



American Intellectual Property Law Association

January 18, 2017

The Honorable Michelle K. Lee  
Under Secretary of Commerce for Intellectual Property and  
Director of the U.S. Patent and Trademark Office  
U.S. Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22314

*Via email: 2014\_interim\_guidance@uspto.gov  
101Roundtable2@uspto.gov*

**Re: Comments of the AIPLA on Notice of Roundtables and Request for  
Comments Related to Patent Subject Matter Eligibility, 81 Fed. Reg. 71485,  
10/17/2016.**

Dear Under Secretary Lee:

The American Intellectual Property Law Association (AIPLA) is pleased to have this opportunity to present its views on patent subject matter eligibility. These comments respond to the October 17, 2016 Federal Register Notice, 81 Fed. Reg. 71485 (“Notice”), announcing U.S. Patent and Trademark Office roundtable discussions on this subject. They supplement our presentations at the November 14, 2016 and December 5, 2016 roundtable events.

AIPLA is a national bar association of approximately 14,000 members engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Moreover, our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

Overall, our experience is that Patent Office examination decisions on patent eligibility have been inconsistent and confusing. At the same time, there has been a sharp uptick in litigating eligibility issues both before the courts and the Patent Trial and Appeal Board. The result is uncertainty and inefficiency for patent applicants and litigants, which is not healthy for our patent system and puts the incentives to innovate at risk.

**AIPLA’s Consistent Positions on Section 101**

In December 2013, AIPLA’s former executive director testified before the Senate Judiciary Committee and noted the following:

Probably the most tumultuous issue in patent law right now is the question of patent eligibility under 35 U.S.C. § 101. While that statutory language is fairly straightforward, identifying the various categories of inventions that are patentable subject matter, the Supreme Court years ago staked out exceptions to statutory subject matter where the patents recite a law of nature, a natural phenomenon, or an abstract idea.

At that same time, the case of *Alice Corp. Pty, Ltd. v. CLS Bank Int'l*, 134 U.S. 2347 (2014), was pending before the Supreme Court. AIPLA believed that case could resolve numerous questions created by past decisions. However, rather than resolve those questions, the Supreme Court's decision in *Alice* and the cases that have followed have continued to create problems and confusion. Section 101 jurisprudence and its application by the USPTO and the courts have become the issues of greatest concern among AIPLA's members.

In the past ten years, AIPLA has filed over a dozen amicus briefs in section 101 cases heard by the Federal Circuit and the Supreme Court. AIPLA's views have been consistent: the language of section 101 sets forth subject matter categories of what is patent eligible, and any limits on eligibility should be few. However, we remain concerned that the courts' expansive application of judicial exceptions to eligibility has had an adverse impact on innovation in the United States.

The Supreme Court has recognized that patent ineligibility determinations require a delicate balance. In *Mayo Collaborative Services v. Prometheus Laboratories*, the Court cautioned that "too broad an interpretation of this exclusionary principle could eviscerate patent law." 132 S. Ct. 1289, 1293 (2012). As applied, however, section 101 too often has been used as an easy, blunt instrument to deny patent protection. In such cases, other grounds for finding patent claims invalid (or claims in an application unpatentable) more prudently could be based on prior art and other conditions of patentability set forth in sections 102, 103 and 112.

One purpose of the judicially excluded subject matter categories has been to prevent patentees from preemptively overreaching in broad areas that suppress rather than incentivize innovation. See, e.g., *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). However, section 101 jurisprudence has been applied in a manner that often overcorrects for overreaching patentees. Broad claiming, poor claim drafting, and poor patent quality in general are all important issues to address, but not through the blunt instrument of patent eligibility.

Section 101, as an enabling provision that identifies particular categories of inventive subject matter, typically is not the proper standard for deciding whether a particular technical advance should receive patent protection. Using section 101 for that purpose has produced the same degree of uncertainty in the law that motivated Congress to enact the non-obviousness requirement in section 103 in 1952 and to establish the Federal Circuit more than 30 years ago. Patent eligibility decisions often turn on the specific facts of each case, including the details of the claim language, the specification, and prosecution history for the patent involved. This has made it difficult for applicants, patentees and the public to discern the limits on what is patent ineligible. The application of the case law sometimes appears inconsistent from case to case.

As noted at the first roundtable on examination guidelines, AIPLA has concerns that a section 101 rejection has become an insurmountable barrier, and that examiners do not feel empowered to recognize when an applicant has met his or her burden of proof. The same barrier also exists in the courts where a section 101 ineligibility analysis has become the first step in litigation.

While this may result, in part, from the assertion of overly broad claims, patent ineligibility should not be the threshold test in typical cases.

### **Compliance with TRIPS and Falling Behind**

AIPLA is also concerned that recent section 101 jurisprudence has put the United States at risk of falling behind the patent systems of other developed countries. Subject to certain exceptions, Article 27 of TRIPS states that “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. ...”

AIPLA has a long history of supporting patent eligibility for all inventions that can be shown to provide a “useful, concrete and tangible result.” When AIPLA first adopted this position in 2001, it noted that “[a]s technology has progressed into previously uncharted areas, the U.S. patent system has been the incubator for groundbreaking means to provide incentives for innovation, ahead of other highly developed patent systems in, e.g., Europe or Japan. ...” As the case law has developed in the United States, we have moved away from the TRIPs standard and risk losing investments in innovation to other countries with more compatible patent systems.

### **AIPLA’s Task Force**

In December 2014, AIPLA formed a Patent Eligible Subject Matter Task Force to explore the concerns of AIPLA members relating to section 101 and to consider mechanisms to address those concerns. The Task Force has continued its work since that time. The issues involved are complex and, in our view, the courts have not been able to adequately address the problems in applying section 101. A legislative solution is needed that will help increase certainty and efficiencies in our patent system and promote innovation in the United States.

#### **I. Roundtable No. 1: Topics for Comment**

The Federal Register notice set out four topics for comment in connection with the roundtable on examiner guidance for determining patent eligibility. The four topics, and AIPLA’s responses, are set out below.

##### **Topic 1:**

“Suggestions on how to improve the Office’s subject matter eligibility guidance, particularly the three recent memoranda.”

##### **Response:**

The USPTO’s memoranda and examples on subject matter eligibility provide a useful starting point, but in practice examiner decisions in this area continue to be confusing from examiner to examiner and from art unit to art unit. We believe that both examiners and applicants would be better served if these guidance materials were compiled in a single and regularly updated document that presents the case law in easy-to-scan tabular form. The table should include not only the claims at issue in the case and the outcome of the case, but also (and importantly) a

synopsis of the court's rationale that supports the outcome. The table should be capable of being sorted by issue and technology to help identify the most pertinent cases.

## **Topic 2:**

“Comments on the May 2016 Life Sciences examples and their effect on prosecution of patent applications in the life sciences, and suggestions of additional examples, or technology areas in which examples would be helpful.”

## **Response:**

The May 2016 Life Sciences examples are certainly appreciated, especially considering the confusing and seemingly conflicting reasoning by the courts as to why certain inventions are eligible and others are not.

Unfortunately, none of the Life Sciences examples illustrate claims that are clearly patterned after the claims held to be eligible by the Supreme Court and Federal Circuit since *Mayo*. Nor do the discussions of the Life Sciences examples illustrating eligible claims explicitly reference or analyze the three cases that have found eligibility. In addition, the discussions do not explain how or why an ineligible example claim might be rewritten to claim eligible subject matter. Instead, many of the discussions include a “*Cf*” citation to *In re Roslin*, 750 F.3d 1333 (Fed. Cir. 2014), a case which found ineligibility and therefore provides no positive guidance to the practitioner as to what the Office considers patent eligible.

The citation of *In re Roslin* throughout the Life Sciences examples is a particular cause of concern. The claims there relate to a recombinantly produced mammal, but the examples include no discussion of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which involved a recombinantly produced microorganism. In addition, the examples do not address the fact that a chemical composition and its properties are inseparable.

The Life Sciences examples also fail to include any examples that extrapolate the reasoning and analyses of recent decisions holding inventions in the computer and software arts patent eligible to various inventions in the life sciences. For example, there is no Life Sciences example that includes a patent eligible claim based on a finding of a technological improvement over the art. There are numerous types of biotech assay inventions, not just diagnostic methods, that are a technological improvement over other prior art methods.

Moreover, the Life Sciences examples make certain assumptions and conclusions that are biased toward a finding of ineligibility. In particular, in several places, the Life Sciences examples simply state the so-called broadest reasonable interpretation of a claim limitation with no analysis of whether the interpretation is actually reasonable, for example, in view of, the disclosure in the specification.<sup>1</sup> Similarly, the Life Sciences examples simply make conclusory

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<sup>1</sup> For example, in the discussion of claim 3 of Example 28 (Vaccines) includes a “broadest reasonable interpretation” of “pharmaceutically acceptable carrier” as “water,” even though plain water is not suitable for as a pharmaceutically acceptable carrier for most modes of administration, *e.g.*, for injection, since water must be sterile and, when used as the reconstituent, a pharmaceutically acceptable salt is also required.

statements such as the claim limitations are considered “well-understood, routine and conventional,” with no analysis or guidance as to how one should determine whether a given claim limitation is actually “well-understood, routine and conventional.” Such conclusory statements should not be provided by the Patent Office in documents intended to provide exemplary actions guiding examiners.

In sum, AIPLA is very concerned about the limited focus of the Life Sciences examples and the use of conclusory statements about claim interpretation. This does not provide the needed guidance to examiners as to what is patent-eligible. It would be helpful to offer a more balanced guidance that includes additional examples and reasoned analysis of what is patent-eligible. Many practitioners are finding that examiners in Group 1600 make conclusory ineligibility rejections and are unwilling to consider any rebuttal evidence that the invention at issue, and as actually claimed, is in fact different from those determined to be ineligible by the courts.

AIPLA therefore urges that the guidelines incorporate well-established Supreme Court law that has not been overruled into its approach to making patent eligibility decisions for all subject matter and take care to avoid incorporating bare conclusory statements in the examples and discussion.

### **Topic 3:**

“Suggestions on how best to make examiners aware of newly issued judicial decisions, and how best to incorporate recent decisions holding claims eligible, such as *Enfish*, *Bascom*, *Rapid Litigation Management*, and *McRO*, into the Office’s subject matter eligibility guidance.”

### **Response:**

Recent decisions show that more careful and objective attention should be given to the preliminary question of the *Mayo* analysis of whether the claims are directed to excluded subject matter. Those features of the recent cases (especially their emphasis on close consideration of the specification) should be incorporated into an easy-to-scan table of case law that is updated by the USPTO’s Deputy Commissioner for Patent Examination Policy or other designated office as each precedential decision of the Federal Circuit and Supreme Court is issued. The subject matter eligibility guidance should lead the examiners and practitioners to the table of case law (and provide a link). The table of case law would include extracts for Examiners to cite to (and analogize) in their section 101 rejections, much like form paragraphs. The case summaries should also list the claims for which eligibility was decided one way or the other for facilitate comparison to pending claims. The cases could be grouped by the Court’s reasoning (*e.g.* a technical solution to a technical problem, or a solution to a problem necessarily rooted in computer technology, *etc.*) or some other mechanism that facilitates easy scanning of the cases. This updated table of case law should be posted on the USPTO website for use by examiners as well as practitioners so that all are working from the same case descriptions. The table would likely need to be published in the Federal Register from time to time (*e.g.* quarterly) to permit substantive feedback from users and to satisfy the USPTO’s rulemaking notice obligations. User groups, including AIPLA, could provide feedback regarding the characterizations of the cases on an ongoing basis, as appropriate.

#### **Topic 4:**

“Concerns on how the Office’s subject matter eligibility guidance and training examples, or how court decisions, are being applied by examiners.”

#### **Response:**

A repeated refrain among our members is that examiners fail to engage with applicants on 101 issues. First, as mentioned briefly above in response to Topic No. 2, examiners make generalized rejections that do not meet their burden of presenting a prima facie case of unpatentability. Second, examiners do not feel empowered to withdraw section 101 rejections even when applicants have made persuasive arguments to overcome the rejections.

Engagement on section 101 issues requires a substantive, detailed analysis of the proposed claims. In our members’ experience, some examiners have developed generalized form paragraphs for section 101 rejections. We believe examiners should be cautioned about using such form paragraphs. Although consistency in decision making can be improved with the appropriate use of form paragraphs, such tools should not be used to shortchange the meaningful analysis of the facts and issues necessary for examination.

Any rejection must identify the case law authority for the rejection and must clearly explain why the case law applies to the proposed claims. The case law supporting the rejection must be selected for the strength and clarity of a court’s reasoning to explain the result. An office action should not cite non-precedential decisions which, by their nature, do not meet that test. Nor should an office action simply cite a long list of cases with a general statement that they are all equally applicable to the examined claims.

The guidance should require that the reasoning for the section 101 rejection be set forth with sufficient particularity to allow the applicant to provide a reasoned counterargument. Indeed, this is consistent with MPEP 2106.III which states that only after a section 101 rejection sets forth in the record *why* the claim is directed to a judicial exception does the burden shift to the applicant. And it is an issue of basic fairness and efficiency. Requiring an applicant to respond to an overgeneralized section 101 rejection is a drain on an applicant’s limited prosecution resources. By contrast, an applicant presented with a well-reasoned and clearly articulated section 101 rejection can counter with a targeted, reasoned response to the rejection or make an informed decision not to proceed with prosecution.

For the same fairness and efficiency reasons, AIPLA recommends that an office action with a section 101 rejection also contain a complete patentability analysis, based on sections 102, 103 and 112. An applicant can then address all rejections in a streamlined response to the office action and keep the prosecution moving forward, or make an informed decision not to continue, conserving the resources of both the applicant and the Office.

More generally, a section 101 rejection has become an insurmountable barrier, and examiners do not feel empowered to recognize when an applicant has met her burden of proof. The practical effect is a presumption of *ineligibility* that can be overcome only if the applicant establishes that the claims presented *match* a current judicial decision where eligibility was found. While the courts have had difficulty drawing the metes and bounds of subject matter eligibility, it is

important to stress that the USPTO is responsible for applying the “judicial exceptions,” not for developing or expanding them.

In this respect, the guidance should instruct examiners to maintain a section 101 rejection only where the claims and specification very closely align to those in a judicial decision finding ineligibility. An applicant who presents a well-reasoned, good faith argument should be able to rebut a *prima facie* section 101 rejection. This rebuttal may include an argument distinguishing the proposed claims from the claims at issue in the closest precedential court decision identified in the section 101 rejection. Examiners are not trained to make the fine distinctions that appear in judicial opinions, and should not be expected to do so. It should be sufficient for the applicant to overcome the section 101 rejection with an argument that is “more persuasive than not.”

## **II. Roundtable 2 Questions**

### **Question 1:**

How has the Supreme Court’s interpretation of 35 U.S.C. 101 in the past several years affected the enforcement of patents and the development of subject-matter- eligibility law? In your response please:

- a. Identify the scope of the problem, including specific examples;
- b. Identify any legal and/or technical inaccuracies;
- c. Suggest possible changes and/or solutions to any problems with section 101; and
- d. Provide explanations and/or any legal, policy, or economic analyses supporting your comments.

### **Response:**

Over the years, the Supreme Court has identified what it deems to be exceptions to the explicit statutory language currently reflected in 35 U.S.C. § 101. In AIPLA’s view, the Supreme Court’s relatively recent interpretations of section 101 and those exceptions have had a profoundly adverse impact on the enforcement of patents and the development of eligibility law. In particular, the Supreme Court has created a test for compliance with Section 101 that is not supported by statutory language or legislative history and conflates subsequent statutory provisions into this test. The Supreme Court’s reliance on its overreaching test has directly resulted in decisions that adversely affect the competitiveness of United States businesses by providing, for example, less patent protection for certain classes of invention than protection available in Europe and China.

In the modern era, the problem began with *Gottschalk v. Benson*, 409 U.S. 63 (1972). Citing exemplary claims 8 and 13, the Court said the “claims were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use.” *Id.* at 44. Yet, method claim 8 was limited to a “reentrant shift register” and specific steps manipulating that register. *Id.* at 73-74.

The Court began with the general proposition that abstract ideas are not patentable “as they are the basic tools of scientific and technological work,” *id.* at 67, but then decided the case based on the facts before it: “The question is whether the method described and claimed is a ‘process’

within the meaning of the Patent Act.” *Id.* at 65 (footnote omitted) (*citing* 35 U.S.C. §§ 100(b) and 101). Despite the specific language of claim 8, the Court explained that the claims at issue were not eligible for patent protection under section 101 because:

The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.

*Id.* at 71-72. The Court also relied upon practical problems identified by the President’s Commission on the Patent System (1966) when that Commission rejected the proposal that computer programs be patentable. *Id.* at 72.

Subsequently, *Parker v. Flook*, 437 U.S. 584 (1978) (6-3), improperly introduced an assessment of obviousness, 35 U.S.C. § 103, into the construction of section 101. The dissent correctly characterized the issues as “whether a claimed process loses its status of subject-matter patentability simply because *one step* in the process would not be patentable subject matter if considered in isolation.” *Id.* at 599 (emphasis in original). Importantly, the dissent correctly predicted that the majority struck a “damaging blow at basic principles of patent law by importing into its inquiry under § 101 the criteria of novelty and inventiveness.” *Id.* at 600. That identified legal inaccuracy continues to reverberate through section 101 jurisprudence despite efforts to disentangle the section 101 analysis from different statutory requirements.

The 5-4 majority in *Diamond v. Diehr*, 450 U.S. 175 (1981), identified three important aspects of an analysis under § 101. First, claims must be considered as a whole. *Id.* at 188. Second, “[t]he ‘novelty’ of any element of steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Id.* at 188-89. Third, case specific analysis of the details in the record of the specific patent is required to identify meaningful limits on the scope of the claim. *Id.* at 191-92.

With that framework, the majority held that the recited “physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter.” *Id.* Although the majority implicitly criticized the analysis applied in *Flook*, it did not correct the legal flaws in *Flook* by overturning it.

Subsequent cases at the Supreme Court have diverged from the *Diehr* majority and the *Flook* dissent. In *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), the Court expressly warned against adopting “categorical rules that might have wide-ranging and unforeseen impacts.” *Id.* at 3230. After a record-specific analysis of “key claims” 1 and 4, directed to a series of steps instructing how to hedge risk and to a mathematical formula reflecting that concept, *Id.* at 3223, the Court concluded that “[Bilski’s] claims are not patentable processes because they are attempts to patent an abstract idea.” *Id.* at 3230-31. “Indeed, all members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.” *Id.* But the Court merely paid lip service to the distinction between section 101 and the requirements in subsequent sections 102, 103 and 112; it ignored the distinction made by the dissenters in *Flook* and rejected post-solution activity as sufficient to satisfy section 101.



The analysis in *Mayo* reflects the same flaws criticized by the *Flook* dissenters. The Court commingled the analysis on which it relied with additional requirements necessarily derived from sections 102, 103, and 112. The Court also rejected the government's efforts in its amicus brief to distinguish section 101 from sections 102, 103, and 112. Furthermore, the Court's expressed concern about disproportionately tying up underlying natural laws is quite troubling because it suggests that a pioneer invention based on a scientific breakthrough should not be entitled broad protection. This over-expansive view of the filter effect of § 101 was continued in *Alice*. The policy decisions underlying these concerns belong in the legislative branch.

As reflected in the comments of AIPLA's representatives at the first and second roundtables, lower courts and the USPTO have struggled to implement the Supreme Court's test in a predictable and consistent manner. Despite good faith efforts by the USPTO, feedback from AIPLA members indicates that there are material disparities in how the examining corps applies the applicable standard in practice. There is a sense that many examiners are concerned about doing something wrong in a case involving section 101.

Based on the foregoing, AIPLA believes that a legislative solution is essential and continues to explore possible solutions. There are a number of solutions under consideration and any ultimate legislative solution needs to be carefully crafted. Possible solutions, at the very least, should decouple a section 101 analysis from analyses under sections 102, 103 and 112. Eligibility under section 101 is not the appropriate tool to deal with overly broad patent claims or to rein in so-called patent troll litigation.

**Question 2:**

Should the patent statute be amended to further define the statutory categories of invention, *i.e.*, process, machine, manufacture, and composition of matter? If so, please identify possible legislative changes, including which sections of title 35 should be amended, *e.g.*, sections 100 or 101.

**Response:**

AIPLA notes that existing Section 101 includes not only the categories of "new and useful process, machine, manufacture, or composition of matter" but also "any new and useful improvement thereof." In light of this, AIPLA does not believe the statute should be amended to add any further definition of the statutory categories of invention. *See* responses to Questions 3 and 6 below.

**Question 3:**

Do you think there should be exceptions to patentable subject matter?

- a. If no, how should section 101 or other patentability provisions operate to address subject matter currently considered to fall within judicial exceptions?
- b. If yes, please explain whether the judicial exceptions are sufficient in scope and if not, please identify other exceptions that should be included in the determination of patent eligible subject matter.

**Response:**

AIPLA believes that the judicial exceptions to patent eligibility, as applied, are unnecessary and overreaching. The Supreme Court historically has recognized only a few narrow exceptions to patent eligible subject matter under Section 101: claims that are directed solely to laws of nature, natural phenomena, and abstract ideas. *Bilski*, 130 S. Ct. at 3225 (citing *Chakrabarty*, 447 U.S. at 309). As recently as 2010, the Court recognized that those exceptions do not “give[] the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute’s purpose and design.” *Id.* at 3226.

But in *Mayo*, *Alice*, and *Myriad*,<sup>2</sup> the Court did exactly that, unnecessarily and confusingly applying those exceptions so broadly as to impose limitations on patentability that are inconsistent with the statutory text, its purpose, and its design. The judicial exceptions have been transformed into something very different from anything the Court originally envisioned. Indeed, U.S. inventors are currently disadvantaged as compared to their foreign competitors given the unduly narrow scope of patent eligibility in the United States after *Mayo*, *Myriad*, and *Alice*. One only needs to apply current-day Supreme Court jurisprudence to claim 5 in the Morse patent, which survived Court scrutiny, to understand the dramatic change in recent years.<sup>3</sup> Because recent decisions have demonstrated that the judicial exceptions fail to strike the necessary balance between incentivizing innovations and protecting the public commons (see discussion below in response to question 6), AIPLA believes that those exceptions are unworkable.

The existing sections 101, 102, 103, and 112 of the Patent Act express the conditions and requirements of patentability. In accord with the statutory language of section 101, if what is claimed is a machine, manufacture, composition of matter, or process, or an improvement of any of these things, and if it is useful, it is an invention eligible for patenting, subject to the conditions and requirements of sections 102, 103, and 112.

**Question 4:**

Should the patent statute be amended to define the judicial exceptions? If so, please suggest possible legislative changes, including which sections of title 35 should be amended, *e.g.*, sections 100 or 101.

**Response:**

For the reasons set forth in response to Question 3, AIPLA does not believe the patent statute should be amended to define the judicial exceptions.

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<sup>2</sup> *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) (“*Myriad*”)

<sup>3</sup> See *O’Reilly v. Morse*, 56 U.S. 62, 112 (1853), which famously invalidated claim 8 of Reissue Patent No. 117 on using the motive power of electric current, but left in force claim 5, reciting a “system of signs consisting of dots and spaces and of dots, spaces and horizontal lines, for numerals, letters, words, or sentences, substantially as herein set forth and illustrated, for telegraphic purposes.”

**Question 5:**

If you identified other exceptions in your response to 3(b), please suggest possible legislative changes, including which sections of title 35 should be amended, *e.g.*, sections 100 or 101.

**Response:**

Not applicable.

**Question 6:**

- a. Do you think that title 35 should be amended to revise the definition for the term “invention” and/or provide a definition for the term “discovery” along with specific examples of subject matter that should not be treated as an invention and/or discovery?
- b. If so, please suggest possible legislative changes, including which sections of title 35 should be amended, *e.g.*, sections 100 or 101.

**Response:**

AIPLA does not believe Title 35 should be so amended. Adding specific definitions for “inventions” or “discoveries” would create a risk of unduly limiting patentable subject matter, especially as technology progresses into uncharted areas. AIPLA recognizes that laws of nature, physical phenomena, and abstract ideas exist in the public domain for all time. An inventor is not entitled to exclusive use of any basic principle because such exclusivity would remove it from the public. Yet, protecting the public commons does not require limits on or exclusions from the four specified categories—“process, machine, manufacture or composition of matter”—of section 101. Instead, it cautions the decision-maker, regardless of category, to ensure unfettered public use of natural or fundamental scientific principles. With this constraint, the patent law can provide the necessary incentives for future innovation without providing excessive rights that may impede the further spread of useful knowledge.

As technology has progressed into previously uncharted areas, the U.S. patent system has provided incentives for groundbreaking innovations, well ahead of other highly developed patent systems, including those in Europe and Japan. To limit patentable subject matter by codifying exceptions to section 101 would risk impeding innovation. Rather, any invention should be eligible for patent protection if it can be shown to provide a “useful, concrete and tangible result.” The fundamental *quid pro quo* of the patent grant is the requirement that inventors fully disclose their inventions so that their knowledge, insights, and achievements become available to everyone, especially to competing innovators, who can then use the patent disclosure to push the frontiers of science even further. Once the patent term expires, all are free to enjoy, commercialize, and improve the claimed inventions. The public interest is not well served by withholding patent protection. A list of patent-ineligible subject matter would most likely serve as a disincentive for inventors to participate in this fundamental *quid pro quo*.

Moreover, a codified list of patent-ineligible subjects would regularly need to be updated and tweaked to accommodate the dynamic and unpredictable direction of technological progress. This is not an ideal way to further develop the law or otherwise legislate in this delicate area.

**Question 7:**

Does the concept of preemption, either separately or in the context of the *Mayo* two-step framework, capture useful insight in guarding against the issuance of overly broad patents? If so, please suggest possible legislative changes to capture those insights.

**Response:**

AIPLA does not believe that the concept of preemption employed in a section 101 analysis captures useful insight in guarding against the issuance of overly broad patents. A pioneer invention should be entitled to patent claims of very broad scope while inventions making incremental advances should have claims of comparably narrower scope. A pioneer invention, such as the transistor, should be entitled to broad protection in return for the disclosure to the public of how to make and use the invention, notwithstanding some preemptive results for a limited period of time. In AIPLA's view, this reflects the balance of policy considerations contained in the Constitution.

**Question 8:**

What does the term "discovery" in sections 100 and 101 mean, and to what extent should a "discovery" be eligible for a patent? Please provide specific examples.

**Question 9:**

What does the term "invention" in sections 100 and 101 mean, and to what extent should a non-naturally occurring product of human ingenuity qualify as an "invention" to be eligible for a patent? Please provide specific examples.

**Response:**

AIPLA answers questions 8 and 9 together as the definitions of "discovery" and "invention" are intertwined.

The Constitution authorizes Congress to "promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries." U.S. CONST. ART I, § 8 ¶ 8. "Invention" is defined in Section 100 as "inventions or discoveries," and section 101 refers to "whoever invents or discovers."

AIPLA believes a "discovery" should be eligible for a patent so long as the "discovery" leads to a new and useful process, machine, manufacture, or composition of matter, *or any new and useful improvement thereof*.

The New Shorter Oxford English Dictionary defines the verb "invent" as "[c]reate, produce or construct by original thought or ingenuity"; it defines the noun "invention" as "[a]n act or action of finding out; discovery ... the solving of a problem." The word "discovery" is defined as "[t]he action or an act of revealing something secret or not generally known; disclosure; .... The action

or act of becoming aware of for the first time; esp. the first bringing to light of a scientific phenomenon.”

An invention, therefore, is a creation arising from original thought or ingenuity, but that “original thought” is necessarily a discovery. In *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), the Court found a relatively simple invention to be patentable: the adjustment of the pitch of a wire in a papermaking machine. Although the invention itself was simple, the discovery of the problem underlying the invention was not. As stated by the Court,

we must not lose sight of the fact that one essential part of Eibel's discovery was that the trouble causing the defective paper product under high machine speed was in the disturbance and ripples some 10 feet from the discharge, and that they were due to the unequal speeds of stock and wire at that point and could be removed by equalizing the speeds. The invention was not the mere use of a high or substantial pitch to remedy a known source of trouble. It was the discovery of the source not before known, and the application of the remedy, for which Eibel was entitled to be rewarded in his patent.

*Id.* at 68. Thus, a relatively simple invention was found to be patentable due to the original thought involved in the discovery of the problem and the application of scientific principles that produced a solution.

The Patent Act defines the term “invention.” 35 U.S.C. § 100. Any non-naturally occurring product of human ingenuity likely should qualify as an invention so long as it meets the requirements of sections 102, 103 and 112. AIPLA does not intend to exclude from this definition any non-naturally occurring product of indirect human ingenuity, such as created through the use of artificial intelligence.

**Question 10:**

To what extent should products that have been isolated from their natural surroundings as a result of human ingenuity be eligible for a patent? Please provide specific examples as well as scientific explanations and/or legal analyses to support your response.

**Response:**

AIPLA believes that patent eligible subject matter may include processes of isolating products from nature and such isolated products, as well as non-naturally occurring compositions comprising products isolated from nature.

The process of isolating, *i.e.*, separating an article from its natural surroundings, should be patent eligible even where properties inherent to the article are used to separate the article. For example, a method of separating gold from a deposit in the earth using a method by which the physical and/or chemical properties of gold are exploited to isolate the gold, should be patent eligible. The fact that the article may be a biomolecule, such as genetic material, protein, glycolipids, etc. is irrelevant. The only time a claim to a process of separating an article from its natural surroundings should be ineligible is where nature itself performs the process exactly as claimed.

In *Myriad*, the Supreme Court reasoned that isolated DNA itself is not patent eligible subject matter because, as isolated, its informational content, *i.e.*, genetic information, is the same as it is in its natural environment. Nucleic acid molecules are unique compounds that are unlike any other in the world. The particular arrangement of the bases that form a nucleic acid molecule and confer the informational content of the nucleic acid molecule remain unchanged even when the nucleic acid molecule is separated from its natural environment, *i.e.*, the genome of an organism.

Other compounds and compositions, including biomolecules such as proteins, antibodies, glycolipids, etc., are different from nucleic acid molecules. They do not carry genetic information that remains unchanged when isolated. In fact, when isolated and purified from their natural environment, many of the other molecules exhibit characteristics, *e.g.*, bioactivities and/or physiochemical properties, which they do not exhibit in their natural environment. Such isolated compounds and compositions that exhibit characteristics that they do not exhibit in their natural environment should be patent eligible. This is consistent with case law and remains unchanged by *Mayo* and *Myriad*.

Additionally, compositions that comprise a purity or a concentration of a compound isolated from nature, where such purity or concentration do not exist in nature, should be patent eligible where the composition, because the purity or concentration of the compound therein, has a function or use that the unpurified compound as it is found in nature does not. Even compositions comprising an unpurified amount of a compound that was obtained from the natural world that also contain another compound, that may or may not be another product obtained from nature should be patent eligible where the composition, as a whole, *i.e.*, the mixture exhibits a function or has a new use that the individual components do not otherwise have as they exist individually in nature.

Finally, where a claim is to a process of isolating, *i.e.*, separating, an article from its natural environment, where the existence of the article was not previously known, the process of isolating the article should be patent eligible even where the steps, alone and in combination, were known or used for isolating other articles, as such steps cannot be said to be “well-understood, routine or conventional” for isolating an article that was not known to exist. Nowhere do the courts hold otherwise.

**Question 11:**

To what extent should a “diagnostic method” be eligible for a patent? Please provide specific examples.

**Response:**

As a preliminary matter, AIPLA notes that neither the Supreme Court nor Federal Circuit has held that diagnostic methods are *per se* patent ineligible. A claim to a true diagnostic method is a claim that requires an active step of providing an actual diagnosis of a specific condition based on the results of the recited method steps. By contrast, the claim at issue in *Mayo* did not require any active step of providing a diagnosis. Instead, the claim simply informed doctors of a law of nature, and, according to the claim, the doctors need not have done anything with the information. Similarly, none of the claims at issue in *Ambry* required an active step of providing

a diagnosis. *University of Utah v. Ambray Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014). Instead, the claims at issue were screening methods without any actual diagnostic step.

The claim that comes closest to a true diagnostic method claim is claim 21 of U.S. Patent No. 6,258,540, which was held ineligible in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *reh. denied*, 809 F.3d 1282 (Fed. Cir. 2015). The claim reads as follows:

21. A method of performing a prenatal diagnosis, which method comprises the steps of:
- (i) providing a maternal blood sample;
  - (ii) separating the sample into a cellular and a non-cellular fraction;
  - (iii) detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction according to the method of claim 1;
  - (iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the fetal nucleic acid.

Although the claim recites actively providing a diagnosis, no actual diagnosis of any particular condition is provided. Hence, not even *Ariosa* holds that a claim to a diagnostic method that requires an active step of providing a diagnosis of a particular condition is ineligible.

Additionally, neither the Supreme Court nor the Federal Circuit has held that man-made correlations are laws of nature and that such contrivances are to be ignored when considering the eligibility of a diagnostic method. Such man-made contrivances result from the particular selection of a handful of biomarkers that are considered apart from the entire plethora of biomarkers in a subject. When one or more biomarkers are considered in isolation and away from their natural environment, their informational value, *i.e.*, correlative weight, concerning a given condition is completely artificial and is not the same as when they are considered in their natural environment, *e.g.*, as influenced by or outweighed by other biomolecules.

Thus, diagnostic methods, when based on a select group of specified biomarkers or on the weights of the select group of specified biomarkers relative to each other, are man-made contrivances. They are not laws of nature and their recitation in a patent should be considered as a claim limitation that can make a method claim patent eligible.

Further, no Supreme Court or Federal Circuit opinion has held that a method employing an algorithm to assign weighted values to a select set of biomarkers is necessarily a patent-ineligible abstract idea. Such a method could include steps requiring the use of tangible reagents and the physical transformation of a biological sample to measure the amounts of the specified biomarkers.

The use of an algorithm to assign weighted values to a selected set of biomarkers in a diagnostic method—which also requires the use of tangible reagents and a physical transformation of biological sample to measure the amounts of the biomarkers—should not render the assay ineligible as nothing more than the algorithm itself.

**Question 12:**

Are there lines that can or should be drawn scientifically or legislatively between different types of compositions of matter for purposes of obtaining patent protection (*e.g.*, between human genes and genes of other species)?

**Response:**

There are scientific distinctions between different types of compositions of matter. As noted above, nucleic acid molecules are unlike any other molecule or composition as their informational content and function remains unchanged when isolated from nature. Additionally, the analysis in *Myriad* holding cDNA claims patent eligible simply does not apply to microorganisms that do not have introns interrupting the sequences of their genes.

However, care should be taken in attempting to use scientific distinctions to render certain subject matter deemed immoral or politically unpopular to be patented as being ineligible.

More generally, AIPLA has serious concerns about attempts to codify patent-ineligible subject matter, including any attempts based on scientific or technological categories because doing so creates the risk that unforeseen scientific or technological advances will be imprudently barred from patent protection (and, as a result, disincentivized).

**Question 13:**

What particular inventions or specific types of technologies that should be patent eligible are not patent eligible, or are likely to be challenged as patent ineligible, under *Mayo/Myriad*? Please provide specific examples and explain why you believe claim drafting strategies will not be sufficient to avoid patent eligibility problems.

**Response:**

Every invention relating to or involving the life sciences is likely to be challenged and could be found ineligible under the overreaching and malleable *Mayo* test.

**Question 14:**

Should patents be available for methods that do not involve a machine or a transformation? If so, please provide specific examples.

**Response:**

The Supreme Court noted in *Bilski* that while “the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101. ... [It] is not the sole test for deciding whether an invention is a patent-eligible “process.” *Bilski*, 561 U.S. at 594. *See also Parker v. Flook*, 437 U.S. 584 (1978) (“a valid process patent may issue even if it does not meet of these qualifications [transformation or machine-implementation]”); *id.* at 589 n.9; AIPLA Amicus Brief in *Bilski v. Kappos*, at 4.



Claiming a machine or transformation should be a safe harbor rather than a condition precedent to eligibility.

Samuel Morse's claim 5 is a historical example of such a process that AIPLA believes was correctly found to be patentable by the Supreme Court.<sup>4</sup> It claimed: "The system of signs, consisting of dots and spaces, and of dots, spaces and horizontal lines, for numerals, letters, words or sentences, substantially as herein set forth and illustrated, for telegraphic purposes." *O'Reilly*, 56 U.S. at 86 (1854). Other examples, from the field of industrial engineering, could include arranging human workers along a particular assembly line in a manner that more efficiently produces products, or particular solutions to the class of "traveling salesmen" problems about efficiently routing delivery-people to route packages to homes under particular circumstances. These sorts of real-world innovations should pass section 101, which the Supreme Court described as "only a threshold test." *Bilski*, 561 U.S. at 594.

**Question 15:**

If you support some form of "machine or transformation test," please identify the best expression of such a test.

- a. Should incorporation of the use of a general purpose computer be enough to satisfy the "machine" part of the test? If not, what more should be required?
- b. Should a transformation that occurs in the human body as a result of a claimed process be enough to satisfy the "transformation" part of the test? If not, what more should be required?

**Response:**

As noted above, any "machine or transformation test" should only be a particular safe-harbor, not an exclusive test. As the Supreme Court noted in *Bilski*, it can be an important clue to patentability, and therefore AIPLA believes that machine or transformation should be sufficient (but not necessary) to comply with section 101. With regard to implementing a "machine or transformation" safe-harbor analysis, AIPLA answers "yes" as to both subparts.

**Question 16:**

To what extent should an invention that involves a business method be eligible for a patent? Please provide specific examples.

**Response:**

AIPLA believes that an invention that involves a business method should be eligible if it is a practical application of a process in the real world.

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<sup>4</sup> See footnote 3, supra.

**Question 17:**

To what extent should an invention that involves computer software be eligible for a patent? Please provide specific examples.

**Response:**

AIPLA believes that if the invention meets a safe-harbor machine or transformation test, it generally should be patent eligible. That should be the case even if the claim involves implementing a specific set of process steps on generic machinery. *See* 35 U.S.C. § 100(b) (“The term ‘process’ means process, art or method, and includes a new use of a known process, *machine*, manufacture, composition of matter, or material.”) (Emphasis added.)

**Question 18:**

What mechanisms, other than the judicial exceptions, can be used to prevent issuance of overly broad software or computer-related patents that cover wide swaths of economic activity? Do you think that other provisions of title 35 (enablement, written description, definiteness, novelty, non-obviousness) could be used more effectively to achieve this goal? If not, please explain why.

**Response:**

The high level answer to the second question above is “yes.” Concerns about overbreadth or preemption of basic laws of nature or abstract ideas are generally best addressed by focusing on the specific facts of each case, especially during examination, and appropriately implementing sections 102, 103, and (in particular) 112. Examiners should be encouraged to make well-reasoned scope and definiteness rejections in the computer arts. One additional mechanism to prevent issuance of overly broad software or computer-related patents could be an additional internal level of review at the USPTO before issuing patents with claims in particular areas, rather than simply based on vague and broad-brush section 101 rejections.

**Conclusion**

AIPLA is grateful for the opportunity to present its views on section 101 jurisprudence and its impact on the U.S. patent system. We look forward to working closely with the Office and others on these issues going forward.

Sincerely,



Mark L. Whitaker

President

American Intellectual Property Law Association