

**PROPOSED AMENDMENTS TO PATENT ELIGIBLE  
SUBJECT MATTER UNDER 35 U.S.C. § 101**

1. **ISSUE:** Whether the IPO should adopt a resolution supporting an amendment to 35 U.S.C. § 101 to restore the scope of patent eligible subject matter that has been restricted by the Supreme Court’s decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice*.

2. **PROPOSED RESOLUTION:**

*RESOLVED*, that IPO supports legislation to amend 35 U.S.C. § 101 as follows:

**101(a) ELIGIBLE SUBJECT MATTER**

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.

**101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY**

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.

**101(c) SOLE ELIGIBILITY STANDARD**

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.

3. **BACKGROUND AND PROPOSAL:**

**A. Executive Summary**

The IPO 101 Task Force proposes legislation to address recent Supreme Court decisions—*Bilski v. Kappos*,<sup>1</sup> *Mayo Collaborative Servs. v. Prometheus Labs.*,<sup>2</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>3</sup> and *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*,<sup>4</sup> (collectively, “the 101 Decisions”)—that have dramatically narrowed the scope of patent protection for life sciences and

<sup>1</sup> 561 U.S. 593 (2010).

<sup>2</sup> 566 U.S. \_\_\_, 132 S. Ct. 1289 (2012).

<sup>3</sup> 569 U.S. \_\_\_, 133 S. Ct. 2107 (2013).

<sup>4</sup> 573 U.S. \_\_\_, 134 S. Ct. 2347 (2014).

software technology by significantly expanding the judicially-created exceptions to patent-eligible subject matter. The proposed legislation will:

- (a) reverse the recent Supreme Court rulings and restore the scope of subject matter eligibility to that intended by Congress in the passage of the Patent Act of 1952 (“the 1952 Act”);
- (b) define subject matter eligibility more clearly and in a technology-neutral manner;
- (c) require an evaluation of subject matter eligibility for the invention as a whole; and
- (d) simplify the subject matter eligibility analysis for the Patent Office, courts, patent applicants, patentees, and the public by prohibiting consideration of “inventiveness” and patentability issues under 35 U.S.C. §§ 102, 103, and 112 in the § 101 analysis.

The analysis developed in the 101 Decisions is contrary to Congressional intent, too restrictive, technologically incorrect, unsound from a policy standpoint, and bad law. After the *Alice* decision, the Federal Circuit quoted from *Bilski* that “In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”<sup>5</sup> Further, the Federal Circuit has recently recognized 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*) might discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.”<sup>6</sup> “[I]t is unsound to have a rule that takes [certain] inventions . . . out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.”<sup>7</sup>

In his dissent in *Diamond v. Diehr*, Justice Stevens stated that “the cases considering the patentability of program-related inventions do not establish rules that enable a conscientious patent lawyer to determine with a fair degree of accuracy which, if any, program-related inventions will be patentable.”<sup>8</sup> Today, 44 years later, the same criticism applies.

The proposed legislation addresses these concerns.

## **B. Analysis**

### **1. Background**

This section discusses the evolution of patent eligibility from the passage of the 1952 Act through subsequent interpretation by the U.S. Supreme Court. As will be appreciated, the issues faced today arise from the Court’s attempts to reconcile the 19<sup>th</sup> century judicial decisions on patentability with the statutory language of § 101. Judicial reasoning has been strained and, as a result, a claimed process may not be a “process” and a claimed product may not be a “product” under the statute despite involving or resulting from human activity. Similarly, inventions that can only be practically implemented by computer systems are deemed to be nothing more than mental steps performed by humans.

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<sup>5</sup> *Allvoice Developments US, LLC v. Microsoft Corp.*, 612 Fed. Appx. 1009 (Fed. Cir. 2015) (quoting *Bilski*, 561 U.S. 593, 601 (2010) and *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)).

<sup>6</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286 (Fed. Cir. 2015) (order denying for request for en banc hearing) (Dyk, J., concurring).

<sup>7</sup> *Id.* (Lourie, J., concurring).

<sup>8</sup> *Diamond v. Diehr*, 450 U.S. 175, 219 (1981) (Stevens, J., dissenting).

The Court’s prime justification for the judicial exceptions to section 101 is that a patent claim should not wholly preempt a natural law, phenomenon, or product or an abstract idea, and thereby foreclose future innovation. To substantiate its reasoning the Court has often referred to fundamental laws of nature such as  $E=mc^2$ , implying a broad impact on future development should *any* natural phenomena or abstract idea be patented. Yet at the same time, the Court has held that that the prohibition cannot be avoided even when a claim is narrowly limited to a specific technological environment.<sup>9</sup> This is precisely how inventors implement inventions that make use of natural laws—by applying them to specific technological fields. Thus, the Court’s framework is entirely inconsistent with the very nature of technological innovation.

Before 1952, U.S. patent law relied on an arbitrary and subjective “invention” standard of patentability. Courts routinely invalidated patents for lacking an “inventive” aspect, without ever defining what makes something “inventive.”<sup>10</sup> In part as a reaction to this subjective “invention” standard, Congress passed the Patent Act of 1952 with the intent that the scope of patent-eligible subject matter be broad and that patentability would be determined on objective basis. This approach was codified in section 103, which bases patentability on non-obviousness, using the objective standard of a person of ordinary skill in the art. Concomitantly, Congress precluded the concept of “inventiveness” from the eligibility analysis.<sup>11</sup>

Since then, the Supreme Court’s judicial exceptions have narrowed Congress’s intended scope of subject matter eligibility by importing into the eligibility analysis the very same approach that Congress intended to exclude. Most recently, the 101 Decisions have paved the way for a return to the subjective “inventiveness” approach, conflating aspects of 35 U.S.C. §§ 102, 103, and 112 with the § 101 analysis and expanding the “inventive concept” requirement even beyond the old “invention” standard.

The results have been dramatic. The lower courts have followed the letter and apparent spirit of the 101 Decisions to their full extent, sometimes despite misgivings of some jurists.<sup>12</sup>

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<sup>9</sup> *Bilski*, 561 U.S. at 610.

<sup>10</sup> See *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1850) (“[F]or unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skilful mechanic, not that of the inventor.”); *McClain v. Ortmyer*, 141 U.S. 419, 427 (1891) (“The truth is the word [invention] cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not.”); *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885) (invention is “[t]he creative work in the inventive faculty.”); *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1882) (invention is “A substantial invention or discovery.”); *Potts v. Craeger*, 155 U.S. 597, 608 (1895) (invention is the “Exercise of the inventive faculty the creative faculty, inventive skill, or inventive effort.”); *Cuno Eng’g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941) (invention requires the “flash of creative genius.”); *Thurber Corp. v. Fairchild Motor Corp.*, 269 F.2d 841, 849 (5th Cir. 1959) (Invention is “[s]omething new, unexpected, and exciting.”).

<sup>11</sup> “[T]he terms invent, inventor, inventive, and the like are unrelated to deciding whether the statutory requirements for patentability under the 1952 Act have been met. . . . Terms like ‘inventive application’ and ‘inventive concept’ no longer have any useful place in deciding questions under the 1952 Act, notwithstanding their universal use in cases from the [19<sup>th</sup>] century and the first half of [the 20<sup>th</sup>].” *In re Bergy*, 596 F.2d at 961 (Rich J.).

<sup>12</sup> See *Synchronoss Techs., Inc. v. Dropbox Inc.*, No. 16-cv-00119-HSG (N.D. Cal. Dec. 22, 2016) (“This Court agrees with those judges who have observed that even post-*Enfish*, the *Mayo/Alice* test provides limited practical guidance for distinguishing software and computer patents that are valid under § 101 from those that are not.”); *Amdocs*, 2016 WL 6440387, at \*4 (“[A] search for a single test or definition [of what an ‘abstract idea’ encompasses] in the decided cases concerning § 101 from this court, and indeed from the Supreme Court, reveals that at present there is no such single, succinct, usable definition or test.”); *Intellectual Ventures I LLC*, 838 F.3d at 1329 (describing the “semantic gymnastics” entailed in applying the *Mayo/Alice* test to software patents) (Mayer, J., concurring); *BASCOM Glob. Internet Servs.*, 827 F.3d at 1352, 1354 (“I have come upon no guide to when a claim crosses the boundary between unacceptable abstractness and acceptable specificity.”) (Newman, J., concurring); *Device Enhancement LLC v. Amazon.com, Inc.*, 2016 WL 2899246, at \*7 (D. Del. May 17, 2016) (discussing the “still difficult-to-discern requirements of the *Alice* analysis,” and the resulting “difficult exercise” under § 101);

Congress intended the scope of patent eligible subject matter to be broad

Patent subject matter eligibility is governed by 35 U.S.C. § 101, which has been unamended since passage of the 1952 Act and includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” Congress intended § 101 to be broadly construed, as is evident both in the language of the statute and accompanying commentary.

The plainest and clearest evidence that Congress intended patent eligible subject matter to be broad in scope is in the House and Senate Reports on the revisions to Title 35. When discussing § 101 and patentability, both state,

A person may have “invented” a machine or a manufacture, *which may include anything under the sun that is made by man*, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.<sup>13</sup>

The same emphasized language was used in Senate hearings by P.J. Federico who, along with Judge Giles Rich, was a principal architect of the 1952 Act.<sup>14</sup> The Supreme Court acknowledged this intent in *Diehr*, stating “we may not be unmindful of the Committee Reports accompanying the 1952 Act which inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”<sup>15</sup> This language reflects the foundational principle that human activity to “make” something is the touchstone of eligibility.

The courts have affirmed that the words used in § 101 manifest Congress’s intent for a broad scope of patent eligible subject matter. For example, the Supreme Court itself observed that “[i]n choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”<sup>16</sup> Judge Rader, in his opinion in *CLS Bank Int’l v. Alice Corp.*, observed that the additions to § 100 of the 1952 Act are also evidence of Congress’ intent that patentable subject matter should be broad in scope:

The 1952 Act shows that the “primary significance” of adding Section 100(b) was to make clear that a method was not “vulnerable to attack, on the ground of not being within the field of patentable subject matter, merely because it may recite steps conventional from a procedural standpoint and the novelty resides in the recitation of a particular substance, which is old as such, used in the process.”<sup>17</sup>

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*Ameranth, Inc. v. Genesis Gaming Solutions, Inc.*, 11-cv-00189 AG (RNBx) (C.D. Cal. Jan. 1, 2015) (“True, it is difficult to understand the difference between (1) a claim “directed” to an abstract idea but saved by an “inventive concept,” and (2) a patent not “directed” to an abstract idea in the first place, but that nonetheless can be said to “embody, use, reflect, rest upon, or apply” an abstract idea. *Alice*, 134 S. Ct. at 2354. But in patents, no less than all other areas of the law, Courts must do their best to follow Supreme Court rulings, no matter how unsatisfying.”).<sup>13</sup> S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952) (emphasis added).

<sup>14</sup> 1951 Hearings at 37; see S. Rep. No. 82-1979, at 5 (stating the same principle: so long as the conditions of patentability are met, anything made by man is patentable).

<sup>15</sup> *Diehr*, 450 U.S. at 182.

<sup>16</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>17</sup> 717 F.3d 1269, 1295 (Fed. Cir. 2013) (Rader J., *dissenting in part, concurring in part*) (citing P.J. Federico’s *Commentary on the New Patent Act*, reprinted in 75 J. Pat. & Trademark Office Soc’y 161, 177 (1993)); see S. Rep. No. 82-1979, at 17 (“The ... definition clarifies the status of processes or methods which involve merely the new use of a known process, machine, manufacture, composition of matter, or material; they are processes or methods under the statute and may be patented provided the conditions of patentability are satisfied.”).

[T]he 1952 Act ...also added the words “or discovered” to the definition of “invention” in Section 100(a). By definition, Congress made it irrelevant whether a new process, machine, and so on was “discovered” rather than “invented.”<sup>18</sup>

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One final point confirming the breadth of Section 101 is the 1952 Act’s deliberate decision to place the substantive requirement for “invention” in Section 103.<sup>19</sup>

Finally, Judge Rader noted that “[T]he central thrust of the 1952 Act removed ‘unmeasurable’ inquiries into ‘inventiveness’ and instead supplied the nonobviousness requirement of Section 103.”<sup>20</sup> This was in concert with how Judge Rich himself explained the problems with such inquiries:

It has generally been stated to be the law that, in addition to being new and useful, an invention, to be patentable, must involve "invention." Merely to state that proposition, in the absence of an initiation into the mysteries, sounds ridiculous.

A neophyte might well ask, "What do you mean, an invention must involve invention?" The sophisticates would answer saying, "Invention,' the Supreme Court has held 'cannot be defined. It is 'that impalpable something' which you must have to get a patent. Experienced patent lawyers, the Patent Office, and the courts understand - what it means, only they never agree."

The various meaningless phrases which have been used to express this essential mystery – something akin to a religious belief – are familiar to everyone:

Patentable novelty, or simply patentable invention  
Exercise of the inventive faculty, the creative faculty,  
inventive skill, or inventive effort.  
The creative work in the inventive faculty.  
A substantial invention or discovery.  
The flash of creative genius.<sup>21</sup>

Thus, Rich and Federico's solution was to rearticulate the vagaries of these judicially created formulations in a new § 103, removing them entirely from the purview of § 101:

With respect to what *used* to be called the requirement of "invention" –and the use of the past tense in referring to it cannot be too strongly urged –the 1952 act did three things:

1. *It put the requirement into the statutes for the first time, in section 103.* The "sufficiently useful and important" clause in RS. 4893 never seems to have been regarded as the true basis for the requirement of "invention," which was treated as the creation of the courts. Though one may call section 103 "codification" it took a case law doctrine, expressed in hundreds of different ways, and put it into statutory language in a single

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*; see also *Dann v. Johnston*, 425 U.S. 219, 225-26 (1976) (explaining that although “an exercise of the inventive faculty” had been used as a judicial test, “it was only in 1952 that Congress, in the interest of uniformity and definiteness, articulated the requirement in a statute, framing it as a requirement of ‘nonobviousness.’” (internal quotation marks and footnote omitted)). The official “Revision Notes” state that § 103 was intended to be the basis for “holding ...patents invalid by the courts[] on the ground of lack of invention.” S. Rep. No. 82-1979, at 18.

<sup>21</sup> Giles Rich, *The Principles of Patentability*, 43 J. Pat. & Trademark Office Soc’y 75-91 (Feb. 1960), reprinted from 28 Geo. Wash. U. L. Rev. 393-407 (Jan. 1960) (internal citations omitted).

form approved by Congress. In such form it became law superior to that which may be derived from any prior court opinion.

2. *The Patent Act of 1952 expresses this prerequisite to patentability without any reference to "invention" as a legal requirement.* Nowhere in the entire act is there any reference to a requirement of "invention" and the drafters did this deliberately in an effort to free the law and lawyers from bondage to that old and meaningless term. The word "invention" is used in the statute only to refer to the thing invented. That is why the requirement of "invention" should be referred to, if at all, only with respect due to that which is dead.

3. *The act sets as the standard of patentability the unobviousness of the invention, at the time it was made, to a person having ordinary skill in the art.* Therefore, what we have today, and have had since January 1, 1953, is a requirement of unobviousness, rather than a requirement of "invention." (It is assumed, of course, that the invention is new and useful and has not run afoul of any statutory provisions such as a statutory bar.).<sup>22</sup>

It is unmistakable from these passages, particularly the statement that "what *used* to be called the requirement of "invention"—and the use of the past tense in referring to it cannot be too strongly urged"—was to replace the entire body of law regarding "inventiveness" with the single test of non-obviousness, leaving § 101 entirely focused on statutory categories and the utility requirement.

As Rich and Federico explained in the 1952 Act "Revision Notes":

the refusal of patents by the Patent Office, and the holding of patents invalid by the courts, on the ground of lack of invention or lack of patentable novelty has been followed since at least as early as 1850. [Section 103] is added with the view that an explicit statement in the statute may have some stabilizing effect.<sup>23</sup>

However, the Supreme Court's *Alice* test has disrupted the *stabilizing effect* intended by Congress precisely by reintroducing the very same tests of "inventiveness" that the 1952 Act sought to eliminate.

We will return to the issue of "invention" in the next section in a discussion of the subsequent judicial interpretation of § 101.

*The Supreme Court's judicial exceptions have narrowed Congress's intended scope of subject matter eligibility, infusing the analysis with issues Congress intended to exclude.*

The difficulties stemming from the 101 Decisions are a result of significant expansion of judicial exceptions to patentability—laws of nature, abstract ideas, and natural phenomena—that themselves emerged from 19<sup>th</sup> century Supreme Court jurisprudence. In *Gottshalk v. Benson*, the Court summarized:

The Court stated in *MacKay Co. v. Radio Corp.*, 306 U.S. 86, 94, 40 USPQ 199, 202, that "While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." That statement followed the long-standing rule that "An idea of itself is not patentable." *Rubber-Tip Pencil Co. v. Howard*, 20 Wall. 498, 507. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; and these cannot be patented, as no one can claim in either of them an exclusive right." *LeRoy v. Tatham*, 14 How. 156, 175. Phenomena of nature, though just discovered, mental processes, abstract intellectual

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<sup>22</sup> *Id.* at 89 (italics in original, emphasis added).

<sup>23</sup> S. Rep. No. 82-1979, at 18 (emphasis added).

concepts are not patentable, as they are the basic tools of scientific and technological work. As we stated in *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130, 76 USPQ 280, 281, “He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”<sup>24</sup>

“[T]he concern that drives this exclusionary principle as one of pre-emption...Laws of nature, natural phenomena, and abstract ideas are the basic tools of scientific and technological work. Monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws. 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.”<sup>25</sup>

What started as narrow judicial exceptions has in essence become a separate patentability requirement. The judicial exceptions were applied in the Supreme Court’s first case addressing § 101 of the 1952 Act, *Gottschalk v. Benson*. The Court in *Benson* considered the patentability of a method of converting signals from binary coded decimal form into binary. The issue was whether the claimed method was a “process” under § 101 of the 1952 Act. The Court focused exclusively on whether the claimed method was a judicial exception to patentability and concluded that the claim “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself,” and constitute patenting of an idea.<sup>26</sup> The Court’s concern with preemption was in turn driven by the Court’s mistaken belief that all mathematical algorithms were scientific truths and thus like laws of nature: “Reasoning that an algorithm, or mathematical formula, is like a law of nature, *Benson* applied the established rule that a law of nature cannot be the subject of a patent.”<sup>27</sup>

The Court’s analysis presumed without comment that the judicial exceptions remained unaltered by the 1952 Act and did not address the changes implemented by the 1952 Act. Nor did the Court address Congress’s intent that “anything under the sun that is made by man” be patentable (although one could speculate that the Court likely would have concluded that the judicial exceptions embody subject matter not “made by man”). More broadly, the Court was writing at time when there was considerable uncertainty about the patentability of computer-implemented inventions, out of concern that the USPTO was not equipped to examine software patents, concerns that are no longer applicable.<sup>28</sup> The Court also appears to have struggled with computer technology, which itself was not new but was new to the Court. However valid those concerns were in 1978, they are no longer an issue, as the USPTO has access to both its own database of patents and numerous collections of prior art in software.

The Court next addressed § 101 in *Parker v. Flook*, which is the seminal basis for the Court’s current analyses in the 101 Decisions and therefore warrants extended consideration.

In *Flook*, the Court considered the patentability of claims to a method of dynamically adjusting an alarm limit (such as a temperature or pressure exceeding safety limits) during catalytic conversion of hydrocarbons.<sup>29</sup> The method employed a mathematical formula to calculate the

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<sup>24</sup> 409 U.S. 63, 67 (1972).

<sup>25</sup> *Alice Corp. v. CLS Bank Int’l*, 110 USPQ2d 1976, 1980 (U.S. 2014) (internal quotations and citations omitted).

<sup>26</sup> *Id.* at 72.

<sup>27</sup> *Parker v. Flook*, 437 U.S. 584, 589 (1978).

<sup>28</sup> *Id.* (“The Patent Office now cannot examine applications for programs because of a lack of a classification technique and the requisite search files. Even if these were available, reliable searches would not be feasible or economic because of the tremendous volume of prior art being generated.”).

<sup>29</sup> The main claim at issue was:

limit. As in *Benson*, at issue was whether the claimed method was a “process” under § 101, and the analysis turned on whether the method fell within the judicial exceptions to patentability:

This case turns entirely on the proper construction of § 101 of the Patent Code, which describes the subject matter that is eligible for patent protection. It does not involve the familiar issues of novelty and obviousness that routinely arise under §§ 102 and 103 when the validity of a patent is challenged. For the purpose of our analysis, we assume that respondent's formula is novel and useful and that he discovered it. We also assume, since respondent does not challenge the examiner's finding, that the formula is the only novel feature of respondent's method. *The question is whether the discovery of this feature makes an otherwise conventional method eligible for patent protection.*<sup>30</sup>

The Court's last question forms the basis upon which the current 101 framework is built. The second part of two-part analysis of the 101 Decisions reframes the *Flook* Court's question as an inquiry into whether a claim's elements, individually and as an ordered combination, contain an “inventive concept” sufficient to transform the claim into patent eligible subject matter. In so doing the Court introduced two concepts into the 101 analysis: (1) dissection of the claims for a specific “point of novelty” independent of any excluded subject matter; and (2) whether the point of novelty had sufficient inventiveness—the latter being the very considerations that 1952 Act intentionally moved into § 103. The IPO Section 101 Legislation Task Force proposal seeks to eliminate these concepts from the § 101 analysis.

The *Flook* Court was not unaware that its § 101 inquiry might be construed as requiring both dissecting the claims and considering inventiveness. Justice Stewart, joined by Chief Justice Burger and Justice Rehnquist, emphatically argued that applying § 101 only at the point of novelty “strikes what seems to me an equally damaging blow at basic principles of patent law by importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness.”<sup>31</sup>

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1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of  $B_0+K$ , wherein  $B_0$  is the current alarm base and  $K$  is a predetermined alarm offset which comprises:
    - (1) determining the present value of said process variable, said present value being defined as PVL;
    - (2) determining a new alarm base,  $B_1$ , using the following equation:  
$$B_1=B_0(1.0 - F)+PVL(F)$$
 where  $F$  is a predetermined number greater than zero and less than 1.0;
    - (3) determining an updated alarm limit which is defined as  $B_1+K$ ; and thereafter
    - (4) adjusting said alarm limit to said updated alarm limit value.

<sup>30</sup> 198 USPQ at 196 (emphasis added). Oddly, despite assuming that the formula was novel, the Court went on state, “because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.” *Id.* at 199 (emphasis added). This characterization of a natural relationship as being within the prior art, regardless of whether it is within the realm of human knowledge, conflates the prior art provisions of §§ 102 and 103 with subject matter eligibility and portends the same approach in the 101 Decisions. But it also raises other issues. As Judge Rich observed in *In re Bergy*, the Court's statement that the algorithm was in the prior art was an unqualified categorization of the mathematical algorithm as “prior art”

even when it was not familiar, was not prior, was discovered by the applicant for patent, was novel at the time he discovered it, and was useful. This gives to the term ‘prior art,’ which is a *very* important term of art in patent law, particularly in the application of § 103 an entirely new dimension with consequences of unforeseeable magnitude.

596 F.2d 952, 965 (C.C.P.A. 1979).

<sup>31</sup> *Flook*, 437 U.S. at 600 (Stewart, J., dissenting). This view is supported by Judge Rich in *In re Bergy*: “[W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in §101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of §103. The confusion creeps in through such phrases as ‘eligible for patent protection,’ ‘patentable process,’ ‘new and useful,’ ‘inventive application,’ ‘inventive concept,’ and ‘patentable invention.’” 596 F.2d at 959.



The separation between eligibility and patentability is found in both the House and Senate reports on the revision to title 35, which state,

Referring first to section 101, this section specifies *the type of material* which can be the subject matter of a patent.

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Section 101 sets forth the subject matter that can be patented, “subject to the conditions and requirements of this title.” The conditions under which a patent may be obtained follow, and section 102 covers the conditions relating to novelty.<sup>32</sup>

Not only do these statements in the House and Senate reports separate novelty from the § 101 analysis, they also indicate that § 101 is directed to *the type of subject matter* that can be patented, whereas *other* sections of the 1952 Act govern patentability. The focus on *type* means that eligibility is about the *categories* of inventions that can be patented, not about a qualitative analysis of the *merits* of an invention. Sections 102 and 103 are where the merits are addressed—whether the invention is novel and non-obvious. As Judge Rich noted in *Bergy*, “Notwithstanding the words “new and useful” in § 101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice.”<sup>33</sup> Judge Rich specifically called out *Flook* as confusing the categorical operation of § 101 with the qualitative function of §§ 102 and 103: “[W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103.”<sup>34</sup>

The dissent in *Flook* became part of the majority in *Diehr*, where the Court correctly rejected *Flook’s* point of novelty approach and its incorporation of novelty considerations in the eligibility analysis. Referring to *Bergy*, the Court expressly acknowledged the limited role of § 101 as not an independent condition of patentability but a general statement of subject matter eligibility:

Section 101, however, is a general statement of the type of subject matter that is eligible for patent protection “subject to the conditions and requirements of this title.” Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is “wholly apart from whether the invention falls in a category of statutory subject matter.”<sup>35</sup>

The Court went on to hold that “the fact that one or more of the steps in respondents’ process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter eligible for patent protection under § 101.”<sup>36</sup> Because § 101 applies to the claim as a whole, “it is inappropriate to dissect the claims into old and new elements,” even if one of those elements is a law of nature or a scientific truth.<sup>37</sup> Despite *Diehr’s* repudiation of *Flook’s* point of novelty approach, the underlying framework of *Flook* came to full fruition in the 101 Decisions.

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<sup>32</sup> S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952) (emphasis added).

<sup>33</sup> *In re Bergy*, 596 F.2d at 960.

<sup>34</sup> *Id.* at 959.

<sup>35</sup> *Diehr*, 450 U.S. at 189-90.

<sup>36</sup> *Id.* at 193; see also *In re Taner*, 681 F.2d 787, 791 (C.C.P.A. 1982) (“*Diehr* rejected the ‘point of novelty’ analysis saying ‘the ‘novelty’ of any element or steps in a process...is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”) (citation omitted).

<sup>37</sup> *Diehr*, 450 U.S. at 188.

*Bilski v. Kappos*

In 2010, the Supreme Court revisited § 101 in *Bilski v. Kappos*. The claims at issue involved carrying out transactions to protect against the risk of price fluctuations.<sup>38</sup> The Federal Circuit had held the claims unpatentable under § 101 on the basis of the “machine-or-transformation test.”<sup>39</sup> The Supreme Court agreed that the claims were unpatentable, but rejected the machine-or-transformation test as the sole test of subject-matter eligibility.<sup>40</sup> Instead, the Supreme Court concluded that the claims at issue were directed to the “concept of hedging” and, as such, amounted to “an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*.”<sup>41</sup>

To reach this conclusion, the Supreme Court began a regression toward historical “inventiveness” and appeared to inject aspects of §§ 102 and 103 into the subject matter eligibility analysis of § 101. Among other things, the Supreme Court expressly relied on the existence of known commodity hedging techniques—that is, prior art that would ordinarily be considered under §§ 102 and 103—in identifying whether a claim is directed to an unpatentable abstract idea under § 101.<sup>42</sup> Even in the oral arguments, Chief Justice Roberts announced that “your claim 1 it seems to me is classic commodity hedging that has been going on for centuries.”<sup>43</sup> Yet the Supreme Court did not hold the claims at issue in *Bilski* as anticipated or obvious under §§ 102 or 103. Instead, by including a novelty/obviousness-type analysis in its holding under § 101, the *Bilski* opinion began a regression toward a subjective inventiveness analysis essentially identical to the inventiveness standard that was eliminated by the 1952 Act.

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<sup>38</sup> For example, claim 1 at issue in *Bilski* recited:

- (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;
- (b) identifying market participants for said commodity having a counter-risk position to said consumers; and
- (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

(App. 19-20.)

<sup>39</sup> *In re Bilski*, 545 F.3d 943, 955 (Fed. Cir. 2008) (*en banc*).

<sup>40</sup> *Bilski*, 561 U.S. at 604 (“This Court’s precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”).

<sup>41</sup> *Id.* at 611. Stating “just like the algorithms” is equating “abstract ideas” generally to mathematical algorithms. This leap of logic was not explained or justified by the Court, especially given that the reason that mathematical algorithms were rejected in *Benson* and *Flook*—the false belief that they were “like laws of nature”—does not apply to abstract ideas. The concept of hedging (*Bilski*) or risk intermediation (*Alice*) are in no way like a law of nature.

<sup>42</sup> *Id.* (“Claims 1 and 4 in petitioners’ application explain the basic concept of hedging, or protecting against risk: ‘Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.’” (citing 545 F.3d at 1013 (Rader, J., dissenting)); see e.g., D. Chorafas, Introduction to Derivative Financial Instruments 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, Financial Accounting: An Introduction to Concepts, Methods, and Uses 581-82 (13th ed.2010); S. Ross, R. Westerfield, & B. Jordan, Fundamentals of Corporate Finance 743-44 (8th ed.2008). The Supreme Court cited D. Chorafas, Introduction to Derivative Financial Instruments 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, Financial Accounting: An Introduction to Concepts, Methods, and Uses 581-582 (13th ed.2010); S. Ross, R. Westerfield, & B. Jordan, Fundamentals of Corporate Finance 743-744 (8th ed.2008).)

<sup>43</sup> See Official Transcript of Proceedings Before The Supreme Court of the United States for Case No. 08-964, at 10, lines 16–18, available at [http://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/08-964.pdf/](http://www.supremecourt.gov/oral_arguments/argument_transcripts/08-964.pdf/).

Mayo v. Prometheus

In a case relevant to the life sciences and to diagnostic methods in particular, the Court in *Mayo v. Prometheus* considered whether a method of optimizing therapeutic efficacy constituted patent eligible subject matter. The claim at issue described a method of optimizing the dosage of a specific drug to improve efficacy and avoid toxic side effects based on the amount of the drug's metabolites in the body. The claim set forth minimum and maximum thresholds for effective and toxic levels. The Court held that the claims constituted an unpatentable law of nature.

As before, the Court's primary concern was with preempting use of laws of nature,<sup>44</sup> and it turned to *Flook* for the analysis:

[Our precedents] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.<sup>45</sup>

...

The question before us is whether the claims do significantly more than simply describe ... natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the [natural law] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.<sup>46</sup>

To address the issue, the Court dissected the claim under consideration into its component parts, dismissing each in turn:

- (a) the step of administering to a patient a drug providing 6-thioguanine, rather than representing human activity, merely identified the relevant audience, namely doctors who treat patients with immune-mediated gastrointestinal disorders,
- (b) the wherein clause simply informed doctors of the natural law, and
- (c) the determining step instructed doctors to "engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field[, which] is not normally sufficient to transform an unpatentable law of nature into patent eligible subject matter."<sup>47</sup>

The Court summarized its analysis as follows:

To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.<sup>48</sup>

In essence, the Court evaluated each claim limitation with respect to its value for imparting subject matter eligibility on the claim and assigned each a value of zero. Not surprisingly, when

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<sup>44</sup> "[Our precedents] warn us against upholding patents that claim processes that too broadly preempt the use of a natural law." 132 S. Ct. at 1294.

<sup>45</sup> *Id.* (citing *Flook*).

<sup>46</sup> *Id.* at 1297.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 1298.

the Court considered the claim as a whole, the sum was zero as well. This part of the Court's analysis conflicts with *Diehr*:

In determining the eligibility of [a] claimed process for patent protection under § 101, [the] claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.<sup>49</sup>

Key to the Court's analysis was its belief that the claim recited a law of nature in the relationship of the thresholds to the efficacy and toxicity of the drug.

Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm....[T]he relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.<sup>50</sup>

But there is no scientific validity to the Court's definition of a law of nature as any natural relationship that exists apart from human action.<sup>51</sup> Scientifically, such relationships are at best scientific facts (if true) and the very type of subject matter that inventors have traditionally discovered and patented. This overly broad definition has decimated patents<sup>52</sup> and pending patent applications directed to diagnostic methods.

And equally troubling is the introduction of issues of novelty and non-obviousness into the analysis—whether the steps were well-understood, routine, conventional activity—issues Congress intended to exclude from the § 101 analysis and consider only under §§ 102 and 103. *Mayo's* consideration of whether a claim limitation was “well-understood, routine, conventional activity” is directly at odds with *Diehr*, which, as noted above, held that the lack of “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining

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<sup>49</sup> *Diehr*, 450 U.S. at 188.

<sup>50</sup> *Id.* at 1967.

<sup>51</sup> See generally Readings on Laws of Nature (J. Carroll, ed., Pittsburgh University Press 2004).

<sup>52</sup> The following cases are examples of so-called laws of nature found by the courts: *Athena Diags., Inc. v. Mayo Collaborative Servs., LLC*, 2016 U.S. Dist. LEXIS 114259 (D. Mass. 2016) (Detecting whether any antibody-antigen complexes are formed between the 125I-MuSK receptor and the antibodies present in said bodily fluid.); *Hemopet v. Hill's Pet Nutrition, Inc.*, 617 Fed. Appx. 997 (Fed. Cir. 2015) (The effect of nutrition on the expression of least one gene in the genomic map of an animal.); *Genetic Veterinary Scis., Inc. v. Canine EIC Genetics, LLC*, 101 F. Supp. 3d 833 (D. Minn. 2015) (Whether a dog is susceptible to “exercise induced collapse” based on the presence of a mutation at position 767 of the DNMI gene.); *Oxford Immunotec Ltd. v. Qiagen, Inc.*, 2016 U.S. Dist. LEXIS 135969 (D. Mass. 2016) (The production of interferon-gamma by CD4 T-cells and CD6 T-cells in response to the presence in vitro to synthetic peptides found in tuberculosis bacterium.); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349 (D. Mass. 2015) (The presence of certain mutations in the kinase domain of a patient's EGFR gene substantially increases the sensitivity of epidermal growth factor receptor to tyrosine kinase inhibitor therapy, in the treatment of epithelial cell cancer.); *Exergen Corp. v. Thermomedics, Inc.*, 2016 U.S. App. LEXIS 12392 (Fed. Cir. 2016) (The relationship between an internal body temperature to ambient (skin) temperature.); *Endo Pharms. Inc. v. Actavis Inc.*, 2015 U.S. Dist. LEXIS 155034 (D. Del. 2015) (The bioavailability of controlled released oxymorphone being affected by renal function.); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, 2014 U.S. Dist. LEXIS 122780 (D. Del. 2014) (The presence of two copies of the 577R allele being positively associated with “elite athletic performance.”).

whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.<sup>53</sup>

Nonetheless, the *Mayo* Court attempted to reinforce its decision by relying on *Diehr*. The *Mayo* Court ignored the underlying tension between *Diehr* and *Flook*, and finessed *Diehr*'s requirement to consider the claim as a whole by simply asserting that it was sufficient to consider all of the claim limitations as an "ordered combination."<sup>54</sup>

The Court placed the judicial exceptions to patentability above Congress's patentability requirements and intent in crafting the 1952 Act to separate "inventiveness" from eligibility by creating § 103. The Court may limit a statute only if application of the statute is unconstitutional in some respect.<sup>55</sup> The only Constitutional issue is whether the statute promotes the useful arts. But never has the Court cited evidence that granting exclusive rights for a limited time on "the basic tools of scientific and technological work" would impede progress to a greater extent than prohibiting patenting such tools, which would eliminate an incentive to discover them and, presumably, impede the discovery of such tools and, consequently, their subsequent use to advance the useful arts.

### *Ass'n for Molecular Pathology v. Myriad*

Of the 101 Decisions, *Myriad* is the only one to address the product of nature judicial exception to subject matter eligibility. In particular, *Myriad* addressed whether particular forms of DNA are precluded from patentability as products of nature—*i.e.*, not made by man. Typical of the claims at issue, claim 1 of *Myriad*'s U.S. Patent 5,747,282 recited:

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<sup>53</sup> See *In re Diehr*, 203 USPQ 44, 50 (C.C.P.A. 1979), from which *Diamond v. Diehr*, is the appeal, in which Judge Rich, writing for the court, stated:

Appellants and the PTO have locked horns over whether the step of continually measuring the temperature in the mold cavity is old in the art. While we are inclined to agree with appellants that the record is devoid of any evidence that this step was ever performed by persons other than appellants, we fail to see what relevance this issue has to the §101 inquiry. Considerations of novelty and obviousness have no bearing on compliance with §101. *In re Bergy*, 596 F.2d 952, 960-61, 962-63, 201 USPQ 352, 361, (CCPA 1979); *Nickola v. Peterson*, 580 F.2d 898, 906-907, 198 USPQ 385, 395-96 (6th Cir. 1978). Thus, the fact that certain limitations in a claim may be novel and certain others may be old is irrelevant to the outcome of this case. The focus of the inquiry should be whether the claim, as a whole, is directed essentially to a method of calculation or mathematical formula. No one step or subgroup of steps determines whether the entire claim defines statutory subject matter. *Flook*, 437 U.S. at 594 n.16, 198 USPQ at 199 n.16; *In re Chatfield*, 545 F.2d at 158, 191 USPQ at 738. We are concerned only with what entire claims define and with whether that falls within § 101.

(footnotes omitted).

<sup>54</sup> *Mayo*, 132 S. Ct. at 1298. The conflict between *Flook-Mayo* and *Diehr* has been widely recognized. See Katerina E. Milenkovski, *Prometheus's Patent Ruled a Myth*, Am. Bar Ass'n Litig. News (May 29, 2012), available at <http://goo.gl/LxksgX> ("Despite quoting heavily from *Diehr* in its *Prometheus* analysis, the Supreme Court nevertheless did exactly what *Diehr* instructed not to do,' according to Robert M. Asher, Boston, co-chair of the Patents Subcommittee of the Section of Litigation's Intellectual Property Litigation Committee."); Eric W. Guttag, *Selective Precedent Amnesia: The Nonsensical Reasoning in the Supreme Court's Mayo Collaborative Services Decision Part 3*, IPWatchdog (Mar. 28, 2012), available at <http://goo.gl/eX2ldL> ("Breyer's opinion in *Mayo Collaborative Services* repeatedly doing what this paragraph from *Diehr* says not to do in an analysis of method or process claims under 35 U.S.C. § 101.... [F]rankly such mishandling of binding Supreme Court precedent in *Mayo Collaborative Services* is a huge problem.")

<sup>55</sup> *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2579 (2012):

Proper respect for a co-ordinate branch of the government" requires that we strike down an Act of Congress only if "the lack of constitutional authority to pass [the] act in question is clearly demonstrated." *United States v. Harris*, 106 U.S. 629, 635 (1883). Members of this Court are vested with the authority to interpret the law; we possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them. It is not our job to protect the people from the consequences of their political choices.

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical human breast cancer gene BRCA1 encodes. Myriad claimed to have discovered this particular sequence and, using an accepted form of claim drafting, recited an “isolated” DNA sequence. The use of “isolated” has been traditionally accepted as sufficient to indicate that the sequence was produced by human intervention because isolation requires specific laboratory processes. In other words, isolated DNA does not exist in nature.

In *Diamond v. Chakrabarty*, the Court held as patent eligible a bacterium that had been modified by the insertion of foreign DNA that enabled the bacterium to break down various components of crude oil.<sup>56</sup> The *Chakrabarty* Court reasoned that the modified bacterium was a product of human ingenuity, a non-naturally occurring manufacture and not a natural phenomenon. It is widely agreed that *Chakrabarty* was instrumental in the growth of the biotech industry in the United States. The *Myriad* Court reasoned that a gene, by contrast, was itself not a modified construct, but rather a naturally occurring product separated from surrounding genetic material by cleavage of the chemical bonds linking it to the surrounding genetic material.

Although the *Myriad* Court recognized that the claimed gene was a non-naturally occurring molecule,<sup>57</sup> the Court nevertheless viewed that as insufficient to make it a man-made product. Rather than focusing on the claimed construct itself, which the Court incorrectly characterized as “simply not expressed in terms of chemical composition,”<sup>58</sup> the Court focused on the genetic information encoded in the gene, which it held to be the same as the gene found in nature. Myriad had argued that it discovered the location of the claimed genes after expending great effort. But the Court was unpersuaded, stating that neither the discovery nor the effort were sufficient to make the claimed genes patent eligible.<sup>59</sup>

The Court did hold that cDNA (a DNA with a non-natural sequence corresponding to the naturally occurring sequence with the non-coding regions absent) was patent eligible because the creation of cDNA requires the handiwork of the laboratory technician. Scientifically, this alleged distinction between isolated genomic DNA and cDNA is specious, because isolating genomic DNA equally requires significant laboratory processing. Thus, the line between patent ineligible DNA and patent eligible DNA falls somewhere between the human activity required to isolate genomic DNA sequence and the activity required to create cDNA, but the Court did not draw this line—nor could it. More significantly, *Myriad* expands the scope of the judicial exceptions by requiring something more of a composition than being non-naturally occurring as it had previously held in *Diamond v. Chakrabarty*.<sup>60</sup>

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<sup>56</sup> *Diamond v. Chakrabarty*, 206 USPQ 193 (U.S. 1980).

<sup>57</sup> 133 S. Ct. at 2118.

<sup>58</sup> The claim’s reference to “SEQ ID NO:2,” an express recitation of a polypeptide sequence, along with the well-known genetic code, provides one of ordinary skill in the art all the information necessary to envision the entire chemical composition of BRCA1 gene. Hence, the claim *does* express the BRCA1 gene in terms of a chemical composition.

<sup>59</sup> Troublingly, the Court did not say that extensive effort is *irrelevant* to the § 101 analysis. Rather, it said such effort is *insufficient*. The distinction suggests that the Court considers the effort involved to be a factor in the § 101 analysis, despite express statutory prohibition under § 103: “Patentability shall not be negated by the manner in which the invention was made.”

<sup>60</sup> One can extend *Myriad*’s reasoning to pharmaceuticals. Consider the case of a previously unknown, naturally occurring compound discovered to have potent anti-cancer activity but useless as a drug because of low solubility. Routine techniques for improving solubility of small molecules are well known in the art (*e.g.*, linking a hydrophilic moiety to the molecule). And consider if that molecule were modified with a hydrophilic moiety using a routine technique that renders the molecule soluble and transforms it from a useless compound to a life-saving drug. The modified molecule could be ineligible subject matter under *Myriad* because, like the DNA held as patent ineligible subject matter in *Myriad*, the compound is merely a natural product transformed using routine techniques.

In *Alice*, the Supreme Court applied the two-part *Mayo* test to claims directed to a method of exchanging obligations between parties.<sup>61</sup> First, the Supreme Court considered whether the claims were directed to a law of nature, a natural phenomenon, or an abstract idea. Second, upon concluding that the claims recited the abstract idea of intermediated settlement, the Court next looked for an “inventive concept” that would “ensure that the patent in practice amounts to significantly more.”<sup>62</sup> The Court ultimately determined that there was no inventive concept. As such, the claims in *Alice* were held to be drawn to patent-ineligible subject matter and therefore invalid.

As with the other 101 Decisions, the Supreme Court in *Alice* continued to mix aspects of §§ 102 and 103 into the analysis of subject-matter eligibility, further entrenching the “inventive concept” analysis back into § 101. In its analysis of step one, the Court supported its conclusion that the claims in *Alice* were directed to an abstract idea by considering the state of the art. Namely, the *Alice* opinion recites numerous texts that presumably set forth the state of the art in economic practice—texts that might more properly be dealt with under §§ 102 and 103—and relies on the apparent ubiquity of the concept of intermediated settlement in these texts to conclude that intermediated settlement is an abstract idea that is beyond the scope of § 101.<sup>63</sup> But even though the Court looked to several published documents describing the state of the art, the Court did not apply the statutory requirements of § 102 to identify the published documents as prior art or whether they, in fact, disclosed the subject matter of the claims as opposed to merely general background. In other words, the *Alice* opinion injected an arbitrary, less rigorous consideration of the state of the art than the longstanding requirement of § 102 to decide whether the claims meet the threshold of § 101. And it is worth noting that many of the documents would not qualify as prior art under § 102, having been published long after the *Alice* patents had issued.

In the second step of the two-part *Mayo* test, the Supreme Court redoubled its support for an inventiveness decision that would more properly be dealt with under § 103. The Court reiterated that § 101 requires an “inventive concept” that adds “significantly more” to any claims deemed to

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<sup>61</sup> Claim 33 of U.S. Patent 5,970,479 at issue, for example, recites:

A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:

- (a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;
- (b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
- (c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party’s shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and
- (d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.

App. 383–84.

<sup>62</sup> 134 S. Ct. at 2355.

<sup>63</sup> *Id.* at 2356 (“Like the risk hedging in *Bilski*, the concept of intermediated settlement is ‘a fundamental economic practice long prevalent in our system of commerce.’ *Ibid.*; see e.g., Emery, Speculation on the Stock and Produce Exchanges of the United States, in 7 Studies in History, Economics and Public Law 283, 346-56 (1896) (discussing the use of a ‘clearing-house’ as an intermediary to reduce settlement risk). The use of a third-party intermediary (or ‘clearing house’) is also a building block of the modern economy. See, e.g., Yadav, The Problematic Case of Clearinghouses in Complex Markets, 101 Geo. L.J. 387, 406-12 (2013); J. Hull, Risk Management and Financial Institutions 103-04 (3d ed. 2012). Thus, intermediated settlement, like hedging, is an ‘abstract idea’ beyond the scope of § 101.”).

recite one of the judicially created exceptions. But this did not simply import the longstanding obviousness standard under § 103 into the § 101 analysis. Rather, the “inventive concept” analysis appears to be a far more arbitrary exercise, dependent on comparisons of the claims at issue to claims in other § 101 opinions. In *Alice*, the Court compared the claims at issue to those of *Mayo*, *Benson*, *Flook*, and *Diehr*.

After *Alice*, the USPTO issued a series of “guidance” memoranda providing instructions to examiners as to how to implement the *Mayo* test.<sup>64</sup> The USPTO called for public comments on the update, and IPO submitted a detailed analysis of the guidance, identifying numerous problems and concerns that the USPTO has not addressed.

### Lower Court 101 Decisions

Unsurprisingly, the lower courts have followed 101 Decisions to their full extent, sometimes despite misgivings of such jurists.

### Impact on Life Sciences

Broad application of the abstract idea exception is not limited to information technology inventions. Patents in the fields of biotechnology and pharmaceuticals have similarly fallen victim to an overly broad application of the exceptions to patent eligibility. Lower court opinions crafted subsequent to the 101 Decisions manifest just how deeply ingrained in the 101 analysis the concept of “inventive concept” has become.

In *Ariosa Diagnostics v. Sequenom*,<sup>65</sup> the Federal Circuit upheld a California court’s grant of a summary judgment motion, holding that claims to a method of detecting “paternally inherited nucleic acid of fetal origin” (*i.e.*, DNA from a fetus that was derived from the father) in maternal serum or plasma were not drawn to patent eligible subject matter.<sup>66</sup> The claimed invention is based on the *discovery* that fetal DNA was detectable in maternal serum and plasma samples that previously were discarded as useless. In his concurrence, Judge Linn described the claimed invention as “truly meritorious” and “groundbreaking,” noting, “The Royal Society lauded this discovery as ‘a paradigm shift in non-invasive prenatal diagnosis,’ and the inventors’ article describing this invention has been cited well over a thousand times.”<sup>67</sup> Undaunted, the Federal Circuit held the claims were directed to a natural phenomenon (the existence of fetal DNA in maternal serum and plasma) and then

examin[ed] the elements of the claim to determine whether the claim contains an inventive concept sufficient to “transform” the claimed naturally occurring phenomenon into a patent-eligible application. We conclude that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention.<sup>68</sup>

Despite joining the court’s opinion in invalidating the claims, Judge Linn concluded that the claims at issue, “[u]nlike in *Mayo*...should be patent eligible.”<sup>69</sup> Judge Linn explained that he joined the court's opinion “only because I am bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories*.”<sup>70</sup>

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<sup>64</sup> See “Preliminary Examination Instructions in view of the Supreme Court decision in *Alice Corp.*” (June 25, 2014); “2014 Interim Guidance on Subject Matter Eligibility” 79 Fed. Reg. 74618 (Dec. 16, 2014); “July 2015 Update: Subject Matter Eligibility,” 80 Fed. Reg. 146 (July 30, 2015).

<sup>65</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

<sup>66</sup> *Id.* at 1380.

<sup>67</sup> *Id.* at 1381 (Linn J, *concurring*).

<sup>68</sup> *Id.* at 1376 (emphasis added).

<sup>69</sup> *Id.* at 1381 (Linn J, *concurring*).

<sup>70</sup> *Id.* at 1380 (Linn J, *concurring*).



In *Univ. of Utah Research Found. v. Ambry Genetics Corp.* the Federal Circuit affirmed a lower court’s holding that claims directed to screening for breast cancer were invalid as directed to ineligible subject matter.<sup>71</sup> A claim at issue was directed to a method of detecting a mutation in a patient’s BRCA gene (a breast cancer gene) by

- (1) comparing the patient’s BRCA1 gene to the naturally occurring gene, wherein a difference in the sequence denoted a mutation, and
- (2) wherein the comparison is made by a hybridization.

To analyze the claim, the court employed the two-step *Alice* test:

First, “we determine whether the claims at issue are directed to a patent-ineligible concept. If so, we then ask, ‘what else is there in the claims before us?’” That is, we next ask whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to “‘transform the nature of the claim’ into a patent-eligible application.” Put another way, there must be a further “inventive concept” to take the claim into the realm of patent-eligibility.<sup>72</sup>

In addition to improperly imposing the “inventive concept” requirement, the court also dissected the claim:

Here, we treat separately the first paragraphs of [the claim], which describe the comparison of wild-type genetic sequences with the subject’s genetic sequence and correspond to the first step of *Alice*, and the second paragraph[], which describe[s] the techniques to be used in making the comparisons and correspond to the second step of *Alice*.<sup>73</sup>

The court held that the first step of the claim was “an abstract mental process of ‘comparing’ and ‘analyzing’ two gene sequences,” and the technique in the second step was “well-understood, routine and conventional activity” and, therefore, “not enough” to transform the patent ineligible “abstract mental process” into patent eligible subject matter.<sup>74</sup>

In *Endo Pharm. Inc. v. Actavis Inc.*<sup>75</sup> the district court considered the patentability of a method of treating pain comprising administering a specified analgesic, taking blood measurements, and adjusting dosage accordingly.<sup>76</sup> The claim was similar to the claim considered in *Mayo*. Not surprisingly, the court upheld the magistrate judge’s ruling that the method constituted unpatentable subject matter:

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<sup>71</sup> 774 F.3d 755 (Fed. Cir. 2014). The court also held as invalid claims to DNA primers whose sequences were identical to naturally occurring DNA sequences, applying the identical analysis the Supreme Court applied to the gene claims in *Myriad*.

<sup>72</sup> *Id.* at 763 (emphasis added).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> 1:14-cv-01381-RGA, slip op. (D. Del. Nov. 17, 2015).

<sup>76</sup> A claim at issue read:

1. A method of treating pain in a renally impaired patient, comprising the steps of:
  - a. providing a solid oral controlled release dosage form, comprising:
    - i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and
    - ii. a controlled release matrix;
  - b. measuring a creatinine clearance rate of the patient and determining it to be (a) less than about 30 ml/min, (b) about 30 mL/min to about 50 mL/min, (c) about 51 mL/min to about 80 mL/min, or (d) above about 80 mL/min; and
  - c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief;wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL.

The Magistrate Judge applied the two-step framework set forth by the Supreme Court in *Mayo* and *Alice*. This framework requires the Court 1) to determine whether the claims are directed to a patent-ineligible concept—such as a law of nature, natural phenomenon, or abstract idea—and, if they are, 2) to determine whether there is an “**inventive concept** ... sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”<sup>77</sup>

And in response to the patentee’s assertion that the court’s basis for invalidation would invalidate all method-of-treatment patents employing known compounds, the court usefully suggested, “Patentees can still avoid invalidation under § 101 by demonstrating an inventive leap beyond merely claiming a law of nature.”

Two other district court cases are telling because the same patent was analyzed for subject matter eligibility by different courts using the exact same analysis, but reached different outcomes, manifesting the complexity and uncertainty of the analysis. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*<sup>78</sup> and *Genetic Techs. Ltd. v. Agilent Techs., Inc.*<sup>79</sup> both considered whether claims to methods for amplifying and analyzing correlations between different regions of a DNA were patent eligible. The *BMS* court characterized the DNA correlations as natural phenomena and, after dissecting the claimed steps and considering each individually, concluded that the parts of the claim other than the natural phenomenon did not “give rise to an ‘inventive concept.’”<sup>80</sup>

The *Agilent* court had no problem concluding that the DNA correlations were natural phenomena. But the court was not convinced that the defendant had proven lack of inventive concept by clear and convincing evidence (the standard required to grant the defendant’s motion to dismiss).

The impact of the 101 Decisions in the life sciences, in which developments often rely on the discovery of a problem, are neither surprising nor unpredictable. Indeed, Judge Rich foresaw the impact nearly 40 years ago when he warned of application of *Flook*:

Insofar as the general patent law is concerned, however, the ... *Flook* doctrine may have an unintended impact in putting an untimely and unjustifiable end to the long-standing proposition of law that patentability may be predicated on discovering the cause of a problem even though, once that *cause* is known, the solution is brought about by obvious means. Such causes may often be classed as laws of nature or their effects. ... The potential for great harm to the incentives of the patent system is apparent.<sup>81</sup>

#### Impact on Software Technologies

The *Alice/Mayo* test appears particularly difficult for courts to apply to software patents, which is of concern because a large majority of patents challenged after *Alice* are software related (as opposed to business methods, biotech, or other categories). Although many software patents have been invalidated under *Alice*, a few examples are sufficient to show the impact.

In *Synopsys, Inc. v. Mentor Graphics Corp.*,<sup>82</sup> the Federal Circuit found ineligible claims for specific methods of translating computer language-based, algorithmic descriptions of hardware circuits into specific hardware-based descriptions used to fabricate the circuit.<sup>83</sup> The court found

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<sup>77</sup> 1:14-cv-01381-RGA., slip op. at 2 (emphasis added, internal citations omitted).

<sup>78</sup> 72 F. Supp. 3d 521 (D. Del. 2014).

<sup>79</sup> 24 F. Supp. 3d 922 (N.D. Cal. 2014).

<sup>80</sup> *Bristol-Myers Squibb*, 72 F. Supp. 3d at 530-31.

<sup>81</sup> *In re Bergy*, 596 F.2d at 965.

<sup>82</sup> 839 F.3d 1138 (Fed. Cir. 2016).

<sup>83</sup> The representative claim in *Synopsys* read:

that the claims were directed to an abstract idea (which they did not identify) because "we continue to "treat[] analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category."<sup>84</sup> Because a human using "pencil and paper" could analyze software code and translate it to a "schematic representation" of the circuit, the claims were found ineligible.<sup>85</sup>

The flaw in this reasoning is that, generally speaking, every algorithm that executes on a computer was designed by a human who thought through the steps of the algorithm in the process of inventing it. If taken literally and to an extreme, this approach invalidates all patents on software implemented algorithms. The fallacy of the pencil and paper test was eloquently stated by the late Judge Marian Pfaelzer in *Cal. Inst. of Tech. v. Hughes Comm'ns Inc.*:

One of Hughes' arguments deserves special attention. Hughes argues that calculating parity bit values involve "mental steps [that] can be performed by a person with pencil and paper." Therefore, Hughes, argues the claim is not patentable. Defs.' Mem. in Supp. of Invalidity at 14, Dkt. No. 126. The Court finds this mode of analysis unhelpful for computer inventions. Many inventions could be theorized with pencil and paper, but pencil and paper can rarely produce the actual effect of the invention. Likewise, with regard to software, a human could spend months or years writing on paper the 1s and 0s comprising a computer program and applying the same algorithms as the program. At the end of the effort, he would be left with a lot of paper that obviously would not produce the same result as the software.

The problems of pencil-and-paper analysis are heightened in the context of software, which necessarily uses algorithms to achieve its goals. Pencil-and-paper analysis can mislead courts into ignoring a key fact: although a computer performs the same math as a human, a human cannot always achieve the same results as a computer.<sup>86</sup>

In *TDE Petroleum Data Solutions, Inc. v. AKM Enter., Inc.*,<sup>87</sup> the Federal Circuit invalidated a software patent directed to evaluating the operating condition of an oil drilling well.<sup>88</sup> Ignoring the obvious parallels to the claims in *Diehr*, the court held that the claims were merely directed to

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A method for converting a hardware independent user description of a logic circuit, that includes flow control statements including an IF statement and a GOTO statement, and directive statements that define levels of logic signals, into logic circuit hardware components comprising:

converting the flow control statements and directive statements in the user description for a logic signal Q into an assignment condition AL(Q) for an asynchronous load function AL() and an assignment condition AD(Q) for an asynchronous data function AD(); and

generating a level sensitive latch when both said assignment condition AL(Q) and said assignment condition AD(Q) are nonconstant;

wherein said assignment condition AD(Q) is a signal on a data input line of said flow through latch;

said assignment condition AL(Q) is a signal on a latch gate line of said flow through latch; and

an output signal of said flow through latch is said logic signal Q.

<sup>84</sup> *Id.* at 1146.

<sup>85</sup> *Id.* at 1148.

<sup>86</sup> 59 F. Supp. 3d 974, 994-995 (C.D. Cal. 2014) (footnotes omitted).

<sup>87</sup> 657 Fed. Appx. 991 (Fed. Cir. 2016).

<sup>88</sup> The representative claim in *TDE* read:

1. An automated method for determining the state of a well operation, comprising:  
storing a plurality of states for a well operation;

receiving mechanical and hydraulic data reported for the well operation from a plurality of systems; and  
determining that at least some of the data is valid by comparing the at least some of the data to at least one limit, the at least one limit indicative of a threshold at which the at least some of the data do not accurately represent the mechanical or hydraulic condition purportedly represented by the at least some of the data; and

when at least some of the data are valid, based on the mechanical and hydraulic data, automatically selecting one of the states as the state of the well operation.

the abstract idea of "collecting information, analyzing it, and displaying certain results of the collection and analysis."<sup>89</sup> The court then used the inventiveness analysis in step 2: "TDE does not and cannot argue that storing state values, receiving sensor data, validating sensor data, or determining a state based on sensor data is individually *inventive*."<sup>90</sup> Again, this reductionist analysis looks merely to the implementation of the invention, rather than to the substance: many software claims, especially those for controlling physical systems, can be generalized to collecting data about the physical world, processing that data, and providing results.<sup>91</sup> By focusing on this generalization of what is claimed, rather the actual substance of the claim, the Federal Circuit's analysis invalidates the claim based "the manner in which the invention was made"—precisely the kind of reasoning that the 1952 Act sought to prohibit in section 103.

### Impact on Other Technologies

The district courts have not limited their ineligibility decisions to software, business methods, and life sciences, but have invalidated other types of technologies as well. Two cases are illustrative.

In *Thales Visionix, Inc. v. United States*,<sup>92</sup> the court invalidated claims to what the court admitted was an "extraordinarily complicated" invention dealing with inertial motion tracking in helmet-mounted display systems worn by fighter pilots that display tactical information on the face shield. The technical challenge is that displayed information must be updated constantly to correlate with the direction the pilot is looking, which requires constantly tracking the orientation of the helmet relative to the moving plane. The patent included system and method claims that recited multiple inertial sensors and a computational element to receive signals from the sensors and compute an updated position. The court invalidated these claims as being directed to mathematical equations for determining the relative position of a moving object to a moving reference frame. The court considered the claimed inertial sensors to be "generic, fungible," and thus "like the computer elements" in *Alice*.

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<sup>89</sup> *Id.* at 993.

<sup>90</sup> *Id.* (emphasis added).

<sup>91</sup> Judge Pfalzer's analysis of software is directly on point: "The essence of software is manipulating existing data and generating additional data through algorithms. See *Oplus Techs. Ltd. v. Sears Holding Corp.*, No. 2:12-cv-5707, 2013 U.S. Dist. LEXIS 35474, 2013 WL 1003632, at \*12 (C.D. Cal. Mar. 4, 2013) ("All software *only* 'receives data,' 'applies algorithms,' and 'ends with decisions.' That is the *only* thing software does. Software does nothing more."). *Cal. Inst. of Tech.*, 59 F. Supp. 3d 974, 987.

<sup>92</sup> No. 14-513C, slip op. (Fed. Cl. July 20, 2015).

In *Exergen Corp. v. Kaz USA, Inc.*,<sup>93</sup> the court invalidated claims to methods and apparatuses for scanning thermometers for measuring human body temperature by detecting the temperature at the forehead covering the temporal artery and computing the internal body temperature using an arterial heat balance approach. An example of the patent-ineligible Exergen thermometer is shown at right. The court held the claims were directed to “patent-ineligible natural phenomena (the blood flow of an artery, or the temporal artery), or facets of the thermodynamic relationship (the correlation between deep body temperature, ambient temperature, and an oral temperature approximation.”<sup>94</sup> In this case as well, the court held that a “radiation detector” was a “generic piece of equipment,” and thus insufficient to impart eligibility.



These two cases exemplify an increasingly common approach of identifying any type of physical part as “generic” unless it is specifically invented, and holding the part insufficient to provide subject matter eligibility under *Alice*. If inertial sensors and radiation detectors are “generic,” then it logically follows that standard mechanical elements (motors, gears, levers, differentials) and electronics (power supplies, transistors, antennas, digital to analog converters, etc.) are also “generic” and cannot contribute to eligibility. This extends the sweep of *Alice* for method claims, and directly contradicts section 100(b) of the statute which allows for methods that cover "a new use of a known process, machine, manufacture, composition of matter, or material."

### *The 101 Decisions Have Had a Broad and Deep Impact in the USPTO and the Courts*

The 101 Decisions purport to be fine-tuning, not intended to have a dramatic effect on eligibility: “There is no dispute that a computer is a tangible system (in § 101 terms, a “machine”), or that many computer-implemented claims are formally addressed to patent-eligible subject matter.”<sup>95</sup> And the Court acknowledges the inherent danger in an overbroad view, promising to “tread carefully in construing this exclusionary principle lest it swallow all of the patent law.”<sup>96</sup> But subsequent lower court decisions demonstrate that the 101 Decisions are not a mere fine tuning of eligibility, and if not swallowing all of patent law, they at least significantly broaden the scope of excluded subject matter by introducing into the analysis concepts Congress specifically intended to exclude and that have long been recognized as inappropriate (*e.g.*, dissecting the claims).

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<sup>93</sup> No. 13-10628-RGS slip op. (D. Mass. Dec. 7, 2015).

<sup>94</sup> *Id.* at 12.

<sup>95</sup> *Alice*, 134 S. Ct. at 2359; *see also Bilski v. Kappos*, 561 U.S. 593, 603:

It is true that patents for inventions that did not satisfy the machine-or-transformation test were rarely granted in earlier eras, especially in the Industrial Age, as explained by Judge Dyk’s thoughtful historical review. But times change. Technology and other innovations progress in unexpected ways. For example, it was once forcefully argued that until recent times, “well-established principles of patent law probably would have prevented the issuance of a valid patent on almost any conceivable computer program.” But this fact does not mean that unforeseen innovations such as computer programs are always unpatentable. Section 101 is a “dynamic provision designed to encompass new and unforeseen inventions.” A categorical rule denying patent protection for “inventions in areas not contemplated by Congress ... would frustrate the purposes of the patent law.”

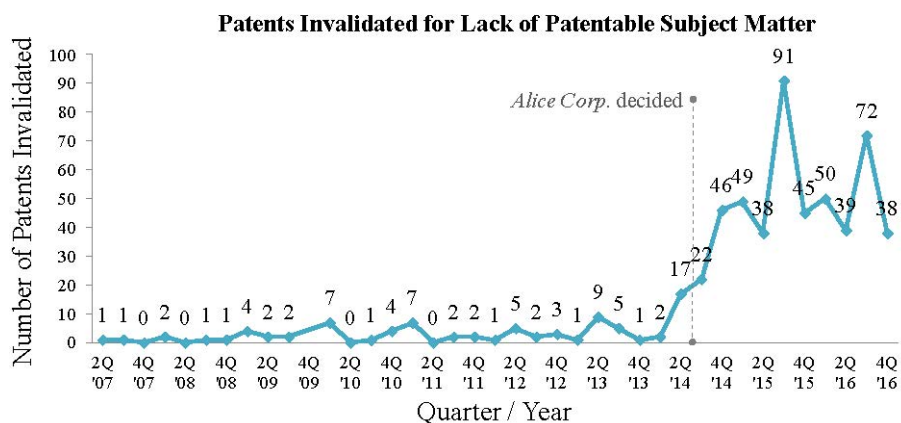
(citations omitted).

<sup>96</sup> *Alice*, 134 S. Ct. at 2354 (citations omitted); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015) (*order denying for request for en banc hearing*) (Lourie, J., concurring) (“All physical steps of human ingenuity utilize natural laws or involve natural phenomena. Thus, those steps cannot be patent-ineligible solely on that basis because, under that reasoning, nothing in the physical universe would be patent-eligible.”).

The impact of the 101 Decisions in both the courts and the USPTO is evident. As of December 31, 2016, the courts have granted 67% of various types of ineligibility motions, invalidating hundreds of patents and thousands of claims, while the PTAB has invalidated 97% of the patents under Covered Business Method reviews based on section 101 challenges:<sup>97</sup>

	Total	Total Invalid Under §101	% Invalid
Fed. Ct. Decisions	421	282	67.0%
Federal Circuit	72	65	90.3%
District Courts	349	217	62.2%
Patents	814	469	57.6%
Motions on Pleadings	228	144	63.2%
PTAB CBM Institutions	152	129	84.9%
PTAB CBM Final	101	98	97.0%
ITC	12	5	41.7%

And should one question the connection between these results and the 101 Decisions, one need only refer to the trend:<sup>98</sup>



But the impact of 101 Decisions has also been felt in the life sciences. One analysis of patent eligibility rejections in Patent Office Group 1600 (Biotechnology and Organic Chemistry) has shown that outside of organic chemistry, there has been a steady increase in § 101 rejections following *Mayo*, *Alice*, and both implementations of the Patent Office’s eligibility guidelines:<sup>99</sup>

<sup>97</sup> Data collected by R. Sachs and A. Lewin; see also R. Sachs, #Alicestorm for Halloween: Was It a Trick or a Treat? Bilskiblog.com (Fenwick & West Nov. 6, 2015), <http://www.bilskiblog.com/blog/2015/11/alicestorm-for-halloween-its-scary-out-there.html>; R. Sachs, #Alicestorm: When It Rains, It Pours..., Bilskiblog.com (Fenwick & West Jan. 22, 2016), <http://www.bilskiblog.com/blog/2016/01/alicestorm-when-it-rains-it-pours.html>

<sup>98</sup> Memorandum from David Kappos, *U.S. Patent System Vital Signs: A Quarterly Update (Q4 2016)*, (Feb. 2017) (on file with author).

<sup>99</sup> Gaudry, Grab & McKeon, *Trends in Subject Matter Eligibility for Biotechnology Inventions*, IPwatchdog (July 12, 2015), <http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/>). Organic chemistry might be immune due the nature of the subject matter—generally new compounds and their uses.

1610 = Organic Compounds: Bio-Affecting, Body Treating, Drug Delivery, Steroids, Herbicides, Pesticides, Cosmetics, and Drugs

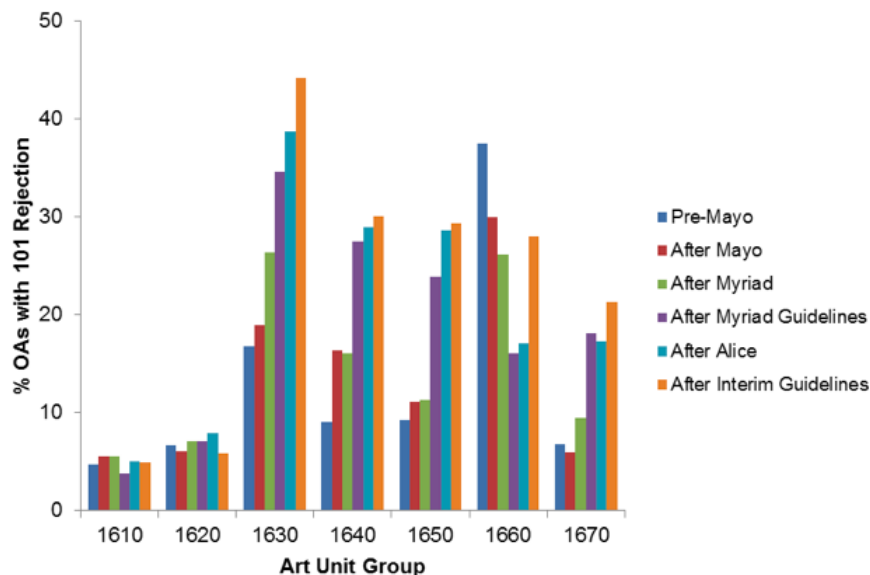
1620 = Organic Chemistry

1630 = Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Recombinant Plants, Combinatorial/Computational Chemistry

1640 = Immunology, Receptor/Ligands, Cytokines, Recombinant Hormones, and Molecular Biology Thereof

1650 = Fermentation, Microbiology, Isolated and Recombinant Proteins/Enzymes

1660 = Plants



The impact on life sciences is also manifest in *Sequenom*, which has become a lightning rod for criticism of the application of the 101 Decisions, particularly with respect to medical diagnostic methods. The Federal Circuit ultimately denied Sequenom’s request for a rehearing *en banc*.<sup>100</sup> And the two concurrences and one dissent lend a flavor to the controversy that the 101 Decisions have created. As Judge Lourie noted in his concurrence,

Appellants and amici have argued before us in briefs that a broad range of claims of this sort appear to be in serious jeopardy. It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.<sup>101</sup>

The 101 Decisions have had an immediate impact on inventors’ ability to obtain and enforce patents. For example, one recent study indicates significant action by the PTO to withdraw allowed applications from issuance after the *Alice* decision.<sup>102</sup> Others show a significant decrease in patent litigation rates.<sup>103</sup> And still others speculate regarding massive losses in R&D investment as large portions of patent portfolios are suddenly of dubious eligibility.<sup>104</sup> Statistics regarding enforcement of software patents after *Alice* make clear that the decision had a significant impact on the ability of software inventors to enforce their rights.<sup>105</sup>

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1670 = Cross-section of TC1600 subject matter uniting technology from the organic, nucleic acid, protein, and antibody arts, with a general focus on pharmacological, diagnostic, and therapeutic aspects

<sup>100</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* 809 F.3d 1282 (Fed. Cir. 2015) (order denying for request for *en banc* hearing).

<sup>101</sup> *Id.* at 1285 (Lourie, J., concurring).

<sup>102</sup> Tristan Gray-Le Coz and Charles Duan, *Apply It to the USPTO: Review of the Implementation of Alice v. CLS Bank in Patent Examination*, Patently-O Patent L.J. (2014).

<sup>103</sup> Brian Howard, *Patent Case Trends and the Business of Litigation*, (Lex Machina Feb. 5, 2015), <https://lexmachina.com/2015/02/patent-case-trends-business-litigation/>.

<sup>104</sup> Joff Wild, *Big US Tech Companies Face Major Patent Losses in the Post-Alice World, IAM Research Reveals*, IAM Blog (IAM Sept. 27, 2014), <http://www.iam-magazine.com/blog/Detail.aspx?g=2028b324-2d4a-4523-9f0d-f0773b8b3fa1>.

<sup>105</sup> Brian McCall, *Lessons from 4 Months of Post-Alice Decisions* (Law360 Oct. 31, 2014), <https://www.law360.com/articles/590465/lessons-from-4-months-of-post-alice-decisions>.

The Misapplication of Mental Steps to Software Based Inventions

*Gottschalk v. Benson* set forth as a legal principle that a general purpose computer operating under program control to execute a given calculation performs essentially the same mental steps that a human would. The foundation for this principle is based at least on the Court's misunderstanding of how computers operate. In its opinion, the Court stated,

A digital computer, as distinguished from an analog computer, is that which operates on data expressed in digits, solving a problem by doing arithmetic as a person would do it by head and hand.<sup>106</sup>

This quote was based on a quotation taken out of context from Benrey's brief by the Solicitor General.<sup>107</sup> The Solicitor General relied upon this statement to argue that a computer performs essentially mental steps when performing calculations, and therefore Benson's invention was ineligible for patent protection. Specifically, the Solicitor General argued that "the functions themselves are the *same procedures* which a human being would perform in working the same computation, but reduced to the physical characteristics of the device."<sup>108</sup> This statement is incorrect. The procedures performed by computer are different both in form and process from what a human does, even if both would ultimately achieve the same results. For example, when a computer multiplies two numbers, the underlying procedures are different from what a human would do. What a human does in a few operations to multiply two digits, say "9 x 8," requires dozens of operations at the level of individual logic gates (complexes of transistors).<sup>109</sup> Nonetheless, the Solicitor General's argument became the basis on which the Supreme Court extended the mental steps doctrine to computer-implemented inventions.

Historically the "mental steps" doctrine was used to exclude claims that recited steps *necessarily performed* in the human mind. The doctrine arose in cases involving inventions that occurred before the use of computers in business and industrial applications: the patent disclosures thus described the invention in terms of mathematical procedures that could only be performed mentally by "head and hand" or human judgments guided by mathematical or other considerations. That is, there was no disclosure of any way to perform the mathematical operations *except* by mental operations.<sup>110</sup> This interpretation of the mental steps doctrine is confirmed in an early treatise on software patent eligibility by noted Prof. Kayton:

Purely "mental steps" are considered to be steps which may only be performed in, or with the aid of, the human mind. This is quite in contrast to "purely physical steps" which may only be performed by physical means, machinery, or apparatus. Purely mental steps (e.g.,

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<sup>106</sup> *Benson*, 409 U.S. at 67 n.3 (citing R. Benrey, *Understanding Digital Computers* 4 (1964)).

<sup>107</sup> See Brief for Amicus Curiae Ronald M. Benrey, in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, at 1 (hereinafter *Benrey*).

<sup>108</sup> Solicitor General Brief, 1972 WL 137527 at \*7.

<sup>109</sup> See *Benrey*, at 16.

<sup>110</sup> See *In re Bologaro*, 20 C.C.P.A 845 (1931) (not patent eligible: a method setting lines of type using a mathematical procedure to determine average number of spaces per line; no disclosure of any machine for performing claimed method); *Don Lee v. Walker*, 61 F.2d 58 (9<sup>th</sup> Cir. 1932) (not patent eligible: a method of determining the weights and positions of counterweights on engine balance shaft; no disclosure of any apparatus to perform the necessary calculations); *Haliburton Oil Well Cementing Co. v. Walker*, 146 F.2d 817 (9<sup>th</sup> Cir. 1944) (not patent eligible: a method of determining the location of an obstruction in a tube by observing time delays of echoes and solving a mathematical equation; "We think these mental steps, even if novel, are not patentable"); *In re Heritage*, 32 C.C.P.A 1170, 1174 (1945) (not patent eligible: method of "producing a porous coated fiber board" including a step of selecting particular amounts of coated fibers, with no disclosure of any apparatus or machine used to make the selection; claims "are essentially directed to a purely mental process of making a selection of the amount of coating material to be used in coating a porous fiber board").



“believing”) are quite different from purely physical steps (e.g., “heating”) in many respects, not the least of which is that the former are much less susceptible to specific definition or delineation....Disclosure of apparatus for performing the process without human intervention may make out a prima facie case that the disclosed process is not mental and is, therefore, statutory.<sup>111</sup>

Thus, until *Benson*, no court had expressly applied the mental steps doctrine to computer-implemented inventions on the basis that the claim steps *could be* performed mentally rather than they *necessarily were* performed mentally. *Benson* has been understood to have extended the mental steps doctrine to computer-implemented inventions,<sup>112</sup> and courts to this day continue to expressly rely on the *Benson* Court’s technically flawed explanation and, more importantly, shift from invalidating claims that were *necessarily* mental in nature to steps that *could be* mentally performed. “Additionally, concepts that courts have found to be abstract have involved processes that humans *can* perform without the aid of a computer, such as processes that can be ‘done mentally’ or using pen and paper. See, e.g., *Benson*, 409 U.S. at 67 (pointing out that the conversion of binary numerals can be done mentally using a mathematical table).”<sup>113</sup> After *Alice*, the courts continue to inappropriately rely on the mental steps doctrine to find software based inventions ineligible on the basis that the steps *could be* performed mentally, even if that is not what the patentee intended *or claimed*.<sup>114</sup>

Similarly, the USPTO has latched on the “mental steps” doctrine to regularly reject patent applications in diverse software fields, including artificial intelligence, expert systems, encryption, compression, databases, signal processing, and user interfaces.

### *Consequences and Impacts of a Restricted Scope of Patent Eligibility*

As Marc Andreessen famously quipped “software is eating the world,” because software plays a central role in innovation in every industry.<sup>115</sup> An unduly narrow scope of patent eligible subject matter reduces the incentive to innovate and undermines research, development, and production in industries that rely on software-based innovation.<sup>116</sup> For example, innovation and investment

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<sup>111</sup> Irving Kayton, *Patent Protectability of Software: Background and Current Law*, The Law of Software 1968 Proceedings B-25 (1968).

<sup>112</sup> See *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011) (“in finding that the process in *Benson* was not patent-eligible, the Supreme Court appeared to endorse the view that methods which *can be* performed mentally, or which are the equivalent of human mental work, are unpatentable abstract ideas—the “basic tools of scientific and technological work” that are open to all”) (citing *Benson* at 409 U.S. at 67) (emphasis added).

<sup>113</sup> *Listingbook, LLC v. Market Leader, Inc.*, 2015 U.S. Dist. LEXIS 153994 (M.D.N.C., Nov. 13, 2015). *DietGoal Innovations LLC v. Bravo Media LLC*, 33 F. Supp. 3d 271 (S.D.N.Y. July 8, 2014). “In *Benson*, the Court held that the computerized method claimed in the patent for converting BCD numerals into pure binary code was directed toward an impermissible abstract idea, in part because “[t]he conversion of BCD numerals to pure binary numerals *can be done mentally*.” 409 U.S. at 66-67) (emphasis added).

<sup>114</sup> See *Planet Bingo LLC v. VKGS LLC*, 576 F. Appx. 1005, 1007-08 (Fed. Cir. 2014) (Managing a bingo game “*can be carried out by a human using pen and paper.*”) (emphasis added); *Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, No. 2:13-CV-655, 2014 WL 4364848, at \*10 (E.D. Tex. Sept. 3, 2014) (“The fact that an invention consists of simple calculations that *can readily be* performed by humans is a factor that has frequently been held to be indicative of unpatentability. . . . Adding a computer to perform those mental steps ‘does not transform a patent-ineligible claim into a patent-eligible one.’”) (Bryson, J.) (citations omitted). *Walker Digital, LLC v. Google, Inc.*, 66 F. Supp. 3d 501 (D. Del. Nov. 3, 2014) (“[T]he claims of the ‘270 patent are merely “a series of mental steps that people, aware of each step, can and regularly do perform in their heads.”); *Bascom Research, LLC v. Facebook, Inc.*, 77 F. Supp. 3d 940, N.D. Cal. Jan. 2, 015) (“[T]he concept of establishing, storing and using associations between documents *can also be* performed mentally.”); *Cogent Med., Inc. v. Elsevier Inc.*, 70 F. Supp. 3d 1058 (N.D. Cal. Nov. 30, 2014) (“[T]he computer does no more than automate what “*can be done mentally*”).

<sup>115</sup> Marc Andreessen, *Why Software Is Eating the World*, Wall Street J. (Aug. 20, 2011), <http://www.wsj.com/articles/SB10001424053111903480904576512250915629460>.

<sup>116</sup> Brief of Amicus Curiae Intellectual Property Owners Association in Support of Neither Party at 25, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); 2013 U.S. Briefs 298 (U.S. Jan. 28, 2014).

in industries that use information technology was the main source of sustained U.S. productivity growth from 2000-2007.<sup>117</sup> The availability of software patents enhances innovation by providing incentives to innovators.<sup>118</sup>

Innovation in the pharmaceutical industry, preventive healthcare, and the diagnostic industry require significant investments to bring products to market. For example, the extensive testing to obtain FDA approval for a pharmaceutical product typically requires 10-15 years and about \$1.5 billion per commercialized drug.<sup>119</sup> An overly broad view of the exceptions to patent eligible subject matter undermines incentives to invest in or develop new drugs and treatment methods.<sup>120</sup>

But not only has the scope of eligibility narrowed, the eligibility inquiry under the 101 Decisions is not well-defined, making the application of the Court's test uncertain.<sup>121</sup> Such uncertainty undermines the rights both of patentees and of the public, and makes determining when and how to apply the exceptions difficult for both the courts and the Patent Office. Uncertainty as to whether a startup company's technology will be protected by patents increases the risks to early stage investors, and thus reduces both the overall likelihood of funding cutting edge technologies, as well as the amount of such investments.

### *Section 101 Is the Wrong Mechanism to Address Patent Trolls*

There has been a significant public backlash caused by the aggressive enforcement of low quality patents by so-called "patent trolls," and consequently much of the focus of recent patent reform efforts is on curbing the issuance and enforcement of such patents. IPO supports a wide variety of measures to improve patent quality, including full funding of the USPTO, improved examiner training, compact prosecution, and other measures.<sup>122</sup> Achieving and maintaining high-quality patents is an important goal for the U.S. patent system and one that IPO supports.<sup>123</sup>

But the 101 Decisions do not provide a framework for improving patent quality, and more generally § 101 is the wrong tool to do it. Using section 101 to invalidate poor quality patents is like using a sledgehammer to crack walnuts: it's hard to stop the damage at just the shell. What distinguishes a good quality patent from a bad one is unrelated to the requirements of eligibility: the quality of the disclosure in terms of enablement, the novelty and non-obviousness of the claims, and their specificity—all factors being expressly mentioned by the courts in deciding patent eligibility cases. The amorphous nature of the *Alice* test is increasing the risk to innovators in the most vital sectors of the U.S. economy and is having and will increasingly have the effect of chilling U.S. innovation.

The narrowed scope of eligibility, the broad nature of the inquiry, the corresponding complexity, and the resulting uncertainty of outcome burden patent applicants, patentees, the Patent Office, the courts, and businesses alike. The IPO Section 101 Legislation Task Force believes amendments to 35 U.S.C. § 101 should be made to counteract the effects of the 101 Decisions by more clearly defining the scope of eligible subject matter, excluding from the eligibility analysis

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<sup>117</sup> *Id.* at 23.

<sup>118</sup> *Id.* at 26.

<sup>119</sup> Letter from IPO to USPTO (July 31, 2014) (commenting on USPTO *Mayo-Myriad* Guidance), <http://www.ipso.org/wp-content/uploads/2014/08/Myriad.pdf>.

<sup>120</sup> *Id.*

<sup>121</sup> "In any event, we need not labor to delimit the precise contours of the "abstract ideas" category in this case." *Alice*, 134 S. Ct. at 2357.

<sup>122</sup> See generally Letter from IPO to USPTO (Dec. 4, 2013) (commenting on USPTO Draft Strategic Plan for FY 2014-2018), <http://www.ipso.org/wp-content/uploads/2013/12/IPO-Comments-to-USPTO-2014-2018-Strategic-Plan1.pdf>.

<sup>123</sup> See *id.*

matters already addressed elsewhere in the patent statute, and returning the scope of eligibility to that originally envisioned by Congress: “[to] include anything under the sun made by man.”

## 2. Proposed Legislation

The proposed legislation is designed to achieve the following goals:

- (a) reverse the recent Supreme Court rulings and restore the scope of subject matter eligibility to that intended by Congress in the passage of the Patent Act of 1952 (“the 1952 Act”);
- (b) define subject matter eligibility more clearly and in a technology-neutral manner;
- (c) require an evaluation of subject matter eligibility for the invention as a whole; and
- (d) simplify the subject matter eligibility analysis for the Patent Office, courts, patent applicants, patentees, and the public by prohibiting consideration of “inventiveness” and patentability issues under 35 U.S.C. §§ 102, 103, and 112 from the § 101 analysis.

To achieve these goals, the proposed legislation expressly excludes from the subject matter eligibility analysis issues of inventiveness and those that are the subject of other sections of the 1952 Act as amended by the America Invents Act (AIA) (*i.e.*, §§ 102, 103, and 112). The other sections are sufficient for addressing the Court’s preemption concerns.<sup>124</sup>

The proposed legislation also forbids dissecting claims into parts—such as process step(s) allegedly directed to a judicial exclusion and additional steps—as otherwise required by *Mayo*.<sup>125</sup>

Existing Statute	Proposed Text	Notes
	<u>I. Basis of Eligibility in Utility and Entitlement to Patent</u>	The structure of the amendments is quite specific in architecture:
<b>35 U.S.C. § 101</b> Inventions patentable.	101 (a) ELIGIBLE SUBJECT MATTER	Section 101(a) establishes (1) entitlement to patent in inventors, (2) the general basis of eligibility in utility and (3) absence of exceptions other than specified by the statute, <i>i.e.</i> , no room for future judicial exceptions.

<sup>124</sup> For example, as Judge Lourie noted in his concurrence in the Federal Circuit’s decision to deny an *en banc* hearing in *Ariosa*:

The claims might be indefinite or too broad in that they do not specify how to amplify and detect, or how to separate, detect, and diagnose. Or they perhaps attempt to claim all known methods of carrying out those steps. But the finer filter of § 112 might be better suited to treating these as questions of patentability, rather than reviewing them under the less-defined eligibility rules.

*Ariosa*, 809 F.3d at 1285 (Lourie, J., concurring).

<sup>125</sup> *Id.* at 1286 (“But applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.”).

Existing Statute	Proposed Text	Notes
Whoever invents or discovers	Whoever invents or discovers	The use of <i>whoever</i> sets forth basis of the right to patent in inventors. This provision ties in with § 151(a) ("If it appears that an applicant is entitled to a patent under the law, a written notice of allowance of the application shall be given or mailed to the applicant.").
	and claims as an invention	Establishes that eligibility is based on the claimed invention, not a reduction of the claim to a gist, a "quick look," or consideration of the purpose of the invention. In addition, the language here sets up the antecedent basis for subsequent mentions of "claimed invention."  Makes the section consistent with sections 102, 103, and 112 which all are directed to the evaluation of the claimed invention. It would be anomalous that Congress would have other requirements of an invention based on a claimed invention but eligibility based on something other than what is claimed. The intent of this provision is thus to direct the court to construe the claims, as done with the other statutory sections which likewise used "claimed invention" to imply the requirement for claim construction.
any new and useful	any useful	Eligibility is based on utility and nothing else. The term "new" is removed from the statute, as the courts have suggested that "new" here provides some distinct requirement other than novelty.  The case law regarding utility, which is generally well developed, is thus called upon as the sole basis of eligibility. Novelty is left to § 102.
process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,	process, machine, manufacture, composition of matter, or any useful improvement thereto,	Removes <i>new</i> , but otherwise the same.
may obtain a patent therefor,	shall be entitled to a patent,	Changes the statute to require the USPTO to issue a patent when all of the statutory provisions are satisfied. As with the use of <i>whoever</i> , this revision conforms to § 151(a).

Existing Statute	Proposed Text	Notes
subject to the conditions and requirements of this title.	subject only to the exceptions and conditions set forth in this Title.	Sets forth that the only exceptions to the entitlement to a patent generally, and to eligibility in particular, are those defined in the statute. The intent is to foreclose the development of any future ‘judicial exceptions’ to section 101. The exceptions are defined in section 101(b).

<u>II. Exception to Eligibility</u>	<u>Notes</u>
<b>(New) 101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY—</b>	Section 101(b) defines the exceptions allowable under section 101(a). This is done in terms of defining the only basis on which eligibility may be denied. As a result, it becomes unnecessary to define laws of nature, natural phenomena or abstract ideas, because regardless of what these terms mean, if the claim does not fall within the exception it is eligible. This approach is also the basis for establishing a common ground between high tech and life sciences: the only thing that needs to be agreed upon are the savings conditions, avoiding the complex problem of defining the precisely what is a law of nature, abstract idea, or product of nature:
A claimed invention	The upshot of <i>Alice</i> has been to look to the gist of a claim, the purpose of a claim, or some other reduction or generalization rather than the claim language itself. The use of <i>a claimed invention</i> here is again to reinforce the focus on claim language and thus a requirement for claim construction, because §§ 102 and 103 use "claimed invention." Reference to the “claimed invention” is also consistent with the requirement to consider the claim as a whole and not individual limitations ( <i>see below.</i> )
is ineligible under subsection (a)	<p>The use of <i>is ineligible</i> was one of many different possible forms considered, including <i>may be ineligible, shall be ineligible. May be</i> suggests that even if the conditions set forth are satisfied, an invention may still be eligible and thus fails to make the subsequent conditions sufficient to cause a claim to be ineligible. Although <i>shall be</i> (and <i>will be</i>) conveys a necessity, it implies the future tense of something to occur.</p> <p>The use of <i>is ineligible</i> is also more clear than formulations using a double negative such as <i>eligibility shall not be negated.</i></p>
if and only if	<p>Various alternatives were considered, such as <i>where, when, if, only if.</i> The goal of the section is to define the necessary and sufficient conditions for ineligible subject matter.</p> <p><i>If</i> by itself (<i>A claimed invention is ineligible if....</i>) would establish a sufficient condition, but would not exclude other</p>

<u>II. Exception to Eligibility</u>	<u>Notes</u>
	<p>conditions. In other words, the courts or USPTO could find other reasons for a claim to be ineligible outside of those stated in the statute, thereby defeating the purpose of the legislation. <i>Only if</i> by itself (<i>A claimed invention is ineligible only if...</i>) makes the following conditions necessary ones but by itself fails to prevent a court from imposing another extrinsic condition for eligibility, such as definiteness.</p> <p>The combination of <i>if and only if</i> is recognized as being the appropriate form to define a closed set of necessary and sufficient conditions. Anything outside of these excluded conditions is eligible. This is important because the district courts and the USPTO routinely confuse <i>necessary</i> and <i>sufficient</i> conditions with particular circumstances that are not even generally applicable. For example, in <i>DDR Holdings</i>, the Federal Circuit held that the claims were eligible in part because “the claimed solution [was] necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.” But this statement by the court cannot be either a necessary or sufficient condition. It clearly was not <i>sufficient</i> because the court went on to say, “We caution, however, that not all claims purporting to address Internet-centric challenges are eligible for patent.” Nor can it be a <i>necessary</i> condition because only a small portion of software has anything to do with the Internet (<i>e.g.</i>, software embedded in control systems, airplanes, automobiles, medical devices, etc.). Nonetheless, numerous courts have read <i>DDR</i> as imposing a necessary requirement,<sup>126</sup> and the USPTO's claim examples in their examiner training materials also suggest this interpretation (“These are meaningful limitations that add more than generally linking the use of the abstract idea (the general concept of organizing and comparing data) to the Internet, because they solve an Internet-centric problem with a claimed solution that is necessarily rooted in computer technology, similar to the additional elements in <i>DDR Holdings</i>.”)<sup>127</sup></p>

<sup>126</sup> See *e.g.*, *Affinity Labs of Tex., LLC v. Amazon.com, Inc.*, No. 6:15-CV-0029-WSS-JCM, 2015 WL 3757497, at \*22 (W.D. Tex. June 12, 2015) (However, unlike the patent in *DDR Holdings*, the claims here do not address a “challenge particular to the internet” nor did the claims solve a problem “specifically arising in the realm of computer networks.”) *Am. Needle, Inc. v. Zazzle Inc.* No. 15-cv-3971 (N.D. Ill. Jan. 22 2016) (contrasting *DDR* and holding that “promoting sales by providing a visual aide to purchasing over “the internet cannot be said to be rooted in computer technology.”); *BASCOM Global Internet Servs., Inc. v. AT & T Mobility LLC*, No. 3:14-cv-3942-M, 2015 WL 2341074, \*8 (N.D. Tex. 2015) (“The first inquiry is whether the Federal Circuit’s holding and reasoning in *DDR Holdings* means BASCOM’s claims are rooted in the Internet and overcome a problem specifically arising in the realm of the Internet.”); *Trading Techs. Int’l, Inc. v. CQG, Inc.*, No. 05-CV-4811, 2015 WL 774655, at \*5 (N.D. Ill. Feb. 24, 2015) (finding that the claims, like those at issue in *DDR Holdings*, were “necessarily rooted in computer technology in order to overcome a problem arising in the realm of computers”).

<sup>127</sup> See *July 2015 Update Appendix 1: Examples*, at 5 (USPTO), available at <https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-app1.pdf>.

<u>II. Exception to Eligibility</u>	<u>Notes</u>
	The use of <i>if and only if</i> appears fifty times in the U.S. Code, and thus Congress is familiar with its use.
the claim as a whole,	The Supreme Court emphasized in <i>Diehr</i> that eligibility is based on the claim as a whole, because every claim can be broken down into individual elements, and it is the entire combination that defines the <i>invention</i> , which must be eligible. <i>Alice</i> refashioned this requirement from <i>Diehr</i> into the statement that the claim limitations need only be considered as "an ordered combination." However, once a court finds the individual limitations are abstract or a law of nature, it rarely finds the combination sufficient. USPTO Examiners routinely decompose the claim limitation-by-limitation, <u>find each limitation itself</u> to be an example of an abstract idea (rather than the claim as a whole) and then give only lip service to the claim as whole, stating that the claimed limitations "together do not offer substantially more than the sum of the functions of the elements when each is taken alone." <sup>128</sup>
as understood by a person having ordinary skill in the art to which the claimed invention pertains,	<p>The primary complaint in section 101 analysis is that it is a subjective exercise.<sup>129</sup> The patent law already provides a standard, objective viewpoint for evaluating the conditions of patentability: the person of ordinary skill in the art (POSITA). Obviousness, enablement, claim construction, written description, doctrine of equivalents all use the person of ordinary skill in the art.<sup>130</sup></p> <p>This use of POSITA is important because a claim limitation that appears to be an abstract idea to a court (<i>e.g.</i>, a database) may have significant technological meaning to persons of ordinary skill in the art. Similarly, in the biotech field, what a court considers a "law of nature" would likely not coincide with the view of a scientist in the relevant field.</p> <p>Additionally, POSITA is technology neutral and evolves over time as technology evolves.</p>

<sup>128</sup> This particular phrasing appears in over 5,800 rejections as of Feb. 3, 2017.

<sup>129</sup> See *Cal. Inst. of Tech. v. Hughes Commc'ns Inc.*, 59 F. Supp. 3d 974, 984 ("In order to best incentivize innovation, however, patent law must be predictable, consistent, and uniform. See *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1282 (Fed. Cir. 2014). *Alice* does not achieve this goal, leaving the boundaries of § 101 undefined. See *McRO, Inc. v. Sega of America, Inc.*, No. 2:12-cv-10327, 2014 WL 4749601, at \*5 (C.D. Cal. Sept. 22, 2014) (Wu, J.) ('[T]he two-step test may be more like a one step test evocative of Justice Stewart's most famous phrase ["I know it when I see it"].)').

<sup>130</sup> Claim construction, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*); indefiniteness, *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1383 (Fed. Cir. 2005); enablement and written description, *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013); obviousness, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); and infringement under the doctrine of equivalents, *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950); see also Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155, 1186-87 (2002) (noting POSITA's use in definiteness, enablement, best mode, claim construction, and doctrine of equivalents).

<u>II. Exception to Eligibility</u>	<u>Notes</u>
<p>exists in nature independently of and prior to any human activity, or</p>	<p>This ineligibility criterion is directed to the laws of nature and natural products. Any claim that is entirely directed to a law of nature or natural product would be directed to something that “exists in nature.”</p> <p>The requirement of “independently of any human activity” reflects the notion of inventions are the result of some act by a human upon the state of nature and thus captures the broad scope of anything made by humans, that is, anything “artificial” in the ordinary sense of the word (“made by human skill; produced by humans (opposed to natural ).”<sup>131</sup></p> <p>This approach is consistent with underlying distinction drawn by the Supreme Court in <i>Myriad</i> between genomic DNA and complementary DNA (cDNA). The <i>Myriad</i> Court stated that while the “nucleotide sequence of cDNA is dictated by nature, not by the lab technician,” “the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a product of nature.”<sup>132</sup> Thus, the cDNA sequence did not exist in nature independently of human activity—it took human activity to create the sequence.<sup>133</sup></p> <p>Consideration was given to other terms such as <i>effort</i>, <i>agency</i>, <i>contribution</i>, <i>involvement</i>, but these were considered as ambiguous (what is <i>involvement</i> or <i>agency</i>?), or suggesting an evaluation of the merits or worthiness of the invention (<i>contribution</i>) or how hard or complex the invention was to create (<i>efforts</i>). <i>Activity</i> is used here to connote simply that a human <i>acted</i> upon nature, <i>i.e.</i>, was the agent that brought about the invention. This conforms with the statement that an invention is “<i>anything under the sun that is made by man.</i>”</p> <p>The net effect is that the any recited subject matter that is useful and that does not exist in nature—in other words, that is the result of human actions as applied to nature—is eligible.</p>

<sup>131</sup> *Artificial*, Dictionary.com, <http://dictionary.reference.com/browse/artificial>.

<sup>132</sup> *Myriad*, 133 S. Ct. at 2119.

<sup>133</sup> How far this distinction goes is unclear in view of *Myriad*, because the Court held that “isolated” gDNA, which also required human activity cut chemical bonds and purify the nucleic acid, was not eligible.



<b><u>II. Exception to Eligibility</u></b>	<b><u>Notes</u></b>
that exists solely in the human mind.	<p>This ineligibility criterion is directed to abstract ideas and thus makes eligible any claim limitation that requires some external involvement with the physical world or any representation thereof (<i>e.g.</i>, data in a computer).</p> <p>As originally stated by the Supreme Court in <i>Benson</i>, the exception was for “abstract <i>intellectual ideas</i>,” <i>i.e.</i>, ideas that do not have physical or tangible aspects. “Phenomena of nature, though just discovered, mental processes, and abstract <i>intellectual</i> concepts are not patentable.”<sup>134</sup> Over time the adjective “intellectual” has been dropped from the expression, and this modification has led to much of the confusion in the case law. Even so, it is clear that the <i>original concern</i> of the Supreme Court was with “ideas” that are purely mental in nature, such as “mental processes” (<i>Benson, Diehr</i>) and “scientific truths.”<sup>135</sup></p> <p>The language here thus returns the abstract idea exception back to its original intent, the exclusion of purely mental phenomena. This makes sense from a policy standpoint, because if mental phenomena were patent eligible, a person could infringe simply by thinking or speaking—anomalous outcomes, surfeit with problems of proof (how does one prove that a person had an infringing thought), let alone First Amendment issues.</p>

<b><u>III. Exclusion of Other <i>Alice</i> and Other Statutory Provisions</u></b>	
<b>(New) 101 (c) SOLE ELIGIBILITY STANDARD.—</b>	Section 101(c) excludes consideration of sections 102, 103, and 112 in determining eligibility.
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,	<p>This clause expressly excludes the use of sections 102 and 103. Although the courts often <i>say</i> that “novelty” is not relevant to eligibility, they in fact use a lack of novelty as the basis for finding claim limitations as not “something more.”</p> <p>This is due to the Supreme Court's introduction of the terms</p>

<sup>134</sup> *Benson*, 409 U.S. at 67 (emphasis added).

<sup>135</sup> *See Diehr*, 405 U.S. at 201; *Benson*, 409 U.S. at 67; *Mackay Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939). Indeed, the traditional definition of “idea” refers *specifically* to the mental phenomenon: “any conception existing *in the mind* as a result of mental understanding, awareness, or activity.” *Idea*, Dictionary.com, <http://dictionary.reference.com/browse/idea> (last visited June 6, 2013); *see also* “Idea,” Webster’s Third New International Dictionary 1122 (2002) (“an object *of the mind* existing in apprehension, conception, or thought; a product of reflection or mental conception”).

	<p><i>conventional, routine, well understood</i> used in <i>Alice</i> and <i>Mayo</i> to exclude limitations from being “significantly more.” See, e.g., <i>OpenTV, Inc. v. Apple Inc.</i> (“The concept of a database is not novel or unique. . .[and] [i]nformation exchanged between a database (as part of or remote from a computer) and the computer is not novel and adds nothing to the 101 analysis.”).<sup>136</sup></p> <p>The use of <i>conventional, routine, well understood</i> as a standard has the effect of making ineligible uses of existing computers for entirely new purposes. As such, it expressly contradicts section 100(b) of the statute, which states, “The term ‘process’ means process, art or method, and includes <u>a new use of a known process, machine, manufacture, composition of matter, or material.</u> District courts have invalidated hundreds of patents based on this exclusion of known machines in the form of “generic computers.”<sup>137</sup> Conversely, other courts have found claims eligible by looking for an “unconventional” approach.<sup>138</sup> This blends the requirements of novelty with eligibility, which, as explained immediately below, the proposed legislation is intended to prevent.</p>
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<sup>136</sup> *OpenTV, Inc. v. Apple, Inc.*, No. 5:15-cv-02008-EJD (N.D. Cal. Jan. 28, 2016).

<sup>137</sup> *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 2015 U.S. Dist. LEXIS 62601 (D. Md. June 11, 2015) (“The use of generic hardware and software running an intrusion detection application is not viewed as new and inventive, but rather an application of existing technology on a network of networks that are themselves already each protected by an intrusion detection system. Neither Dr. Meldal’s Declaration nor his deposition testimony add any further specificity to the claimed invention.”).

<sup>138</sup> See *Motio, Inc. v. BSP Software LLC*, 134 F. Supp. 3d 434, No. 4:12CV-647, 2016 WL 26043, at \*4 (E.D. Tex. Jan. 4, 2016) (concluding that claims drawn to the abstract idea of maintaining versions of electronic documents contained an inventive concept that meaningfully limited the abstract idea, as they “describe a non-conventional method [of doing so], by providing an ‘automated agent’ distinct from a business intelligence system to provide a type of version control”).

and 112 of this Title,	Excludes the use of section 112 requirements in regards to specificity, written description, or enablement of the claims. Some courts have found claims ineligible for lack of specificity, <sup>139</sup> and similarly, other courts have focused on specificity to find a claim eligible. <sup>140</sup> Other courts have found claims ineligible using section 101 as a proxy for whether the claims are enabled. <sup>141</sup>
or the manner in which the claimed invention was made or discovered,	Mirrors the last clause of § 103 “Patentability shall not be negated by the manner in which the invention was made.” As discussed above, Congress enacted § 103 to prevent the courts from making qualitative judgments about the inventive merit of the invention based on how it was made. As has been demonstrated, courts now routinely consider how the invention was made, <i>e.g.</i> , in terms of automating existing processes or taking so-called “pre-Internet” concepts and applying them to the Internet. <sup>142</sup> This provision is thus intended to preclude such approaches.

<sup>139</sup> See *Intellectual Ventures I v. Canon Inc.* (D. Del. Nov. 9, 2015) (Noting that *DDR Holdings* provides “a benchmark of specificity to which other claims can be compared,” and that “even though most of the patent claims now being challenged under § 101 would have survived such challenges if mounted at the time of issuance, these claims are now in jeopardy under the heightened specificity required by the Federal Circuit post-*Alice*.”); *Clear With Computers LLC v. Altec Indus., Inc.* 2015 U.S. Dist. LEXIS 28816 (E.D. Tex. Mar. 3, 2015) (“The additional recitation of specific computer components such as a “database,” “memory,” “transceiver” and “wire-based network,” and computer functions such as “storing,” “transmitting” and “receiving,” are incapable of conferring the requisite specificity.”); *Source Search Techs., LLC v. Kayak Software Corp.*, 111 F. Supp. 3d 603, 617 (D.N.J. 2015) (“That specificity removes the claims from the abstract realm.” (emphasis in original)); *TriPlay, Inc. v. WhatsApp Inc.*, Civil Action No. 13-1703-LPS, 2015 WL 1927696, at \*5 (D. Del. Apr. 28, 2015) (holding that the claim at issue did not contain an inventive concept where it “does not purport to limit itself to a specific way of converting a message from one layout to another—it simply covers the act of ‘converting’ messages”) (emphasis in original); *Intellectual Ventures II LLC v. JP Morgan Chase & Co.*, 2015 U.S. Dist. LEXIS 56092 (S.D.N.Y. Apr. 28, 2015) (“[T]he ‘694 Patent fails to describe the claimed process at any level of specificity. The patent in *DDR Holdings*, in contrast, recited specific steps to accomplish the desired result of retaining website traffic.”).

<sup>140</sup> *Brassring, Inc. v. HireAbility.com, LLC*, No. 12-10943-FDS, 2015 WL 1943826, at \*7 (D. Mass. Apr. 28, 2015) (concluding that claims were “not manifestly invalid for lack of inventiveness” where they did not simply recite the use of digital data, but also recited a specific method of digital extraction that plaintiff contended was not conventional); *Messaging Gateway Solutions, LLC v. Amdocs, Inc.*, No. 14-732-RGA, 2015 WL 1744343, at \*4-5 (D. Del. Apr. 15, 2015) (finding that a claim directed to the translation of mobile phone language into Internet language contained an inventive concept where “[i]t specifies how an interaction between a mobile phone and a computer is manipulated in order to achieve a desired result which overrides conventional practice”). *Intellectual Ventures I, LLC v. Motorola Mobility LLC*, 81 F. Supp. 3d 356 (D. Del. Feb. 24, 2015) (“Dependent claims 2, 3, 5, 8 and 9 add additional specificity, reciting particular packet-centric protocols, particular coupling methodologies and particular generic packet types. For the foregoing reasons, the court finds that the asserted claims of the ‘450 patent are directed to patent-eligible subject matter.”).

<sup>141</sup> See *e.g.*, *Vehicle Intelligence Sys. v. Mercedes-Benz USA*, No. 2015-1411 (Fed. Cir. Dec. 28, 2015) (“[N]either the claims at issue nor the specification provide any details as to how this “expert system” works or how it produces faster, more accurate and reliable results.”; “None of the claims at issue are limited to a particular kind of impairment, explain how to perform either screening or testing for any impairment, specify how to program the “expert system” to perform any screening or testing, or explain the nature of control to be exercised on the vehicle in response to the test results.”).

<sup>142</sup> See *e.g.*, *Advanced Auctions LLC v. eBay Inc.*, 2015 U.S. Dist. LEXIS 39588 (S.D. Cal. Mar. 26, 2015) (finding ineligible “claims [] directed to implementation of a pre-Internet world business practice.”); *IPLearn-Focus, LLC v. Microsoft Corp.*, 2015 U.S. Dist. LEXIS 90077 (N.D. Cal. July 10, 2015) (finding ineligible “claims [that] recite pre-Internet and pre-computer educational practices performed with computers and the Internet.”).

<p>or the claimed invention's inventive concept.</p>	<p>The Supreme Court reintroduced the "inventive concept" analysis into § 101 in <i>Mayo</i>, instructing courts to "search" for this elusive construct. As noted above, it was the intent to eliminate this approach that motivated the development of § 103.</p> <p>One of the frequently-cited examples of an alleged lack of "inventive concept" is automating an existing manual process. See, e.g., <i>GT Nexus, Inc. v. Intra, Inc.</i> ("Here, the Court finds that the patent claims merely automate the practice of booking and tracking shipping containers; this automation is insufficient to transform the nature of the patents.")<sup>143</sup> Historically, whether automation was sufficiently "inventive" has been properly treated under section 103. See, e.g., MPEP 2144 "Supporting a Rejection under 35 U.S.C. § 103" (discussing automation of manual processes).</p>
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<sup>143</sup> U.S. Dist. LEXIS 150579 (N.D. Cal. Nov. 5, 2015); see also *Vehicle Intelligence Sys. v. Mercedes-Benz USA*, No. 2015-1411 (Fed. Cir. Dec. 28, 2015) ("Generic computer automation of the conventional "screening" step does not amount to an "inventive concept."); *OIP Techs., Inc. v. Amazon.com, Inc.* 788 F.3d 1359 ( Fed. Cir., 2015) ("At best, the claims describe the automation of the fundamental economic concept of offer-based price optimization through the use of generic-computer functions."); *Hewlett-Packard Co. v. ServiceNow, Inc.*, 2015 U.S. Dist. LEXIS 29384 (N.D. Cal. Mar. 10, 2015 ("the automation of IT incident resolution is an abstract idea, not patentable under § 101."); *Parus Holdings, Inc. v. Sallie Mae Bank*, 2015 U.S. Dist. LEXIS 137444 (D. Del. Oct. 8, 2015) ("Organizing business functions based on commands provided by a user is tantamount to the automation of the management of business communications usually performed by human administrative assistants (the identified purpose of the invention."); *Cogent Med., Inc. v. Elsevier Inc.*, 70 F. Supp. 3d 1058, 1060 (N.D. Cal. 2014) ("[T]he '879 Patent claims no more than a computer automation of what 'can be performed in the human mind, or by a human using a pen and paper.'"); *Voxathon LLC v. Alpine Elecs. of Am., Inc.*, No. 2:15-cv-562-JRG (E.D. Tex. Jan. 20, 2016) ("Claim 1 is really nothing more than the automation of responding to the sender of a message received on a telephone.").