pathology v. Myriad Genetics* (2013); *Mayo v. Prometheus* (2012); and *Bilski v. Kappos* (2010).

The problems with these decisions stem not just from the rulings, but also how those rulings have been applied. Patent assessment should rest on exacting analyses of usefulness, novelty, non-obviousness, and written descriptions that enable use, not on vague discussions regarding abstraction and nature.

The *Alice* decision has had a dramatic effect on the validity of software patents. Since *Alice*, these patents have suffered a very high mortality rate; hundreds of patents have been invalidated under Section 101 in federal district courts. Applying *Alice*, district court judges have found many of these claims to be patent-ineligible abstract ideas. The result has been a landscape inhospitable to commercialization that threatens to slow, if not stifle, the bringing to market of ground-breaking technologies such as artificial intelligence (an area in which the U.S. is currently seeking to remain in the lead globally).

Similarly, judicial interpretations of patent eligibility law under Section 101 have created confusion and uncertainty regarding biotechnology, including medical diagnostics. These technologies have the potential to provide more effective care for patients at a lower cost by, among other things, detecting medical conditions earlier, monitoring those conditions more easily, and predicting outcomes more accurately.