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# AIPLA QUARTERLY JOURNAL

VOLUME 44, NUMBER 2

SPRING 2016

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SPRING 2016

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Published by the American Intellectual Property Law Association and distributed to all members *gratis*.

Non-Member and Law Library Subscription (per year)	\$95.00
Foreign Rate (per year)	\$109.00
Single Issue Price	\$25.00
Double Issue Price	\$40.00

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ISSN: 0883-6078

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**THE TIME HAS COME TO AMEND 35 U.S.C. § 101**

*Jorge A. Goldstein, Michelle K. Holoubek, & Krishan Y. Thakker\**

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## I. INTRODUCTION

The recent triad of Supreme Court decisions on eligibility (*Mayo*,<sup>1</sup> *Myriad*,<sup>2</sup> and *Alice*<sup>3</sup>), and their interpretation by the courts and the United States Patent and Trademark Office (“USPTO”), has given rise to an unworkable doctrine in patent law. Under this recent § 101 case law, a claim that is “directed to” a *per se* ineligible law of nature, a natural phenomenon, or abstract idea (the “Exceptions”) must be dissected into two portions—first, a portion drawn to the Exceptions and, second, a portion drawn to “everything else” (queried, in the immortal words of the Supreme Court in *Mayo* as, “What else is there in the claims?”<sup>4</sup>). Only if the “what else” portion includes an “inventive concept” is the claim as a whole “significantly more” than a patent on the first, ineligible, portion. Not only is this artificial dissection unworkable, but also the test for eligibility on the “what else” portion hopelessly commingles eligibility with non-obviousness.

The time is ripe for an amendment to 35 U.S.C. § 101. This article proposes an amendment that would remove inventiveness concepts from § 101 and make the law more workable. Without affecting the basic requirements of patentability (so that only novel, useful, nonobvious, well enabled and described, and clearly claimed inventions receive patents), and without disrupting the Exceptions jurisprudence, the proposed amendment will lift a major cloud from innovation-dependent sectors of the U.S. economy, such as the life sciences and software industries. Additionally, the time for amendment is ripe because, due to the recent enactment of the America Invents Act, including the dramatically expansive 35 U.S.C. § 102(a)(1), the scope of what is not novel in the U.S. now includes anything available to the public anywhere in the world.<sup>5</sup> This new,

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<sup>1</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

<sup>2</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>3</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

<sup>4</sup> *Mayo Collaborative Servs.*, 132 S. Ct. at 1297.

<sup>5</sup> *E.g.*, 35 U.S.C. § 102(a)(1) (2012) of the America Invents Act (“AIA”) contains a geographically unlimited novelty provision: “(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . . .” (emphasis added). Notably, this AIA version of

global view of lack of novelty stands an excellent chance of solving one major concern raised by the Supreme Court in the Triad: preemption.

Let us start with the proposed amendment to § 101 (additions emphasized):

Whoever invents or discovers any new and useful *invention, which is a physically implemented process, or machine, manufacture, or composition of matter, or any new and useful improvement thereof*, may obtain a patent therefor. *While the claimed invention is subject to the conditions and requirements of other sections of this title, no further conditions than novelty and usefulness of the claimed invention as a whole are required under this Section.*

This article will address why Congress should enact this proposed amendment. First, this article will provide background by describing the unworkable state of current patent eligibility law and why the amendment is necessary. Then, this article will explain how this amendment would restore § 101 to a more workable state. Finally, this article will analyze the amendment's constitutionality and will show how it would change (or would not change) existing Supreme Court jurisprudence.

## II. THE ELIGIBILITY CRASH OF 2012–2014

### A. *Themes from the Supreme Court Triad of § 101 Cases*

After a decades-long period of precedents expanding the eligibility of contemporary inventions in fields as disparate as software and biotechnology, the Supreme Court Triad brought the expansion to a sudden end. Three major themes arose from the Triad: the requirement for claim dissection, the focus on a judicially-created concept of “§ 101-inventiveness,” and the caution to avoid preemption of the field by a skillfully drafted claim.

#### 1. Claim Dissection

In its 2012 decision in *Mayo*, the Supreme Court held ineligible a claim to optimize the therapeutic efficacy of a drug, which included a first step of administering the drug at a certain dosage, and a second step of determining the level of a derived metabolite as an indication of whether the dosage would be

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§ 102(a) substitutes the phrase “the invention was known or used by others in this country” from the pre-AIA version. 35 U.S.C. § 102(a) (2006).

effective or harmful.<sup>6</sup> The Court interpreted the claim as directed to applications of a “natural correlation.”<sup>7</sup> In analyzing the claim, the Court dissected the claim into the *per se* ineligible “natural correlation” (i.e. between the levels of the metabolite and the therapeutic efficacy) and the “what else” portion—the steps of administering the drug and determining metabolite levels.<sup>8</sup> The Court concluded that the “what else” steps were nothing but “conventional” and “routine” at the filing date,<sup>9</sup> and did not “add enough” to make the claim a “patent-eligible process[] that appl[ies] natural laws.”<sup>10</sup>

The 2013 Supreme Court decision in *Myriad*<sup>11</sup> involved a composition of matter claim, not a method claim like in *Mayo*, thus the Court did not lay out the dissection between ineligible elements and “everything else” in the claims as clearly as it did in *Mayo*. The claim was to an “isolated DNA” encoding Breast Cancer Antigen 1 (BRCA1) polypeptide.<sup>12</sup> Notwithstanding that the claim was essentially to an isolated *molecule*, the Court gave short thrift to the term “isolated” and interpreted the claim as drawn to the DNA *sequence* itself, which it

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<sup>6</sup> *Mayo Collaborative Servs.*, 132 S. Ct. at 1294.

<sup>7</sup> *See id.* at 1298.

<sup>8</sup> *See id.* at 1297–98.

<sup>9</sup> *Id.* at 1298. The fact that the additional two steps were physical and transformative (and might have passed an earlier “machine or transformation test” (“MOT”)) was not dispositive, in that the Court had ruled in *Bilski* that the MOT was only a “clue” to eligibility and not the only way of analyzing 35 U.S.C. § 101. *See Bilski v. Kappos*, 561 U.S. 593, 614–20 (2010) (Stevens, J., concurring).

<sup>10</sup> *Mayo Collaborative Servs.*, 132 S. Ct. at 1297. A serious conceptual difficulty with *Mayo* is that the Supreme Court seems to confuse a natural *law* with a natural *process*. *See, e.g., id.* at 1297 (“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.”). The metabolism of a synthetic drug, however, while controlled by natural *processes* such as enzymatic degradation, is not a natural *law*, such as  $E=mc^2$ .

<sup>11</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>12</sup> *Id.* at 2113 (citing claim 1 of U.S. Patent 5,747,282).

equated with the identical (and ineligible) sequence in nature.<sup>13</sup> In other words, the term “isolated” did not “add enough” to make the claim as a whole eligible.

In 2014, in the context of a method claim to a computer-implemented algorithm for eliminating settlement risks, the Court in *Alice* reinforced the *Mayo* test of dissection.<sup>14</sup> The Court separated the claim into a first portion, a *per se* ineligible abstract idea, and a second portion, the implementation of the idea by a generic computer.<sup>15</sup> In applying the *Mayo* test, the Court found that the addition of the computer was not “enough” to transform the abstract idea into a patent-eligible invention.<sup>16</sup>

## 2. Lack of § 101-Inventiveness in the “What Else” Portions

After dissecting the claims, the Court in each of the Triad cases held that none of the “what else” portions was “sufficient” to satisfy this judicially-created and illusory concept that we will refer to as “§ 101-inventiveness.” In *Mayo*, the Court held that the steps of “administering” and “testing” were routine and conventional.<sup>17</sup> Then in *Myriad*, the Court, relying on the concept from *Diamond v. Chakrabarty* that genetically-engineered microbes with novel oil-degradation pathways are “markedly different” than the naturally occurring microbes,<sup>18</sup> held that isolating the claimed DNA did not render it “markedly different.”<sup>19</sup> Finally, in *Alice*, the Court found that generic computer implementation was not

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<sup>13</sup> *Id.* at 2118 (“*Myriad*[’s] . . . claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.”); *id.* at 2109 (holding that “*Myriad*’s DNA claim falls within the law of nature exception. *Myriad*’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes”).

<sup>14</sup> See *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2353, 2357 (2014).

<sup>15</sup> *Id.* at 2356–57.

<sup>16</sup> *Id.* at 2360.

<sup>17</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

<sup>18</sup> 447 U.S. 303, 310 (1980).

<sup>19</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

“enough.”<sup>20</sup> The Court has further defined the § 101-inventiveness concept as something more than “human ingenuity,”<sup>21</sup> such as the presence of an “inventive concept.”<sup>22</sup>

Nowhere in the Triad does the Supreme Court equate § 101-inventiveness with non-obviousness under 35 U.S.C. § 103. The new concept seems to be something more than novelty but not quite non-obviousness. As we demonstrate below, § 101-inventiveness could be *less* than non-obviousness, but it could also be *more*.

### 3. Preemption and the Draftsman's Art

The Court was concerned in the Triad with one central problem: claims should not be so broad as to pre-empt the Exceptions themselves. A corollary message is that the courts need to remain ever vigilant to the use of the “draftsman's art,” which, in the guise of adding conventional and routine steps or limitations to a claim, only semantically eludes the prohibition against patenting the basic building blocks of technology. According to the Court, the very introduction of § 101-inventiveness into eligibility is needed to preclude preemption.<sup>23</sup>

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<sup>20</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. at 2360.

<sup>21</sup> *Id.* at 2350 (“In applying the § 101 exception, this Court must distinguish patents that claim the ‘buildin[g] block[s]’ of human ingenuity, which are ineligible for patent protection, from those that integrate the building blocks into something more . . . .” (citing *Mayo Collaborative Servs.*, 132 S. Ct. at 1303)).

<sup>22</sup> *Mayo Collaborative Servs.*, 132 S. Ct. at 1294. We have described step two of this analysis as a search for an “inventive concept”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Id.*

<sup>23</sup> *Cf. Alice Corp.*, 134 S. Ct. at 2354–55, 2360 (“This Court has long ‘warn[ed] . . . against interpreting § 101 ‘in ways that make patent eligibility “depend simply on the draftsman’s art.”’”); *Myriad Genetics*, 133 S. Ct. at 2114; *Mayo Collaborative Servs.*, 132 S. Ct. at 1294 (“[A] process that focuses upon the use of a natural law [must] also contain other elements, or a combination of elements, sometimes referred to as an ‘inventive concept.’”).

**B. Implementations by the Lower Tribunals and Their Consequences**

It took no time for the lower courts to adopt the lessons from the Triad. The Court of Appeals for the Federal Circuit (“CAFC”) fell in line quickly, at times complaining, yet clearly impotent and unwilling to act in opposition to the Supreme Court.<sup>24</sup>

**1. Implementation by the CAFC**

**a. Biotechnology Decisions**

Inspired by *Mayo*, the CAFC, in *Association for Molecular Pathology v. USPTO*, held that a method of detecting germline alterations in the BRCA1 gene was ineligible.<sup>25</sup> The steps of “comparing” sequences and “analyzing” the differences were abstract mental steps and did not prevent the claims from preempting a natural law.<sup>26</sup>

In *In re Roslin Institute (Edinburgh)*, the CAFC held that a live born clone of a donor sheep was ineligible because the clone did not have “markedly different” characteristics than those found in the pre-existing farm animal.<sup>27</sup> Ominously, the CAFC said in *dicta* that, even if the claim had been made absolutely novel over the farm animal by including limitations related to the presence of foreign mitochondrial DNA (mDNA) in the cloned sheep, the claim would only be eligible if the foreign mDNA led the clone to be “distinct in any relevant way” from the farm animal.<sup>28</sup>

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<sup>24</sup> See generally *Ariosa Diagnostics v. Sequenom*, 788 F.3d 1371 (Fed. Cir. 2015); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F. 3d 1245 (Fed. Cir. 2014); *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014); *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005 (Fed. Cir. 2014); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 1335 (Fed. Cir. 2013); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1349 (Fed. Cir. 2012) *aff'd in part, rev'd in part sub nom.*, 133 S. Ct. 2107 (2013).

<sup>25</sup> 689 F.3d at 1349.

<sup>26</sup> *Id.* at 1334–35, 1349.

<sup>27</sup> 750 F.3d at 1339.

<sup>28</sup> *Id.*

In the 2014 case of *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, the claim was directed to a pair of DNA primers for determination of a part or whole of a BRCA1 gene by amplification.<sup>29</sup> The CAFC dissected the claim into the ineligible pair of human DNA sequences and “everything else,” *i.e.*, their function of being able to amplify.<sup>30</sup> The CAFC held that the functional limitations were not—as alleged by Myriad—“fundamentally different” than those found in nature.<sup>31</sup>

In *Ariosa Diagnostics v. Sequenom*, the CAFC dissected a claim for detecting paternally inherited nucleic acid of fetal origin in maternal serum into two portions: 1) the appearance of paternal DNA in the serum of the mother (a natural phenomenon) and, 2) everything else, *i.e.*, the steps of “amplifying” and “detecting” DNA.<sup>32</sup> The CAFC found that the steps were routine and conventional at filing and held the claim ineligible.<sup>33</sup>

b. *Software Decisions*

In *Planet Bingo, LLC v. VKGS, LLC*, the CAFC read an explicit recitation of a computer out of the claims and found that the claims could be “done

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<sup>29</sup> 774 F.3d at 757.

<sup>30</sup> *See id.* at 763.

<sup>31</sup> *Id.* at 760–61.

<sup>32</sup> 788 F.3d 1371, 1376 (Fed. Cir. 2015).

<sup>33</sup> *Id.* at 1377. The CAFC also rejected Sequenom’s petition for *en banc* rehearing on December 2, 2015, reasoning, *inter alia*, that it is bound to follow *stare decisis* under *Mayo* and *Myriad*, but expressing concerns that their narrow reading (*i.e.* by equating laws of nature with processes of nature) could stifle innovation and discourage development and disclosure of new diagnostic and therapeutic methods in life sciences, driven by the discovery of new natural laws and phenomena. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*1 (Fed. Cir. Dec. 2, 2015). Sequenom submitted a petition for certiorari to the U.S. Supreme Court in March 2016, arguing that the CAFC overextended *Mayo*’s reach, warranting SCOTUS’ intervention to clarify its precedents over patenting methods of detecting/amplifying paternally-inherited cffDNA in maternal plasma. Petition for a Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, No. 15-1182 (U.S. Mar. 21, 2016) at 13–14, 24, 30. The petition concludes that this may be SCOTUS’ final chance to clarify *Mayo*’s test before disincentivization of innovation occurs in the life sciences/biomedical field. *Id.* at 35.

mentally.”<sup>34</sup> Although this seemed to contravene the long-standing principle that “all the limitations of the claim must be considered meaningful,”<sup>35</sup> the court found claims ineligible as directed to an abstract idea.<sup>36</sup>

Before *Alice*, the CAFC had found two computer-implemented claims eligible in *Ultramerical, Inc. v. Hulu, LLC*.<sup>37</sup> After *Alice*, however, the CAFC held the claims to be directed to the ineligible abstract idea of “showing an advertisement before delivering free content,” even though at least some of the eleven recited steps “were not previously employed in this art.”<sup>38</sup> Disconcertingly, the CAFC said that these claims would also not survive the MOT test, because the Internet was too ubiquitous to be a “novel machine,” the computer was too “conventional,” and “[a]ny transformation from the use of

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<sup>34</sup> 576 F. App'x 1005, 1005, 1008 (Fed. Cir. 2014) (“Like the claims at issue in *Benson*, not only can these steps be ‘carried out in existing computers long in use,’ but they also can be ‘done mentally.’”) (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). The first step of the claim recited: “providing a system for managing a game of Bingo which comprises: a computer with a central processing unit (CPU) and with a memory and with a printer connected to the CPU; an input and output terminal connected to the CPU and memory of the computer; and a program in the computer enabling” further method steps. U.S. Patent No. 6,398,646 (filed Jan. 6, 2000).

<sup>35</sup> See, e.g., *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (citing *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532-33 (Fed. Cir. 1987)); MPEP § 2143.03 (9th ed. Mar. 2014).

<sup>36</sup> *Planet Bingo*, 576 F. App'x at 1008.

<sup>37</sup> 772 F.3d 709, 711 (Fed. Cir. 2014).

<sup>38</sup> *Id.* at 715–16. Note that former Chief Judge Rader retired from the CAFC on June 30, 2014, just over four months before the Circuit altered its position on finding the *Ultramerical* subject patent claims as ineligible. Gene Quinn, *CAFC Shock: Judge Randall Rader Announces Retirement*, IPWATCHDOG (June 13, 2014), <http://www.ipwatchdog.com/2014/06/13/cafc-shock-judge-randall-rader-announces-retirement/id=50075/>. In the prior, vacated *Ultramerical* decision, *Ultramerical, Inc. v. Hulu, LLC*, 772 F.3d 1335 (Fed. Cir. 2013), Judge Rader’s majority opinion held the *same* claimed invention as eligible (*i.e.* internet/computer-based method for monetizing copyrighted product), before it was vacated on June 30, 2014 by the Supreme Court, and remanded back for further consideration in light of its decision in *Alice*. *WildTangent, Inc. v. Ultramerical, LLC*, 134 S. Ct. 2870, 2870. Judge Rader’s opinion was recognized as making clear he viewed § 101 as a “coarse filter” intended to provide only rare exceptions to patentable subject matter.



computers or the transfer of content between computers is merely what computers do and does not change the analysis.”<sup>39</sup>

With *DDR Holdings, LLC v. Hotels.com, L.P.*<sup>40</sup> came the CAFC's only post-*Alice* decision (at the time of drafting this article) identifying eligible claims. Here, the CAFC found the claimed invention eligible as “necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.”<sup>41</sup> Even so, the CAFC cautioned, “not all machine implementations are created equal. . . . The bare fact that a computer exists in the physical rather than purely conceptual realm ‘is beside the point.’”<sup>42</sup>

In *Internet Patents Corp. v. Active Network*, the CAFC acknowledged, “precision has been elusive in defining an all-purpose boundary between the abstract and the concrete, leaving innovators and competitors uncertain as to their legal rights.”<sup>43</sup> The CAFC also agreed that the current jurisprudence draws on the “rules of patentability” for §§ 102 and 103 and, accordingly, found the claims to web-browser functionality ineligible.<sup>44</sup>

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<sup>39</sup> *Ultramercial, Inc.*, 772 F.3d at 716–17.

<sup>40</sup> 773 F.3d 1245 (Fed. Cir. 2014).

<sup>41</sup> *Id.* at 1257.

<sup>42</sup> *Id.* at 1255–56.

<sup>43</sup> 790 F.3d 1343, 1345 (Fed Cir. 2015).

<sup>44</sup> *Id.* at 1347, 1349.

## 2. Implementation by the District Courts

Table 1. Statistics on District Court Dispositive Motions Under § 101 for the Years 2010-2015

Year	Motions under 12(b)(6), 12(c) or 56(a) for lack of eligibility	% Granted / Partially granted	% Denied	% Other <sup>45</sup>
2010	10	20.0/30.0	40.0	10.0
2011	15	33.3/26.7	40.0	0
2012	23	34.8/4.3	56.5	4.3
2013	24	54.2/4.2	41.7	0
2014	52	55.8/11.5	32.7	0
2015	165	55.2/10.3	30.9	3.6

Table 1 shows statistics on dispositive motions from district court cases at either summary judgment (under Rule 56(a)) or initial pleading stage (under Rules 12(b)(6) and 12(c)) based on § 101 grounds.<sup>46</sup>

The statistics through 2015 reflect the dramatic effects of the Triad on district court patent litigation. By the end of 2015, more than ten times as many dispositive motions were brought that challenged patent validity on § 101

<sup>45</sup> “Other” refers to those dispositive motions that were not decided, *e.g.*, they were withdrawn, stayed, continued pending discovery, referred to a magistrate judge, or the case settled.

<sup>46</sup> *See, e.g., Docket Navigator Analytics*, DOCKET NAVIGATOR, <https://www.docketnavigator.com/browse/results/62529470-ce26-ee6f-ad20-2e2a06abddb2> (as of Jan. 1, 2016) (search for challenging pleadings (all subcategories) or dispositive motions (all subcategories) and legal issue (unpatentable subject matter (35 U.S.C. § 101) (all subcategories)).

eligibility grounds than in 2010, and twice as many of the challenged patents were held invalid or dismissed on eligibility grounds than five years earlier.<sup>47</sup>

If the Supreme Court's intent in the Triad cases was to remove (newly defined) ineligible patents from consideration, then it seems to be succeeding. However, the statistics tell only part of the story. The procedural posture of a motion to dismiss—alleging that the patent holder fails to state a claim upon which relief can be granted—currently places a serious due process burden on the patentee. Although the CAFC has confirmed that § 101-eligibility is appropriate at the pleadings stage because such an issue is a question of law,<sup>48</sup> the CAFC has also held that a legal conclusion “may contain underlying factual issues.”<sup>49</sup> Thus, district courts are split as they grapple with the appropriate standard of proof and evidentiary burden required in dealing with § 101-based 12(b)(6) motions.<sup>50</sup> This makes the situation prejudicial to patentees. The

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

<sup>48</sup> *See, e.g.,* OIP Techs., Inc. v. Amazon.com, Inc., No. 15-642, 2015 WL 7258645 (U.S. Dec. 14, 2015) (denying patentee's petition for writ of certiorari, where CAFC at the motion to dismiss stage held invalid a price-optimization patent covering computer-implemented methods for testing demand to improve pricing, despite the fact that all allegations in a complaint must be assumed as true); Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A., 776 F.3d 1343, 1351 (Fed. Cir. 2014) (affirming dismissal of infringement claim for failure to state eligible subject matter); buySAFE, Inc. v. Google, Inc., 765 F.3d 1350, 1355 (Fed. Cir. 2014) (affirming grant of judgment on pleadings based on 101); *In re Comiskey*, 554 F.3d 967, 969 (Fed. Cir. 2009) (finding that the claims at issue were unpatentable subject matter under § 101).

<sup>49</sup> *See* Accenture Global Servs., GmbH v. Guidewire Software, Inc., 728 F.3d 1336, 1340–41, 1345 (Fed. Cir. 2013); Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 1335, 1339 (Fed. Cir. 2013) (“[T]he analysis under § 101, while ultimately a legal determination, is rife with underlying factual issues.”).

<sup>50</sup> Execware, LLC v. BJ's Wholesale Club, Inc., No. 14-233, 2015 WL 4275314, at \*3 (D. Del. July 15, 2015) (“Some members of the [CAFC] have suggested that ‘any attack on an issued patent based on a challenge to the eligibility of the subject matter must be proven by clear and convincing evidence[.]’ CLS Bank Int'l v. Alice Co. Pty. Ltd., 717 F.3d 1269, 1304–05 (Fed. Cir. 2013) (Rader, J., concurring and dissenting-in-part), but at least one other member of that Court has come to the opposite conclusion, *see* Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 720–21 (Fed. Cir. 2014) . . . (Mayer, J., concurring), all of which has led to some uncertainty regarding the appropriate standard of proof in Section 101 cases . . .”).

confusion is exacerbated by the fact that it is not clear if there is a presumption of eligibility under § 101 at the 12(b)(6) stage, similar to the presumption of validity, and whether the infringer needs to prove ineligibility by “clear and convincing evidence.”<sup>51</sup>

Additionally, a patentee at this threshold stage (in contrast to a motion for summary judgment later in the proceeding) generally cannot put forward evidence outside the “eight corners” (*i.e.* the complaint and the patent) in order to rebut the challenger's argument.<sup>52</sup> Thus, although an accused infringer can raise lack of § 101-inventiveness in a motion under 12(b)(6), it would do so without having given the patentee the opportunity for fact and expert discovery. A patentee generally does not have the ability to introduce relevant evidence on inventiveness (that a court may wish to consider), such as the level of skill in the art, or why and who would have thought to combine elements of the prior art.<sup>53</sup>

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<sup>51</sup> *Id.*

<sup>52</sup> *See, e.g.,* Ultramercial, LLC v. Hulu, LLC, No. 09-06918, 2010 WL 3360098, at \*1 (C.D. Cal. Aug. 13, 2010), *rev'd sub nom.*, 722 F.3d 1335 (Fed. Cir. 2013), *but aff'd sub nom.*, 772 F.3d 709 (Fed. Cir. 2014). But courts can take into account those materials either incorporated by reference in, or used as exhibits attached to, a complaint, as well as public record or other orders. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). And if either party does so, there is a chance that courts will treat a 12(b)(6) motion as one for Rule 56 summary judgment, per FRCP 12(d). *See, e.g.,* eDekka LLC v. 3Balls.com, Inc., No. 2:15-CV-541 JRG, 2015 WL 5579840 (E.D. Tex. Sept. 21, 2015).

<sup>53</sup> *See, e.g.,* Ben Roxborough, *Guest Post: The Blurring of §§ 101 and 103—A Double-Edged Sword that Cuts the Other Way*, PATENTLY-O (Oct. 6, 2015, 9:40 PM), [http://patentlyo.com/patent/2015/10/blurring-%c2%a7%c2%a7-double.html?utm\\_target=/feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+PatentlyO+%28Dennis+Crouch%27s+Patently-O%29](http://patentlyo.com/patent/2015/10/blurring-%c2%a7%c2%a7-double.html?utm_target=/feedburner&utm_medium=feed&utm_campaign=Feed%3A+PatentlyO+%28Dennis+Crouch%27s+Patently-O%29). Roxborough argues that, given the new “§ 101-inventiveness” standard of the Triad, courts should simply assume that it is identical to “§ 103-non-obviousness” and require plaintiff-patentees to rebut such standards with a description of a skilled artisan’s background in the complaint or patent, better utilization of a patent’s specification to demonstrate “new and useful” solution, reasons to combine prior art, secondary considerations, and the full panoply of other evidence. *Id.* Of course, currently, such rebuttal by a patentee is difficult to achieve procedurally at the stage of a 12(b)(6) motion, even with an expert declaration, since a patentee generally does not possess an established

### 3. Implementation by the USPTO

In December 2014, the USPTO issued a 2014 Interim Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products.<sup>54</sup> This set forth the following preliminary inquiry: 1) if a claim is directed to one of the four categories in § 101, it looks to see, 2) if the claim “recites or involves” the Exceptions and, if so, it asks, 3) “Does the claim as a whole recite something 'significantly' different than the judicial exception(s)?”<sup>55</sup>

Note the second query is whether the claim “involves” a judicial exception, such as a natural law. Yet, what technology does not “involve” a natural law, such as—to name a handful—gravity, thermodynamics, ionic interactions or electromagnetism? Under the USPTO's expansive use of “involve,” all claims are subject to further examination under § 101-inventiveness. Note also the USPTO's term of choice, “significantly different,” which may or may not be identical to the *Myriad* Supreme Court's “markedly different.”<sup>56</sup> For example, when dealing with the patenting of natural products (such as, *e.g.*, antibiotics), the Guidance effectively limits the § 101 inquiry to the presence/absence of *structural* differences;<sup>57</sup> only those will be “significantly

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record of evidence that could undercut a defendant-infringer's argument of ineligibility (and particularly since the litigants have not engaged in claim construction and fact/expert discovery). Our proposal takes into account the presumption of validity that attaches to granted patents, by naturally requiring a consideration of both underlying facts and construction of the claims during district court proceedings that implicate 101 issues. This echoes J. Rader's concerns from the vacated CAFC *Ultramercial* (2013) decision. *See supra* note 38.

<sup>54</sup> 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1). This was supplemented in July 2015 with responses to public comments. July 2015 Update on Subject Matter Eligibility, 80 Fed. Reg. 45,429 (July 30, 2015) (to be codified at 37 C.F.R. pt. 1).

<sup>55</sup> *See* 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,619, 74,621 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

<sup>56</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

<sup>57</sup> 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,625–26 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

different” from the natural products. This would render ineligible natural products that remain unchanged structurally, but are purified.<sup>58</sup>

These broad interpretations of the Triad suggest that the USPTO has created the Guidance from an assembly of separate precedents. The Guidance seems to misinterpret holdings of the Triad and applies them to a broader range of subject matter than intended. If left untouched, this would take decades for the judiciary to resolve.

### C. *The Present (Unworkable) Legal Situation*

In invoking the new concept of § 101-inventiveness, the Triad and its progeny have made the law confusing. In essence, the Triad has moved the focus of § 101 (“Whoever *invents* or discovers *any* new and useful . . . .”) from the historically expansive concept of “any” to the concept of “invents,” and has given the term “invents” an unworkable meaning. The Triad has created a vague patentability requirement beyond “new” and “useful.” Because of the focus on “invents,” the § 101 condition of “new” is no longer enough for eligibility.<sup>59</sup> Even

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<sup>58</sup> See generally Chenghua Luo & Jorge Goldstein, *Patenting Purified Natural Products by Specific Activity: Eligibility and Enablement*, BLOOMBERG BNA: LIFE SCI. LAW & INDUSTRY REP. (May 29, 2015), [http://www.skgf.com/uploads/1307/doc/Patenting\\_Purified\\_Natural\\_Products.pdf](http://www.skgf.com/uploads/1307/doc/Patenting_Purified_Natural_Products.pdf) (providing a solution to the eligibility of purified, structurally unchanged, natural products).

<sup>59</sup> Historically, the term “new” in § 101 has not been a patentability requirement apart from “novel” in § 102. See S. REP. NO. 82-1979, at 6 (1952) (legislative history to 1952 Patent Act) (“Section 102, in general, may be said to describe the statutory novelty required for patentability, and includes, in effect, an amplification and definition of ‘new’ in section 101.”). The concepts have been considered to be one and the same. Under this view, the only unique patentability requirement in § 101 was “useful.” All other requirements were (and still are) encompassed in the statutory phrase “. . . subject to the conditions and requirements of this title.” Those conditions and requirements were (and still are) § 102 novelty, § 103 non-obviousness, and § 112 enablement, written description, best mode, and clarity. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *In re Bergy*, 596 F.2d 952, 960–62 (C.C.P.A. 1979). In *Diamond v. Diehr*, 450 U.S. 175, 190 (1981), however, things started becoming less clear. In *Diehr* the Supreme Court held that the statutory meaning of “new” in § 101 can be distinguished from “novel” in § 102; the former being a general statement governing the threshold of entry into the patent system for further consideration, the latter setting the conditions and limitations of patentable novelty. *Id.* at 189–91 (“Section 101,

if “new” in § 101 means something different than “novel” in § 102, after the Triad, an invention needs to be more than novel to be eligible. Thus, the method of evaluating therapeutic effectiveness in *Mayo* was novel but the implementing steps were “conventional and routine”; the isolated genes claimed by sequence in *Myriad* were chemically novel but not “markedly different” than their sequence in the genome; and the computer-implemented risk-of-settlement elimination algorithm in *Alice* was novel, but the general computer in the claim was “not enough” to make the claim eligible.<sup>60</sup>

The decisions and implementations seem to conflate the § 101 term “invents” (which hitherto had been interpreted as “human intervention”) with non-obviousness under § 103. And yet, the many terms used by the tribunals and the USPTO (“ingenuity,” “inventiveness,” “inventive concept,” “not routine,” “not conventional,” “not enough,” “markedly different,” “significantly different,” “fundamentally different,” “distinct in a relevant way”) may or may not be the same concepts of § 103-non-obviousness. This requires further exploration.

If the § 101 and § 103 concepts are the *same*, then the law now requires a full § 103 analysis as part of the § 101 inquiry.<sup>61</sup> And, if we are heading into a full-fledged analysis of non-obviousness under the four factors of *Graham v. John Deere*,<sup>62</sup> what is the prior art to which we are to compare the claim as a whole?

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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.”) Regardless of the interpretation, our proposed amendment uses “novel,” not “new,” and says, “no further conditions than *novelty* and usefulness . . . are required . . . .” (emphasis added).

<sup>60</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2358 (2014); *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

<sup>61</sup> *See supra* note 53. The Federal Circuit in its recent decision in *Internet Patents Corp. v. Active Network, Inc.* also acknowledged that a “pragmatic analysis of § 101 is facilitated by considerations analogous to those of §§ 102 and 103.” 790 F.3d 1343, 1347 (Fed. Cir. 2015).

<sup>62</sup> The four factors are: 1) the scope and content of the prior art, 2) the level of skill of a person of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) any indicia of secondary considerations. 383 U.S. 1, 17 (1966).

For example, if we are claiming a purified, hitherto unknown, natural product, it is reasonable to assume that the crude product in nature is the closest prior art, at least for novelty purposes.<sup>63</sup> Then, in the guise of an eligibility analysis, we would have to compare the natural and purified products to prove § 101-inventiveness of the purified one. In the Triad, the Supreme Court was worried about preempting a “law of nature,” coining it a “basic tool of scientific and technological work,” and earlier, in *Parker v. Flook*, the Court had called it “a familiar part of the prior art.”<sup>64</sup> But a newly discovered “law or phenomenon” of nature (such as the genetic correlation in *Mayo*) or “abstract idea” (such as the numerical calculation in *Parker*) were not familiar, were not even prior, and were discovered by the inventor.<sup>65</sup>

Upon closer reading, moreover, the Triad and the Federal Circuit suggest that § 101-inventiveness and § 103-non-obviousness are *not* the same concepts. For example, in *Myriad* the Supreme Court recognized that identifying, finding and isolating the BRCA1 gene was a complex process, but warned that even “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”<sup>66</sup> The CAFC in *Roslin Institute* praised the brilliance in creating a cloned sheep, yet found that it was not eligible, since it was not “markedly different” from the farm animal.<sup>67</sup> And in *Ariosa*, the CAFC also praised the invention of detecting paternal DNA in the mother's serum as a brilliant breakthrough, but held that it was not eligible.<sup>68</sup>

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<sup>63</sup> See, e.g., *In re Bergstrom*, 427 F.2d 1394, 1401–02 (C.C.P.A. 1970) (holding claim to purified PGE2 as “new,” since no one had obtained a prostaglandin in pure, crystalline form, despite being known to be present in semen in tiny amounts).

<sup>64</sup> 437 U.S. 584, 592 (1978).

<sup>65</sup> *Mayo Collaborative Servs.*, 132 S. Ct. 1289, 1304 (2012).; *Parker*, 437 U.S. at 598–99 (Stewart, J., dissenting).

<sup>66</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2110, 2117 (2013).

<sup>67</sup> *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1337, 1338 (Fed. Cir. 2014).

<sup>68</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379–80 (Fed. Cir. 2015); see also *id.* at 1381 (Linn, J., concurring) (“But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.”). The CAFC's decision denying *en banc* rehearing contained a sharp dissent by Judge Newman, who among other arguments, reasoned



So, if the new—and ever growing—collection of terms used for § 101-inventiveness are different than the concepts used for § 103-non-obviousness, then it is fair to ask: What do these new terms mean? How do they differ from non-obviousness in § 103? Inventors, assignees, attorneys, examiners, judges, investors and potential opponents are entitled to know. For example, the praise heaped upon the inventors of *Ariosa* or *Roslin*, and tentatively bestowed on those of *Myriad* suggests that § 101-inventiveness is *less* than § 103-non-obviousness. After all, “markedly different” is *less* than brilliant or groundbreaking. In contrast, it is not hard to envision a case where § 101-inventiveness would actually be *more* than § 103-non-obviousness. Take, for example, our newly discovered and purified antibiotic. It is well established since *In re Hoeksema* that a claim to a novel yet otherwise structurally obvious chemical compound—as a composition of matter—is non-obvious if there was in the prior art no known or obvious method of making it.<sup>69</sup> Thus, if there was no known or obvious method of isolating and purifying our natural antibiotic in the prior art (never mind discovering it in the first place) then a claim to the purified molecule itself (not just to the method of purifying it) is non-obvious under *Hoeksema*. In this example, § 101-inventiveness places on eligibility a higher burden than simple § 103-non-obviousness. The non-obvious purified antibiotic would not be eligible.

In sum, the situation with § 101-inventiveness is unworkable. Dissecting claims into Exceptions and “everything else” goes against basic tenets of considering the invention as a whole. The § 101-inventiveness standards are confusing and vague, and only years of litigation and higher court decisions will give us a framework to understand what the courts mean by the phrase “markedly different” (and all its synonyms). The situation is procedurally

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that “[p]recedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting; the Court has cautioned against such generalizations.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*10 (Fed. Cir. Dec. 2, 2015) (Newman, J., dissenting). Judge Newman also mentioned that the inventors are not claiming the scientific fact of the discovery of paternal DNA in the blood of a pregnant woman; rather, they are claiming the discovery and development of a new diagnostic method of using the information. *Id.*

<sup>69</sup> 399 F.2d 269, 274 (C.C.P.A. 1968) (“[I]t is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public.”).

stacked against patent holders: patent infringement defendants have been able to rely on §§ 102 and 103 arguments to invalidate patents on eligibility grounds at the stage of motions to dismiss, where there is little chance for the patent holder to rebut with evidence.<sup>70</sup> Challengers have also been able to argue that any additional steps beyond the first ineligible claim portion are “routine and conventional” because they can either be found in the specification or are commonly known in the scientific community.<sup>71</sup> Thus, § 101 has become a largely un-rebuttable, *de facto*, § 103 defense, and prior art in the specification is now used against the patentee to support the challenger’s position.<sup>72</sup>

### III. CONSEQUENCES TO THE COMMERCIALIZATION OF U.S. INNOVATION

We live in an online world of ingenious computer-implemented algorithms, whether we make reservations for a flight, order lunch from the neighborhood deli, or buy a pencil from Amazon.com. Yet the inventors of these algorithms are now largely precluded from patent protection. The present legal situation is gutting developments, not just in software technology, but in natural products research, and in the application of discoveries of useful (but “routinely implemented”) natural correlations such as disease diagnosis. The lack of predictable patent protection is or will have a detrimental effect over investment and innovation in the U.S. economy and, ultimately, on its beneficiaries, the consumers and patients.<sup>73</sup>

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<sup>70</sup> See *supra* notes 52–53.

<sup>71</sup> In *Mayo*, Justice Breyer cited admissions in the specification that the processes for determining the level of metabolites in a patient’s blood were “well known in the art,” and the patent was held to lack “inventive concept” due to this. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1291–92 (2012).

<sup>72</sup> See, e.g., *McRO, Inc. v. Namco Bandai Games Am., Inc.*, No. CV 12-10327-GW, 2014 WL 4749601, at \*11 (C.D. Cal. Sept. 22, 2014) (holding that McRo’s patents on lip-sync animation technology are invalid using the “point of novelty” test under *Alice* for claiming the abstract idea of using rules to create computer animation).

<sup>73</sup> These concerns were foreshadowed by industry players in amicus briefs submitted to the Federal Circuit in *Bilski*, and to the Supreme Court in *Alice*. For instance, the American Express, Accenture, and Pitney Bowes’ amicus briefs in *Bilski* raised the fact that the ability to patent computer-implemented business methods and processes contributes significant

Lack of predictability leads to costly litigation, as parties resort to either district courts or USPTO post-grant proceedings to determine which patents do or do not claim patent-eligible subject matter. The prevailing confusion also encourages speculative litigation, as plaintiffs exploit increased uncertainty during trial to obtain greater settlement leverage.

A loss of market competitiveness to foreign nations, such as those in the European Union, which have more open-ended eligibility requirements under Article 52(1) of the European Patent Convention, is also a significant policy concern.<sup>74</sup> The European Patent Office (“EPO”) allows more inventions to be eligible than its U.S. counterpart, both in the natural products space,<sup>75</sup> as well as for computer-implemented inventions.<sup>76</sup>

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positive economic effect to the U.S. economy and financial services industry, and that patent protection of business-related processes results in disclosure of useful financial methods, providing a social utility. *See* Brief for Datacorp Inc., American Express et al. as Amici Curiae in Support of Neither Party at 32, *Bilski v. Doll*, 561 U.S. 593 (2009) (No. 08-964); Brief for Accenture & Pitney Bowes Inc. as Amici Curiae in Support of Petitioners at 4–5, *Bilski v. Doll*, 561 U.S. 593 (2009) (No. 08-964). And, the Clearing House LLC’s amicus brief in *Alice* stated that “Uncertainty over whether computer-aided processes are patent eligible prevents amici’s members from accurately gauging the value or enforceability of their intellectual property, and also leaves them unsure whether they can offer certain products or services without infringing others’ patents.” Brief for The Clearing House Ass’n LLC & The Financial Services Roundtable as Amici Curiae Supporting Respondents at vi, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014) (No. 13-298).

<sup>74</sup> *See generally* Gary P. Pisano & Willy C. Shih, *Restoring American Competitiveness*, HARV. BUS. REV. (July–Aug. 2009), <https://hbr.org/2009/07/restoring-american-competitiveness/ar/1>; Michael E. Porter & Jan W. Rivkin, *The Looming Challenge to U.S. Competitiveness*, HARV. BUS. REV. (Mar. 2012), <https://hbr.org/2012/03/the-looming-challenge-to-us-competitiveness>. Additionally, the CAFC in denying *en banc* rehearing in *Ariosa*, also foreshadowed that a limited view of the Exceptions from the Triad could hamper innovation and disincentivize development of new diagnostic and therapeutic methods, driven by the discovery of new natural laws/phenomena. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*4 (Fed. Cir. Dec. 2, 2015) (Dyk, J., concurring).

<sup>75</sup> Article (3)(1) of EP Directive 98/44 EC, issued in 1998, states that inventions shall be patentable “even if they concern a product consisting of or containing biological material or a process by means of which the biological

The very prominence of the U.S. as a world-class center of innovation and applied creativeness is now under a major cloud. The time is therefore ripe for Congress to intervene, and not just to clarify the law, but also to support our world-renowned innovative economy.<sup>77</sup>

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material is produced . . . ." Article (3)(2) further confirms that, "[b]iological material which is isolated from its natural environment . . . may be the subject of an invention even if it previously occurred in nature." Council Directive 98/44,3(1-2), 1998 O.J. (EC). Thus, in European practice, identity of a product with a natural product is not a barrier to patentability as long as an application describes the industrial applicability of the claimed subject matter. This is borne out in the fact that the *Mayo* and *Myriad* European National Phase applications have not experienced anything like the challenge to eligibility that their corresponding U.S. patent applications experienced.

<sup>76</sup> Article 3.6 of the EPC Guidelines for Examination ("Programs for Computers") states that, "any claimed subject-matter defining or using a technical means is an invention within the meaning of Art. 52(1) . . . applies even if the technical means are commonly known; for example, the inclusion of a computer, a computer network, a readable medium carrying a program, etc. in a claim lends technical character to the claimed subject-matter." European Patent Convention Guidelines for Examination, Part G art. 52(2)(c), Nov. 1, 2015. While an analysis of the "technical character" is still required and a "further technical effect" identified, the EPO Board of Appeal confirmed that "the identified further technical effect need not be new." (G 0003/08, para. 10.4).

<sup>77</sup> Such concerns were rejected by SCOTUS when it denied OIP's petition for certiorari in *OIP Techs., Inc. v. Amazon.com, Inc.*, No. 15-642, 2015 WL 7258645 (Dec. 14, 2015). OIP had argued, *inter alia*, that 1) the CAFC ignored *Diehr* when it held invalid as an abstract idea a price-optimization patent that solved a technological problem (claims covered computer-implemented methods for testing demand to improve pricing processes), as well as 2) that intervention by SCOTUS is needed to clarify how courts apply *Alice*, since otherwise protection over areas of innovation important to U.S. commerce will be impeded. Petition For a Writ of Certiorari at 16-17, *OIP Technologies, Inc. v. Amazon.com, Inc.*, No. 15-642, 2015 WL 7258645 (Dec. 14, 2015); see Ryan Davis, *High Court Refuses Patent Case On How Courts Apply Alice*, LAW360 (Dec. 14, 2015, 8:21 PM), <http://www.law360.com/articles/737407/high-court-refuses-patent-case-on-how-courts-apply-alice>.

#### IV. NEED FOR CONGRESSIONAL ACTION

The need to reverse the negative effects that the eligibility crash of 2012-2014 is having on the U.S. patent system and on U.S. competitiveness calls for congressional intervention. It is not feasible for the U.S. innovation community to wait a decade or two, hoping that the newly minted judicial concepts of § 101-inventiveness are clarified, case-by-case. It is *Congress* that needs to clarify the law, and re-legislate § 101 to show that § 101-inventiveness is not part of the statute.

##### A. *Explanation of the Amendment*

The central rationale of our proposed amendment is to remove the inventiveness analyses from § 101. Otherwise, the amendment is cautious in its reach, avoiding a major overhaul of long-established concepts in the law of eligibility. The amendment retains the main body of existing § 101, but modifies the concluding phrase, “subject to the conditions and requirements of this title,” by adding the italicized words:

*While the claimed invention is subject to the conditions and requirements of other sections of this title, no further conditions than novelty and usefulness of the claimed invention as a whole are required under this Section.*

- We believe that the starting words of the statute—“Whoever invents”—already indicate that there must be human intervention.<sup>78</sup> Our amendment says that once human intervention is shown, all that is necessary is that the claimed invention comply with §§ 102, 103, 112, as well as the rest of 35 U.S.C.
- Nothing beyond analyses of novelty and usefulness is required of § 101. We have added “novelty *and* usefulness” to make sure that, while the proposed amendment is read to properly require no more than novelty, it still requires usefulness (since the word “useful” in § 101 is not found anywhere else in “this title,” *i.e.*, Title 35).
- We advisedly use the term “novelty” instead of “new.” We mean our term “novelty” to be identical to that in § 102.<sup>79</sup>

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<sup>78</sup> 35 U.S.C. § 101. Query what will happen if, as seems increasingly the case, inventions are made by programmed robots. The statutory word “whoever” will then have to be interpreted to mean the human programmers.

<sup>79</sup> See *supra* note 59.

- If the invention is novel and useful, it is *eligible*. This does not mean that it is *patentable*. It will be patentable if it complies with all other requirements of Title 35 including, quite critically, the non-obviousness requirement of § 103.
- We have also included the phrase “. . . novelty . . . of the claimed invention as a whole,” to make clear that the novelty does not need to be found in any one individual step implementing the invention. Even if all implementing steps are routine and conventional (and by definition not novel) the novelty needs to be analyzed on the claim(s) *as a whole, i.e.* on the combination of the non-novel steps with the underlying discovery or invention.
- In the first sentence, we propose to include the words “physically implemented” before the word “process.” This assures that the proposed amendment stays focused on removing § 101-inventiveness without removing the judicial Exceptions from the law. Without these words, *Parker v. Flook* would be overturned.<sup>80</sup> After the amendment, abstract and pure thoughts, not implemented through a computer, are still ineligible.<sup>81</sup>
- The addition of “physically implemented” does overturn *Gottschalk v. Benson*.<sup>82</sup> The *Benson* claims explicitly required implementation on a computer, yet they were found ineligible as preempting all useful implementations of the data-type conversion process.<sup>83</sup> We think that overturning *Benson* is the right outcome, and we discuss our rationale below, with respect to preemption and abstract ideas.
- Also in the first sentence, we insert a minor antecedent basis for “invention” (i.e. “new and useful *invention, which is a . . .*”), to emphasize that absolute novelty and utility is required for the four, independent categories of statutory subject matter, to clarify that the qualifier

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<sup>80</sup> See *infra* Appendix I; see also *Parker v. Flook*, 437 U.S. 584, 593 (1978).

<sup>81</sup> To an extent, such addition of the qualifier “physically implemented” for patent-eligible process claims was hinted at by Judge Lourie *in dicta* in his opinion in *Ariosa* denying Sequenom’s request for *en banc* rehearing. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*2 (Fed. Cir. Dec. 2, 2015) (Lourie, J., concurring) (“[S]teps that involve machines, which are tangible, steps that involve transformation of tangible subject matter, or tangible implementations of ideas or abstractions should not be considered to be abstract ideas.”).

<sup>82</sup> 409 U.S. 63 (1972).

<sup>83</sup> *Id.* at 71.

“physically implemented” *only* conditions process claims, and such that the two sentences are interrelated. We also recite “*the* claimed invention” in the second sentence to show that we refer to the previously mentioned invention.

Our proposed amendment is a minimal statutory intervention to clarify the law of eligibility without overturning major legal doctrines.<sup>84</sup> We have chosen

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<sup>84</sup> Other proposals to amend 35 U.S.C. § 101 have recently been made. For example, David Bender proposes the amendment to read as follows:

§ 101 Patent Eligibility. Subject to the conditions and requirements of this title, any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be claimed in a patent. Patent eligibility shall not depend on whether claimed subject matter is novel, or on whether it is non-obvious. In any patent eligibility determination, a claim shall be considered as a whole, and shall not be deemed ineligible solely or partly by virtue of the type of subject matter in any portion thereof.

David Bender, *Software-Related Inventions, Business Methods, and Patent Eligibility: Why We Need a New §101, and a Few Hints on Survival Until We Get It*, in INTELLECTUAL PROPERTY LAW INSTITUTE COURSE HANDBOOK SERIES NUMBER G-1242, 115 (2015), [https://discover.pli.edu/Details/Details?rows=10&fq=title\\_id~3A2822~59139~2229202B~id~3A282B22~59139~CH1~2229~&facet=true&qt=legal\\_boolean](https://discover.pli.edu/Details/Details?rows=10&fq=title_id~3A2822~59139~2229202B~id~3A282B22~59139~CH1~2229~&facet=true&qt=legal_boolean). This is a more invasive change to § 101 than the one suggested in this paper, in that it removes both non-obviousness and novelty from consideration of eligibility; it is in conformance with our proposal in that it stresses consideration of the invention as a whole. Alternatively, Michael Risch argues a less formal proposal—similar to that of Judge Newman in the CAFC Alice decision, *infra* note 102—saying:

The currently confused and inconsistent jurisprudence of patentable subject matter can be clarified by implementing a single rule: any invention that satisfies the Patent Act's requirements of category, utility, novelty, non-obviousness, and specification is patentable. In other words, if a discovery otherwise meets the requirements of patentability, then the discovery will be properly patentable without need to consider non-statutory matter restrictions such as the bars against mathematical algorithms, products of nature, or natural phenomena.

not to modify the statute in any other way. Thus, for example, while it is recognized that the terms “invents or discovers” mean the same thing,<sup>85</sup> we have chosen not to remove the word “discovers.” Doing so might be interpreted to imply that the two words do *not* mean the same thing, and that the amendment is meant not to provide protection for discoveries. We have also not removed the word “new,” so as not to disturb the Supreme Court’s suggestion in *Diamond v. Diehr* that “new” in § 101 may not mean the same as “novel” in § 102.<sup>86</sup>

**B. Effects of the Amendment on the Triad and Earlier Supreme Court Jurisprudence**

It is not the purpose of the amendment to overrule by legislation the Exceptions to eligibility, *i.e.*, natural laws, natural phenomena or abstract ideas. After the amendment, inventors will still not be able to patent such fundamental discoveries as an unpurified natural product, Einstein’s  $E=mc^2$ , or an algorithmic decision tree not implemented by a computer (a.k.a., “mental steps”).

The novelty test for eligibility is well established in the case law. The CAFC has used it at length and it has the advantage of being part of our jurisprudence.<sup>87</sup> It is binary, and thus simple to apply. It is not obscured by the

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Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 591 (2008).

<sup>85</sup> CLS Bank Int’l v. Alice Corp. Pty., 717 F.3d 1269, 1295 (Fed. Cir. 2013) (Rader, C.J. concurring in part and dissenting in part) (reasoning that “Congress made it irrelevant whether a new process, machine, and so on was ‘discovered’ rather than ‘invented’ [by adding the words ‘or discovered’ to Section 100(a)]. Both inventions and discoveries are eligible for patenting. This addition confirmed the principle articulated again in Section 103 that an invention ‘shall not be negated by the manner in which [it] . . . was made.’ 35 U.S.C. § 103. The language of the Act shows that the authors of the 1952 Act wanted that principle incorporated into the eligibility section of the Act as well as the patentability sections.”); *cf.* Parker v. Flook, 437 U.S. 584, 593 (1978) (“The obligation to determine what type of *discovery* is sought to be patented [so as to determine whether it falls within the ambit of section 101] must precede the determination of whether that *discovery* is, in fact, new or obvious.”) (emphasis added); *see also* U.S. CONST. art. I, § 8, cl. 8. (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”) (emphasis added).

<sup>86</sup> 450 U.S. 175, 190–91 (1981); *see also supra* note 59.

<sup>87</sup> *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289, 1292 (2012); Ultramarcial, Inc. v. Hulu, LLC, 772 F.3d 709, 715 (Fed. Cir. 2014);



uncertainty of § 101-inventiveness. Only § 101-inventiveness will be gone from the law after the amendment. Confusion with § 103 will disappear and the analyses of § 101 will be more workable.

At the end of the paper, in Appendix 1, we show a list of post-1952 decisions from the Supreme Court on § 101-eligibility, and the effect that the proposed amendment will have on them. Except for those of the Triad relying on § 101-inventiveness (*Mayo*, *Myriad*, and at least some claims in *Alice Corp.*) the results are, for the most part (*i.e.*, except for *Benson*), unchanged.

The next part of the article evaluates two concerns: whether the amendment could be argued to be unconstitutional, and whether it passes muster under the preemption doctrine of the Supreme Court. As we will see, these two issues merge into one, in that we conclude that preemption concerns are based on the Constitution. The newly clarified § 101, however, in the context of the whole of patent law, will readily take care of these concerns.

### C. *The Amendment is Constitutional*

The Constitution, under the patent provisions of Article I, Section 8, Clause 8, grants broad powers to Congress “To promote the Progress of . . . [the] useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”<sup>88</sup>

The question is whether the proposed amendment, by removing the inventiveness analysis of the Triad from § 101 (while leaving all other requirements and conditions of the title alone, including non-obviousness under § 103), somehow violates Article I, section 8, clause 8. It does not appear to do so. The major concern of the Triad, in introducing § 101-inventiveness, was to safeguard against the use of the draftsman's art to allow patents on the Exceptions, *i.e.*, on the basic building blocks of invention. Thus, the question becomes whether the Exceptions are constitutionally-mandated. While this article will show they are, it will further show that the amendment does not disturb any constitutional requirements.

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Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1327–29 (Fed. Cir. 2012); *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970).

<sup>88</sup> U.S. CONST. art. I, § 8, cl. 8.

## 1. Preemption is Rooted in the Constitution

The Supreme Court has never expressly said whether the Exceptions originate from the Constitution or solely from the text of § 101. It is clear, however, that in the majority of its decisions, the Court's main rationale for the Exceptions has been that of avoiding preemption. In its most recent decision of the Triad—*Alice*—the Court agreed with *Myriad* that they have “long held that [§ 101] . . . contains an important implicit exception,” and that it had so interpreted it for “more than 150 years,”<sup>89</sup> citing *Le Roy v. Tatham*<sup>90</sup> and *O’Reilly v. Morse*.<sup>91</sup> In *Le Roy* the Court first inherently recognized the Exceptions. Then, in *O’Reilly*, the Court expressly made the Exceptions into a central tool for analyzing lack of eligibility; there, the Court held a claim directed to a telegraph invalid because it pre-empted the use of future inventions involving an electrical mode of writing at a distance without using any part of the specific embodiments in Morse’s specification.<sup>92</sup> Ever since *O’Reilly*, the Court’s eligibility jurisprudence has been anchored in preemption. In *Benson*, the Court held that a patent claim may not “wholly pre-empt the [use of a] mathematical formula” or “algorithm.”<sup>93</sup> The Court discussed preemption as a rationale for the Exceptions in *Flook*,<sup>94</sup> *Diehr*,<sup>95</sup> and *Bilski*,<sup>96</sup> even when analyzing claims that did not wholly preempt a

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<sup>89</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013)).

<sup>90</sup> 55 U.S. (14 How.) 156 (1852).

<sup>91</sup> 56 U.S. (15 How.) 62 (1853).

<sup>92</sup> *See, e.g., Bilski v. Kappos*, 561 U.S. 593, 649 (2010) (Stevens, J. concurring) (“explaining that Morse’s patent on electromagnetism for writing would preempt a wide swath of technological developments” (quoting *O’Reilly*, 56 U.S. (15 How.) at 113)); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015) (“We have described the concern that drives this exclusionary principle as one of pre-emption.” (quoting *Alice Corp.*, 134 S. Ct. at 2354)).

<sup>93</sup> *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

<sup>94</sup> *See Parker v. Flook*, 437 U.S. 584, 589–90, 599 (1978) (“The Court of Customs and Patent Appeals held that the process is patentable subject matter, *Benson* being inapplicable since ‘[t]he present claims do not preempt the formula or algorithm contained therein’ . . . . That decision seems to me wholly in conformity with basic principles of patent law.”).

<sup>95</sup> *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (“Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-

law of nature, physical phenomena, or abstract idea.<sup>97</sup> More recently, in *Mayo*, in referring to 35 U.S.C. § 101, the Court stated that the Exceptions were “implicit” in the statute,<sup>98</sup> but said nothing about whether they were mandated by the Constitution. In *Myriad*, in explaining the phenomenon of nature Exception, the Court said that the point of patents is to “promote creation” and that “products of nature are not created.”<sup>99</sup> While with this language, the Court did seem to get closer to the constitutional concept of “promotion,” the affirmation leaves unclear if the Court was talking about promoting the useful arts or promoting human inventiveness. The authors of this article believe that it was the latter, and that the Court was not proffering a constitutional interpretation.

Now, if the Court's preemption concerns are analyzed as crucial to not inhibiting further discovery by improperly tying up future uses of the building blocks, it must be inferred that the court has been worried about *not inhibiting* the progress of the useful arts.<sup>100</sup> This inexorably leads to the conclusion that preemption is indeed a constitutional doctrine—avoiding preemption is entirely in line with, and central to the goal of, promoting the “Progress of . . . useful Arts.”<sup>101</sup> This constitutional concern, however, does not necessarily need to be

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empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”).

<sup>96</sup> *Bilski*, 561 U.S. at 611–12 (“Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”).

<sup>97</sup> *See, e.g., Flook*, 437 U.S. at 589–90 (acknowledging that the patentee did “not seek to ‘wholly preempt the mathematical formula,’ since there are uses of his formula outside the petrochemical and oil-refining industries,” yet finding that the addition of mere “post-solution activity” was insufficient to “transform an unpatentable principle into a patentable process . . .”); *see also Bilski*, 561 U.S. at 611–12 (finding that a set of claims directed to hedging risks in “energy markets” was not patent eligible, even though it did not “pre-empt use of [hedging] in all fields . . .”).

<sup>98</sup> *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012) (“The Court has long held that this provision contains an important implicit exception.”).

<sup>99</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

<sup>100</sup> *See id.*

<sup>101</sup> U.S. CONST. art. I, § 8, cl. 8.

solved by introducing an ill defined and poorly understood concept of “inventiveness” into 35 U.S.C. § 101. As this article will demonstrate, there are alternative means to achieve the same results.

Because in the arena of software patents, the courts have been concerned with avoiding preemption of abstract ideas, the next section will first analyze this legal concept.

## 2. Defining an Abstract Idea

The lack of clarity surrounding what is an “abstract idea” is at the root of all confusion in § 101 software jurisprudence today. Without knowing the strict boundaries of what “abstract idea” is being preempted and defining such an abstract idea, it is almost impossible to know *what* claims to compare to the idea, as well as *how* to compare the claims to the idea; it is not possible to determine whether a patented claim preempts an unknown, either through novelty or § 101-inventiveness analyses.<sup>102</sup>

Originally, the Supreme Court's intent was to clarify that “mental steps” (i.e., human thought) could not be patented.<sup>103</sup> But, more recently, the concept of

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<sup>102</sup> Such concern was raised by Judge Newman's concurrence and dissent-in-part, in the CAFC decision in *Alice*. Here, Judge Newman advocated a somewhat similar proposal as we do, which is to hold § 101 as an “inclusive statement of patent-eligible subject matter” by providing an inclusive listing of the “useful arts,” and then upon crossing this threshold into the patent system, to examine the subject matter on substantive criteria of patentability that would eliminate claims that are “abstract” or “preemptive” under §§ 102, 103, and 112. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 1322 (2014) (Newman, J. concurring in part and dissenting in part). Even the USPTO Guidelines allude to inquiring whether the claims preempt an abstract idea. *See, e.g.*, 2014 Interim Guidance on Patent Subject Matter, 79 Fed. Reg. 74,618, 74,622 (to be codified at 37 C.F.R. pt. 1) (explaining that “[s]uch [] claim[s] requires closer scrutiny for eligibility because of the risk that it will ‘tie up’ the excepted subject matter and pre-empt others from using the law of nature, natural phenomenon, or abstract idea. Courts tread carefully in scrutinizing such claims because at some level all inventions embody, use, reflect, rest upon, or apply a law of nature, natural phenomenon, or abstract idea”) (citing *Mayo Collaborative Servs.*, 132 S. Ct. at 1301); *see also id.* at 74,625 and 74,627.

<sup>103</sup> *See, e.g.*, Howard B. Barnaby Jr, *Patent Law—Computer Programs—Unpatentable Mental Process—Gottschalk v. Benson*, 14 B.C. L. REV. 1050, n.26 (1973) (“As the term is used by the patent courts, a ‘mental step’ is: a step in

not patenting thoughts has been stretched beyond the original intent. An unfortunate broadening of the concept of “abstract idea” has resulted in the unworkable and confusing situation in which we now find ourselves with software patents.

The misapplication of the preemption doctrine to “abstract ideas” began with the Supreme Court's decision in *Gottschalk v. Benson*.<sup>104</sup> Donald Chisum has noted that “the Court [in *Benson*] provided no explanation of why a precise step-by-step algorithm is an 'idea,' much less an 'abstract idea.’”<sup>105</sup> Chisum continued succinctly, “*Benson* is a failure,” in that it satisfied short-term goals but wreaked havoc on the software industry long-term.<sup>106</sup> To this day, neither the Supreme Court nor the CAFC have clearly defined the term “abstract idea.”<sup>107</sup>

We propose in our amendment to overturn *Benson* in order to clarify the law. The courts' difficulties would be eliminated by returning the concept to its roots—an “abstract idea” should be defined as “an idea without physical implementation, such that it is performed in the human mind.” Specifying a physical implementation for the idea takes it out of abstractness, and removes

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a claimed process which may be performed by the human brain in combination with such peripheral devices as eyes and hands, but which may also be executed by a mechanical or electrical device. . . . Under the mental steps doctrine, mental steps, even if novel, are not patentable.”).

<sup>104</sup> 409 U.S. 63, 67 (1972) (“Phenomena of nature . . . mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”). Because the operations performed by the *Benson* claims were the same operations that a human would perform in converting the numbers, the *Benson* court equated the claimed steps to mental processes despite their explicit recitation of operation on a shift register. *Id.*; see also *id.* at 73–74, Appendix to Opinion (reciting, for example, representative method claim 8). Having read the general-purpose computer out of the claims, the Supreme Court found the *Benson* claims ineligible. *Id.* at 64–65, 73. But steps explicitly performed on a computer cannot, by definition, read on truly “mental steps.”

<sup>105</sup> Donald S. Chisum, *Patenting Intangible Methods: Revisiting Benson (1972) After Bilksi (2010)*, 27 SANTA CLARA HIGH TECH. L. J. 445, 454 (2010).

<sup>106</sup> *Id.* at 446.

<sup>107</sup> In the pre-*Alice Ultramercial, Inc. v. Hulu, LLC* decision, the CAFC stated, “[a]n abstract idea is one that has no reference to material objects or specific examples . . . .” 772 F.3d 1335, 1343 (Fed. Cir. 2013). But this definition is now of little import as the claims were later found ineligible post-*Alice*.

concerns of its preemption (under its originally-intended purpose). Therefore, one further advantage of our amendment is that it clarifies how to analyze Exceptions such as “abstract ideas” that are not well defined, and that are subjective rather than objective.<sup>108</sup>

### 3. Alternative Solutions for Preemption Concerns

Whether a claim may preempt subsequent innovation requiring the use of the claimed invention is best addressed by § 102, § 103 and § 112, the well-established criteria for patentability.

*Novelty and non-obviousness.* One major attraction of our proposed amendment is that it comes in the same historical timeframe as the recent enactment of the AIA. Under the newly-enacted 35 U.S.C. § 102(a)(1), the world of novelty-defeating prior art in the U.S. has been expanded to encompass a universe of worldwide acts that had not been prior art when the major eligibility decisions of the Triad were decided.<sup>109</sup> It should be apparent that this expansion will aid in the determination of absolute novelty as the proposed threshold for eligibility. If a business method, such as that declined eligibility in *Alice*, is tested as to its absolute novelty (without involving § 101-inventiveness), it is possible

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<sup>108</sup> See Brief for Advanced Biological Laboratories, SA as Amici Curiae In Support of Petitioner, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (No. 13-298) (“An abstract idea or abstraction may be very common and well known, but that does not make it a ‘fundamental truth’ or the type that this Court has indicated as being ineligible for patent.”).

<sup>109</sup> Compare, e.g., pre-AIA 35 U.S.C. § 102 (2006): Conditions for patentability; novelty and loss of right to patent (“A person shall be entitled to a patent unless—(a) the invention was known or used by others *in this country*, or patented or described in a printed publication in this or a foreign country, *before the invention* thereof by the applicant for a patent; or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale *in this country*, more than *one year prior to the date of application* for patent *in the United States.*”) (emphases added) with post-AIA 35 U.S.C. § 102 (2013) (“(a) Novelty; prior art. A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public *before the effective filing date* of the claimed invention . . . .”) (emphasis added). See also Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith American Invents Act, 78 Fed. Reg. 11,059, 11,074 (Feb. 14, 2013) (to be codified at 37 C.F.R. pt. 1).

post-AIA to bring to the fore as prior art, all public knowledge or use (or, in the words of the statute, anything else “otherwise available to the public,”<sup>110</sup>) anywhere in the world.<sup>111</sup> This will provide the patent community (examiners, applicants, owners, challengers, judges, or investors) a much harsher standard to measure lack of novelty. Thus,

- If an abstract business method was previously known or used, say, in Germany in the 1970s, it is not novel under § 102(a)(1) and not eligible under § 101.
- If the abstract business method was previously known or used but is claimed as implemented by a computer, it becomes novel and eligible under our amendment. Simple computer implementation of a known method, however, will likely be found obvious under § 103.
- If the abstract business method was not known or used anywhere in the world it may be novel even if claimed without implementation by a computer, but will not be eligible since the claim is not to a physically implemented method, as required by the amendment.

These conclusions lead to the same constitutionally-mandated results as those achieved by preemption, without the need to invoke inventiveness under § 101.<sup>112</sup>

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<sup>110</sup> 35 U.S.C. § 102(a)(1).

<sup>111</sup> See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith American Invents Act, 78 Fed. Reg. 11,059, 11,074 (Feb. 14, 2013) (to be codified at 37 C.F.R. pt. 1) (“[T]here is no geographic limitation on where prior public use or public availability occurs.”).

<sup>112</sup> Such notion was explored by Judge Newman in her sharp dissent in the CAFC’s denial of *en banc* rehearing of *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). She said, “This subject matter is not ineligible under Section 101, but warrants standard legal analysis for compliance with the requirements of patentability, that is, novelty, unobviousness, specificity of written description, enablement, etc., and whether the claims are appropriately limited . . . . The subject matter should be reviewed for compliance with Sections 102, 103, and 112, and any other relevant provisions of the patent law.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*11 (Fed. Cir. Dec. 2, 2015) (Newman, J., dissenting).

*Scope and Written Description.* Considerations under 35 U.S.C. § 112 can be brought to bear if the scope of the claims is so broad as to encompass subject matter that is not well described or enabled. Especially in the unpredictable arts, such as biotechnology, the CAFC has recently stressed how important it is to describe all foreseeable embodiments within a patent specification in order to achieve broad claim scope.<sup>113</sup> Thus, for example, if the scope of a claim to a purified natural product is so broad as to read on the product in its natural state, then this section of the law, rather than eligibility, will invalidate such claims.<sup>114</sup>

*Clarity.* Challenging for lack of clarity claims that are barely beyond an Exception will force patent holders and challengers to define the Exception and to make sure that the claims stay clear of it. Thus, during prosecution, a claim term such as “isolated” can be challenged as vague under 35 U.S.C. § 112 (second paragraph), and the applicant forced to introduce such concepts as specific activity into the claims.<sup>115</sup> Similarly, in the computer context, a claim that does

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<sup>113</sup> See *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014) (“We have explained that ‘requiring a written description of the invention plays a vital role in curtailing claims . . . that have not been invented, and thus cannot be described.’ . . . [T]he purpose of the written description requirement is to “ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.””) (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352–54 (Fed. Cir. 2010)).

<sup>114</sup> See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2015 WL 9914886, at \*3 (Fed. Cir. Dec. 2, 2015) (Lourie, J. and Moore, J., concurring) (reasoning that §§ 112 and 103 are more appropriate tools for dealing with preemption concerns than § 101). *But see id.* at \*11, n.5 (Dyk, J., concurring in part and dissenting in part) (“It has been suggested that the requirements of enablement and written description will guard against the dangers of overclaiming a law of nature. Those doctrines, important as they are, generally require only that one or a handful of representative embodiments be described by the patentee.”).

<sup>115</sup> Cf. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1217–18 (Fed. Cir. 1991) (holding claim of patent for method for purification of Erythropoietin and Erythropoietin compositions are invalid for indefiniteness because the claim limitation “at least about” had no support “as to what range of specific activity is covered by the term ‘about’”); *STX, Inc. v. Brine, Inc.*, 37 F. Supp. 2d 740, 745, 755 (D. Md. 1999) (claiming term indefinite where the “alleged limitation is subjective on so many levels it is impossible to determine the



not clearly recite how the computer is involved would be vague, and the applicant may have to introduce specific limitations on the implementation.

## V. CONCLUSIONS

The minimally intrusive amendment proposed in this article will not damage the constitutional requirement to “promote the progress of the useful arts;” the main concerns of preemption can be dealt with through other sections of the statute. In fact, it is the present unworkable state of the law that is encumbering major sectors of our inventing community.<sup>116</sup> Natural product scientists, software engineers, algorithm creators, and genetics diagnosticians, are prevented from properly protecting their inventions. This is hindering rather than promoting the progress of the useful arts. And it is undermining the very core of our national economic strength: our inventors, their investors, and the rest of us who benefit from predictable intellectual property.

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scope of [the] term”) (internal quotation marks omitted); *see also supra* note 58.

<sup>116</sup> Three significant events have occurred since this article went to print. *First*, SCOTUS has before it Sequenom’s petition for certiorari, which echoes J. Newman’s dissent in the CAFC *en banc* denial. *Supra* notes 33, 68, and 112. *Second*, On April 8, 2016, the CAFC decided *Genetic Techs. Ltd. v. Merial LLC*, upholding a lower court dismissal motion, given what it deemed to be ineligible method claims of amplifying genetic mutations. Nos. 15-1202, -1203, at 9–10 (Fed. Cir. Apr. 8, 2016). The CAFC reasoned that the claim at issue is “quite similar” to *Mayo’s* blood-test patent claiming a natural law, and “remarkably similar” to the prenatal DNA patent in *Sequenom. Id.* at 9–10, 13–14. *Third*, on April 12, 2016, the former director of the U.S.P.T.O., David Kappos, called for the abolition of § 101 of the Patent Act, saying that decisions like *Alice* on the eligibility issue are a “real mess” and threaten patent protection for key U.S. industries. *See* Ryan Davis, *Kappos Calls for Abolition of Section 101 of Patent Act*, LAW360 (Apr.12, 2016), [http://www.law360.com/ip/articles/783604?nl\\_pk=adcf0c1f-40d6-4bf5-b60effe46da2cfd2&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=ip](http://www.law360.com/ip/articles/783604?nl_pk=adcf0c1f-40d6-4bf5-b60effe46da2cfd2&utm_source=newsletter&utm_medium=email&utm_campaign=ip). These events indicate that congressional action in line with the proposal to amend § 101 set forth in this article remains a critical option to the patent-eligibility conundrum.

## VI. APPENDIX 1

SCOTUS Case on § 101 (post-1952 Patent Act)	Claim and Holding: Reasoning	Outcome under Proposed § 101 Amendment?
<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972)	<p><b>Claim 8:</b> A method of converting signals from binary coded decimal form into binary which comprises carrying out calculations of an algorithm on shift registers within a general computer.</p> <p><b>Held ineligible:</b> No other use for algorithm than claimed process, so claim preempts every possible application. "Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."</p>	Now <b>eligible</b> , since it applied changes to physical shift registers, which is a "physically implemented process."
<i>Parker v. Flook</i> , 437 U.S. 584 (1978)	<p><b>Claim:</b> Mathematical formula/algorithm that calculated range at which a catalytic converter operated and sounded alarm when value left range.</p> <p><b>Held ineligible:</b> Process not operated to transform materials to a different state or thing, <i>a/k/a/</i> "point of novelty" or "MOT" test.</p>	Still <b>ineligible</b> because it does not involve a "physically implemented process."
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981)	<p><b>Claim:</b> Use of mathematical formula in a process for producing cured synthetic rubber products and using a mathematical algorithm to calculate curing time.</p> <p><b>Held eligible:</b> Although claiming the algorithm alone was not patentable, a practical application (i.e., curing rubber) using the algorithm was eligible.</p>	Still <b>eligible</b> since it involves a "physically implemented process."

SCOTUS Case on § 101 (post-1952 Patent Act)	Claim and Holding: Reasoning	Outcome under Proposed § 101 Amendment?
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980)	<p><b>Claim:</b> A live genetically engineered bacterium that contains multiple oil-degradation pathways.</p> <p><b>Held eligible:</b> The engineered bacterium has “markedly different characteristics from any found in nature” due to additional plasmids.</p>	Still <b>eligible</b> in that the “claimed invention as a whole is novel.”
<i>Bilski v. Kappos</i> , 561 U.S. 593 (2010)	<p><b>Claim:</b> An algorithmic method for hedging/protecting against risk.</p> <p><b>Held ineligible:</b> Claims only “mental and/or abstract processes.”</p>	Still <b>ineligible</b> in that it does not involve any physically implemented process.
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012)	<p><b>Claim:</b> Evaluation of the dosage for the use of a drug by administering the drug and determining the level of a derived metabolite and then correlating the level to the dosage.</p> <p><b>Held ineligible:</b> Steps of administering drug, and determining metabolite levels were routine and conventional and lacked inventive concept.</p>	Now <b>eligible</b> , since claim involves physically implemented process steps, and is novel as a whole.
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013)	<p><b>Claim:</b> An isolated DNA claimed by the sequence of the protein it encodes.</p> <p><b>Held ineligible:</b> While “isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule...the claim is concerned primarily with the information contained in the genetic sequence...”</p>	Now <b>eligible</b> , in that the claim is to a novel composition of matter.

SCOTUS Case on § 101 (post-1952 Patent Act)	Claim and Holding: Reasoning	Outcome under Proposed § 101 Amendment?
<p><i>Alice Corp. Pty. Ltd. v. CLS Bank Int'l</i>, 134 S. Ct. 2347 (2014)</p>	<p><b>Claims:</b> Computer-implemented systems and processes for eliminating settlement risk by using third-party intermediary.</p> <p><b>Held ineligible:</b> Abstract idea not made eligible by merely requiring generic computer implementation. Not sufficient “inventive concept.”</p>	<p>Computer system is now <b>eligible</b> in that it is a “machine” claim that is novel “as a whole.”</p> <p>If the process is construed as computer-implemented (which was a stipulation in the case) the computer process would also be <b>eligible</b> as involving a “physically implemented process.”</p>