



**PATENT ELIGIBLE SUBJECT MATTER:
REPORT ON VIEWS AND
RECOMMENDATIONS FROM THE PUBLIC**

United States Patent and Trademark Office

July 2017

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I. INTRODUCTION

To be entitled to a patent, a claimed invention must satisfy certain patentability requirements. Perhaps the most basic requirement is that the subject matter sought to be patented is in fact eligible for patent protection. In addition, the invention must meet other patentability requirements, including novelty, non-obviousness, written description, and enablement. Like the other requirements, the eligibility requirement is established by statute: 35 U.S.C. § 101. But the Supreme Court long ago carved out certain exceptions to patent eligibility for abstract ideas, laws of nature, and natural phenomena.

Between 2010 and 2014, the United States Supreme Court issued four decisions (*Bilski*, *Mayo*, *Myriad*, and *Alice*) that shifted the dividing line between eligible and ineligible subject matter. Specifically, the Court articulated a new *Mayo/Alice* two-step test to distinguish eligible subject matter from subject matter that falls within one of the exceptions. The United States Court of Appeals for the Federal Circuit and the United States Patent and Trademark Office (USPTO) have worked to understand and apply the Supreme Court's test. But the impact of that test and its application by the Federal Circuit and the USPTO have sparked considerable discussion in the patent community, both critical and favorable, of the Supreme Court's jurisprudence.

On October 17, 2016, the USPTO issued a Federal Register Notice¹ seeking public input on patent eligible subject matter in the wake of the recent decisions by the Supreme Court. In the Notice, the USPTO announced the convening of two roundtables: one focused on the examination guidance developed by the USPTO to implement the recent Supreme Court and subsequent Federal Circuit precedent; and a second focused more broadly on the current state of the law of patent eligibility. The second roundtable, *Roundtable 2—Exploring the Legal Contours of Patent Eligible Subject Matter*, is the subject of this report.

The Notice invited members of the public to present their views at the roundtable or to share their views through written comments. To solicit input on the impact of the Supreme Court's recent § 101 jurisprudence, including legal, policy, or economic analyses, the Notice set forth a series of questions. Many of the questions focused on two technology areas believed to be especially affected by recent law: life sciences and computer-related technologies.

Roundtable 2 was held on December 5, 2016, at Stanford University. The roundtable consisted of seven interactive panels that included speakers who participated locally, as well as those that spoke remotely from USPTO headquarters in Alexandria, Virginia, and each of the USPTO regional offices. There were over 250 participants from across the country representing a broad cross-section of the patent community, including industry, private practice, academia, associations, inventors, and small businesses.

¹ Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 81 Fed. Reg. 71,485 (October 17, 2016); *see* Appendix I.

Following the roundtable, 26 written comments were submitted to the USPTO by a similarly diverse group.²

II. OVERVIEW

This report is intended to provide a comprehensive review of patent eligibility law and a record of public views on the impact of the recent Supreme Court patent eligibility jurisprudence and public recommendations for a path forward.

Section III provides a historical overview of patent eligibility law. It begins by discussing the basis in the Patent Act, then summarizes Supreme Court jurisprudence leading up to and including the four recent cases that significantly impacted eligibility law, and finally reviews the Federal Circuit's application of the Supreme Court's *Mayo/Alice* two-step eligibility test. It also provides an overview of patent eligibility law internationally, beginning with a discussion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), then summarizing the assessment of patent subject matter eligibility in other IP5 patent offices, and finally discussing differing approaches in life sciences and computer-related technologies.

Section IV summarizes public views on patent eligibility jurisprudence as recorded during the roundtable and in written comments submitted to the USPTO. It documents both critical and favorable views of the Supreme Court's two-step test and the application of that test by the Federal Circuit. It also summarizes public reports on the impact of the current law on science and innovation, and the asserted repercussions of having differing eligibility standards in the United States and abroad. Finally, it summarizes public views on the effect of recent law in the two most-affected areas of technology, life sciences, and computer-related technologies.

Section V reviews public recommendations on what, if any, measures should be taken to address the recent changes in patent eligibility law. The recommended measures generally fall into three categories: continued development of the law by the judiciary; administrative measures by the USPTO; and proposed legislative changes.

² The webcast of the roundtable is available at <https://livestream.com/uspto/RoundtableStanford>. A transcript of the roundtable, as well as the agenda, speaker presentations, and written comments submitted following the roundtable, are available at: <https://www.uspto.gov/patent/initiatives/patent-subject-matter-eligibility-roundtable-2>. See Appendix II for a list of roundtable participants and Appendix III for a list of parties that submitted written comments.

III. BACKGROUND

A. Historical Development of Patent Subject Matter Eligibility in the United States

1. Statutory Basis for Patent Eligibility

The statutory basis for patent eligible subject matter is set forth in 35 U.S.C. § 101:

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.³

This statutory language has changed little during the history of U.S. patent law. The first patent statute permitted patenting of “any useful art, manufacture, engine, machine, or device, or any improvement therein.”⁴ Enacted three years later, the second patent statute provided for patent protection for “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter.”⁵ This language is nearly identical to the current statutory language.

In 1930, Congress enacted the Plant Patent Act to extend patent protection to asexually reproduced plants.⁶ This Act was effectuated through an amendment to the patent eligibility provision.⁷ But, in the Patent Act of 1952, Congress moved the plant patent provision to another section, replaced the word “art” with “process,” and provided a definition for the latter.⁸

³ In addition to being patent eligible, an invention must also satisfy the other statutory requirements for patentability to qualify for patent protection. 35 U.S.C. § 102 (novelty), § 103 (non-obviousness), § 112 (written description, enablement, definiteness). Furthermore, a separate requirement for utility is grounded in the term “useful” in 35 U.S.C. § 101.

⁴ Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

⁵ Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793).

⁶ Act of May 23, 1930, Pub. L. No. 71-245, ch. 312, 46 Stat. 376.

⁷ *Id.* (“Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, *or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant, . . .* may . . . obtain a patent therefor.”) (emphasis added).

⁸ 66 Stat. 797, ch. 10, § 101 (1952) (“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.”); *id.* § 100(b) (defining “process” to mean “process, art, or method”); *id.* § 161 (1952) (providing for patent protection for plants); *see Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

2. Early Supreme Court Jurisprudence

The Supreme Court has long recognized limits on patent eligible subject matter beyond those explicitly set out in the statute. These judicially created exceptions to patent eligibility have been applied and interpreted by the lower courts. As early as the mid-1800s, the Court stated that “[a] principle, in the abstract, is a fundamental truth,” which “cannot be patented.”⁹ Nor can an exclusive right be obtained for a new power, such as steam or electricity.¹⁰ In contrast, the Court noted that a patent could be obtained if the principle is applied to effectuate a practical result.¹¹ Regarding the claimed invention, a combination of machinery for manufacturing pipes with a new property of lead, the Court concluded that it could not be patented without first establishing its novelty.¹² In the same time period, the Court held Morse’s claim to the use of electromagnetism for “marking or printing intelligible characters, signs, or letters at any distances” to be unpatentable.¹³ The Court explained that Morse had not shown “that the electro-magnetic current, used as motive power, in any other method, and with any other combination, will do as well.”¹⁴ These early decisions formed the foundation of the Court’s prohibition against patenting natural principles.

Then, in *Rubber Tip Pencil*,¹⁵ the Supreme Court extended the patent eligibility prohibition to abstract ideas in rejecting a patent for a rubber head “to be attached to a pencil or something else of like character.”¹⁶ The Court concluded that a “piece of rubber with a hole in it” was not new, and the fact that “the cavity must be made smaller than the pencil . . . [to] be held thereon by the inherent elasticity of the rubber . . . add[ed] nothing to the patentable character of the invention.”¹⁷ Therefore, what was left was simply the idea of attachment of the rubber head to the pencil for convenient use as an eraser, but the Court explained that “[a]n idea of itself is not patentable.”¹⁸ That same year, the Court held that “a pulp suitable for the manufacture of paper, made from wood or other vegetable substances” was unpatentable.¹⁹ The Court reasoned that “[t]here are many things well known and valuable in medicine or in the arts which may be extracted from divers[e] substances”; however, “the extract is the same, no matter from what it has been taken.”²⁰ While the extraction process “may be the creature of invention,” the Court concluded that “the thing itself when obtained cannot be called a new manufacture.”²¹

⁹ *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

¹⁰ *Id.*

¹¹ *Id.* at 175.

¹² *Id.* at 176-77.

¹³ *O’Reilly v. Morse*, 56 U.S. 62, 112-120 (1853).

¹⁴ *Id.* at 117.

¹⁵ *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498 (1874).

¹⁶ *Id.* at 505.

¹⁷ *Id.* at 506-07.

¹⁸ *Id.* at 507.

¹⁹ *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 577, 593-94 (1874).

²⁰ *Id.* at 593.

²¹ *Id.* at 593-94.

The Supreme Court first considered patent eligibility for processes in *Cochrane v. Deener*.²² At the time, the Patent Act recited “art” rather than “process.” The Court in *Cochrane* defined an eligible process to be “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing,” provided it is new and useful.²³ Shortly thereafter, the Court reaffirmed “[t]hat a patent can be granted for a process,” explaining that “[a] manufacturing process is clearly an art within the meaning of the law.”²⁴ The Court thus held that the applicant could patent his process of manufacturing fat acids and glycerin from fat using water at high temperature and pressure.²⁵ While recognizing that a patent may not be obtained for “a mere principle,” the Court explained that the applicant did not claim the underlying chemical principle that the elements of fat must be “severally united with an atomic equivalent of water in order to separate from each other and become free.”²⁶ Instead, he claimed “a particular mode of bringing about the desired chemical union between the fatty elements and water.”²⁷

In *The Telephone Cases*,²⁸ the Supreme Court found Bell’s invention to be patent eligible, distinguishing it from the unpatentable invention in *O’Reilly v. Morse*.²⁹ While recognizing that Morse’s claim to the “use of magnetism as a motive power, without regard to the particular process with which it was connected in the patent, could not be claimed,” the Court explained that Bell’s “claim is not for the use of a current of electricity in its natural state as it comes from the battery, but for putting a continuous current, in a closed circuit, into a certain specified condition, suited to the transmission of vocal and other sounds, and using it in that condition for that purpose.”³⁰ The Court thus declined to hold his patent invalid.³¹ Notably, the Court credited Bell with both discovery and invention: discovery in finding the art (process) of using electricity to reproduce at a distance vibrations caused by the voice, and invention in putting his art to practical use.³²

3. Significant Cases of the 20th Century

During the 20th century, the Supreme Court continued to define the contours of patent eligible subject matter. Early in the century, the Court began by identifying subject matter that was not patent eligible because it was too closely tied to a judicial exception. Two of those cases related to natural products. First, in *American Fruit Growers*,³³ the Court held that citrus fruit treated with borax to render it resistant to mold is not a “manufacture” under the statute because “[a]ddition of borax to the rind of the natural

²² *Cochrane v. Deener*, 94 U.S. 780 (1876).

²³ *Id.* at 788.

²⁴ *Tilghman v. Proctor*, 102 U.S. 707, 722 (1880).

²⁵ *Id.* at 721, 729-30.

²⁶ *Id.* at 729.

²⁷ *Id.*

²⁸ *The Telephone Cases*, 126 U.S. 1 (1888).

²⁹ *Id.* at 534.

³⁰ *Id.*

³¹ *Id.* at 535.

³² *Id.* at 533.

³³ *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931).

fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property.”³⁴ Moreover, the Court explained, “[t]here is no change in the name, appearance, or general character of the fruit.”³⁵ Second, in *Funk Bros.*,³⁶ the Court held that an inoculant for plants comprising a combination of different bacterial strains to improve nitrogen fixation was not “an invention or discovery within the meaning of the patent statutes.”³⁷ In so holding, the Court reasoned that “[t]he combination of species produces no new bacteria”; rather “[e]ach species has the same effect it always had. The bacteria perform in their natural way.”³⁸ The Court further explained that the recognition that certain strains can be mixed without inhibiting each other “is a discovery of their qualities of non-inhibition,” which is “no more than the discovery of some of the handiwork of nature and hence is not patentable.”³⁹

The Supreme Court also identified patent ineligible subject matter involving mathematical formulas. In analyzing the patentability of an antenna system for radio communication, the Court explained that “[w]hile a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”⁴⁰ Thereafter, the Court held that a method for programming a general purpose computer to convert binary-coded decimal (BCD) signals to pure binary signals is not a “process” within the statute.⁴¹ The Court observed that the claimed process is “so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion.”⁴² A patent on the claimed process, the Court concluded, “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”⁴³ Similarly, the Court held that a method for updating alarm limits during catalytic conversion, which includes a mathematical formula, is ineligible for patenting.⁴⁴ The reason, according to the Court, is “not because [the claimed invention] contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.”⁴⁵ Explaining that a mathematical formula “cannot support a patent unless there is some other inventive concept,” the Court noted that the chemical processes of catalytic conversion, calculating alarm limits, and readjusting limits based on variables were all well known.⁴⁶

Toward the end of the century, the Supreme Court changed course and issued a pair of decisions identifying eligible subject matter. First, the Court held that a bacterium genetically engineered with two plasmids providing separate hydrocarbon degradative

³⁴ *Id.* at 6, 11.

³⁵ *Id.* at 12.

³⁶ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

³⁷ *Id.* at 128 n.1, 132.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Mackay Radio & Telegraph Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).

⁴¹ *Gottschalk v. Benson*, 409 U.S. 63 (1972).

⁴² *Id.* at 68.

⁴³ *Id.* at 71-72.

⁴⁴ *Parker v. Flook*, 437 U.S. 584 (1978).

⁴⁵ *Id.* at 594.

⁴⁶ *Id.*

pathways, for use in treatment of oil spills, was patent eligible.⁴⁷ While recognizing that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter,” the Court reasoned that the inventor “has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own.”⁴⁸

One year later, the Court held that a process for molding synthetic rubber products, using the Arrhenius equation to calculate cure time, is patent eligible subject matter.⁴⁹ The Court observed that the claimed process “involve[s] the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing” and comprises a series of steps “beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure.”⁵⁰ While recognizing that Arrhenius’s equation alone is not patent eligible, the Court concluded that “a process for curing rubber . . . which incorporates in it a more efficient solution of the equation . . . is at the very least not barred at the threshold by § 101.”⁵¹ The Court further cautioned that “[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”⁵² After these two decisions, the Supreme Court remained silent on the contours of § 101 until very recently.

4. The Supreme Court’s *Bilski*, *Mayo*, *Myriad*, and *Alice* Decisions

Over the past seven years, the Supreme Court has issued a series of decisions—*Bilski*,⁵³ *Mayo*,⁵⁴ *Myriad*,⁵⁵ and *Alice*⁵⁶—that have significantly impacted patent eligibility law and continues to generate substantial public debate.

Bilski, decided in 2010, involved a business method for hedging risk.⁵⁷ In analyzing patent eligibility, the Supreme Court recognized that § 101 specifies four independent categories of inventions or discoveries that are eligible for patent protection (processes, machines, manufactures, and compositions of matter), but judicial precedent provides three specific exceptions to patent eligibility for laws of nature, physical phenomena, and abstract ideas.⁵⁸ The Court rejected the view of the U.S. Court of Appeals for the Federal Circuit that the so-called “machine or transformation test” is the exclusive test for assessing patent eligibility of a process.⁵⁹ Under that test, a process claim is patent eligible provided it is (1) tied to a particular machine or apparatus, or (2)

⁴⁷ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴⁸ *Id.* at 309-10.

⁴⁹ *Diamond v. Diehr*, 450 U.S. 175 (1981).

⁵⁰ *Id.* at 184.

⁵¹ *Id.* at 188.

⁵² *Id.*

⁵³ *Bilski v. Kappos*, 561 U.S. 593 (2010).

⁵⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, __U.S.__, 132 S. Ct. 1289 (2012).

⁵⁵ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, __U.S.__, 133 S. Ct. 2107 (2013).

⁵⁶ *Alice Corp. v. CLS Bank Int’l*, __U.S.__, 134 S. Ct. 2347 (2014).

⁵⁷ *Bilski v. Kappos*, 561 U.S. 593, 599 (2010).

⁵⁸ *Id.* at 601.

⁵⁹ *Id.* at 604.

transforms a particular article into a different state or thing.⁶⁰ The Court explained that although the machine-or-transformation test “is a useful and important clue,” it is “not the sole test for deciding whether an invention is a patent-eligible ‘process.’”⁶¹ The Court held that the claims at issue were invalid because they were directed to the unpatentable abstract idea of hedging risk in the energy market and added only token post-solution components, namely, use of well-known random analysis techniques to establish inputs.⁶² The Court observed that hedging is a long prevalent fundamental economic practice, and that allowing the patent claims “would pre-empt use of [risk hedging] in all fields” and “effectively grant a monopoly over an abstract idea.”⁶³ The Court, however, left open the possibility that at least some business methods are patent eligible.⁶⁴

Following *Bilski*, the Supreme Court in *Mayo* addressed a method for optimizing drug dosages for treatment of autoimmune diseases in humans.⁶⁵ The inventors discovered the relationship between the concentration of a metabolite in the blood following administration of the drug and the likelihood that the administered dosage would be ineffective or produce harmful side effects.⁶⁶ The inventors obtained a patent claiming a method of determining whether a given dosage level is too low or too high based on the metabolite level.⁶⁷ The Court held the claims to be patent ineligible.⁶⁸ In analyzing the claims, the Court introduced a two-step framework for distinguishing patent ineligible concepts from patent eligible applications of those concepts.⁶⁹ The first step is to consider whether the claims are directed to a judicially recognized exception to patentability, i.e., abstract ideas, laws of nature, or natural phenomena.⁷⁰ If so, then the second question is “whether the claims do significantly more than simply describe these natural relations,” i.e., whether additional elements considered separately or as an ordered combination “transform the nature of the claim” into “a patent-eligible application” of the judicial exception.⁷¹ Applying the first step of this framework to the claims at issue, the Court found that the claims were directed to a law of nature: the relationship between the concentration of a particular metabolite in the blood and the likelihood that a dosage of a drug will be ineffective or harmful.⁷² Assessing the second step, the Court determined that the claims did not do “significantly more” than describe this natural relationship, i.e., the additional elements considered separately and as an ordered combination did not “transform the nature of the claim” into “a patent-eligible application” of the judicial exception.⁷³

⁶⁰ *Id.* at 602.

⁶¹ *Id.* at 604.

⁶² *Id.* at 612.

⁶³ *Id.* at 611-12.

⁶⁴ *Id.* at 606-07.

⁶⁵ *Mayo*, 132 S. Ct. at 1294-95.

⁶⁶ *Id.* at 1294.

⁶⁷ *Id.*

⁶⁸ *Id.* at 1305.

⁶⁹ *Id.* at 1296-98; *see Alice*, 134 S. Ct. at 2355 (summarizing two-part test in *Mayo*).

⁷⁰ *Id.* at 1296-97, 1293; *see Alice* 134 S. Ct. at 2355.

⁷¹ *Id.* at 1297-98; *see Alice* 134 S. Ct. at 2355.

⁷² *Id.* at 1296.

⁷³ *Id.* at 1297-98.

At issue in *Myriad* was the patent eligibility of claims to isolated DNA (genes) associated with an increased risk of breast cancer, and synthetic DNA created from RNA known as complementary DNA (cDNA).⁷⁴ The Supreme Court held that the isolated genes “fell squarely within the law of nature exception.”⁷⁵ The Court explained that discovering the location of the genes does not render the genes patent eligible, nor does the act of separating them from their surrounding genetic material.⁷⁶ While acknowledging that claims to a product “with markedly different characteristics from any found in nature” may be patent eligible,⁷⁷ the Court explained that *Myriad*’s claims to isolated genes lacked such characteristics because they do not rely on any chemical changes resulting from isolation, and are not even expressed in terms of chemical composition.⁷⁸ The Court did, however, rule that the claimed cDNAs were patent eligible because they differed from naturally occurring DNA by the absence of intron regions (i.e., non-coding nucleotide sequences).⁷⁹

Finally, in *Alice*, the Court reaffirmed the *Mayo* two-step framework and applied it to claims reciting a computer-implemented process, computer system, and computer readable medium for mitigating settlement risk.⁸⁰ Under step one of the framework, the Court concluded that the claims were directed to the abstract idea of intermediated settlement.⁸¹ In assessing step two, the Court considered whether the claim elements, individually or as an ordered combination, “‘transform the nature of the claim’ into a patent-eligible application.”⁸² The Court referred to the second step as “a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”⁸³ Looking at the claims at issue, the Court concluded that mere generic computer implementation does not transform the abstract idea into a patent-eligible invention.⁸⁴ Thus, the court held the process claims, as well as the claims to the computer system and computer-readable medium, to be patent ineligible.⁸⁵

5. The Federal Circuit’s Application of the Supreme Court’s Framework

Since the Supreme Court’s *Bilski/Mayo/Myriad/Alice* decisions and prior to the Stanford roundtable, the Federal Circuit issued numerous precedential decisions applying the Supreme Court’s framework to a broad spectrum of subject matter. The cases generally fall into two categories: life sciences and computer-related technologies.

⁷⁴ *Myriad*, 133 S. Ct. at 2112-13.

⁷⁵ *Id.* at 2117.

⁷⁶ *Id.* at 2117-18.

⁷⁷ *Id.* at 2117 (quoting *Chakrabarty*, 447 U.S. at 310).

⁷⁸ *Id.* at 2118.

⁷⁹ *Id.* at 2119.

⁸⁰ *Alice*, 134 S. Ct. at 2355, 2352.

⁸¹ *Id.* at 2355-57.

⁸² *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1294).

⁸³ *Id.* (internal quotation marks omitted).

⁸⁴ *Id.* at 2357-60.

⁸⁵ *Id.* at 1260.

a. Life Sciences Technologies

In the life sciences context, the Federal Circuit has applied the Supreme Court framework to hold many life science inventions to be patent ineligible.⁸⁶ In one of those cases, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the claimed invention was a method for detecting cell-free fetal DNA (cffDNA) in maternal blood and diagnosing a pre-natal condition based on such DNA.⁸⁷ The inventors developed tests for detecting paternally inherited cffDNA in maternal blood to diagnose certain genetic defects thereby avoiding the risks of other more invasive techniques.⁸⁸ The Federal Circuit determined that the claimed methods were patent ineligible because they begin and end with a natural phenomenon, cffDNA, and each of the steps was well-understood, routine, and conventional.⁸⁹ Judge Linn concurred in the judgment.⁹⁰ While he felt “bound by the sweeping language of the test set out in *Mayo*,” in his view, “the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*.”⁹¹ Specifically, he criticized the Supreme Court for “discount[ing], seemingly without qualification, any ‘post-solution activity that is purely conventional or obvious.’”⁹² As a consequence, the Court left him no room to distinguish *Mayo*, “even though here *no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers.”⁹³

Following the Federal Circuit’s panel decision, Sequenom filed a petition for rehearing en banc.⁹⁴ The Federal Circuit denied rehearing, with Judge Lourie (joined by Judge Moore) and Judge Dyk concurring separately in the denial, while Judge Newman dissented.⁹⁵ Judge Lourie felt bound to deny rehearing, finding “no principled basis to distinguish this case from *Mayo*.”⁹⁶ He acknowledged that the claims “may be indefinite or too broad,” but he thought “the fine filter of § 112 might be better suited to treating these as questions of patentability, rather than reviewing them under the less-defined eligibility rules.”⁹⁷ He also felt that the claims “should not be patent-ineligible on the ground that they set forth natural laws or abstractions.”⁹⁸ In his view, “it is unsound to

⁸⁶ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (method for detecting cell-free fetal DNA and diagnosing pre-natal conditions in pregnant woman); *Genetic Techs., Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016) (method for detecting genetic variation in coding regions based on noncoding regions); *Univ. of Utah Research Found. v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014) (DNA primer and method for detecting BRCA1 gene mutation); *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014) (cloned mammals).

⁸⁷ *Ariosa*, 788 F.3d at 1373-74.

⁸⁸ *Id.* at 1373.

⁸⁹ *Id.* at 1376-78.

⁹⁰ *Id.* at 1380-81.

⁹¹ *Id.* at 1380.

⁹² *Id.* (quoting *Mayo*, 132 S. Ct. at 1299) (original alterations omitted).

⁹³ *Id.* at 1381 (emphasis in original).

⁹⁴ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015).

⁹⁵ *Id.*

⁹⁶ *Id.* at 1284.

⁹⁷ *Id.* at 1286.

⁹⁸ *Id.* at 1285.

have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps.”⁹⁹

Judge Dyk agreed that “a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences,” yet he likewise felt bound by *Mayo*.¹⁰⁰ He found *Mayo* to be problematic “insofar as it concludes that inventive concept cannot come from discovering something new in nature, e.g., identification of a previously unknown natural relationship or property.”¹⁰¹ Instead, he proposed an approach to “limit[] the scope of patents based on new discoveries to narrow claims covering applications actually reduced to practice.”¹⁰² He considered the major defect in the claims at issue to be “not that [they] lack inventive concept but rather that they are overbroad.”¹⁰³ Judge Newman dissented from the denial of rehearing because in her view the claimed method was not previously known, unlike the medicinal product and metabolites in *Mayo*, and therefore the claimed invention was distinguishable from *Mayo*.¹⁰⁴

After denial of en banc rehearing, Sequenom petitioned the Supreme Court for writ of certiorari.¹⁰⁵ Twenty-two amicus briefs were filed, all but one in support of the petitioner.¹⁰⁶ Despite the significant amicus support, and the separate opinions below, the Supreme Court denied certiorari.¹⁰⁷

In contrast to *Ariosa*, there have been two cases in which the Federal Circuit has applied recent Supreme Court jurisprudence to hold life science subject matter to be patent eligible. First, shortly after *Bilski* but prior to *Mayo*, *Myriad*, and *Alice*, the Federal Circuit issued a decision holding two of three patents related to immunization schedules to be patent eligible.¹⁰⁸ The two patents claimed a method for screening immunization schedules for the risk of causing an immune-mediated disorder to identify the lowest risk schedule, and administering vaccines according to that schedule.¹⁰⁹ The third patent was limited to a method of determining the disease risk of an immunization schedule.¹¹⁰ The court found that two patents were “directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule,” and thus to “a specific, tangible application.”¹¹¹ The court thus concluded that, in accordance with the guidance in *Bilski* that “exclusions from patent-eligibility should be applied ‘narrowly,’ . . . the subject matter of these two patents

⁹⁹ *Id.* at 1287.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 1289.

¹⁰² *Id.* at 1292.

¹⁰³ *Id.* at 1293.

¹⁰⁴ *Id.* at 1293-94.

¹⁰⁵ *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016)

¹⁰⁶ See SCOTUSblog, <http://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc>.

¹⁰⁷ *Ariosa*, 136 S. Ct. at 2511.

¹⁰⁸ *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).

¹⁰⁹ *Id.* at 1060-61.

¹¹⁰ *Id.* at 1061.

¹¹¹ *Id.* at 1066.

traverses the coarse eligibility filter of § 101.”¹¹² In contrast, the court observed that the third patent is directed to “comparing known immunization results . . . found in the scientific literature, but does not require using this information for immunization purposes.”¹¹³ The court explained that the patent covered “the idea of collecting and comparing known information,” and is therefore limited to “the abstract principle that variation in immunization schedules may have consequences for certain diseases.”¹¹⁴ In sum, the court concluded that “the immunization step moves the [two patents] through the coarse filter of § 101, while the abstraction of the [third patent] is unrelieved by any movement from principle to application.”¹¹⁵

More recently, following the *Mayo/Alice* two-step framework, the court ruled that a method of cryopreserving hepatocytes (liver cells) was patent eligible.¹¹⁶ The claimed method included subjecting the cells to density gradient fractionation to separate viable from nonviable hepatocytes, recovering the viable cells, and refreezing the viable cells.¹¹⁷ Under step one of the analysis, the court found that the claims are not “‘directed to’ a patent-ineligible concept.”¹¹⁸ The court explained that “the claims are simply not directed to the ability of hepatocytes to survive multiple freeze thaw cycles” but instead “are directed to a new and useful laboratory technique for preserving hepatocytes.”¹¹⁹ Moreover, according to the court, at step one of the analysis “it is not enough to merely identify a patent-ineligible concept underlying the claim.”¹²⁰ Rather, the relevant inquiry is “whether that patent-ineligible concept is what the claim is ‘directed to.’”¹²¹ Having determined the invention was patent eligible under step one, the court did not need to proceed to step two. Yet, according to the court, even if it did analyze the claims under step two, it would similarly find them to be patent eligible.¹²²

b. Computer-Related Technologies

In a large majority of cases pertaining to computer-related inventions, many of which involve business methods, the Federal Circuit has applied the framework to find claims to be ineligible.¹²³ In several cases, however, the Federal Circuit has held claims

¹¹² *Id.*

¹¹³ *Id.* at 1067.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 1068.

¹¹⁶ *Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

¹¹⁷ *Id.* at 1045-46.

¹¹⁸ *Id.* at 1047.

¹¹⁹ *Id.* at 1048.

¹²⁰ *Id.* at 1050.

¹²¹ *Id.*

¹²² *Id.* at 1050-52.

¹²³ *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336 (Fed. Cir. 2013) (system and method for processing insurance claims); *Affinity Labs of Tex., LLC v. Amazon.com Inc.*, 838 F.3d 1266 (2016) (system for delivering streaming content to handheld device); *Affinity Labs of Tex., LLC v. DIRECTTV, LLC*, 838 F.3d 1253 (Fed. Cir. 2016) (system for delivering regional broadcast signals to cell phone); *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229 (Fed. Cir. 2016) (system for generating and transmitting menus); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266 (Fed. Cir. 2012) (system, method, and computer readable medium for administering and tracking life insurance policies); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350 (Fed. Cir. 2014) (method and computer readable

involving computer technology to be patent eligible. As discussed further below, often eligibility turns on the presence of a technological solution to a technological problem in the claimed invention.

First, shortly after *Bilski* and prior to *Mayo* and *Alice*, the Federal Circuit considered the eligibility of patents directed to a method for rendering half-tone images of a digital image.¹²⁴ The court noted that *Bilski* “refocused this court’s inquiry into processes on the question of whether the subject matter of the invention is abstract.”¹²⁵ The court found “nothing abstract” in the claimed processes “for rendering a halftone image of a digital image by comparing, pixel by pixel, the digital image against a blue noise mask.”¹²⁶ Instead, the court found that “[t]he invention presents functional and palpable applications in the field of computer technology.”¹²⁷ While acknowledging that algorithms and formulas play a “significant part” in the claimed methods, the court found that they did “not bring th[e] invention even close to abstractness.”¹²⁸ Accordingly, the court found the claims to be patent eligible.¹²⁹

medium for guaranteeing party performance in online transaction); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat’l Ass’n*, 776 F.3d 1343 (Fed. Cir. 2014) (method of extracting and storing information from hard copy documents); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. 2011) (method and computer readable medium for detecting fraud during Internet credit card transactions); *Dealertrack, Inc. v. Huber*, 674 F.3d 1315 (Fed. Cir. 2012) (method for electronic processing of credit applications); *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344 (Fed. Cir. 2014) (device profile, and method of creating, within a digital image processing system); *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016) (system and method for real-time performance monitoring of an electric power grid); *Fair Warning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089 (Fed. Cir. 2016) (method and system for detecting improper access to patient’s protected health information); *Fort Properties, Inc. v. Am. Master Lease LLC*, 671 F.3d 1317 (Fed. Cir. 2012) (method for creating real estate investment instrument for tax-deferred exchanges); *In re Smith*, 815 F.3d 816 (Fed. Cir. 2016) (method for conducting wagering game); *TLI Commc’ns LLC v. AV Automotive, LLC*, 823 F.3d 607 (Fed. Cir. 2016) (method for taking, transmitting, and organizing digital images); *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363 (Fed. Cir. 2015) (method for tracking and storing financial information for budgeting; system for customizing webpage content); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307 (Fed. Cir. 2016) (method for screening e-mail for unwanted content; system for routing e-mail messages; method for screening viruses on a telephone network); *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343 (Fed. Cir. 2015) (method, system, and computer readable medium for navigating online application without data loss); *Mortgage Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314 (Fed. Cir. 2016) (method and system for assisting borrower in obtaining a loan); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359 (Fed. Cir. 2015) (method for price optimization); *Synopsis, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138 (Fed. Cir. 2016) (method for designing a logic circuit); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014) (method for distributing copyrighted products over the Internet); *Versata Dev. Group, Inc. v. SAP Am., Inc.*, 793 F.3d 1306 (Fed. Cir. 2015) (method, apparatus, and computer readable medium for determining product price using organizational hierarchies).

¹²⁴ *Research Corp. v. Microsoft Corp.*, 627 F.3d 859, 865, 867-69 (Fed. Cir. 2010).

¹²⁵ *Id.* at 868.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.* at 869.

¹²⁹ *Id.*

Following the establishment of the two-step test in *Mayo/Alice*, the Federal Circuit applied that framework in *DDR Holdings*.¹³⁰ At issue was a system for generating a composite webpage by combining certain elements of a “host” website with content of a third-party merchant.¹³¹ Specifically, the claimed system provided that when a user clicks on an advertisement for a third-party product displayed on a host website, the user is directed to a hybrid web page that combines the “look and feel” of the host website and product information from the third-party website.¹³² Beginning with step one of the two-step analysis, the court found that the claims did not “merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet.”¹³³ Instead, the court found that “the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.”¹³⁴ The court further observed that “the claims at issue do not attempt to preempt every application of the idea of increasing sales by making two web pages look the same.”¹³⁵ Thus, the court concluded that the claimed system was patent eligible.¹³⁶

Similarly, in *Enfish*,¹³⁷ the Federal Circuit determined that claims to a data storage and retrieval system for a computer memory are not directed to an abstract idea.¹³⁸ The system at issue incorporated a self-referential logical model, which allowed faster searching and more effective storage of data.¹³⁹ As an initial matter, the court declined to “read *Alice* to broadly hold that all improvements in computer-related technology are inherently abstract and, therefore, must be considered at step two.”¹⁴⁰ Analyzing the claimed invention under the first step of the *Alice* inquiry, the court found that the claims “are not directed to an abstract idea within the meaning of *Alice*,” but rather “to a specific improvement to the way computers operate, embodied in the self-referential table.”¹⁴¹ The court distinguished from situations in which “general-purpose computer components are added post-hoc to a fundamental economic practice or mathematical equation,” finding instead that “the claims are directed to a specific implementation of a solution to a problem in the software arts.”¹⁴² Because the claims were not directed to an abstract idea under step one, the court did not proceed to step two of the analysis and concluded that the claims were patent-eligible.¹⁴³

¹³⁰ *DDR Holdings, LLC v. Hotels.com, LP*, 773 F.3d 1245 (Fed. Cir. 2014).

¹³¹ *Id.* at 1249-50.

¹³² *Id.* at 1257.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.* at 1259.

¹³⁶ *Id.*

¹³⁷ *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016).

¹³⁸ *Id.* at 1336.

¹³⁹ *Id.* at 1333.

¹⁴⁰ *Id.* at 1335.

¹⁴¹ *Id.* at 1336.

¹⁴² *Id.* at 1339.

¹⁴³ *Id.*

In the same year as *Enfish*, the Federal Circuit issued three more decisions finding computer-based inventions to be patent eligible under § 101. In *Bascom*,¹⁴⁴ the court considered the patent eligibility of a system for filtering Internet content.¹⁴⁵ Under step one, the court found the claims to be directed to an abstract idea because “filtering content is . . . a longstanding, well-known method of organizing human behavior, similar to concepts previously found to be abstract.”¹⁴⁶ Thus, unlike in *Enfish*, the court proceeded to step two of *Alice*.¹⁴⁷ While agreeing with the district court that “the limitations of the claims, taken individually, recite [a] generic computer, network and Internet components,” the court found that “the ordered combination of limitations” recites something more—“the installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user.”¹⁴⁸ The court further noted that the claims do not “preempt all ways of filtering content on the Internet; rather, they recite a specific, discrete implementation of the abstract idea of filtering content.”¹⁴⁹ Therefore, the court concluded that “the claims pass step two of *Alice*’s two-part framework.”¹⁵⁰

Shortly thereafter, the Federal Circuit determined that a method for automatically animating lip synchronization and facial expression of 3-D characters was patent eligible subject matter.¹⁵¹ The court concluded that the claimed invention was not drawn to an abstract idea, explaining that “[w]hether at step one or step two of the *Alice* test . . . a court must look to the claims as an ordered combination, without ignoring the requirements of the individual steps.”¹⁵² The court viewed the claimed invention to be an improvement that “allow[s] computers to produce ‘accurate and realistic lip synchronization and facial expressions in animated characters’ that previously could only be produced by human animators.”¹⁵³ Thus, according to the court, “[t]he claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters.”¹⁵⁴ The court further observed that the claim “does not preempt approaches that use rules of a different structure or different techniques.”¹⁵⁵

Finally, in November 2016, the court issued its decision in *Amdocs*,¹⁵⁶ determining that a computer readable medium and method for collecting and processing network accounting records over a network is patent eligible.¹⁵⁷ The court first observed that prior decisions had found facially-similar claims to be eligible either under step one

¹⁴⁴ *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016).

¹⁴⁵ *Id.* at 1345.

¹⁴⁶ *Id.* at 1348.

¹⁴⁷ *Id.* at 1349.

¹⁴⁸ *Id.* at 1349-50.

¹⁴⁹ *Id.* at 1350.

¹⁵⁰ *Id.* at 1352.

¹⁵¹ *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016).

¹⁵² *Id.* at 1313.

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 1315.

¹⁵⁵ *Id.* at 1316.

¹⁵⁶ *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016).

¹⁵⁷ *Id.* at 1299-1306.

or step two.¹⁵⁸ The court then explained that even if the claimed invention “is directed to an ineligible abstract idea under step one, [it] is eligible under step two because it contains a sufficient ‘inventive concept’” by “require[ing] ‘computer code for using the accounting information with which the first network accounting record is correlated to enhance the first network accounting record.’”¹⁵⁹ In other words, in the court’s view, the claims “recite[] a series of limitations that, when considered individually and as an ordered combination, provide an inventive concept sufficient to confer eligibility.”¹⁶⁰ The court further explained that the claimed invention “is narrowly drawn to not preempt any and all generic enhancement of data in a similar system, and does not merely combine the components in a generic manner, but instead purposefully arranges the components in a distributed architecture to achieve a technological solution to a technological problem specific to computer networks.”¹⁶¹

Since the roundtable, the Federal Circuit has continued to issue decisions interpreting the Supreme Court’s recent jurisprudence.¹⁶²

B. International Approaches to Defining Patent Eligible Subject Matter

1. The TRIPS Agreement

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets forth the minimum requirements applicable to all WTO members for the protection and enforcement of intellectual property rights, including patent rights.¹⁶³ The United States is a WTO member and a signatory to the TRIPS Agreement.¹⁶⁴ Article 27(1) of the TRIPS Agreement generally requires WTO members to make patents “available for *any inventions*, whether products or processes, in all fields of technology,” provided they satisfy other basic conditions of patentability.¹⁶⁵

¹⁵⁸ *Id.* at 1300.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 1306.

¹⁶¹ *Id.* at 1301.

¹⁶² *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 850 F.3d 1332 (Fed. Cir. 2017); *Intellectual Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315 (Fed. Cir. 2017); *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017); *Mentor Graphics Corp. v. Eve-USA, Inc.*, 851 F.3d 1275 (Fed. Cir. 2017); *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322 (Fed. Cir. 2017); *Credit Acceptance Corp. v. Westlake Servs.*, 859 F.3d 1044 (Fed. Cir. 2017); *The Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017).

¹⁶³ Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS].

¹⁶⁴ See WIPO (World Intellectual Property Organization), Contracting Parties/Signatories to TRIPS, http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=231&group_id=22 (last visited July 24, 2017).

¹⁶⁵ TRIPS, *supra* note 163, art. 27(1) (emphasis added). Specifically, inventions must also satisfy the criteria of novelty, inventive step/non-obviousness, and industrial applicability/utility. *Id.*

Other provisions of TRIPS permit members to exclude certain inventions from patent protection, mainly on the basis of moral or public policy considerations. For instance, Article 27(2) of TRIPS provides that members:

[M]ay exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.¹⁶⁶

Separately, Article 27(3) permits WTO members to categorically exclude from patent eligibility: plants and animals (other than microorganisms); diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; and “essentially biological processes for the production of plants or animals.”¹⁶⁷

2. Patent Eligibility Laws

An examination of the laws applicable in the world’s five largest patent offices—those of the United States, China, Japan, Korea, and Europe—reveals varied approaches for determining patent eligible subject matter. These jurisdictions were selected for comparison because they receive approximately 80 percent of the world’s patent applications,¹⁶⁸ meaning their corresponding laws are applied in examining and granting the overwhelming majority of patents in the world. With this in mind, the laws and practices of these jurisdictions are examined below with respect to patent subject matter eligibility generally, followed by a more detailed assessment of eligibility in life sciences and computer-related technologies.

a. Europe

All member states of the European Union (EU) and several non-EU European states are contracting parties to the European Patent Convention (EPC), which effectively establishes a pan-European law regarding the grant of patents.¹⁶⁹ Article 52 of the EPC

¹⁶⁶ *Id.*, art. 27(2).

¹⁶⁷ *Id.*, art. 27(3).

¹⁶⁸ The Five IP Offices (IP5) is the name given to the collaborative framework comprising the five largest intellectual property offices: the European Patent Office, the Japan Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People’s Republic of China, and the United States Patent and Trademark Office. The IP5 Offices together handle about 80% of the world’s patent applications, and 95% of all work carried out under the Patent Cooperation Treaty. *See generally* IP5, About IP5 Cooperation, <http://www.fiveipoffices.org/about.html> (last visited July 24, 2017). In 2015, the year for which the most recent data exists, a total of 2,383,711 patent applications were filed at the IP5 Offices, an increase of 8.6 % over the previous year. IP5, IP5 STATISTICS REPORT 2015 EDITION (2015) 56, available at <http://www.fiveipoffices.org/statistics/statisticsreports/2015edition/chapter4.pdf>.

¹⁶⁹ Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 [hereinafter EPC]; *see also* Implementing Regulations to the Convention on the Grant of European Patents, Oct. 5, 1973, as adopted by the decision of the Administrative Council of the European Patent Organization, June 27, 2012, European

sets forth a definition for patentable inventions.¹⁷⁰ Article 52(1) of the EPC provides that “European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.”¹⁷¹ Article 52(2), however, identifies specific subject matter that “shall not be regarded as inventions within the meaning of” Article 52(1), including discoveries, scientific theories, and mathematical methods; aesthetic creations; schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and presentations of information.¹⁷² Accordingly, under the EPC, to the extent that a patent application relates to subject-matter “as such,” it is excluded from patentability.¹⁷³

Article 53 of the EPC excludes from patentability “inventions the commercial exploitation of which would be contrary to *ordre public* or morality”; “plant or animal varieties”; “and essentially biological processes for the production of plants and animals.”¹⁷⁴ Article 53(c) specifies a number of exceptions to patentability in the field of medicine, including “methods for treatment of the human or animal body by surgery or therapy” and “diagnostic methods practised [sic] on the human or animal body.”¹⁷⁵

b. Japan

Japan statutorily defines an invention to be the “highly advanced creation of technical ideas utilizing the laws of nature.”¹⁷⁶ Examiner guidelines issued by the Japan Patent Office (JPO) explain that this definition bars from patent eligibility the per se use of non-natural laws (e.g., principles of economics or business); arbitrary arrangements (e.g., rules of games or computer programming languages); mathematical formulae; and the mental activity of humans.¹⁷⁷ Article 32 of the Japan Patent Act, precludes from eligibility inventions that are liable to negatively affect public order, morality, or public health.¹⁷⁸

Patent Office (15th ed. Sept. 2013) [hereinafter EPC Rules]. European patents are distinct from national patents, as the rights granted inure to each European member country and are independently enforceable or invalidated at the national level. *See generally* European Patent Office, GUIDE FOR APPLICANTS: HOW TO GET A EUROPEAN PATENT (16th ed. 2016) 10 (The Guide for Applicants has been designed to provide inventors, companies, and their representatives with an outline of the procedure involved in applying for a European patent.).

¹⁷⁰ EPC, *supra* note 170, art 52.

¹⁷¹ *Id.*, art 52(1).

¹⁷² *Id.*, art. 52(2).

¹⁷³ *Id.*, art. 52(3).

¹⁷⁴ *Id.*, art. 53(a), (b).

¹⁷⁵ *Id.*, art. 53(c).

¹⁷⁶ Tokyo Ho [Japan Patent Law], Act No. 121 of 1959, as last amended by Law No. 55 of 2015 [hereinafter Japan Patent Act], art. 2(1), *available in English at* <http://www.wipo.int/edocs/lexdocs/laws/en/jp/jp206en.pdf>.

¹⁷⁷ Examination Guidelines for Patent and Utility Models in Japan (Oct. 2015) [hereinafter JPO Guidelines], pt. III, ch. 1, § 2.1.4.

¹⁷⁸ Japan Patent Act, *supra* note 177, art. 32.

c. Korea

Article 2 of the Korea Patent Act defines “invention” to mean the “highly advanced creation of technical ideas utilizing laws of nature.”¹⁷⁹ Further, Article 32 of the Act codifies prohibitions on patent eligibility for inventions that are “feared to have risks to contravene public order or morality or to injure public health.”¹⁸⁰ Examiner guidelines issued by the Korean Intellectual Property Office (KIPO) further explain that laws of nature (e.g., the law of conservation of energy) and mere presentations of information or skills (e.g., a method of performing musical instruments) are not patent eligible.¹⁸¹

d. China

Like Japan and Korea, China’s patent law provides a statutory definition for the term “invention.” According to Article 2 of China’s Patent Act, “invention” refers to “new technical solutions proposed for a product, a process or the improvement thereof.”¹⁸² In addition, Article 5 of the Act precludes patents to “invention-creations that violate the law or social ethics, or harm public interests.”¹⁸³ Article 25 of the Act additionally precludes patents to scientific discoveries, rules and methods for intellectual activities, methods for the diagnosis or treatment of diseases, and animal or plant varieties.¹⁸⁴

3. Specific Technologies

Two scientific fields—life sciences and computer-related technologies—are most directly affected by limits on patent eligibility. Below is a synopsis of the patent eligibility laws in the other four IP5 jurisdictions that affect these two scientific disciplines.

a. Life Sciences Technologies

As discussed above, Europe, Japan, Korea, and China each exclude certain diagnostic methods from patenting. Other diagnostic-related inventions, however, may be eligible for protection and there is some commonality in the types of diagnostics that can be protected in all four jurisdictions.¹⁸⁵ For example, even though “diagnostic methods

¹⁷⁹ [Korea Patent Law], Law No. 950 of Dec. 31, 1961, as amended up to Law No. 11962 of July 30, 2013 [hereinafter Korea Patent Act], art. 2(1).

¹⁸⁰ *Id.*, art. 32.

¹⁸¹ Korea Intellectual Property Office Patent Examination Guidelines (July 2013) [hereinafter KIPO Guidelines], pt. III, ch. 1, § 4.1.

¹⁸² Patent Law of the People’s Republic of China (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 12, 1984, as amended Dec. 27, 2008) 1984 Fagui Huibian 529 [hereinafter China Patent Act], art. 2.

¹⁸³ *Id.*, art. 5.

¹⁸⁴ *Id.*, art. 25.

¹⁸⁵ See EPC, *supra* note 170, art 53(c) (stating that patents should not be granted on “diagnostic methods practiced on the human or animal body.”); JPO Guidelines, *supra* note 178, pt. III, ch. 1, § 3.1 (stipulating that inventions of methods of surgery, therapy or diagnosis of humans are industrially inapplicable

practiced on the human or animal body” are prohibited under the EPC, methods that do not result in a deductive medical decision may be patent eligible in Europe. Specifically, in 2005, the EPO’s Enlarged Board of Appeal¹⁸⁶ held that a claim is directed to a diagnostic method within the meaning of Article 53(c) of the EPC only if the claim includes all the steps necessary for a medical (i.e., clinical) diagnosis.¹⁸⁷ Since then, the Technical Boards of Appeal¹⁸⁸ have followed that reasoning to find several diagnostic methods, which involve only data acquisition and do not lead to a particular clinical diagnosis, to be eligible for patent. In particular, a method of determining ear temperature¹⁸⁹ and a method of imaging an artery using magnetic resonance imaging techniques¹⁹⁰ were each found to be patent eligible.

Likewise, Japan, Korea, and China recognize that method claims may be eligible for patenting when they do not lead to a particular medical or clinical diagnosis.¹⁹¹ In China, for example, a method of obtaining treatment information that is an intermediate step, rather than a final diagnostic result, may be patent eligible.¹⁹²

Other diagnostic-related inventions that are eligible for patenting in Europe include methods in which steps of a “technical nature” that lead to a diagnosis are carried out without any interaction with the human body.¹⁹³ For instance, the Enlarged Board of Appeal held that a diagnostic method in which key steps were carried out using a specific software program, or in vitro on a tissue or fluid sample obtained from a subject, was not

inventions, and thus not eligible for patent); KIPO Guidelines, *supra* note 182, pt. III, ch. 1, § 5.1.1 (stipulating that a “method for treatment of the human body by surgery or therapy and a diagnostic method practiced on the human body are considered to be industrially inapplicable inventions.”); China Patent Act, *supra* note 183, art. 25.

¹⁸⁶ The boards of appeal of the EPO are independent of the European Patent Office in their decisions. There are currently 28 Technical Boards of Appeal, plus the Legal Board of Appeal and the Enlarged Board of Appeal. The Technical Boards of Appeal and the Legal Board of Appeal examine appeals from the examining and opposition divisions of the EPO. To ensure uniform application of the law, or if an important point of law arises, a question can be referred to the Enlarged Board of Appeal, either by a board of appeal or by the President of the EPO. *See* EPC, *supra* note 170, art. 21-22.

¹⁸⁷ Case G 0001/04, EPO Enlarged Bd. App. (Dec. 16, 2005).

¹⁸⁸ *See supra* note 187.

¹⁸⁹ Case T 1255/06, EPO Technical Bd. App. (Sept. 23, 2008).

¹⁹⁰ Case T 663/02, EPO Technical Bd. App. (Mar. 17, 2011).

¹⁹¹ State Intellectual Property Office of the People’s Republic of China, Guidelines for Examination (Feb. 2010, as revised Apr. 2017) [hereinafter SIPO Guidelines] pt. II, ch. 1, § 4.3.1.2(2); *see also* JPO Guidelines, *supra* note 178, pt. III, ch. 1, § 3.2.1(3)(i),(ii) (Diagnostic methods are not eligible. “Method of extracting samples and data from the human body, or methods of analyzing, e.g., comparing such samples and data with standards, by utilizing samples and data extracted from the human body [...] preparatory treatment for measuring structures or functions of various organs of the human body” are not such diagnostic methods so long as they are not claimed in conjunction with diagnosing a disease); KIPO Guidelines, *supra* note 182, pt. III, ch. 1, § 5.1(2)(3) (“A method for treating samples that have been extracted from a human body (e.g., blood, urine, skin, hair, cells or tissue) or discharged from a human body (such as urine, excrement, placenta, hair and nail) and a method for gathering data by analyzing such samples are considered to be industrially applicable on the assumption that they are composed of separate steps separable from medical practice.”).

¹⁹² SIPO Guidelines, *supra* note 192, pt. II, ch. 1, § 4.3.1.2.

¹⁹³ Case G 0001/04, EPO Enlarged Bd. App. (Dec. 16, 2005).

excluded from patentability.¹⁹⁴ Similarly, the Technical Board of Appeal held that a method for diagnosing predisposition for breast cancer, by looking for a mutation in a specific gene in a tissue sample taken from a subject, was patent eligible because the steps of a “technical nature” were carried out in vitro and not directly on the subject.¹⁹⁵

In Japan, methods that include steps performed outside the body, such as in vitro analysis of tissues or fluids taken from the human body, are not considered ineligible diagnostic methods.¹⁹⁶ Analogously, methods to obtain information from a living human or methods to treat or test body tissues or fluids are patent eligible in China provided that such methods do not result in obtaining a diagnostic result.¹⁹⁷

As in most jurisdictions, naturally occurring products existing in their natural form generally are not patent eligible subject matter in Europe, Japan, Korea, and China.¹⁹⁸ However, all of these jurisdictions allow the patenting of certain naturally occurring products that have been isolated from their natural environment. For example, in Japan and Korea, if naturally occurring substances are artificially isolated from their environment, they can be patent eligible.¹⁹⁹

In Europe, the patentability of biotechnology inventions is generally governed by the EU Biotechnology Directive.²⁰⁰ Of particular relevance, the Directive affirms that biological material “isolated from its natural environment or produced by means of a technical process” may be patented “even if it previously occurred in nature.”²⁰¹ More specifically, the Directive provides that elements isolated from the human body may constitute a patentable invention, despite the fact that the isolated element is structurally identical to the element in situ.²⁰² In a similar fashion, the examination guidelines issued by the State Intellectual Property Office of China (SIPO) explain that a gene or a DNA fragment, and the process of obtaining it, can constitute patent eligible subject matter if: (1) it is isolated or extracted for the first time from nature; (2) the structure, morphology, or other physical/chemical parameters are unknown in the prior art; (3) it can be definitely characterized; and (4) it can be exploited industrially.²⁰³

¹⁹⁴ *Id.*

¹⁹⁵ Case T 666/05, EPO Technical Bd. App. (Nov. 13, 2008).

¹⁹⁶ JPO Guidelines, *supra* note 178, pt. III, ch. 1, § 3.2.1(3)(i),(ii).

¹⁹⁷ SIPO Guidelines, *supra* note 192, pt. II, ch. 1, § 4.3.1.2.

¹⁹⁸ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L213), art. 5(1) [hereinafter EU Directive]; EPC Rules, *supra* note 170, R. 29(1); JPO Guidelines, *supra* note 178, pt. III, ch. 1, § 2.1.2; KIPO Guidelines, *supra* note 182, pt. III, ch. 1, § 4.1.2; SIPO Guidelines, *supra* note 192, at pt. II, ch. 10, § 2.1.

¹⁹⁹ KIPO Guidelines, *supra* note 182, pt. III, ch. 1, § 4.1.2; JPO Guidelines, *supra* note 178, pt. III, ch. 1, § 2.1.2.

²⁰⁰ EU Directive, *supra* note 199, at 13 (This Directive was implemented initially to harmonize diverging EU Member State national laws and practices regarding patentability of biotechnology inventions but has since been given broader application by virtue of its reference in the EPC Implementing Regulations. The EPC contracting states decided to incorporate the EU Directive as secondary legislation into the Implementing Regulations to the EPC.).

²⁰¹ EU Directive, *supra* note 199, art. 3(2); EPC Rules, *supra* note 170, R. 27(a).

²⁰² EU Directive, *supra* note 199, art. 5(2); EPC Rules, *supra* note 170, R. 29(2).

²⁰³ SIPO Guidelines, *supra* note 192, pt. II, ch. 10, § 2.1 (stipulating that natural substances isolated and/or extracted from nature for the first time may be eligible for patent).

b. Computer-Related Technologies

Each of the other four IP5 jurisdictions treat patent eligibility of computer-related inventions slightly differently. In Europe, Article 52(2) and 52(3) of the EPC explicitly exclude programs for computers “as such” from patent eligible subject matter.²⁰⁴ However, if the claimed invention causes a further technical effect beyond those effects which occur inevitably when any program is run (e.g., current flowing through circuitry), it is not considered a computer program “as such.”²⁰⁵ In China, Article 25.1(2) of the Patent Act provides that patents are not available for “rules and methods for mental activities.”²⁰⁶ SIPO, however, revised its examination guidelines in April 2017.²⁰⁷ According to the revised guidelines, a claimed invention having technical characteristics will not be excluded from patentability because it contains a business method or rule.²⁰⁸

Under the JPO examination guidelines, the eligibility of computer-related technology turns on whether, when the invention is considered as a whole, its information processing aspects are required to be “specifically implemented by using hardware resources.”²⁰⁹ The guidelines provide non-exhaustive examples of patent eligible computer-related inventions, which include software to control a rice cooker or an engine, or software to perform information processing based on the relationship between a gene sequence and expression of a trait in a living body, or based on the physical or chemical relationship between bound substances.²¹⁰ Regarding Korea, the KIPO guidelines expressly state that computer programs per se are not patent eligible.²¹¹ Nevertheless, the guidelines indicate that if computer software is claimed in conjunction with hardware, then the combination, the operating method of the combination, and a computer-readable medium containing the software that implicates the combination is patent eligible.²¹²

²⁰⁴ EPC, *supra* note 170, art. 52(2) and art. 52(3).

²⁰⁵ Case G 0003/08, EPO Enlarged Bd. App. (May 12, 2010), 36; *see also* Case T 1173/97, EPO Technical Bd. App. (July 1, 1998), 1999 O.J. EPO 609 (“a computer program claimed by itself is not excluded from patentability if the program [...] brings about [...] a technical effect which goes beyond the “normal” physical interactions between the program (software) and the computer (hardware) on which it is run.”), *available at* <http://www.epo.org/law-practice/case-law-appeals/pdf/t971173ex1.pdf>.

²⁰⁶ China Patent Act, *supra* note 183, art. 25.1(2).

²⁰⁷ SIPO Guidelines, *supra* note 192.

²⁰⁸ *Id.*, pt. II, ch. 2, § 4.2.

²⁰⁹ JPO Guidelines, *supra* note 178, Annex B, ch. 1, § 2.1.1.2.

²¹⁰ *Id.*

²¹¹ KIPO Guidelines, *supra* note 182, pt. III, ch. 1, section 4.1.8 (“a computer program is not considered as a statutory invention.”).

²¹² *Id.* (“However, in the case of an invention where data processing with a computer program is specifically executed using a hardware, a data processing unit (machine) operating in association with the computer program, its operating method, and a computer readable medium carrying the computer program, the invention is viewed as a statutory invention.”).

IV. SUMMARY OF PUBLIC VIEWS ON PATENT ELIGIBLE SUBJECT MATTER

A. General Views on Recent Supreme Court Decisions

Both during the roundtable and through written comments, members of the public expressed their views on the recent Supreme Court jurisprudence. In general, commentators agreed that the Court decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* have had a significant impact on the scope of patent eligible subject matter. However, commentators disagreed as to whether the impact was positive or negative. This section summarizes those public views and identifies the key arguments in favor of, and against, the Supreme Court decisions. In preparing this summary, the USPTO carefully considered each and every remark and written comment to ensure that the report reflects all views. The USPTO has also made every attempt to reference in the citations all the members of the public that expressed a particular view.

1. Views Supportive of the Supreme Court's Decisions

a. Common Law Process at Work

Some members of the public viewed the Supreme Court's decisions as simply part of the normal judicial process. For example, one participant urged that the Court's decisions reflect an appropriate exercise of the separation of powers between the executive and judicial branches.²¹³ In his view, the Court intentionally tried "to be parsimonious in its decisions" and "tried very hard not to make blanket and broad statements."²¹⁴

Similarly, one academic described the Court's recent development of the law as part of the "arc of history" and cautioned against pushing back against the Court's trajectory.²¹⁵ She warned that many of the Federal Circuit's recent decisions, including *Amdocs*, *Enfish*, and *McRO*, "have come perilously close to . . . reversal from below," and she questioned whether these decisions if appealed would "be greeted any more warmly by the Supreme Court than" prior cases.²¹⁶

In contrast to this academic, some members of the public supportive of the Supreme Court's decisions also viewed the Federal Circuit's developing common law to be headed in the right direction. In particular, several commentators welcomed the

²¹³ Noonan (MBHB), Roundtable Transcript, at 103-104.

²¹⁴ *Id.* at 105.

²¹⁵ Feldman, Roundtable Transcript, at 37-39.

²¹⁶ *Id.* at 39-40.

Federal Circuit's recent precedent focusing on a technological improvement or technological solution as the key to patent eligibility.²¹⁷

b. Weeds Out Overly Broad Patents

In addition to crediting recent Supreme Court precedent as part of the common law process, some members of the public viewed the Court's newly established eligibility standard as the appropriate standard for subject matter eligibility.²¹⁸ Specifically, one representative from the computer industry contended that "the Supreme Court's two-part eligibility test established in *Mayo*, developed in *Alice*, and adapted and applied by the Federal Circuit, leads to sound outcomes when properly employed."²¹⁹ Another viewed the case law that has developed since *Alice* as a "sensible approach to weeding out vague, low-quality patents."²²⁰ One commentator considered the Court's recent jurisprudence to be a reaction to "a whole bunch of patents, particularly issued in the 1990s and the early 2000s that are written in extremely broad functional terms."²²¹ Similarly, several representatives from the software industry as well as public interest groups urged that *Alice* was a welcome course correction in patent eligibility for overly broad claims.²²²

These commentators generally considered other statutory provisions (anticipation, obviousness, enablement, written description, definiteness) to be inadequate to prevent issuance of overly broad patent claims.²²³ According to one non-profit organization, "none of these other provisions prevented the issuance over the past twenty years of an enormous number of low-quality patents covering software and electronic commerce."²²⁴

c. Requires Claiming a Specific Way, Not Just a Result

In applauding the Supreme Court's decisions, many commenters emphasized a distinction between claiming only results, which should not be patent eligible, and claiming specific ways of achieving a result, which may be patent eligible.²²⁵ One

²¹⁷ Auth (NYIPLA), Roundtable Transcript, at 91-92; Google, Written Comments, at 4-7; IA & CCIA, Written Comments, at 3; 5-8; Lo (Google), Roundtable Transcript, at 252-53; Reed, Roundtable Transcript, at 114-118; SIIA, Written Comments, at 5-6.

²¹⁸ IA & CCIA, Written Comments, at 2; Public Knowledge, Written Comments, at 3-4.

²¹⁹ IA & CCIA, Written Comments, at 2.

²²⁰ Google, Written Comments, at 2.

²²¹ Lemley, Roundtable Transcript, at 46.

²²² Lettelleir (J.C. Penney), Roundtable Transcript, at 138; Lo (Google), Roundtable Transcript, at 250; Mozilla, Written Comments, at 1; Nazer (EFF), Roundtable Transcript, at 257; Public Knowledge, Written Comments, at 1; *see also* EFF, Written Comments, at 4 ("*Alice* is an essential tool for Internet and software companies to strike down patents that should not have issued."); Engine, Written Comments, at 1 ("*Alice* and its progeny have been good for the development of the law, in particular as it relates to the startup community"); Google, Written Comments, at 1 (*Alice* represented a vital course correction").

²²³ Mozilla, Written Comments, at 3; Public Knowledge, Written Comments, at 2, 5.

²²⁴ Public Knowledge, at 5.

²²⁵ Dean (Amazon), Roundtable Transcript, at 151-54, 178-80; Google, Written Comments, at 1, 4; IA & CCIA, Written Comments, at 3; Lemley, Roundtable Transcript, at 46-47; *see also* SIIA, Written Comments, at 9 (arguing that *Alice* "balances the benefits of incentives to innovate against the downside of preemption by prohibiting patents that broadly claim a result rather than a means of accomplishing that result").

participant traced that rule back to the Court’s decision in *Morse*.²²⁶ He asserted that people should be awarded a patent only for the particular way they invented, whereas the public should have the “right to achieve the exact same utility and result in a different way.”²²⁷ In the context of software patents, he urged that the particular way is defined by an algorithm; if an algorithm is not disclosed in the patent application, there is not a candidate for further examination.²²⁸ While acknowledging that the enablement and written description requirements guard against certain kinds of preemption, he asserted that patent eligibility serves a third purpose, which is “to ask the question is there a candidate for examination in the first place.”²²⁹

According to one representative from the computer industry, “[c]laims that identify a problem and claim the abstract idea of overcoming it, not a specific way of achieving that goal, preempt particular solutions that the inventors themselves may never have contemplated.”²³⁰ Similarly, another viewed the Court’s “abstract idea” exception as a critical tool for policing patent eligibility and preventing preemption.²³¹ Moreover, according to one public interest group representative, *Alice* may serve other policy goals, including “boost[ing] the ‘informational value of patents’ by creating additional incentives for applicants to improve both the disclosure in their specifications and the specificity of the claims.”²³²

d. Litigation Tool Against Patent Assertion Entities

Perhaps one of the most lauded benefits of the Supreme Court’s heightened patent eligibility standard is its use in fending off lawsuits. Many members of the public welcomed the Court’s jurisprudence as a useful tool against patent assertion entities, i.e., entities that acquire patents for the purpose of aggressively enforcing them and that employ abusive patent litigation practices.²³³ According to these commentators, the prior more relaxed eligibility standard enabled patent assertion entities to place a tax on innovation by suing companies that were contributing technological advancements.²³⁴ One participant traced the inception of the problem to the Supreme Court’s decision in *Diehr* and the Federal Circuit’s subsequent decision in *State Street Bank*, which opened

²²⁶ Dean (Amazon), Roundtable Transcript, at 151, 153.

²²⁷ *Id.* 153-155; *see also* IA & CCIA, Written Comments, at 9 (“Overly broad claims that recite a mere result and thus cover every way of accomplishing that result retard innovation by limiting future innovators’ ability to exploit superior methods for bringing about the same results.”).

²²⁸ *Id.* at 156, 189.

²²⁹ *Id.* at 180-82.

²³⁰ Google, Written Comments, at 9.

²³¹ SIIA, Written Comments, at 9 (noting that *Alice* “balances the benefits of incentives to innovate against the downside of preemption by prohibiting patents that broadly claim a result rather than a means of accomplishing that result through better software programming or advances in computer technology.”).

²³² Public Knowledge, Written Comments, at 3-4.

²³³ SIIA, Written Comments, at 8; *see also* EFF, Written Comments, at 1 (“Under *Alice*, courts and the PTAB have invalidated many abstract software patents that had no value except as litigation weapons.”); ESA, Written Comments, at 2 (reporting that the video game industry “has become a constant target of patent assertion entities employing poor-quality patents in order to extract unfair settlements.”).

²³⁴ SIIA, Written Comments, at 8; *see also* Engine, Written Comments, at 2.

the door to software and business method patents.²³⁵ In her view, those decisions spawned patent enforcement programs by non-practicing entities that “were significantly disruptive to operating entities.”²³⁶

Supporters of the Supreme Court’s recent patent eligibility jurisprudence emphasized that it provides a cost-saving, efficient tool to adjudicate claims of invalidity, especially those alleged in response to perceived abusive claims of infringement, at the motion to dismiss stage.²³⁷ As explained by several commentators, after *Alice* and *Bilski*, it is now possible to get rid of a suit at the pleading stage rather than having to bear the expense of going through trial.²³⁸ This is especially true for software. According to one academic, “the patentable subject matter case law . . . has had in software a mostly desirable practical effect, which is, it’s allowed us to weed out at an early stage a number of claims that should die on some ground.”²³⁹ Another participant reported that an ineligibility defense is a particularly useful tool for small startup companies because 82 percent of patent assertion entity activity targets small- and medium-sized businesses and 52 percent of patent assertion entity suits are filed against startups.²⁴⁰

In the view of these commentators, an overly broad scope of patent eligibility would operate to stifle rather than promote innovation.²⁴¹ According to one nonprofit public interest group, since *Alice* software companies have outperformed the rest of the market.²⁴² The group estimated that “a person who invested \$10,000 in an exchange traded fund of software companies on the day *Alice* was decided could have grown that amount to \$13,534 by January 13, 2017 compared to \$12,212 if the money had been invested in the S&P 500.²⁴³ Moreover, the group reported that R&D spending on software and the Internet was 16.5 percent during the 12 months prior to *Alice*, but over

²³⁵ Lettelleir (J.C. Penney), Roundtable Transcript, at 136-37. In *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), the Federal Circuit held that a data processing system for implementing an investment structure for use in administering mutual funds was patent eligible, and that there is no business method exception to patent eligibility, relying on the “useful, concrete, and tangible result” test. *Id.* at 1370-76. The decision was abrogated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

²³⁶ Lettelleir (J.C. Penney), Roundtable Transcript, at 137.

²³⁷ Lemley, Roundtable Transcript, at 48; Nazer (EFF), Roundtable Transcript, at 259; Samuels (Engine), Roundtable Transcript, at 268; Schmitt (Intel), Roundtable Transcript, at 169; SIIA, Written Comments, at 6, 8.

²³⁸ Schmitt (Intel), Roundtable Transcript, at 167-69; Mozilla, Written Comments, at 3; *see also* EFF, Written Comments, at 4 (*Alice* has been especially valuable as a tool to promptly resolve weak cases where a defendant would otherwise be subject to settlement pressure created by the cost of litigation.”); Public Knowledge, Written Comments, at 6 (“§ 101 challenges . . . are especially effective against overbroad patents of dubious validity, where a plaintiff might otherwise exploit the structure and expenses of litigation to pursue a settlement prior to final adjudication.”).

²³⁹ Lemley, Roundtable Transcript, at 48.

²⁴⁰ Samuels (Engine), Roundtable Transcript, at 266; *see also* Engine, Written Comments at 2 (“*Alice* and its progeny have provided startups with a crucial new tool to push back on spurious claims of infringement that otherwise might have proven to be a real threat.”).

²⁴¹ Google, Written Comments, at 9-10; Lettelleir (J.C. Penney), Roundtable Transcript, at 142.

²⁴² EFF, Written Comments, at 2.

²⁴³ *Id.*

27 percent in the 12 months after *Alice*.²⁴⁴ A software company similarly reported no decline in innovation in the wake of *Alice*.²⁴⁵

e. May Give U.S. Entities an Advantage

Even if the Supreme Court’s new eligibility standard differs from standards abroad, a few commentators projected that the difference could actually operate to the benefit of the United States. For example, one commentator argued that because foreign entities have an increasing stake in the U.S. patent system, “[g]eopolitical considerations . . . weigh heavily in favor of” the Supreme Court’s *Mayo* and *Alice* decisions.²⁴⁶ In fact, she cautioned that if the U.S. were to adopt an overly expansive patentability standard, then not only would “American inventors, American companies, American investors, and the American public” benefit, but an “equal or greater benefit [would] inure to foreign inventors, foreign companies, and, in some cases foreign governments.”²⁴⁷ Another participant asserted that “if a company is innovating because it can get patents in Germany or Europe but it may not be able to get as much protection in the U.S., that innovation is still happening.”²⁴⁸ And, she added, “if our consumers can benefit from the additional competition that a lack of patent [protection] provides and pay lower prices here” and “the innovator can still get their investments recouped by getting monopoly profits elsewhere” that may not be a bad deal for our consumers.²⁴⁹

2. Views Critical of the Supreme Court’s Decisions

a. Decisions Are Legally Flawed

Several members of the public questioned the legal foundation of the Supreme Court’s decisions on patent eligibility. One commenter argued that “the *Mayo/Alice* cases are deeply flawed in terms of statutory legislative history and jurisprudence.”²⁵⁰ Specifically, this panelist argued that in *Mayo* the Supreme Court misconstrued *Neilson*, an old English case.²⁵¹ In his view, while the Court got the case completely right in *Morse*, it got it completely wrong in its later decisions in *Flook* and *Mayo*.²⁵² He also argued that the Supreme Court failed to appreciate the statutory history for the term “discover,” including the legislative history for the 1836 Act, which expressly stated “that the purpose of the patent system is to reveal the mysteries of nature,” and the Plant Patent Act, which permitted patents on discoveries.²⁵³ The panelist noted that he and others filed

²⁴⁴ *Id.* at 3.

²⁴⁵ Mozilla, Written Comments, at 2.

²⁴⁶ Lettelleir (J.C. Penney), Roundtable Transcript, at 139.

²⁴⁷ *Id.*

²⁴⁸ Chien, Roundtable Transcript, at 354.

²⁴⁹ *Id.*

²⁵⁰ Menell, Roundtable Transcript, at 381.

²⁵¹ *Id.* at 382-83; see *Neilson v. Harford*, Webster’s Patent Cases 295 (1841).

²⁵² *Id.* at 383-85, 388-89.

²⁵³ *Id.* at 385-87.

briefs in *Ariosa* hoping the Supreme Court would fix the problem, but the Court did not.²⁵⁴

Another panelist asserted that the definition of “useful arts” at the time of the Patent Act of 1790 was very broad “encompassing all that was useful in the real world and commerce.”²⁵⁵ He argued that this definition continued up to the *Diehr* and *Chakrabarty* decisions, which reinforced the view that “anything under the sun that is made by man” could be patented.²⁵⁶ He further asserted that *Morse* has been improperly labeled as an early eligibility case when it was really about indefiniteness and written description.²⁵⁷ Similarly, an industry association argued that recent Supreme Court jurisprudence is at odds with the broad scope of patent eligibility Congress intended when it created § 101 in 1952.²⁵⁸

One commentator argued that the problem with the Supreme Court’s case law is its insistence on trying to reconcile *Diehr* with its earlier decision in *Flook*, which it overruled.²⁵⁹ According to this commentator, the two decisions say inconsistent things and involved 5-4 majorities in which one justice switched.²⁶⁰ Another commentator remarked, however, that an advantage of the Supreme Court’s “unwillingness to overrule its earlier case law is that it makes it possible to distinguish cases that should be patented from some of these decisions.”²⁶¹

According to some commentators, “[m]any in the patent profession . . . have come to the conclusion that there is no constitutional or policy justification” for the *Mayo/Alice* test²⁶² and that the Supreme Court’s holdings in at least some cases are “arguably unconstitutional.”²⁶³ Others asserted that the Court has imposed improper limitations on the full scope of Congress’s authority under the Constitution to promote progress in science and the useful arts.²⁶⁴ In particular, regarding the judicially-created exceptions to patent eligibility, several members of the public accused the Court of having invented extra-statutory eligibility criteria.²⁶⁵

²⁵⁴ *Id.* at 389.

²⁵⁵ Sobon (Sobon Consulting), Roundtable Transcript, at 394.

²⁵⁶ *Id.* at 396.

²⁵⁷ *Id.* at 395.

²⁵⁸ IPO, Written Comments, at 4-9.

²⁵⁹ Lemley, Roundtable Transcript, at 67-68; *see also* IBM, Written Comments, at 7 (“Even though there are fundamental inconsistencies between *Flook* and *Diehr*, the Supreme Court has not overruled either case and instead has treated them both as good law”).

²⁶⁰ Lemley, Roundtable Transcript, at 67.

²⁶¹ Noonan (MBHB), Roundtable Transcript, at 107.

²⁶² Armitage (IP Strategy & Policy), Roundtable Transcript, at 367.

²⁶³ HIPLA, Written Comments, at 15.

²⁶⁴ Armitage (IP Strategy & Policy), Written Comments, at 11; PhRMA, Written Comments, at 7-8; *see* U.S. CONST. art. 1, § 8 (granting Congress the power “[t]o promote the progress of science and useful arts”).

²⁶⁵ Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 208; R&D Companies, Written Comments, at 3.

b. Judicial Exceptions Are Overly Broad

Another criticism of the Supreme Court’s recent decisions is that the Court has expanded the judicially-created exceptions to eligibility to the point that they are now overbroad. According to these commentators, the Court has effectively allowed the judicial exceptions—abstract idea, law of nature, and natural phenomenon—to swallow the eligibility rule.²⁶⁶

For example, one commenter argued that the “abstract idea” exception has essentially subsumed the *Mayo/Alice* analysis.²⁶⁷ Another contended that the concept of “abstract idea” has become in effect “a euphemism for broad claims,” which is not fair to those that saw a void in the marketplace and created a product to fill that void.²⁶⁸ Others complained about the impact of the Court’s *Alice* decision on business and financial-related inventions, arguing that it “devalued entire patent portfolios.”²⁶⁹

Similarly, representatives from the life sciences criticized overbreadth of the “law of nature” and “natural phenomena” exceptions, noting that most biopharmaceutical innovation “relates to laws of nature and natural phenomena in some way.”²⁷⁰ One participant asserted that “inventive preparations based on naturally-occurring substances have historically been of great importance in biotechnology,” and warned that “thousands of existing patents have come under a cloud of unpatentability and invalidity after large investments have been made over decades.”²⁷¹

c. Two-Step Test Is Unclear and Causes Unpredictability

Commentators critical of the Supreme Court’s cases also complained that the Court has failed to articulate objective, predictable criteria for allowing judges, patent examiners, or the public to determine whether a claim is drawn to eligible or ineligible

²⁶⁶ HIPLA, Written Comments, at 8; IPO, Written Comments, at 21; R&D Companies, Written Comments, at 3-4.

²⁶⁷ Lemley, Roundtable Transcript, at 75-76.

²⁶⁸ Fisher (Blaze Mobile), Roundtable Transcript, at 364.

²⁶⁹ Chiang, Roundtable Transcript, at 96-97; Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 193, 195-96; *see also* Thomas (RelaxExpress.net), Roundtable Transcript, at 24 (discussing the impact of the application of the exception before the USPTO).

²⁷⁰ PhRMA, Written Comments, at 8.

²⁷¹ Sauer (BIO), Roundtable Transcript, at 212-13; *see also* IPO, Written Comments, at 22 (reporting that “[a]s of December 31, 2016, the courts have granted 67 percent of various types of ineligibility motions, invalidating hundreds of patents and thousands of claims”).

subject matter.²⁷² Labeling the *Mayo/Alice* two-step test as a “nightmare”²⁷³ and “hopelessly subjective and unworkable,”²⁷⁴ they argued that it is untenable and creates unpredictability in the issuance and enforcement of patents. Several participants asserted that the problem with the two-step test is that it is a negative test.²⁷⁵ Others noted that the test fails to define crucial terms, such as “abstract” and “substantially more.”²⁷⁶ Indeed, some commentators urged that “[i]t is impossible to define ‘abstract idea’ with sufficient certainty to serve as a legal standard for anything, let alone the important determination of whether an invention is patent eligible.”²⁷⁷

Many members of the public argued that the two-part test provides an unworkable framework for the USPTO to make patent eligibility determinations with any reliability.²⁷⁸ They also observed that the new standard yields unpredictable results in courts, leaving the public unsure whether something patented today, will be patent eligible tomorrow.²⁷⁹ In short, commentators expressed concern that “the overall impact of recent rulings has been diminished clarity regarding patent eligibility, which results in confusion among patent-intensive industry sectors, individual inventors and innovators.”²⁸⁰

Some members of the public chronicled their experiences and challenges in prosecuting patent applications post-*Mayo/Alice*. Several expressed frustration with the

²⁷² Taylor, Written Comments, at 2 (“Section 101 eligibility jurisprudence has devolved into something approaching chaos.”); ABA-IPL, Written Comments (Jan. 18, 2017), at 3 n.3 (arguing that Congress intended eligibility criteria to be “objective in character and [] produce predictable results”); Armitage (IP Strategy & Policy), Written Comments, at 14 (“[T]ransparent, objective, predictable, and simple rules must define all aspects of patentability.”); *id.* at 15 (“[P]atent-eligibility limitations [should] be amendable to objective, predictable, and administrable standards for determining eligible subject matter that make clear what otherwise patentable subject matter would be rendered unpatentable.”); Participants in the Conference on *Patenting Genes, Natural Products and Diagnostics: Current Status and Future Prospects*, The Banbury Center, Cold Spring Harbor, NY (Nov. 9-11, 2016) [hereinafter Banbury Participants], Written Comments, at 1 (The Supreme Court’s two-part test “has proven to be highly subjective and arbitrary in its application.”); IBM, Written Comments, at 1 (“The *Alice* test is unworkably ambiguous.”); R&D Companies Written Comments, at 3 (Subject matter eligibility law is “in disarray and confusion.”).

²⁷³ Armitage (IP Strategy & Policy), Written Comments, at 13.

²⁷⁴ Sunstein, Written Comments, at 1; *see also* R&D Companies, Written Comments, at 3 (calling the abstract ideas exception “unworkable” and “unnecessary”).

²⁷⁵ Su (Dentons USA LLP), Roundtable Transcript, at 54-55; Auth (NYIPLA), Roundtable Transcript, at 123.

²⁷⁶ Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 194; R&D Companies, Written Comments, at 3-6; Snyder (Mainsequence.net), Written Comments, at 3.

²⁷⁷ R&D Companies, Written Comments, at 6; *see also* IBM, Written Comments, at 3 (“The identification of an ‘abstract idea’ is itself too abstract an exercise to be of any value towards reaching a rational decision on whether an invention is patentable subject matter.”).

²⁷⁸ Auth (NYIPLA), Roundtable Transcript, at 91; Taylor, Written Comments, at 2; Van Pelt, Roundtable Transcript, at 63; *see also* HIPLA, Written Comments, at 10 (discussing the uncertainty regarding method claims in view of current § 101 jurisprudence); PhRMA, Written Comments, at 7 (“[T]he *Mayo* two-step framework has been arbitrarily and inconsistently applied.”).

²⁷⁹ ABA-IPL, Written Comments (Jan. 18, 2017), at 2; Armitage (IP Strategy & Policy), Written Comments, at 14; Digimarc, Written Comments, at 1; Snyder (Mainsequence.net), Written Comments, at 6

²⁸⁰ Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 194; *see also* IBM, Written Comments, at 5 (asserting that “the law of subject matter eligibility [remains] as confusing today as it has been for the last thirty-five years”).

confusion and inconsistency in examiner decisions on patent eligibility within the USPTO.²⁸¹ Others expressed concern that eligibility rejections seem to be mandated by the USPTO depending on the subject matter of the claim, resulting in inconsistent results across technologies.²⁸² Some practitioners urged the USPTO to construe the Supreme Court’s ruling narrowly,²⁸³ whereas others recommended that when a close question of patent eligibility arises the USPTO should err on the side of eligibility.²⁸⁴

d. Preemption Conflates § 101 With Other Patentability Provisions

Another common criticism of the Supreme Court’s recent decisions is its focus on preemption as part of the patent eligibility analysis. Many practitioners urged that by analyzing preemption, the Court has conflated eligibility with the more rigorous patentability requirements set forth in 35 U.S.C. §§ 102 and 103. Critics remarked that importing considerations of novelty and nonobviousness into the eligibility analysis creates systemic problems because eligibility becomes a blunt instrument for denying patent rights. In the words of one commenter, the “conflation of § 101 with § 103 [in the Court’s *Mayo/Alice* test] increasingly functions to circumvent the whole body of obviousness law that has been developed over more than one hundred and fifty years to make essentially the same conclusion (obviousness) applying essentially the same criteria, but without any of the rigor of analysis that is required of a proper obviousness determination.”²⁸⁵ According to this commenter, the test for eligibility “has effectively evolved into a watered-down obviousness analysis.”²⁸⁶ Others criticized the Court’s two-step framework for failing to consider the claim as a whole, as during an obviousness analysis, but to instead “strip away” what are viewed as conventional limitations.²⁸⁷

Regarding the Court’s concern with broad patents that preempt other innovators, some members of the public argued that §§ 102, 103, and 112 are the more appropriate tools to “deal with overly broad patent claims.”²⁸⁸ Likewise, several commentators

²⁸¹ Fisher (Blaze Mobile), Roundtable Transcript, at 322; Israel (AIPLA), Roundtable Transcript, at 157; Jones (Microsoft), Roundtable Transcript, at 377-78; Kuhn, Roundtable Transcript, at 309; Lo (Google), Roundtable Transcript, at 277; SIIA, Written Comments, at 13; Taylor, Written Comments, at 2.

²⁸² Thomas (RelaxExpress.net), Roundtable Transcript, at 25; *see also* Bernstein (Singularity LLP), Roundtable Transcript, at 31 (“[I]t shouldn’t be a reflex action to simply decide that a computer implemented invention is directed to an abstract idea.”); Israel (AIPLA), Roundtable Transcript, at 161 (“AIPLA has concerns that a § 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.”).

²⁸³ Coalition for 21st Century Medicine, Written Comments, at 2.

²⁸⁴ Noonan (MBHB), Roundtable Transcript, at 125; Auth (NYIPLA), Roundtable Transcript, at 126; Reed, Roundtable Transcript, at 126; *but see* Chiang, Roundtable Transcript, at 128 (advocating for a hybrid approach because forcing applicant to argue why a claim is eligible may further clarify the written record for later prosecution or litigation).

²⁸⁵ R&D Companies, Written Comments, at 8.

²⁸⁶ R&D Companies, Written Comments, at 4; *see also* Armitage (IP Strategy & Policy), Written Comments, at 9 (“the Court has never been challenged to explain how [...] the required ‘inventive concept’ differs from the otherwise required *inventiveness* under 35 U.S.C. § 101.”) (emphasis in original).

²⁸⁷ *See, e.g.*, IBM, Written Comments, at 5.

²⁸⁸ AIPLA, Written Comments (Jan. 18, 2017), at 9, 18; ABA-IPL, Written Comments (Mar. 28, 2017), at 2; IPO, Written Comments, at 26; R&D Companies, Written Comments, at 13.

asserted that there are other more robust statutory grounds to address broad claims that “might preempt or prevent access to any underlying concept,” namely, lack of adequate written description, enablement, and definiteness.²⁸⁹ As one member of the public explained: “Subject matter eligibility does not address the matters that critics of the patent system complain about such as patents that are vague, old or overbroad. This is the work of the other statutory requirements found in Sections 102, 103 and 112.”²⁹⁰ In sum, a recurring theme among critics of the Court’s jurisprudence is that it has improperly imported separate statutory patentability requirements into the § 101 eligibility analysis.²⁹¹

e. Jurisprudence Stifles Innovation and Hurts Businesses

Some members of the public stressed that a healthy patent system is critical to economic growth and development in the United States.²⁹² These members of the public asserted that the current jurisprudence has inappropriately expanded the reach of the judicial exceptions to § 101²⁹³ and has become “unjustifiably punitive.”²⁹⁴ While recognizing that determining the legal limits for patent eligible subject matter is a delicate balance,²⁹⁵ these commenters opined that an overly broad interpretation of the judicial exceptions to patent eligibility is likely to have an adverse impact on U.S. innovation.²⁹⁶ One commentator urged that it could even “eviscerate patent law.”²⁹⁷ A representative from a startup company asserted that the *Alice* decision “tilt[ed] the playing field toward large, incumbent entities and restrict[ed] the ability of new innovators in technologies reliant on software to receive patent protection.”²⁹⁸

According to these members of the public, in the past, an expansive scope of subject matter eligibility has allowed the United States to serve as an incubator for

²⁸⁹ Armitage (IP Strategy & Policy), Written Comments, at 11-12; IBM, Written Comments, at 6 (asserting that functional language should be rejected if inadequately disclosed under §§112(b) or 112(f)); Taylor, Written Comments, at 3 (arguing that “the utility, written description, and definiteness requirements, as well as the limit on functional claiming, already address concerns with abstractness and inadequate disclosure”).

²⁹⁰ Underweiser (IBM), Roundtable Transcript, at 401; *see also* IBM, Written Comments, at 10 (asserting that overbroad claims should be invalidated under §§ 102, 103 or 112, rather than under § 101).

²⁹¹ Bachmann (Bachmann Law Group), Roundtable Transcript, at 148-49; AIPLA, Written Comments (Jan. 18, 2017), at 8; PhRMA, Written Comments, at 7; Sobon (Sobon Consulting), Roundtable Transcript, at 415.

²⁹² Lettelleir (J.C. Penney), Roundtable Transcript, at 142; ABA-IPL, Written Comments (Jan. 18, 2017), at 1; Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 192-93.

²⁹³ Armitage (IP Strategy & Policy), Written Comments, at B2; IPO, Written Comments, at 21.

²⁹⁴ Armitage (IP Strategy & Policy), Written Comments, at 6; IBM, Written Comments, at 12.

²⁹⁵ Israel (AIPLA), Roundtable Transcript, at 159; ABA-IPL, Written Comments (Jan. 18, 2017), at 1; Engine, Written Comments, at 2; Google, Written Comments, at 9; Lo (Google), Roundtable Transcript, at 276.

²⁹⁶ Israel (AIPLA), Roundtable Transcript, at 159; AIPLA, Written Comments (Jan. 18, 2017), at 2; Marqeta, Written Comment, at 2-3; PhRMA, Written Comments, at 6; R&D Companies, Written Comments, at 1, 4.

²⁹⁷ Israel (AIPLA), Roundtable Transcript, at 159.

²⁹⁸ Marqeta, Written Comments, at 2.

groundbreaking innovations ahead of other highly-developed countries.²⁹⁹ In contrast, “[t]he [more recent] jurisprudence related to patentable subject matter is undermining U.S. global leadership, especially in [high] technology and biopharma industry sectors.”³⁰⁰ These commentators also predicted that the uncertainty brought about by the current jurisprudence, and the increase in patent invalidation in the courts and at the Patent Trial and Appeal Board, will likely diminish the incentive to innovate.³⁰¹ They urged that the problem of enforcement of bad patents by patent assertion entities has been, or can be, addressed by other reforms.³⁰²

In the wake of the *Mayo/Alice* two-step framework for patent eligibility, some participants even suggested that innovators have begun to consider trade secrets in lieu of patents to protect inventions they had not traditionally protected by trade secrets.³⁰³ One life sciences industry group asserted that a shift towards trade secret protection will likely lead to less public disclosure of innovation, and consequently diminished downstream benefit to the public.³⁰⁴

f. Consistency of U.S. Law with International Norms

Lastly, as an additional criticism of the Supreme Court’s two-part test, many members of the public raised questions regarding the relationship between the Supreme Court test and international norms.³⁰⁵ Some pointed to U.S. obligations under Article 27 of the TRIPS Agreement, which requires that patents be “available for any inventions, whether products or processes, in all fields of technology.”³⁰⁶

²⁹⁹ Israel (AIPLA), Roundtable Transcript, at 162-63; Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 193.

³⁰⁰ Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 193; Israel (AIPLA), Roundtable Transcript, at 162-63.

³⁰¹ Israel (AIPLA), Roundtable Transcript, at 157-58; ABA-IPL, Written Comments (Jan. 18, 2017), at 2; AIPLA; Written Comments (Jan. 18, 2017), at 1; Banbury Participants, Written Comments, at 1; Jones (Microsoft), Roundtable Transcript, at 378-79; PhRMA, Written Comments, at 6, 7; Taylor, Written Comments, at 2; Underweiser (IBM), Roundtable Transcript, at 403.

³⁰² Marqeta, Written Comments, at 3; IBM, Written Comments, at 11.

³⁰³ See Jackson, Roundtable Transcript, at 199, 243; Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 243-44; Menell, Roundtable Transcript, at 411.

³⁰⁴ PhRMA, Written Comments, at 8.

³⁰⁵ Cullen (U.S. Chamber of Commerce), Roundtable Transcript, at 192-93, 196-97; ABA-IPL, Written Comments (Jan. 18, 2017), at 2; Banbury Participants, Written Comments, at 1; Israel (AIPLA), Roundtable Transcript, at 162-63; Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 206-07; PhRMA, Written Comments, at 8-9; R&D Companies, Written Comments, p. 1, 10; Sauer (BIO), Roundtable Transcript, at 211-12; Sobon (Sobon Consulting), Roundtable Transcript, at 398-99; Su (Dentons US LLP), Roundtable Transcript, at 72-73.

³⁰⁶ Israel (AIPLA), Roundtable Transcript, at 162-63, 182-83; AIPLA, Written Comments (Jan. 18, 2017), at 3; see also Sauer (BIO), Roundtable Transcript, at 211-12 (“[T]he development of extra-statutory law in this area is a significant departure from internationally accepted norms of patentability.”); Armitage (IP Strategy & Policy), Written Comments, at 15 (advocating that legislative changes to § 101 must ensure TRIPS compliance).

Several commenters were also concerned with having a patent eligibility standard in the United States they see as inconsistent with that of other countries.³⁰⁷ They observed that the scope of eligible subject matter in the United States is narrower than that of foreign jurisdictions, such as Europe and China, which especially impacts software and biological innovations.³⁰⁸ In fact, several commentators noted that many biopharmaceutical inventions that are patent eligible in other industrialized countries are not eligible for protection in the United States.³⁰⁹ According to a trade association, having inconsistent standards internationally could place the United States at an economic disadvantage if the patent system failed to adequately stimulate future research and development.³¹⁰ One commentator warned that foreign companies may have an economic advantage in the global marketplace because they will enjoy a “free ride” in the United States.³¹¹

Representatives from the life sciences industry stressed the importance of worldwide patent protection for the successful commercialization of pharmaceutical therapies.³¹² One commenter asserted that there is little incentive to invest in a market that does not provide adequate patent protection, and that trade secret protection is not a viable option internationally due to the disclosure requirements in other countries.³¹³

Several members of the public also emphasized the advantages of harmonization of patent eligibility laws across jurisdictions.³¹⁴ For example, one commentator from the software industry noted that having more consistent patent eligibility standards throughout the world would simplify patent drafting and prosecution and yield efficiencies for U.S. businesses filing in multiple jurisdictions.³¹⁵

B. Technology-Specific Views

Among members of the public, there was a general consensus that two industries have been most directly affected by the recent Supreme Court jurisprudence: life sciences

³⁰⁷ Israel (AIPLA), Roundtable Transcript, at 162-63; AIPLA, Written Comments (Jan. 18, 2017), at 3, 10; Jones (Microsoft), Roundtable Transcript, at 378-79; Sauer (BIO), Roundtable Transcript, at 217; Sobon (Sobon Consulting), Roundtable Transcript, at 398.

³⁰⁸ *Id.*

³⁰⁹ Banbury Participants, Written Comments, at 1.

³¹⁰ PhRMA, Written Comments, at 8-9; *see also* R&D Companies, Written Comments, at 10 (The United States is “at risk of technically falling behind other countries, such as China, Japan, and the countries of the European Union.”).

³¹¹ Sauer (BIO), Roundtable Transcript, at 217; *see also* IBM, Written Comments, at 9 (“If information technology inventions are more broadly eligible for patent protection outside the U.S. than in the U.S., this will encourage investors to fund companies outside the U.S., inhibit U.S. industry, and send U.S. jobs overseas.”).

³¹² Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 231; PhRMA, Written Comments, at 9.

³¹³ Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 231; *see also* PhRMA, Written Comments, at 8 (discussing the difficulties in seeking trade secret protection for pharmaceutical inventions).

³¹⁴ Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 206-07; Armitage (IP Strategy & Policy), Written Comments, at 15.

³¹⁵ Lo (Google), Roundtable Transcript, at 299.

and computer-related technologies. This stems from the fact that innovations in these fields are often closely linked to the judicial exceptions—abstract ideas, laws of nature, and natural phenomena.³¹⁶ The following section provides a more detailed summary of public views from the life sciences and computer-related industries.

1. Life Sciences Technologies

Criticism of the *Alice/Mayo* two-step framework was especially strong among representatives of the life sciences community. Indeed, nearly all participants from the life science industry expressed concern with the recent holdings of the Supreme Court, which reportedly have seriously harmed thousands of companies through patent invalidations or the prospect thereof.³¹⁷ Several commentators asserted that the new eligibility test is disproportionately impacting the biopharmaceutical sector, given the industry’s reliance on patent rights to cover the enormous investment costs associated with developing new medicines and bringing them to the market.³¹⁸ According to a trade association, “developing a new medicine takes between 10 and 15 years of work and costs an average of \$2.6 billion of investment in [research and development].”³¹⁹ Thus, a national law association argued that without patent protection, “emerging businesses and universities would be at risk with respect to their ability to attract needed investment, and established businesses would risk losing an important mechanism for protecting their investment in new products.”³²⁰

Representatives from the life sciences industry noted that natural products and their derivatives form the basis for many biopharmaceutical innovations.³²¹ Therefore, some members of the public argued that, contrary to the Court’s decision in *Myriad*, the act of isolating a natural product should be sufficient for patent subject matter eligibility, at least when isolation permits the product to be used or applied in a new or different way.³²² Regarding the scope of eligible subject matter after *Myriad*, one representative from the biotechnology industry offered the following anecdote from one of his member companies: “I couldn’t get a claim to a laundry detergent enzyme but I could get a claim to a method of washing laundry in a washing machine using a washing liqueur that contains the enzyme.”³²³ He explained that, “at the end of the day, everyone understands that claim scope is vastly different under these circumstances and has very different

³¹⁶ See, e.g., Google, Written Comments, at 1 (“[P]atents drawn to abstract ideas . . . pose particular challenges for the software and Internet industries.”).

³¹⁷ Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 206; HIPLA, Written Comments, at 2; PhRMA, Written Comments, at 5.

³¹⁸ Lemley, Roundtable Transcript, at 72; Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 206-07.

³¹⁹ PhRMA, Written Comments, at 2; Lemley, Roundtable Transcript, at 72.

³²⁰ ABA-IPL, Written Comments (Jan. 18, 2017), at 1; cf. Feldman, Roundtable Transcript, at 74 (expressing concern about “schemes that are driving prices up in the drug industry,” including life cycle management games, that sometimes involve weak patents).

³²¹ See, e.g., Sauer (BIO), Roundtable transcript, at 212.

³²² Coalition for 21st Century Medicine, Written Comments, at 3-4; HIPLA, Written Comments, at 12; PhRMA, Written Comments, at 10-11.

³²³ Sauer (BIO), Roundtable Transcript, at 222.

commercial applications.”³²⁴ Citing a recent study by the National Institutes of Health, one commentator estimated that about 75 percent of antibacterial drugs and 80 percent of anti-cancer drugs approved by the FDA between 1981 and 2010 would be unpatentable under a strict application of the *Myriad* test.³²⁵

The effect of the Court’s recent jurisprudence extends beyond biopharmaceutical drug products. Several members of the public complained about their inability to obtain patents on diagnostic innovations under the *Mayo* two-step test, and warned of the impact this could have on health care, particularly in the emerging field of personalized medicine.³²⁶ One participant reported that even if diagnostic patents could be obtained under the *Mayo* two-step test, they are limited to greatly reduced—perhaps commercially impractical—claim scope.³²⁷ For example, he stated that instead of claiming ten biomarkers used in a molecular diagnostics test, they are forced to claim the specific algorithm in which the biomarkers are combined.³²⁸ He explained that while companies that develop new chemistry to detect a molecule or a new machine for implementing that chemistry probably do fine, the content makers—the companies that “take those platforms and implement them in a very specific way to detect a new cancer or prognose a cancer using specific biomarkers”—are really struggling.³²⁹ Such anecdotal evidence was validated by studies of an academic. According to her research, although there has been no real decline in the number of diagnostic patent applications filed since the *Mayo* decision, there has been a measurable narrowing of claim scope as determined by claim length.³³⁰ She attributed the steady rate of patent application filings to the fact that the diagnostic industry is heavily dominated by non-profit and public entities that are not as dependent on patents.³³¹

Some commentators from the life sciences industry indicated that their inability to obtain adequate patent protection has led them to explore other forms of intellectual property protection for their innovations, such as trade secrets.³³² However, one participant reported that trade secrets offer inadequate protection due to the publication requirements “to get reimbursement in the case of diagnostics or to get regulatory approval in the case of drugs.”³³³ In addition, a trade association representative asserted that given “modern reverse engineering and federally mandated disclosures” pharmaceutical inventions are hard to protect under trade secret law.³³⁴

³²⁴ *Id.* at 222-23.

³²⁵ Noonan (MBHB), Roundtable Transcript, at 107-08; *see also* HIPLA Written Comments, at 12-14 (describing old patents to adrenaline, insulin, and vitamin B12 in purified form).

³²⁶ *See* Sauer (BIO), Roundtable Transcript, at 213; Coalition of 21st Century Medicine, Written Comments, at 1; PhRMA, Written Comments, at 11.

³²⁷ *See, e.g.*, Jackson, Roundtable Transcript, at 220.

³²⁸ *Id.*

³²⁹ *Id.* at 223-24.

³³⁰ Chien, Roundtable Transcript, at 320-21; *see also* IPO, Written Comments, at 22 (documenting a steady increase in § 101 rejections at the USPTO in biotechnology following *Mayo* and *Alice*).

³³¹ Chien, Roundtable Transcript, at 350-51.

³³² Jackson, Roundtable Transcript, at 199, 243; PhRMA, Written Comments, at 8.

³³³ Jackson, Roundtable Transcript, at 243;

³³⁴ PhRMA, Written Comments, at 8.

2. Computer-Related Technologies

In contrast to the life sciences field, those in the computer industry were more sharply divided in their views of recent Supreme Court precedent. Some members of the public welcomed the Court's intervention in the law of patent eligibility. Far from sounding the "death knell" for software innovation,³³⁵ several members of the public argued that *Alice* instead addresses the very real problem of abusive patent litigation driven by overly broad patents.³³⁶ According to these commentators, the decision has made patent litigation more efficient and has provided companies with an important tool to defend against spurious lawsuits.³³⁷ Likewise, others characterized *Alice* as striking an appropriate balance between innovators and downstream users of computer-implemented inventions.³³⁸ One participant doubted that the Supreme Court, if directly confronted with the issue, would actually hold "that software is not patentable."³³⁹ Another argued that *Alice* doesn't go far enough, and that patents are "an imposition" on people that write software and "slow down their ability to create."³⁴⁰

Many representatives from the software industry were in favor of giving the courts the opportunity to continue to develop the law on patent eligibility under *Alice*.³⁴¹ They argued that the Federal Circuit is helping to refine the boundaries between eligible and ineligible subject matter.³⁴²

One commenter representing the interests of startup companies cautioned against overemphasizing patents as a driver for investment in startups.³⁴³ Likewise an academic suggested that current trends indicate that investors are placing less weight on whether a company has a patent when making funding decisions.³⁴⁴ Highlighting the empirical nature of the inquiry, another academic indicated that he had not seen any evidence of a decrease in venture capital funding in the software field since the *Alice* decision.³⁴⁵

On the other side of the debate, some members of the computer industry complained that the law being developed by the Supreme Court is negatively impacting

³³⁵ Lo (Google), Roundtable Transcript, at 249; EFF, Written Comments, at 2; Google, Written Comments, at 1; IA & CCIA, Written Comments, at 10; Mozilla, Written Comments, at 1-2; SIIA, Written Comments, at 14-15.

³³⁶ Lemley, Roundtable Transcript, at 46; Google, Written Comments, at 1-2; Mozilla, Written Comments, at 2; SIIA, Written Comments, at 8.

³³⁷ Schmitt (Intel), Roundtable Transcript, at 169; EFF, Written Comments, at 4; Engine, Written Comments, at 2; Public Knowledge, Written Comments, at 2; SIIA, Written Comments, at 10-11; Sutton, Roundtable Transcript, at 171.

³³⁸ Nazer (EFF), Roundtable Transcript, at 286; Google, Written Comments, at 2; IA & CCIA, Written Comments, at 2.

³³⁹ Lemley, Roundtable Transcript, at 46.

³⁴⁰ Nazer (EFF), Roundtable Transcript, at 256.

³⁴¹ Lemley, Roundtable Transcript, at 45-46; Google, Written Comments, at 2; IA & CCIA, Written Comments, at 10; Public Knowledge, Written Comments, at 4.

³⁴² Google, Written Comments, at 2; IA & CCIA, Written Comments, at 5-8; SIIA, Written Comments, at 11-13.

³⁴³ Samuels (Engine), Roundtable Transcript, at 302.

³⁴⁴ Feldman, Roundtable Transcript, at 70.

³⁴⁵ Lemley, Roundtable Transcript, at 71.

their businesses, which rely on software innovations.³⁴⁶ For example, in-house counsel at a small company contended that *Alice* has “shifted litigation outcomes and strategies wholesale, devalued entire patent portfolios,” and “impacted an unknowable number of key business decisions for many a small business.”³⁴⁷ Another representative from a small company asserted that *Alice* has affected companies like itself that create technology and have never been on the receiving end of suits by patent assertion entities.³⁴⁸ While acknowledging that only one percent of patents are litigated, one representative from a small software company explained that for companies like hers “they are largely used to secure financing and attract investors.”³⁴⁹ And, another representative reported that such investment has declined.³⁵⁰

The portion of the software industry critical of the Supreme Court’s *Alice* decision favored legislative change, blaming the decision for injecting uncertainty into their business practices.³⁵¹ Recalling the uncertainty that was created by the decades-old decisions in *Flook* and *Diehr*, one representative from a large computer company argued that “the information technology industry can’t wait another thirty-five years while courts try to sort [patent eligibility] out.”³⁵²

Another representative from a large software company stressed the importance of patents, noting that his company “spend[s] over \$11 billion a year on research and development, which . . . rivals most pharma companies.”³⁵³ Furthermore, one commentator highlighted the downstream economic benefits of software, reporting that “the software and information technology industries have been a bright spot in an economy that often struggles to create jobs, directly employing more than 2.5 million Americans in 2014 and indirectly supporting nearly 7.5 million more jobs.”³⁵⁴

C. Public Recommendations

In addition to soliciting feedback on the impact of the Supreme Court’s current jurisprudence on patent subject matter eligibility, the USPTO also invited the public to make recommendations as to what, if any, measures should be taken to address the Court’s heightened patent eligibility standard. Public recommendations were directed to all three branches: the judicial, legislative, and executive branches.

³⁴⁶ Gardner (Marqeta), Roundtable Transcript, at 281; IBM, Written Comments, at 8; Marqeta, Written Comments, at 2; *see also* Giblin (451 Degrees), Roundtable Transcript, at 330 (“I believe in patents, and the reason is they’re important. They protect inventors[.]”).

³⁴⁷ Chiang, Roundtable Transcript, at 96-97.

³⁴⁸ Gardner (Marqeta), Roundtable Transcript, at 246-47.

³⁴⁹ Kuhn, Roundtable Transcript, at 311-12.

³⁵⁰ Thomas (RelaxExpress.net), Roundtable Transcript, at 27.

³⁵¹ Underweiser (IBM), Roundtable Transcript, 400-01; *cf.* Jones (Microsoft), Roundtable Transcript, at 378-79 (noting that the Federal Circuit is currently trending in the correct direction, but expressing an openness to legislative options if such trends do not continue).

³⁵² IBM, Written Comments, at 7.

³⁵³ Jones (Microsoft), Roundtable Transcript, at 378.

³⁵⁴ Underweiser (IBM), Roundtable Transcript, at 403-04; *see also* IBM, Written Comments, at 8 (explaining that “innovations in almost every sector of our economy generally involve and are embodied in computer technology (e.g., software)”).

1. Allow Judicial Developments to Continue

Many members of the public who were generally supportive of the recent Supreme Court decisions, especially representatives from the software community, saw no need for legislative intervention.³⁵⁵ Instead, they recommended allowing the judiciary to continue to develop the eligibility case law, noting that it takes time for the jurisprudence to evolve.³⁵⁶ One commentator asserted that a similar process occurred following the Court's decision in *KSR* pertaining to the law of obviousness.³⁵⁷ She observed that "there were several years of what you really can only call churn where district courts and the federal circuit were working out how that standard was actually going to be applied."³⁵⁸ She contended that "we're still not at the point where we know whether or not legislative solutions can be appropriate."³⁵⁹ Her view was echoed by other speakers, who argued that congressional action would be disruptive and therefore the common law and administrative processes should be allowed to play out.³⁶⁰

Several participants welcomed recent Federal Circuit decisions, such as *Enfish*, *Amdocs*, *McRO*, and *Rapid Litigation*.³⁶¹ For example, one academic explained that the courts are "engaging in a common law process that . . . gets them to the right result in particular cases."³⁶² In his view, the Federal Circuit is beginning to define a "set of standards" to distinguish between an ineligible invention and one that is directed to a specific algorithm or improvement in computer technology.³⁶³ Other participants similarly welcomed the Federal Circuit's recent focus on a technological improvement or solution to a technological problem.³⁶⁴ According to an internet company representative, "[a]s the Federal Circuit issues more decisions applying a technical problem/technical solution approach, the line between patent-eligible and patent-ineligible software claims will become more and more predictable. This is the nature of the common law process on which our legal system is built. And we would want to allow the courts more time to work this out."³⁶⁵

³⁵⁵ Lo (Google), Roundtable Transcript, at 255, 306; Gardner (Marqeta), Roundtable Transcript, at 306; Google, Written Comments, at 10; IA & CCIA, Written Comments, at 11; Mozilla, Written Comments, at 4; Nazer (EFF), Roundtable Transcript, at 306; Public Knowledge, Written Comments, at 4; Samuels (Engine), Roundtable Transcript, at 306.

³⁵⁶ Jones (Microsoft), Roundtable Transcript, at 376-77; Kuhn, Roundtable Transcript, at 360-361; Lo (Google), Roundtable Transcript, at 253; Reed, Roundtable Transcript, at 127; Samuels (Engine), Roundtable Transcript, at 271; Mozilla, Written Comments, at 4.

³⁵⁷ Kuhn, Roundtable Transcript, at 360-61.

³⁵⁸ *Id.* at 360.

³⁵⁹ *Id.* at 361.

³⁶⁰ Lo (Google), Roundtable Transcript, at 255; Engine, Written Comments, at 3.

³⁶¹ Auth (NYIPLA), Roundtable Transcript, at 91-92; Jones (Microsoft), Roundtable Transcript, at 376-77; Lo (Google), Roundtable Transcript, at 252; Reed, Roundtable Transcript, at 114-118.

³⁶² Lemley, Roundtable Transcript, at 45.

³⁶³ *Id.* at 49-50.

³⁶⁴ Auth (NYIPLA), Roundtable Transcript, at 91-92; Google, Written Comments, at 3-7; Lo (Google), Roundtable Transcript, at 252-53; Reed, Roundtable Transcript, at 114-118.

³⁶⁵ Lo (Google), Roundtable Transcript, at 253.

Another patent attorney in the computer arts agreed that *Enfish* was headed in the right direction; however, he didn't think it went far enough.³⁶⁶ Instead, he argued, the Federal Circuit got it right 20 years ago in *Alappat*, when they said that "every time you program a general purpose processor, you've got a new machine."³⁶⁷ He was troubled by how the case law might be applied in the field of robotics and was worried that a processor that improves the control of a robot with better programming might be considered patent ineligible.³⁶⁸

2. Take Administrative Measures

Some members of the public proposed administrative measures to improve application of the Supreme Court's two-part eligibility test by the USPTO. Several commenters expressed a desire for more consistent treatment of eligibility issues, and development of a full and clear record, by the examiners.³⁶⁹ One commentator suggested that the examiners be required to provide detailed reasoning on eligibility, much like they are required to do for prior art rejections.³⁷⁰ Another suggested that examiners be required to "specifically rebut applicants' arguments," not simply dismiss them as not persuasive.³⁷¹ Some commentators reported that the perceived inconsistency in treatment of eligibility issues by examiners was leading to "forum-shopping" by practitioners, i.e., classifying applications to attempt to steer them to art units that are less likely to enter § 101 rejections.³⁷²

A couple legal associations recommended that the § 101 examination guidelines be amended to provide further guidance and more examples.³⁷³ In their view, the current guidelines do not offer enough examples of patent eligible subject matter, particularly in the life sciences.³⁷⁴ In addition, they were disappointed that the examples do not provided guidance on how patent ineligible claims might be rewritten to claim patent eligible subject matter.³⁷⁵

Some commenters requested better guidance for evaluating eligibility of claims under the *Mayo* two-part test.³⁷⁶ One such commentator from the medical diagnostics

³⁶⁶ Bernstein (Singularity LLP), Roundtable Transcript, at 34-36.

³⁶⁷ *Id.* at 32. In *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994), the Federal Circuit held that an improvement to an oscilloscope that produces a smooth waveform and thus a clearer picture was patent eligible, rejecting the notion that a programmed general purpose computer could never be patent eligible subject matter. *Id.* at 1537, 1541-45. In so holding, the court relied on the "useful, concrete, and tangible result" test for patent eligibility. *Id.* at 1544. The decision was abrogated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

³⁶⁸ Bernstein (Singularity LLP), Roundtable Transcript, at 36-37.

³⁶⁹ Chiang, Roundtable Transcript, at 100; Fisher (Blaze Mobile), Roundtable Transcript, at 325-26; Thomas (RelaxExpress.net), Roundtable Transcript, at 28.

³⁷⁰ Fisher (Blaze Mobile), Roundtable Transcript, at 326.

³⁷¹ Thomas (RelaxExpress.net), Roundtable Transcript, at 28.

³⁷² Sutton (Oracle), Roundtable Transcript, at 175-76; ESA, Written Comments, at 2.

³⁷³ AIPLA, Written Comments (Jan. 18, 2017), at 4-5; HIPLA, Written Comments, at 16.

³⁷⁴ *Id.*

³⁷⁵ AIPLA Written Comments (Jan. 18, 2017), at 4.

³⁷⁶ AIPLA, Written Comments (Jan. 18, 2017), at 4-5; PhRMA, Written Comments, at 4.

industry urged examiners to guard against application of bright line tests and to “appreciate how diagnostics work and how the claims typically sought in diagnostic medicine differ from decades-old claims held in court decisions to simply recite a law of nature.”³⁷⁷

Other commenters recommended revising USPTO guidance to make clear that claims directed to computer software may be patent eligible under § 101, asserting that the current guidelines can be read to discourage or even prohibit direct claiming of computer software.³⁷⁸ On the other hand, a nonprofit group expressed concern that the guidelines are effectively putting “a thumb on the scale in favor of eligibility.”³⁷⁹ This group recommended that the Manual of Patent Examination Procedure (MPEP) be amended to include a clear explanation of how *Alice* overruled prior authority or, at the very least, include *Alice*’s holding that “mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.”³⁸⁰

Lastly, several members of the public recommended that the USPTO clarify what is meant by a technical solution to a technical problem, terminology that has been used by the Federal Circuit in analyzing patent eligibility under § 101.³⁸¹ Another commentator suggested that the courts can, and perhaps should, defer to the agency’s expertise and that the USPTO should, as it has done in the past, “tell[] the Federal Circuit when it thinks that they’re wrong.”³⁸²

3. Push for Legislative Reform

While some commentators recommended either allowing the judiciary to develop the case law or taking administrative measures, many other commenters pressed for legislative change. Representatives from law firms, legal associations, industry groups, and life sciences companies agreed that the legislature is the appropriate body to recalibrate the proper scope of patent eligibility.³⁸³ In particular, representatives from the life sciences industry asserted that the Supreme Court’s denial of certiorari in *Sequenom* demonstrated that it was unwilling to revisit its eligibility standard, leading them to consider a legislative solution.³⁸⁴

³⁷⁷ Coalition for 21st Century Medicine, Written Comments, at 6.

³⁷⁸ Pollinger and Tolliver, Written Comments, at 1.

³⁷⁹ EFF, Written Comments, at 5.

³⁸⁰ *Id.* at 6.

³⁸¹ Lo (Google), Roundtable Transcript, at 254-55, 277; Google, Written Comments, at 10; SIIA, Written Comments, at 7-8; *see also* Patel (Holzer, Patel, Drennan), Roundtable Transcript, at 89-90 (recommending including a technological improvement or solution in the specification).

³⁸² Noonan (MBHB), Roundtable Transcript, at 106, 110-111.

³⁸³ ABA-IPL, Written Comments (Jan. 18, 2017), at 3; AIPLA, Written Comments, at 9; Auth (NYIPLA), Roundtable Transcript, at 94-95; HIPLA, Written Comments, at 15; PhRMA, Written Comments, at 9; R&D Companies, Written Comments, at 9; Sauer (BIO), Roundtable Transcript, at 215; Sobon (Sobon Consulting), Roundtable Transcript, at 399-400; Sunstein, Written Comments, at 3; Taylor, Written Comments, at 2; Underweiser (IBM), Roundtable Transcript, at 408.

³⁸⁴ Jackson, Roundtable Transcript, at 200; Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 205-08.

Members of the public proposed a variety of different legislative amendments, many of which involved abrogating the Court’s two-part eligibility test. Their varying approaches are described below. The full text of the legislative recommendations to amend § 101 can be found in Appendix IV.

a. Replace Two-Part Test With Technological or Useful Arts Test

Several legislative proposals called for the elimination of the two-part *Mayo/Alice* eligibility test in favor of a technological or useful arts requirement.³⁸⁵ Acknowledging that patents should be reserved for contributions to the technological or useful arts, these members of the public recommended that the patent eligibility standard be similarly focused on whether what is claimed is a technological or useful invention.³⁸⁶

Seeking to restore “the historic availability of patent protection for medicines and diagnostics,” a group of representatives from the life sciences industry advocated that Congress should make patents available to all “technological inventions, i.e., inventions contributing to the technological arts.”³⁸⁷ Another life sciences representative also supported a technology-based patent eligibility standard, recommending that Congress reaffirm “traditional boundaries between practical applications of scientific knowledge in all fields of technology, as contrasted with other manifestations of human creativity that are not themselves technological.”³⁸⁸ One commenter proposed that § 101 be amended to provide that inventions that contribute to the useful arts be entitled to a patent provided that all of the conditions and requirements of Title 35 are satisfied.³⁸⁹ This proposal further defined useful arts as referring “to all fields of technology, without restriction or limitation.”³⁹⁰ On the other hand, one participant expressed concern that a useful arts or technological arts test wouldn’t address some of the concerns in the diagnostics area.³⁹¹

Several legislative proposals recommended revising § 101 to eliminate the “new” requirement, while maintaining the “useful” requirement.³⁹² For example, the Intellectual Property Owners Association (IPO) offered the following text:

Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention

³⁸⁵ Armitage (IP Strategy & Policy), Written Comments, at 21-22; Banbury Participants, Written Comments, at 1; Sauer (BIO), Roundtable Transcript, at 216; *see also* Jones (Microsoft), Roundtable Transcript, at 379 (recommending some sort of “advance in technology” approach, if legislation becomes necessary).

³⁸⁶ *Id.*

³⁸⁷ Banbury Participants, Written Comments, at 1.

³⁸⁸ Sauer (BIO), Roundtable Transcript, at 216.

³⁸⁹ *See* Armitage (IP Strategy & Policy), Written Comments, at A1.

³⁹⁰ *Id.*

³⁹¹ Menell, Roundtable Transcript, at 410.

³⁹² IPO, Written Comments, at 28; ABA-IPL, Written Comments (Mar. 28, 2017), at 3; *see also* HIPLA, Written Comments at 15 (discussing possible unconstitutionality of Supreme Court precedent holding “useful” discoveries to be ineligible).

thereof, subject only to the exceptions, conditions, and requirements set forth in this Title.³⁹³

In contrast to the current version of § 101 that requires inventions to be both “new and useful,” the proposed revision only requires claimed inventions to be “useful.”³⁹⁴ The proposal also makes explicit that eligibility is based on the invention as claimed and not based on a “quick look” or consideration of the purpose of the invention as described in the specification.³⁹⁵

The Houston Intellectual Property Law Association (HIPLA) likewise proposed the following amendment to § 101:

A claimed invention directed to any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, shall be eligible for patenting by its inventor [sic].³⁹⁶

In addition, two legal associations also proposed legislative amendments that would make useful inventions patent eligible.³⁹⁷

Under other legislative approaches, patent eligibility turns on whether an invention has a practical utility or application.³⁹⁸ For example, one commenter suggested that “[s]ubject matter may not be patented unless claimed in terms of a practically useful process, machine, manufacture, or composition of matter, or a practically useful improvement thereto.”³⁹⁹ Analogously, the New York Intellectual Property Law Association (NYIPLA) urged that a patent eligible claim “may recite a practical application of a law of nature, abstract idea, or natural phenomena.”⁴⁰⁰

b. Expressly Define Exceptions to Eligibility

Several legislative proposals sought to define the scope of patent eligible subject matter by expressly articulating exceptions to eligibility.⁴⁰¹ For example, two legal associations proposed codifying the judicially-created exceptions to patent eligibility.⁴⁰² Both proposals focused on the notion of preemption. One provided that a claim would be denied eligibility on the “ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural

³⁹³ IPO, Written Comments, at 1.

³⁹⁴ *Id.* at 28.

³⁹⁵ *Id.*

³⁹⁶ HIPLA, Written Comments, at 16.

³⁹⁷ ABA-IPL, Written Comments (Mar. 28, 2017), at 3; AIPLA, Written Comments (May 12, 2017), at 4.

³⁹⁸ Auth (NYIPLA), Roundtable Transcript, at 94; Armitage (IP Strategy & Policy), Written Comments, at A1.

³⁹⁹ Armitage (IP Strategy & Policy), Written Comments, at A1.

⁴⁰⁰ Auth (NYIPLA), Roundtable Transcript, at 94.

⁴⁰¹ ABA-IPL, Written Comments (Mar. 28, 2017), at 3; Auth (NYIPLA), Roundtable Transcript, at 94.

⁴⁰² ABA-IPL, Written Comments (Mar. 28, 2017), at 3; HIPLA, Written Comments, at 16.

phenomenon, or abstract idea.”⁴⁰³ The other specified that a claim “may not claim or preempt a law of nature, abstract idea or a natural phenomenon.”⁴⁰⁴ Under these legislative proposals, claimed inventions may not preempt laws of nature, abstract ideas, or natural phenomena, but practical applications of these exceptions are patent eligible.⁴⁰⁵ In contrast, a legal association proposed precise definitions of the terms law of nature, natural product, and abstract idea, to attempt to limit the scope of the exceptions to patent eligibility.⁴⁰⁶

Other commentators suggested different approaches to codifying exceptions to eligibility.⁴⁰⁷ For example, IPO proposed defining a single narrow exception to eligibility:

A claimed invention is ineligible . . . if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.⁴⁰⁸

Thus, rather than reciting the judicial-created exceptions to eligibility (abstract ideas, laws of nature, and natural phenomena), the proposed statutory amendment defines a new exception to eligibility for claimed inventions that exist in nature independent of human intervention or exist only in the human mind.⁴⁰⁹ The amendment also requires that the claims be considered as a whole and that they be interpreted from the perspective of a person of ordinary skill in the art.⁴¹⁰ The American Intellectual Property Law Association (AIPLA) proposed nearly identical language, defining a sole exception to patent eligibility:

A claimed invention is ineligible . . . only if the claimed invention as a whole exists in nature independent and prior to any human activity, or can be performed solely in the human mind.⁴¹¹

One representative from the life sciences industry proposed legislation containing specific enumerated exceptions to patent eligibility.⁴¹² Under this proposal, only claimed inventions falling within legislatively-articulated exceptions would be ineligible for patent protection.⁴¹³ Some suggested exceptions included: a process in which every step can be performed in the human mind; a natural cause and effect relationship; a natural

⁴⁰³ ABA-IPL, Written Comments (Mar. 28, 2017), at 3.

⁴⁰⁴ Auth (NYIPLA), Roundtable Transcript, at 94.

⁴⁰⁵ Auth (NYIPLA), Roundtable Transcript, at 94; ABA-IPL (Mar. 28, 2017), Written Comments, at 3.

⁴⁰⁶ HIPLA, Written Comments, at 16.

⁴⁰⁷ Jackson, Roundtable Transcript, at 202-05; HIPLA, Written Comments, at 16; IPO, Written Comments, at 1, 29-33.

⁴⁰⁸ IPO, Written Comments, at 1.

⁴⁰⁹ *Id.* at 29-33.

⁴¹⁰ *Id.* at 31.

⁴¹¹ AIPLA, Written Comments (May 12, 2017) at 4.

⁴¹² Jackson, Roundtable Transcript, at 202-05 (discussing slides 15-20 of his presentation).

⁴¹³ *Id.*

product unmodified from its intact natural state; and an entire human organism.⁴¹⁴ This commenter remarked that “human cloning and germline editing of the human germline” raise ethical considerations and therefore should possibly be considered off limits.⁴¹⁵ Another practitioner from the life sciences industry suggested that “we may want to codify that human genes are in fact not patentable, period.”⁴¹⁶

c. Distinguish Eligibility from Other Patentability Requirements

Some legislative proposals focused on restoring patent eligibility to a threshold inquiry,⁴¹⁷ while ensuring that the other patentability requirements set forth in the Patent Act are not imported into the § 101 analysis.⁴¹⁸ To this end, one practitioner suggested the following amendment:

Whoever invents or discovers any new or useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, unless the conditions and requirements of this title have not been satisfied.⁴¹⁹

In explaining the amendment, he asserted that “the provisions of 35 U.S.C. § 102, § 103, and § 112 are sufficient as written and interpreted by the [c]ourts to address all the imagined problems articulated by the Court.”⁴²⁰ Going even further, another commentator suggested eliminating the eligibility requirement entirely and instead relying on the other statutory conditions for patentability.⁴²¹

Several members of the public offered provisions that expressly distinguish patent eligibility from other patentability requirements and prohibit consideration in the eligibility analysis of factors relevant only to the other patentability provisions (e.g., inventive concept).⁴²² These proposals include language to prevent reliance on some of the Supreme Court’s recent jurisprudence interpreting § 101.⁴²³ For example, IPO and AIPLA proposed the following language:

The eligibility of a claimed invention . . . shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112

⁴¹⁴ *Id.*

⁴¹⁵ *Id.* at 240.

⁴¹⁶ Linnik (Nutter, McClennen & Fish LLP), Roundtable Transcript, at 238.

⁴¹⁷ Armitage (IP Strategy & Policy), Written Comments, at A6; Auth (NYIPLA), Roundtable Transcript, at 95; IBM, Written Comments, at 14; PhRMA, Written Comments, at 9; Sobon (Sobon Consulting), Roundtable Transcript, at 399-400.

⁴¹⁸ ABA-IPL, Written Comments (Jan. 18, 2017), at 3; AIPLA, Written Comments (May 12, 2017), at 3.

⁴¹⁹ Sunstein, Written Comments, at 3.

⁴²⁰ *Id.* at 2.

⁴²¹ Taylor, Written Comments, at 4.

⁴²² ABA-IPL, Written Comments (Mar. 28, 2017), at 3-4; Armitage (IP Strategy & Policy), Written Comments, at A2; IPO, Written Comments, at 1.

⁴²³ *Id.*

of this Title, the manner in which the claimed invention was made or discovered, or the claimed invention’s inventive concept.⁴²⁴

Similarly, the Intellectual Property Law Section of the American Bar Association (ABA-IPL) proffered language mandating that eligibility “not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.”⁴²⁵ Another practitioner offered more generic language to achieve similar results:

No additional limitations on or exceptions to eligibility for patenting shall exist or may be implied for a claimed invention that meets the requirements for eligibility under this section.⁴²⁶

d. Establish Research Exemption to Infringement

Several commentators proposed a legislative amendment to recognize a research exemption from patent infringement for experimentation conducted to better understand or improve a claimed invention.⁴²⁷ According to these commentators, such an amendment would address the Supreme Court’s preemption concerns, i.e., concerns that patents on foundational technological tools may stifle scientific progress by tying up the basic building blocks of human ingenuity.⁴²⁸ One commentator suggested that the exemption could be tailored such that “patents on research tools would be unaffected, but research on a patented invention itself would not be subject to infringement allegations.”⁴²⁹

⁴²⁴ IPO, Written Comments, at 1; AIPLA, Written Comments (May 12, 2017), at 4.

⁴²⁵ ABA-IPL, Written Comments (Mar. 28, 2017), at 4.

⁴²⁶ Armitage (IP Strategy & Policy), Written Comments, at A2.

⁴²⁷ Sauer (BIO), Roundtable Transcript, at 215-16; Banbury Participants, Written Comments, at 1; Sunstein, Written Comments, at 2; Taylor, Written Comments, at 3.

⁴²⁸ *Alice*, 134 S. Ct. at 2354 (“We have ‘repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of’ these building blocks of human ingenuity.”) (quoting *Mayo*, 132 S. Ct. at 1301).

⁴²⁹ Sunstein, Written Comments, at 2.

V. CONCLUSION

Members of the public who expressed their views either at the roundtable or in written submissions generally agreed that the Supreme Court's recent jurisprudence altered the landscape of patent eligibility law. Some commentators supported the Court's decisions and subsequent lower court case law developments, viewing them as simply the common law process at work. They asserted that the *Mayo/Alice* two-step test provides a beneficial way to challenge overly broad patents and helps to improve patent quality by indicating that claims be directed to a specific implementation of an inventive solution instead of a vaguely-claimed functional result. Supporters also argued that the new eligibility test gives them a useful tool to defend against abusive lawsuits by patent assertion entities and may even give the United States a competitive advantage internationally.

On the other side of the debate, commentators opposed to the Court's recent decisions argued that they are legally flawed and that the judicially-created exceptions to eligibility are too broad. Detractors also asserted that the two-step test is difficult to apply, leading to inconsistent decisions and unpredictability, and that it conflates § 101 analysis with other patentability requirements. Finally, critics argued that the Court's jurisprudence stifles innovation, hurts businesses, and harms American competitiveness to the extent that the patent systems of other countries allow for a broader scope of patent protection.

The life sciences and computer-related technologies are considered to be the two areas of innovation most significantly affected by the Court's decisions. Representatives from the life sciences industry almost uniformly opposed the Court's recent precedents. They argued that many biopharmaceutical inventions are derived from natural products and that such innovations, as well as many innovations in diagnostics, are not patent eligible under the Court's precedent.

Representatives from computer-related industries, especially software, were divided in their views of the Court's jurisprudence. Some argued that it protects against abusive patent litigation and has had little impact on software innovation. Others asserted, however, that patents are important to foster investment and that *Alice* has devalued patent portfolios and injected uncertainty into their business practices, hurting innovation.

Members of the public were split in their views on how best to respond to the Supreme Court's recent jurisprudence. In general, supporters of the decisions, many of whom were from the software industry, recommended that the judiciary be given time to develop the case law further. Many were pleased by the emerging pattern of Federal Circuit case law that frames the eligibility inquiry as a search for a technological solution or improvement to a problem.

Some commentators recommended administrative actions to address the impact of the Court's decisions, for example, that the USPTO take steps to increase consistency between examiners and clarity of § 101 rejections in office actions. Several asked for

additional guidance, examples, or revisions to the Manual of Patent Examining Procedure (MPEP).

A majority, however, recommended legislative change. A call for legislation was particularly strong from the life sciences industry but also had many supporters from computer-related industries. According to these participants, the Court's precedent is having such a harmful impact on innovation and business development that a legislative solution is critical. The proposed approaches to legislation varied. Some suggested replacing the *Mayo/Alice* two-step test with a technological or useful arts test or expressly defining exceptions to eligibility. Others suggested clearly separating eligibility from other patentability requirements. Finally, in addition to addressing the statutory requirements for eligibility, some recommended including a research exception to infringement to address the Court's preemption concerns.

APPENDIX I:
NOTICE OF ROUNDTABLES AND REQUEST FOR COMMENTS

recommended that NMFS issue the Stephens EFP (<http://www.pcouncil.org/wp-content/uploads/2016/09/0916decisions.pdf>).

If the two extensions and the Stephens EFP are approved, they would exempt a limited number of federally permitted commercial fishing vessels from requirements of the HMS FMP pertaining to non-authorized gear types. The EFPs would authorize up to 13 DSBG vessels to fish year-round in areas within the EEZ off the U.S. West Coast. Aside from the exemption described above, vessels fishing under an EFP would be subject to all other regulations implementing the HMS FMP, including measures to protect sea turtles, marine mammals, and seabirds. The three applicants requested EFP issuance for two fishing seasons or the 2017 and 2018 calendar years.

The Council suggested NMFS impose requirements on the Stephens EFP consistent with one of the existing EFPs, including, but not limited to:

- (1) 30 percent observer coverage on each vessel's fishing trips;
- (2) fishing only in federal waters; and
- (3) the operator of the fishing vessel operating under a DSBG EFP must actively tend all gear at all times and maintain the gear within sight (typically within 2–4 nautical miles of the gear) of the EFP participant fishing vessel.

NMFS is seeking public comment on the extension of the two existing EFPs, as well as the Stephens EFP application and the Council's recommended conditions.

In accordance with NOAA Administrative Order 216–6, appropriate National Environmental Policy Act documents will be completed prior to the issuance of the EFPs. Additionally, NMFS will consider all applicable laws, including Section 7(a)(2) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*), to determine if the proposed action is likely to jeopardize the continued existence and recovery of any endangered or threatened species or result in the destruction or adverse modification of critical habitat.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 11, 2016.

Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
 [FR Doc. 2016–24973 Filed 10–14–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2016–0041]

Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of public roundtables and request for comments related to patent subject matter eligibility.

SUMMARY: The United States Patent and Trademark Office (“USPTO”) seeks public input on patent subject matter eligibility in view of recent decisions by the Supreme Court and Court of Appeals for the Federal Circuit. The USPTO remains interested in feedback from members of the public to improve the USPTO’s existing subject matter eligibility guidance and training examples. The USPTO is also interested in facilitating a discussion among members of the public regarding the legal contours of eligible subject matter in the U.S. patent system. The USPTO will be facilitating these discussions by hosting two roundtable events. The first roundtable will be directed to receiving feedback from members of the public to improve the USPTO’s existing subject matter eligibility guidance and training examples. The second roundtable will be focused on receiving feedback regarding larger questions concerning the legal contours of eligible subject matter in the U.S. patent system. The roundtables will provide a forum for discussion of the topics identified in this notice.

DATES: The meeting dates are:

1. November 14, 2016, 1 p.m. to 5 p.m., Alexandria, VA.
 Written comments will be accepted on an ongoing basis.
2. December 5, 2016, 8 a.m. to 5 p.m., Stanford, CA.
 Written comments are due by January 18, 2017.

ADDRESSES: The meeting locations are:

1. United States Patent and Trademark Office, Madison Building, Madison Auditorium, 600 Dulany Street, Alexandria, Virginia 22314.
2. Paul Brest Hall, 555 Salvatierra Walk, Stanford University, Stanford, California 94305.

Submit written comments to: 2014_interim_guidance@uspto.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding registration and speaker presentations should be directed to the

attention of Elizabeth Shaw, by telephone at 571–272–9300, or by email at elizabeth.shaw2@uspto.gov. Requests for additional information regarding the topics for written comments and discussion at Roundtable 1 should be directed to Carolyn Kosowski, by telephone at 571–272–7688, or by email at carolyn.kosowski@uspto.gov. Requests for additional information regarding the topics for written comments and discussion at Roundtable 2 should be directed to Amy Nelson, by telephone at 571–272–8978, or by email at amy.nelson@uspto.gov.

SUPPLEMENTARY INFORMATION:

Roundtable 1: USPTO Subject Matter Eligibility Guidelines

Instructions and Information on Roundtable 1: Roundtable 1 will be held on November 14, 2016, at the United States Patent and Trademark Office, Madison Building, Madison Auditorium, 600 Dulany Street, Alexandria, Virginia 22314. The roundtable will begin at 1:00 p.m., Eastern Standard Time (“EST”) and end at 5:00 p.m., EST. The roundtable will also be available via webcast enabling individuals who cannot attend in person to watch the roundtable via the Internet in real time. The agenda and webcast information will be available before the roundtable on the USPTO’s Roundtable 1 Web page www.uspto.gov/patent/notice-roundtables-and-request-comments-related-patent-subject-matter-eligibility. On-line registration will be available from that Web page, and attendees may register at the door. Attendees are encouraged to register online before the roundtable.

Written Comments: The USPTO continues to accept comments on its subject matter eligibility guidance and training examples on an ongoing basis. Those comments, as well as any written comments on the topics for discussion in Roundtable 1, should be sent by electronic mail message via the Internet addressed to 2014_interim_guidance@uspto.gov. Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

Instructions and Information on Roundtable 2: Roundtable 2 will be held on December 5, 2016, at Paul Brest Hall, 555 Salvatierra Walk, Stanford University, Stanford, California 94305. The roundtable will begin at 8:00 a.m., Pacific Standard Time (“PST”) and end

at 5:00 p.m. PST. The roundtable will also be available via webcast enabling individuals who cannot attend in person to watch the roundtable via the Internet in real time. The agenda and webcast information will be available before the roundtable on the USPTO's Roundtable 2 Web page www.uspto.gov/patent/laws-and-regulations/comments-public/notice-roundtables-and-request-comments-related-patent. On-line registration will be available from that Web page, and attendees may register at the door. Attendees are encouraged to register on-line before the roundtable.

Written Comments: For those wishing to submit written comments on the topics to be addressed by Roundtable 2, the deadline for receipt of those comments for consideration by the USPTO is January 18, 2017. Written comments should be sent by electronic mail message via the Internet addressed to 101Roundtable2@uspto.gov.

Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

1. Background

As the world's most innovative economy, the United States relies heavily on intellectual property to support economic growth and business development. The U.S. patent system is a critical piece of the nation's robust system of intellectual property rights. To obtain patent protection, the requirement of subject matter eligibility under 35 U.S.C. 101 must be satisfied. Over the past six years, the Supreme Court has issued a series of decisions—*Bilski*,¹ *Mayo*,² *Myriad*,³ and *Alice*⁴—that have significantly impacted patent eligibility law and continue to generate substantial public debate. These cases are briefly summarized below.

Bilski, decided in 2010, involved a business method for hedging risk.⁵ In analyzing patent eligibility, the Supreme Court recognized that section 101 specifies four independent categories of inventions or discoveries that are eligible for patent protection (processes, machines, manufactures, and compositions of matter), but judicial precedent provides three specific exceptions to patent eligibility for laws of nature, physical phenomena,

and abstract ideas.⁶ The Court rejected the view of the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) that the so-called “machine or transformation test” is the exclusive test for assessing patent eligibility of a process.⁷ Under that test, a process claim is patent eligible provided it is (1) tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing.⁸ The Court explained that although the machine or transformation test “is a useful and important clue,” it is “not the sole test for deciding whether an invention is a patent-eligible ‘process.’”⁹ The Court held that the claims at issue were invalid because they were directed to the unpatentable abstract idea of hedging risk in the energy market and added only token post-solution components, namely, use of well-known random analysis techniques to establish inputs.¹⁰ The Court observed that hedging is a long prevalent fundamental economic practice, and that allowing the patent claims “would pre-empt use of [risk hedging] in all fields” and “effectively grant a monopoly over an abstract idea.”¹¹ The Court, however, left open the possibility that at least some business methods are patent eligible.¹²

Following *Bilski*, the Supreme Court in *Mayo* addressed a method for optimizing drug dosages for treatment of autoimmune diseases in humans.¹³ The inventors discovered the relationship between the concentration of a metabolite in the blood following administration of the drug and the likelihood that the administered dosage would be ineffective or produce harmful side effects.¹⁴ The inventors obtained a patent claiming a method of determining whether a given dosage level is too low or too high based on the metabolite level.¹⁵

The Court held the claims to be patent ineligible.¹⁶ In analyzing the claims, the Court introduced a two-step framework for distinguishing patent ineligible concepts from patent eligible applications of those concepts.¹⁷ The first step is to consider whether the claims are directed to a judicially

recognized exception to patentability, *i.e.*, abstract ideas, laws of nature, or natural phenomena.¹⁸ If so, then the second question is “whether the claims do significantly more than simply describe these natural relations,” *i.e.*, whether additional elements considered separately or as an ordered combination “transform the nature of the claim” into “a patent-eligible application” of the judicial exception.¹⁹ Applying the first step of this framework to the claims at issue, the Court found that the claims were directed to a law of nature: The relationship between the concentration of a particular metabolite in the blood and the likelihood that a dosage of a drug will be ineffective or harmful.²⁰ Assessing the second step, the Court determined that the claims did not do “significantly more” than describe this natural relationship, *i.e.*, the additional elements considered separately and as an ordered combination did not “transform the nature of the claim” into “a patent-eligible application” of the judicial exception.²¹

At issue in *Myriad* was the patent eligibility of claims to isolated DNA (genes) associated with an increased risk of breast cancer, and synthetic DNA created from RNA known as complementary DNA (cDNA).²² The Supreme Court held that the isolated genes “fell squarely within the law of nature exception.”²³ The Court explained that discovering the location of the genes does not render the genes patent eligible, nor does the act of separating them from their surrounding genetic material.²⁴ While acknowledging that claims to a product “with markedly different characteristics from any found in nature” may be patent eligible,²⁵ the Court explained that *Myriad*'s claims to isolated genes lacked such characteristics because they do not rely on any chemical changes resulting from isolation, and are not even expressed in terms of chemical composition.²⁶ The Court did, however, rule that the claimed cDNAs were patent eligible because they differed from naturally occurring DNA by the absence of intron regions (*i.e.*, non-coding nucleotide sequences).²⁷

⁶ *Id.* at 601.

⁷ *Id.* at 604.

⁸ *Id.* at 602.

⁹ *Id.* at 604.

¹⁰ *Id.* at 612.

¹¹ *Id.* at 611–12.

¹² *Id.* at 606–07.

¹³ *Mayo*, 132 S. Ct. at 1294–95.

¹⁴ *Id.* at 1294.

¹⁵ *Id.*

¹⁶ *Id.* at 1305.

¹⁷ *Id.* at 1296–98; see *Alice*, 134 S. Ct. at 2355 (summarizing two-part test in *Mayo*).

¹⁸ *Id.* at 1296–97, 1293; see *Alice* 134 S. Ct. at 2355.

¹⁹ *Id.* at 1297–98; see *Alice* 134 S. Ct. at 2355.

²⁰ *Id.* at 1296.

²¹ *Id.* at 1297–98.

²² *Myriad*, 133 S. Ct. at 2112–13.

²³ *Id.* at 2117.

²⁴ *Id.* at 2117–18.

²⁵ *Id.* at 2117 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

²⁶ *Id.* at 2118.

²⁷ *Id.* at 2119.

¹ *Bilski v. Kappos*, 561 U.S. 593 (2010).

² *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, ___ U.S. ___, 132 S. Ct. 1289 (2012).

³ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, ___ U.S. ___, 133 S. Ct. 2107 (2013).

⁴ *Alice Corp. v. CLS Bank Int'l*, ___ U.S. ___, 134 S. Ct. 2347 (2014).

⁵ *Bilski v. Kappos*, 561 U.S. 593, 599 (2010).

Finally, in *Alice*, the Court reaffirmed the *Mayo* two-step framework and applied it to claims reciting a computer-implemented process, computer system, and computer readable medium for mitigating settlement risk.²⁸ Under step one of the framework, the Court concluded that the claims were directed to the abstract idea of intermediated settlement.²⁹ In assessing step two, the Court considered whether the claim elements, individually or as an ordered combination, “transform the nature of the claim’ into a patent-eligible application.”³⁰ The Court referred to the second step as “a search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”³¹ Looking at the claims at issue, the Court concluded that mere generic computer implementation does not transform the abstract idea into a patent-eligible invention.³² Thus, the court held the process claims, as well as the claims to the computer system and computer-readable medium, to be patent ineligible.³³

These cases continue to have a substantial effect on patent eligibility in the United States. On the one hand, they have overturned decades-old USPTO practice regarding patent eligibility of isolated genes, placing the United States at odds with the practices of major trading partners, including Europe.³⁴ On the other hand, the *Mayo* two-step test has generally raised the bar for patent eligibility in all fields of technology.

In the wake of these cases, the Federal Circuit has issued several decisions applying the Supreme Court test to a broad spectrum of subject matter, from the life sciences³⁵ to computer-related inventions (including business

methods).³⁶ Although most of the Federal Circuit decisions have held claims to be patent ineligible, several of the decisions have held claims to be patent eligible.³⁷ In addition, the USPTO has issued and updated guidance documents to aid the public and patent examiners in understanding how these cases apply to the patent examination process. In light of the changing landscape regarding subject matter eligibility in the United States, the USPTO is interested in inviting public discussion on these issues to help refine, if necessary, its guidance and to obtain views on the legal contours of subject matter eligibility.

2. Topics for Public Comment and Discussion At Roundtable 1: USPTO Subject Matter Eligibility Guidelines

The USPTO has issued a series of guidance documents and training examples to instruct examiners on how to apply section 101 during examination, which incorporates previously received public input.³⁸ The most recent documents include the May 2016 Life Sciences examples and three memoranda to the Patent Examining Corps: The May 4, 2016 memorandum titled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection”; the May 19, 2016 memorandum titled “Recent Subject Matter Eligibility Decisions (*Enfish, LLC v. Microsoft Corp.* and *TLI Communications LLC v. A.V. Automotive, LLC*); and the July 14, 2016 memorandum titled “Recent Subject Matter Eligibility Rulings (*Rapid Litigation Management v. CellzDirect* and *Sequenom v. Ariosa*).” The USPTO remains interested in feedback from interested stakeholders or members of the public to improve the USPTO’s subject matter eligibility guidance and training examples, and is already

accepting comments on those documents.³⁹ For discussion at Roundtable 1, the Office is particularly seeking views and comments on the following:

1. Suggestions to how to improve the Office’s subject matter eligibility guidance, particularly the three recent memoranda discussed above;

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;

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; and

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

3. Topics for Public Comment and Discussion At Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

The public is invited to submit comments on any topics related to patent subject matter eligibility under 35 U.S.C. 101 that they deem relevant. This roundtable event is not seeking additional input on the examiner guidance and training examples referenced above. Instead, the USPTO is seeking to promote conversation on how the current section 101 jurisprudence is evolving; what the optimum legal contours for patent eligibility should be; and how best to achieve these goals. Specifically, the USPTO would like to facilitate discussion and create a public record with relevant information on the actual or perceived impact of existing law on particular technology areas, and the effects on investment in research and development, and innovation generally. The USPTO would appreciate comments on whether developments in patent-eligibility law should be left primarily to the courts or whether other administrative initiatives are desirable. In addition, the USPTO would appreciate comments on whether legislative changes are desirable and, if so, views on the elements of such changes.

³⁹ May 2016 Subject Matter Eligibility Update, 81 FR 27381 (May 6, 2016); available at <https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10724.pdf>.

²⁸ *Alice*, 134 S. Ct. at 2355, 2352.

²⁹ *Id.* at 2355–57.

³⁰ *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1294).

³¹ *Id.* (internal quotation marks omitted).

³² *Id.* at 2357–60.

³³ *Id.* at 1260.

³⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 O.J. (L 213) 18 (Art. 5(2) provides “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”).

³⁵ See, e.g., *In re Roslin Inst.(Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014); *Univ. of Utah Research Found. v. Ambray Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *Genetic Techs., Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016); *Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

³⁶ See, e.g., *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014); *Versata Dev. Group, Inc. v. SAP Am., Inc.*, 793 F.3d 1306 (Fed. Cir. 2015); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016); *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016); *McRO, Inc. dba Planet Blue v. Bandai Namco Games Am. Inc.*, No. 2015–1080, 2016 WL 4896481 (Fed. Cir. September 13, 2016).

³⁷ *DDR Holdings*, 773 F.3d 1245; *Enfish*, 822 F.3d 1327; *Bascom*, 827 F.3d 1341; *Rapid Litigation*, 827 F.3d 1042; *McRO*, 2016 WL 4896481.

³⁸ See, e.g., 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 FR 74,618 (Dec. 16, 2014); July 2015 Update on subject Matter Eligibility, 80 FR 45,429 (July 30, 2015); May 2016 Subject Matter Eligibility Update, 81 FR 27,381 (May 6, 2016); see also additional guidance materials available at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>.

To facilitate the launch of this data-gathering exercise, the USPTO is particularly interested in receiving views and comments on questions presented below. However, the tenor of the questions should not be taken as an indication that the USPTO is predisposed to any particular views, positions, or actions. The USPTO also invites the public to share their views and insights on other aspects of patent subject matter eligibility that are not addressed in the questions.

Impact of Judicial Interpretation of Section 101

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.

Statutory Categories of Patentable Subject Matter

To be eligible for patent protection, an invention must comply with section 101 of the Patent Act, which limits entitlement to a patent to "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter." The four categories of invention enumerated in the statute—process, machine, manufacture, and composition of matter—exhaust the possible types of inventions for which a patent may be obtained.

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.

Exceptions to Patentable Subject Matter

The Supreme Court has articulated three exceptions to patent eligibility under section 101: Laws of nature, natural phenomena, and abstract ideas.

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.

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.

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.

6. Other jurisdictions, *e.g.*, Europe and Japan, provide examples of subject matter that does not qualify as an invention or discovery for purposes of patent eligibility. For example, in Europe, scientific theories, methods for performing mental acts, computer programs per se, and presentations of information are not regarded as inventions.

- 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.

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.

Patentable Subject Matter in the Life Sciences

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.

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.

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.

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

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)?

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.

Process Patents and the Machine or Transformation Test

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

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?

Patentability of Business Methods

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

Patentability of Software/Computer-Related Inventions

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

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.

Roundtable 1: USPTO Subject Matter Eligibility Guidelines

Requests to Speak: Individuals interested in speaking at Roundtable 1 must complete the on-line registration

no later than October 26, 2016, and include their name, contact information (telephone number and email address), the organization(s) the person represents, if any, the topics they wish to address, and the approximate length of the presentation. To ensure a balanced array of views, there is the possibility that not all persons who wish to make a presentation will be able to do so given time constraints; however, the USPTO will do its best to try to accommodate as many persons as possible. Selected speakers will be notified thereafter. However, all members of the public are encouraged to submit written comments by electronic mail message via the Internet addressed to 2014_interim_guidance@uspto.gov.

The public is invited to speak at Roundtable 1 by appearing, in person, at the USPTO in Alexandria, Virginia or one of the following USPTO Regional Offices: the Midwest Regional Office, 300 River Place Drive, Suite 2900, Detroit, Michigan 48207; The Rocky Mountain Regional Office, 1961 Stout Street, Denver, Colorado 80294; the West Coast Regional Office, 26 S. Fourth Street, San Jose, California 95113; or the Texas Regional Office, 207 South Houston Street, Suite 159, Dallas, Texas 75202. Individuals requesting to speak at one of the aforementioned Regional Offices will be provided with the opportunity to speak at the roundtable and engage with USPTO representatives in Alexandria, Virginia in real time. If requesting to speak at this roundtable, please check the appropriate location when completing the on-line registration.

Public Availability of Transcripts and Public Comments: The transcript of Roundtable 1 and the written comments submitted on the USPTO's subject matter eligibility guidance and training examples will be made available for public inspection upon request at the Office of the Commissioner for Patents, located at 600 Dulany Street, Madison East Building, Tenth Floor, Alexandria, Virginia and via address: <http://www.uspto.gov>.

Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

Requests to Speak: Individuals interested in speaking at Roundtable 2 must complete the on-line registration no later than November 14, 2016, and include their name, contact information (telephone number and email address), the organization(s) the person represents, if any, the topics they wish to address, and the approximate length of the presentation. To ensure a balanced array of views, there is the

possibility that not all persons who wish to make a presentation will be able to do so given time constraints; however, the USPTO will do its best to try to accommodate as many persons as possible. Selected speakers will be notified thereafter. However, all members of the public are encouraged to submit written comments by electronic mail message via the Internet addressed to 101Roundtable2@uspto.gov.

The public is invited to speak at Roundtable 2 by appearing, in person, at Stanford University, Stanford, California or at one of the following USPTO Regional Offices: The Midwest Regional Office, 300 River Place Drive, Suite 2900, Detroit, Michigan 48207; the Rocky Mountain Regional Office, 1961 Stout Street, Denver, Colorado 80294; or the Texas Regional Office, 207 South Houston Street, Suite 159, Dallas, Texas 75202. Individuals requesting to speak at one of the aforementioned Regional Offices will be provided with the opportunity to speak at the roundtable and engage with USPTO representatives in Stanford, California in real time. If requesting to speak at this roundtable, please check the appropriate location when completing the on-line registration.

Public Availability of Transcripts and Public Comments: The transcript of Roundtable 2 and the written comments submitted will be made available for public inspection upon request at the Office of Policy and International Affairs in the Executive Library located at 600 Dulany Street, Madison West Building, Tenth Floor, Alexandria, Virginia, 22314, telephone number 571-272-9300 and via the Roundtable 2 Web page www.uspto.gov/patent/laws-and-regulations/comments-public/notice-roundtables-and-request-comments-related-patent.

Special Accommodations for Roundtables 1 and 2: The roundtables will be physically accessible to people with disabilities. Individuals requiring accommodation, such as sign language interpretation or other ancillary aids, should communicate their needs to Elizabeth Shaw, by telephone at 571-272-9300, by email at elizabeth.shaw2@uspto.gov, or by postal mail addressed to: Mail Stop OPIA, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313-1450, ATTN: Elizabeth Shaw, at least seven (7) business days prior to the roundtable.

Dated: October 11, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016-24888 Filed 10-14-16; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA-2015-0015]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 16, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Recreation Area and Visitor Center Visitor Comment Cards; OMB Control Number 0710-XXXX.

Type of Request: New.
Number of Respondents: 45,000.
Responses per Respondent: 1.
Annual Responses: 45,000.
Average Burden per Response: 5 minutes.

Annual Burden Hours: 3,750.
Needs and Uses: The information collection requirement is necessary to understand and determine the satisfaction of recreation visitors to US Army Corps of Engineers managed recreation areas.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.
OMB Desk Officer: Ms. Jasmeet Sehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Sehra, DoD Desk Officer, at Oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

**APPENDIX II:
SPEAKERS AT ROUNDTABLE 2**

The USPTO offers its special thanks to all of the individuals and organizations who participated in our Roundtable on the Legal Contours of Patent Eligible Subject Matter. Those participants are listed below with their affiliated organization.

A recording of the roundtable is available for viewing at:
<https://livestream.com/uspto/RoundatbleStanford>

The full transcript of the roundtable is available at:
<https://www.uspto.gov/sites/default/files/documents/RT2%20Transcript%20FINAL.pdf>

The agenda for the roundtable and presentations by participants at the roundtable are available at:
<https://www.uspto.gov/patent/initiatives/patent-subject-matter-eligibility-roundtable-2>

Name	Organization	Organization Abbreviation
Robert Armitage	IP Strategy & Policy	
Dorothy Auth	New York Intellectual Property Law Association	NYIPLA
Steve Bachmann	Bachmann Law Group	
Frank Bernstein	Singularity LLP	
Steve Chiang*	RPX Corporation	
Colleen Chien*	Santa Clara University Law School	
Frank Cullen	U.S. Chamber of Commerce	
Jeffrey H. Dean	Amazon.com	
Robin Feldman*	University of California Hastings	
Michelle Fisher	Blaze Mobile	
Jason Gardner	Marqeta, Inc.	
Patrick Giblin	451 Degrees	
Sharon Israel*	American Intellectual Property Law Association	AIPLA

Benjamin Jackson*	Myriad Genetics, Inc.	
David Jones	Microsoft	
Jennifer Kuhn*	Mattersight Corporation	
Mark Lemley	Stanford University	
Diane Lettelleir	J.C. Penney Corporation, Inc.	
Konstantin M. Linnik	Nutter, McClennen & Fish LLP	
Allen Lo	Google Inc.	
Peter Menell*	University of California Berkeley	
Daniel Nazer	Electronic Frontier Foundation	EFF
Kevin Noonan	McDonnell Boehnen Hulbert & Berghoff LLP	MBHB
Chirag Patel	Holzer Patel Drennan	
James Reed*	Squire Patton Boggs	
Kim Rubin	Patent Agent	
Julie Samuels	Engine Advocacy	Engine
Hans Sauer	Biotechnology Innovation Organization	BIO
Kim Schmitt	Intel	
Wayne Sobon	Wayne Sobon Consulting	
Peter Su*	Dentons US LLP	
Eric Sutton	Oracle	
Neil Thomas	RelaxExpress.net	
Marian Underweiser	IBM	
Lee Van Pelt*	University of California Berkeley	

* The views expressed by these speakers are solely attributed to the speakers and do not reflect the views of their affiliated organizations.

APPENDIX III:
WRITTEN COMMENTS ON ROUNDTABLE 2

The USPTO wishes to thank all individuals and organizations who submitted comments in response to our Federal Register Notice. Those commenters are listed below.

The written comments are available at:

<https://www.uspto.gov/patent/initiatives/patent-subject-matter-eligibility-roundtable-2>

Associations & Groups	Abbreviation
American Bar Association Section of Intellectual Property Law (Comments received on Jan. 18, 2017 and Mar. 28, 2017)	ABA-IPL
American Intellectual Property Law Association (Comments received on Jan. 18, 2017 and May 12, 2017)	AIPLA
Participants in the Conference on <i>Patenting Genes, Natural Products and Diagnostics: Current Status and Future Prospects</i> , The Banbury Center, Cold Spring Harbor, NY, Nov. 9-11, 2016	Banbury Participants
Coalition for 21 st Century Medicine	
Electronic Frontier Foundation	EFF
Engine Advocacy	Engine
Entertainment Software Association	ESA
Houston Intellectual Property Law Association	HIPLA
Intellectual Property Owners Association	IPO
Internet Association and the Computer & Communications Industry Association	IA and CCIA
R & D Companies (InterDigital, Fallbrook Technologies Inc., Digimarc Corporation)	R & D Companies
Pharmaceutical Research and Manufacturers of America	PhRMA
Public Knowledge	
Software and Information Industry Association	SIIA

Companies
Digimarc Corporation
Google Inc.
IBM
Marqeta
Mozilla
Individuals
Robert Armitage, IP Strategy & Policy
Rajendra K. Bera,* Acadinnet Education Services India Private Limited
Colleen Chien,* Santa Clara University Law School and Arti Rai,* Duke Law School
Steven Pollinger,* McKool Smith and Craig N. Tolliver,* McKool Smith
Martin Snyder,* Main Sequence Technology, Inc.
Bruce D. Sunstein,* Sunstein Kann Murphy & Timbers LLP
David O. Taylor,* Dedman School of Law, Southern Methodist University

* The views expressed by these commenters are solely attributed to the commenters and do not reflect the views of their affiliated organizations.

APPENDIX IV:
LEGISLATIVE RECOMMENDATIONS

Public proposals and measures to amend § 101 of the Patent Act are reproduced below. Original versions of these recommendations are available at:

<https://www.uspto.gov/patent/initiatives/patent-subject-matter-eligibility-roundtable-2>

Intellectual Property Owners Association (IPO) Proposal to Amend § 101	
§ 101 Amendments	<p>101(a) ELIGIBLE SUBJECT MATTER</p> <p>Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention thereof, subject only to the exceptions, conditions, and requirements set forth in this Title.</p> <p>101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY</p> <p>A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.</p> <p>101(c) SOLE ELIGIBILITY STANDARD</p> <p>The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112 of this Title, the manner in which the claimed invention was made or discovered, or the claimed invention's inventive concept.</p>

**American Intellectual Property Law Association (AIPLA)
Proposal to Amend § 101 (May 12, 2017)**

<p>§ 101 Amendments</p>	<p>101(a) ELIGIBLE SUBJECT MATTER</p> <p>Whoever invents or discovers any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.</p> <p>101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY</p> <p>A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.</p> <p>101(c) SOLE ELIGIBILITY STANDARD</p> <p>The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.</p>
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**American Bar Association – Section of Intellectual Property Law
Proposal to Amend § 101 (Mar. 28, 2017)**

<p>§ 101 Amendment</p>	<p>§ 101. Conditions for patentability: eligible subject matter.</p> <p>(a) Eligible Subject Matter.- Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.</p> <p>(b) Exception.- A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.</p>
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**New York Intellectual Property Law Association (NYIPLA)
Proposal to Amend § 101**

§ 101 Amendment	<p>35 U.S. Code § 101 - Inventions patentable</p> <p>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. A claim complying with this section may recite a practical application of a law of nature, abstract idea or a natural phenomena but may not claim or preempt a law of nature, abstract idea or natural phenomenon.</p>
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**Houston Intellectual Property Law Association (HIPLA)
Proposal to Amend § 101**

§ 101 Amendments	<p>35 U.S. Code § 101 - Eligible Subject Matter</p> <p>101(a) A claimed invention directed to any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, shall be eligible for patenting by its inventor.</p>
Related Amendments	<p>100(b)(1) The term “process” means process, art, method, or algorithm, and includes any use of a known process, machine, system, computer, manufacture, composition of matter, or material, regardless of physical embodiment or means of implementation.</p> <p>100(b)(2) The term “machine” means a system or apparatus, made by human agency, regardless of physical embodiment or means of implementation.</p> <p>[...]</p> <p>100(k) A “law of nature” means an express statement of a physical, causal relationship governing the natural properties or behaviors of physical objects, and that is recognized by the relevant scientific community.</p> <p>100(l) A “natural product” means a material, substance, composition as entirely as it appears in nature without any processing by human agency, and excludes any purified, simulated, copied, isolated, replicated product.</p> <p>100(m) An “abstract idea” means a purely mental concept that is incapable of any physical embodiment and excludes any process performed by a computer program.</p>

**Robert Armitage
Proposal to Amend § 101**

<p>§ 101 Amendments</p>	<p>(1) Strike section 101 of title 35, United States Code, and insert:</p> <p>§ 101. Right to patent inventions; eligible subject matter</p> <p>(a) RIGHT TO A PATENT; USEFUL ARTS DEFINED.—An inventor shall be entitled to a patent for an invention that contributes to the useful arts, absent a finding that one or more conditions or requirements under this title have not been met. For the purposes of this section, the useful arts refer to all fields of technology, without restriction or limitation.</p> <p>(b) ELIGIBLE CATEGORIES; PRACTICAL UTILITY REQUIRED.—Subject matter may not be patented unless claimed in terms of a practically useful process, machine, manufacture, or composition of matter, or a practically useful improvement thereto.</p> <p>(c) ELIGIBLE SUBJECT MATTER LIMITATION; RELATIONSHIP TO ABSTRACT CONCEPTS.— For the purposes of this section, the discovery of a natural law or phenomenon or other abstract concept shall be deemed not to contribute to the useful arts. Notwithstanding the preceding sentence, eligibility for patenting under this section shall not be negated because a claimed invention is based upon or otherwise relates to an abstract concept.</p> <p>(d) ADDITIONAL LIMITATIONS AND EXCEPTIONS BARRED.—No additional limitations on or exceptions to eligibility for patenting shall exist or may be implied for a claimed invention that meets the requirements for eligibility under this section.</p>
<p>Related Amendments</p>	<p>(2) The section heading for section 101 of title 35, United States Code, is amended to read as follows: “§ 101. Right to patent inventions; eligible subject matter”</p> <p>(3) In section 102 of title 35, United States Code, strike “A person shall be entitled to a patent unless” and insert “A patent for a claimed invention may not be obtained if”</p> <p>(4) Section 287(c) of title 35, United States Code, and Sections 14 and 33 of the Leahy-Smith America Invents Act, Public Law 112-29 (September 16, 2011), are repealed.</p> <p>(5) In Section 18 of the Leahy-Smith America Invents Act, for any claimed invention for which the amendments made under this subsection to section 101 of title 35, United States Code, apply— (A) the term “technological invention” shall mean a claimed invention that is eligible for patenting under amended section 101; (B) the regulations promulgated pursuant to paragraph (d)(2) shall be inapplicable; and (C) the rule of construction under subsection (e) shall be inapplicable.</p>

**Benjamin Jackson
Proposal to Amend § 101**

**§ 101
Amendments**

35 U.S.C. §101(a): Inventions Patentable.
Except for subject matter expressly excluded by sub-section 101(c) of this title, and subject to the requirements of sub-section 101(b) and sections 102, 103 and 112 of this title, whoever invents or discovers any subject matter, including but not limited to any process, machine, manufacture, or composition of matter, or any improvement thereof, may obtain a patent therefor.

§101(b): **[[no text provided, just a placeholder for a utility requirement]]**

§101(c): Excluded Subject Matter.

A patent may not be issued on any application in which any functional embodiment of any claim is any of the following per se:

- (i) any process in which every step can be readily performed by an unaided human mind of average intelligence;
- (ii) a statement of a direct, natural cause and effect relationship;
- (iii) any event or process acting solely according to or under the influence of any subject matter in (ii), unaltered by human activity;
- (iv) any undivided element, mineral or organism entirely unmodified from its intact natural state;
- (v) a discrete, natural unit of any subject matter in (iii) whose function is unaltered from its natural state;
- (vi) an entire human organism, any portion thereof comprising any portion of a central nervous system ,or processes for producing either;
- (vii) any process for modifying the germ-line genetic make-up of any human organism;
- (viii) any process for modifying the genetic make-up of any non-human animal wherein such modification is likely to cause such animal suffering without any substantial medical benefit to man or animal; or
- (ix) any product or process relating to the use of any embryo comprising a human cell for industrial or commercial purposes;
- (x) surgical procedures as defined in §287(c);
etc.

Participants in the Conference on *Patenting Genes, Natural Products and Diagnostics: Current Status and Future Prospects*, The Banbury Center, Cold Spring Harbor, NY, Nov. 9-11, 2016

Proposed Measures to Address Patent Subject Matter Eligibility

Proposed Measures	<ol style="list-style-type: none">1. Clarify that patent protection shall be available for inventions in all fields of technology and better conform U.S. patent law with internationally accepted norms of patentability. To this end, [...] that Congress enact a substitute requirement limiting patent eligibility to technological inventions, i.e., inventions contributing to the technological arts. Such a measure would codify the standard set out in the concurring opinion in <i>Kappos v. Bilski</i> and foster greater harmony between U.S. patent law and the patent law in Europe.2. Enact a substitute, statutory eligibility standard that overrules the “implicit exception” and the two-part test used to implement it. The Court’s rationale for imposing a judicial exception fails to take full account of the collective effect of the set of statutory requirements that limit the availability of conceptual patents—and that preclude the possibility that patents can either cover or preclude access to natural materials, laws, or phenomena. Maintaining a judicial exception is, therefore, unnecessary for any articulated constitutional or policy reason.3. Exempt from patent infringement research uses of patented inventions where the exempted experimentation is limited to activities to better understand or improve the patented subject matter. Such an exemption should be limited and targeted in a manner that is consistent with the 2006 recommendation of the National Academies for doing so. This clarification that research performed on patented inventions is non-infringing would assure that no vestige remains of the Supreme Court’s justification for imposing a judicial eligibility exception.
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