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## A Logical and Lawful Application of § 101 Jurisprudence: The USPTO's 2019 Subject Matter Eligibility Guidance

Dustin Luetttgen

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**A LOGICAL AND LAWFUL APPLICATION OF § 101  
JURISPRUDENCE: THE USPTO’S 2019 SUBJECT  
MATTER ELIGIBILITY GUIDANCE**

*Dustin Luetttgen\**

*In recent years, 35 U.S.C. § 101 has been a topic of great concern within the patent bar due to uncertainty surrounding the patentability of inventions drawn to the three judicial exceptions to patent-eligible subject matter: abstract ideas, natural phenomena, and laws of nature. In response to this lingering uncertainty and in an effort to provide for the lawful and consistent application of patent law, the United States Patent and Trademark Office released guidance as to the subject matter eligibility of claims drawn to judicial exceptions. This Article provides a review of § 101 jurisprudence, summarizes the USPTO Guidance, and presents an analysis of why the USPTO’s Guidance is both a lawful and logical application of patent law in view of the Supreme Court and Federal Circuit’s § 101 jurisprudence.*

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## INTRODUCTION

The scope of patent-eligible subject matter is defined by 35 U.S.C. § 101, and subject matter eligibility is the first statutory requirement of a U.S. patent.<sup>1</sup> In recent years, § 101 has been a topic of great concern within the patent bar due to a significant expansion in the application of the judicial exceptions to patentable subject matter. While the three judicial exceptions for claims drawn to abstract ideas, natural phenomena, and laws of nature have been part of the Supreme Court's § 101 jurisprudence for years,<sup>2</sup> it was rare for a patent application to be rejected or an issued patent to be declared invalid on § 101 grounds prior to 2010.<sup>3</sup> However, through the course of several decisions between 2010 and 2014, the Supreme Court drastically altered what is now considered to be patent-eligible subject matter under § 101. Depending on the art, qualifying as patent-eligible subject matter under § 101 is no longer the simple task it once was.

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<sup>1</sup> 35 U.S.C. § 101 (2018).

<sup>2</sup> See, e.g., *O'Reilly v. Morse*, 56 U.S. 62, 63 (1853). The judicial exceptions were created in order to further the underlying policy goals of promoting the progress of science and the useful arts and to ensure that issued patents would not stifle technological advancement by tying up the basic tools of scientific discovery.

<sup>3</sup> See Bruce Berman, *Study: Alice v. CLS Bank Led to a Strong Increase in Subject Matter Patent Invalidations*, IP CLOSEUP (Apr. 14, 2015), <https://ipcloseup.com/2015/04/14/study-alice-v-cls-bank-led-to-a-strong-increase-in-subject-matter-patent-invalidations/>.

The Supreme Court's decisions in *Bilski v. Kappos*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. v. CLS Bank International* retroactively invalidated thousands of patents issued by the United States Patent and Trademark Office ("USPTO" or "PTO").<sup>4</sup> Following these decisions, patents once thought to be valid and enforceable suddenly became worthless. Many lawsuits ensued where patents once considered strong were found invalid and unenforceable.<sup>5</sup> Following suit, the USPTO severely restricted what it considered to be patent-eligible subject matter in certain arts, as indicated by an increase in § 101 rejections.<sup>6</sup> Inventions drawn to software, biotechnology, and diagnostics were impacted the most severely. For a time, it seemed that software and certain areas of biotechnology were *per se* unpatentable subject matter.<sup>7</sup> While recent Federal Circuit decisions and patents issued by the USPTO have shown this not to be the case, there is nonetheless still some uncertainty as to the subject matter eligibility of inventions that operate based upon abstract ideas, natural phenomena, and laws of nature. Particularly as they relate to the abstract idea exception—the broadest of the three judicial exceptions—Federal Circuit decisions applying Supreme Court § 101 jurisprudence in the context of electronically implemented methods, software, and internet-based features of inventions are at times arbitrary and unpredictable, making it difficult for patent applicants to navigate § 101 jurisprudence as to the abstract idea exception.

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<sup>4</sup> *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012); *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

<sup>5</sup> See, e.g., *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014).

<sup>6</sup> See Dennis Crouch, *The Impact of 101 on Patent Prosecution*, PATENTLYO (Oct. 21, 2018), <https://patentlyo.com/patent/2018/10/impact-patent-prosecution.html>.

<sup>7</sup> See *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (holding claims for "mathematical calculations" to be directed to an abstract idea); see also *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015) (holding patent for detecting paternally inherited cell-free fetal DNA circulating in blood of pregnant women invalid as being directed to a natural phenomenon).

In an effort to respond to this lingering uncertainty and provide guidance to patent applicants and examiners, the USPTO released its 2019 Revised Patent Subject Matter Eligibility Guidance (“2019 Guidance”).<sup>8</sup> The 2019 Guidance seeks to promote the consistent and correct application of patent law in § 101 determinations made by examiners of the USPTO.<sup>9</sup> This Article will present an analysis of the 2019 Guidance in view of Supreme Court and Federal Circuit precedent and demonstrate that the 2019 Guidance is a lawful and logical application of § 101 jurisprudence supported by precedent.

The analysis begins in Part I with an overview of the old regime of patent-eligible subject matter prior to the jurisprudential changes beginning in 2010. Next, it presents a review of the Supreme Court’s § 101 test resulting from the decisions in *Alice*, *Mayo*, and *Bilski*.<sup>10</sup> This is followed by a review of recent Federal Circuit decisions that have refined the Supreme Court’s *Alice* test for subject matter eligibility. Part II follows with a summary of the 2019 Guidance as examiners have been instructed to apply it. Finally, Part III presents a detailed analysis of how the 2019 Guidance is a lawful and logical application of § 101 jurisprudence supported by substantial Federal Circuit and Supreme Court precedent.

## I. THE LEGAL STANDARD FOR SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. § 101

Section 101 of U.S. Code Title 35 defines the scope of patent-eligible subject matter and is the first statutory requirement of a U.S. patent. The statute provides, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>11</sup> The function of the statute is to set forth what sorts of inventions are

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<sup>8</sup> 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 57 (Jan. 7, 2019) [hereinafter 2019 Guidance].

<sup>9</sup> *See id.*

<sup>10</sup> *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012); *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

<sup>11</sup> 35 U.S.C. § 101 (2018).

patentable, provide some limitation on what sorts of technologies for which the public may seek patent protection, and establish that patent rights will initially vest in the inventor.

*A. Pre-2010 Supreme Court § 101 Jurisprudence*

The following Section presents the Supreme Court's pre-2010 jurisprudence as it related to the three judicial exceptions to patent-eligible subject matter: abstract ideas, natural phenomena, and laws of nature.

i. Technologies Embodying Abstract Ideas; What Is Not Enough to Qualify as Patent-Eligible?

The judicial exception that excludes abstract ideas from patentable subject matter is nothing new, as the Supreme Court has long sought to prevent patents from *stifling* technological improvements within an art as opposed to *promoting* them. The Court has accomplished this by holding that claims directed to abstract ideas without practical application do not present patentable subject matter, even before holding in *Alice Corporation Pty. v. CLS Bank International* that method claims to the abstract idea of an intermediated settlement, which were generically implemented on a computer, were not patentable.<sup>12</sup> In other words, even practical applications of abstract ideas were held unpatentable when the only novel aspect was an abstract idea.<sup>13</sup>

The most famous examples of such holdings are the Court's decisions from the 1970s in *Gottschalk v. Benson* and *Parker v. Flook*.<sup>14</sup> In *Benson*, the invention at issue was directed to a mathematical formula for converting binary-coded decimal

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<sup>12</sup> See *Alice*, 573 U.S. at 216; see, e.g., *Parker v. Flook*, 437 U.S. 584, 590 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972).

<sup>13</sup> See *Flook*, 437 U.S. at 590.

<sup>14</sup> *Id.* (holding method claims for applications of a mathematical formula which updated alarm limit values in an industrial process to be an unpatentable abstract idea); *Benson*, 409 U.S. at 72 (holding method claims for converting binary-coded decimal numbers into binary numerals for use by a computer to be an unpatentable abstract idea).

numbers into binary numerals for use by a computer.<sup>15</sup> In *Flook*, the invention in question was directed to a mathematical formula for calculating updated alarm limit values in a catalytic conversion process.<sup>16</sup>

In these decisions following challenges to the patents' validity, the Court characterized the inventions as patent-ineligible abstract ideas, stating that "mental processes[] and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."<sup>17</sup> Paramount in both of these decisions is the concern that allowing such patents to stand would tie up the mathematical formulas themselves, preventing others from using them in any manner and stifling technological improvements to the art rather than promoting them—contrary to the underlying policy goals of the U.S. patent system.<sup>18</sup> Those policy goals are to promote the progress of science and the useful arts by providing an incentive to develop and disclose to the public new technological advancements, in exchange for a brief period of exclusivity in the commercialization of the invention.

The policy issue of ensuring patent law promotes, and does not hinder, the progress of science and the useful arts continues to be the primary concern even today when the Court considers the § 101 eligibility of inventions directed to abstract ideas. Subsequent decisions relating to § 101 eligibility have often turned upon whether the claims would have the practical effect of preventing others from making use of the underlying idea present in the invention.<sup>19</sup> When considering this policy concern, the decisions in *Benson* and *Flook* make sense: allowing *Benson*'s patent to stand likely would have prevented the development of computers because of the essential need to convert binary-coded decimal numbers into binary numerals in the operation of *any* computer, and allowing

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<sup>15</sup> *Benson*, 409 U.S. at 65.

<sup>16</sup> *Flook*, 437 U.S. at 585–86.

<sup>17</sup> *Id.* at 589.

<sup>18</sup> *See id.* at 589; *Benson*, 409 U.S. at 67.

<sup>19</sup> *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).



Flook's patent to stand likely would have prevented the use of the mathematical formula in other applications.<sup>20</sup>

Consideration of the Court's pre-2010 § 101 jurisprudence relating to abstract ideas makes clear that the Court has long used § 101 to prevent patents from *stifling* technological improvements within an art as opposed to *promoting* them.<sup>21</sup> This jurisprudential tendency, both prior to 2010 and still now, has proven especially strong when the claims involve abstract ideas essential to the development of technology, such as mathematical formulas.<sup>22</sup> Pre-2010 jurisprudence did not hold that the use of an abstract idea in an invention would render the invention *per se* unpatentable,<sup>23</sup> but even prior to *Alice*, it was clear *something more* than the abstract idea itself was required in order for a claim to present patent-eligible subject matter.

ii. Technologies Embodying Abstract Ideas and  
Laws of Nature; What Is Enough to Qualify as  
Patent-Eligible?

*Diamond v. Diehr*<sup>24</sup> is likely the most famous example from the Court's pre-2010 jurisprudence of what is sufficient to make claims involving an abstract idea patentable. In *Diehr*, claims directed to a process for the production of rubber that utilized a computer to constantly recalculate the curing time of the rubber using the Arrhenius equation were held to present patentable subject matter.<sup>25</sup>

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<sup>20</sup> See *Flook*, 437 U.S. at 592 (finding claim embodied a "very valuable" principle and mathematical formula); *Benson*, 409 U.S. at 68 (finding formula embodied in claim was a "basic tool[] of scientific and technological work").

<sup>21</sup> See, e.g., *Benson*, 409 U.S. at 67–68 (finding formula embodied in claim was a "basic tool[] of scientific and technological work").

<sup>22</sup> See *id.*; see also *O'Reilly v. Morse*, 56 U.S. 62, 63 (1853) (holding claims drawn to electromagnetism in a telegraph invalid, reasoning they would preempt uses of electromagnetism in subsequent inventions).

<sup>23</sup> See, e.g., *Flook*, 437 U.S. at 590 ("[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.").

<sup>24</sup> *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (holding claims to an industrial rubber-curing process that utilized the Arrhenius equation to constantly recalculate the cure time to be patent-eligible).

<sup>25</sup> *Id.* at 191–92.

The Arrhenius equation is a well-known chemical formula often employed in chemical engineering applications; it is used to estimate rates of reaction and, in the case of the patent at issue in *Diehr*, the estimated time of reaction completion.<sup>26</sup> Because the Arrhenius equation is a mathematical equation that describes the natural temperature dependence of reaction rates, it can be considered both an abstract idea and a law of nature.<sup>27</sup>

In reaching its decision, the Court reaffirmed its prior holdings in *Benson* and *Flook* that “an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent.”<sup>28</sup> However, the Court distinguished the patent at issue in *Diehr* by finding that “the respondents here [did] not seek to patent a mathematical formula. Instead, they [sought] patent protection for a process of curing synthetic rubber.”<sup>29</sup> The Court found that while the “process admittedly employ[ed] a well-known mathematical equation, [respondents did] not seek to pre-empt the use of that equation. Rather, they [sought] only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”<sup>30</sup> These steps “include[d] installing rubber in a press, closing the mold, constantly determining the temperature of

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<sup>26</sup> *Id.* at 177.

The equation is named after its discoverer Svante Arrhenius and has long been used to calculate the cure time in rubber-molding presses. The equation can be expressed as follows:

$$\ln v = CZ + x$$

wherein  $\ln v$  is the natural logarithm of  $v$ , the total required cure time;  $C$  is the activation constant.

*Id.* at n.2.

<sup>27</sup> *Id.* at 185 (“An idea . . . [like a] principle, . . . an original cause[,] . . . [and] a motive . . . cannot be patented, as no one can claim in either of them an exclusive right.” (citations omitted)); *id.* at n.11 (“He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”). Because it is often mathematical equations which are used to describe phenomena of nature in science, there is often overlap between the two categories.

<sup>28</sup> *Id.* at 186–87.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 187.

the mold, constantly recalculating the appropriate cure time through the use of the [Arrhenius] formula and a digital computer, and automatically opening the press at the proper time.”<sup>31</sup> Also of note is dictum wherein the Court stated that “one does not need a ‘computer’ to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of ‘overcuring’ or ‘undercuring,’ the process as a whole does not thereby become unpatentable subject matter.”<sup>32</sup> This is significant in that it indicated the mere use of a computer in an otherwise patentable claim should not itself render the claim ineligible.<sup>33</sup>

In *Diehr*, the underlying policy concern of promoting technological innovation as opposed to stifling innovation was again at the forefront of the Court’s reasoning and analysis.<sup>34</sup> But in contrast to *Flook* and *Benson*, the claims in *Diehr* were narrowly tailored to the claimed embodiment of curing rubber, not seeking to patent the formulas themselves.<sup>35</sup> Allowing the patent to stand in *Diehr* did not prevent others from making use of the Arrhenius equation generally—not even in the production of rubber.<sup>36</sup> It only prevented the use of the equation when used to produce rubber when all of the structural and process limitations set forth in the claims were present. Because the claims in *Diehr* were narrowly tailored to the practical application of automatically producing rubber in combination with a number of structural and process limitations associated with the automatic production of rubber, the Court found the patent valid under § 101, notwithstanding the use of the

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<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *See id.*

<sup>34</sup> *See, e.g., id.*

<sup>35</sup> Compare *Parker v. Flook*, 437 U.S. 584, 590 (1978) (finding broad claim embodying a “very valuable” principle and mathematical formula to be ineligible subject matter), and *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972) (finding broad claims to a mathematical formula which was a “basic tool[] of scientific and technological work” to be ineligible subject matter), with *Diehr*, 450 U.S. at 182 (holding claims narrowly drawn to an industrial rubber-curing process that utilized the Arrhenius equation to constantly recalculate the cure time to be patent-eligible).

<sup>36</sup> *Diehr*, 450 U.S. at 192–93.

Arrhenius equation and a computer to complete the calculation being included as elements of the claims. Following this trend, more recent cases with claims that embodied abstract ideas but which were still valid under § 101 have similarly utilized abstract ideas in combination with sufficient structural and process limitations to ensure the claims were narrowly drawn to their specific inventive embodiments.<sup>37</sup>

Overall, the Court’s pre-2010 § 101 jurisprudence relating to abstract ideas and natural phenomena indicates that § 101 was primarily used to prevent private parties from stifling innovation by tying up the basic tools of scientific discovery in a patent.<sup>38</sup> Under this pre-2010 § 101 jurisprudence, a patent was not *per se* invalid simply because an abstract idea, law of nature, or computer-based calculation was present in the claims; but in order to withstand § 101 scrutiny, such claims were required to be narrowly tailored to the specific application and structured in manner as not to prevent others from making use of the abstract idea or law of nature.

### iii. Some Natural Phenomena and Laws of Nature Are Patentable When Incorporated into Biotechnology

Another important aspect of the Court’s § 101 jurisprudence is illustrated in the famous case *Diamond v. Chakrabarty*.<sup>39</sup> In *Chakrabarty*, the Court held that a patent claiming a living organism—a genetically modified bacterium capable of breaking down crude oil—was valid under § 101.<sup>40</sup> At issue in this case was whether the judicial exception for inventions drawn to natural

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<sup>37</sup> See *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1249–50 (Fed. Cir. 2014) (holding claims drawn to abstract ideas to be § 101-eligible due in part to significant process limitations in claim).

<sup>38</sup> See, e.g., *Flook*, 437 U.S. at 589; *Benson*, 409 U.S. at 67; *Diehr*, 450 U.S. at 187.

<sup>39</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 304 (1980) (holding claims to a genetically modified bacterium produced to break down crude oil was not outside the scope of patentable inventions merely because it was drawn to a “live organism” and qualified under the statute as a new or useful “manufacture” or “composition of matter”).

<sup>40</sup> *Id.* at 309.

phenomena rendered the patent invalid and whether a microorganism's creation fell within the statutory language of a "manufacture" or "composition of matter."<sup>41</sup> In support of its holding, the Court found that the use of the word "any" in § 101<sup>42</sup> was intended to give the statute a broad scope of patentable subject matter, and it also found that the bacterium was not a natural phenomenon because it had been genetically modified to break down crude oil, a property which no known natural bacterium exhibits.<sup>43</sup>

In holding that the claimed bacterium fell within the statutory language and was not barred by the natural phenomena exclusion, the Court in essence declared that living organisms and biotechnology were patentable and were not *per se* barred by § 101. Under this pre-2010 § 101 jurisprudence relating to natural phenomena, then, all that was required for biotechnology patents to be valid under § 101 was that the underlying invention be something produced by man and not found in nature.<sup>44</sup> This trend of requiring a manmade contribution to the application of the invention has continued in modern § 101 jurisprudence.<sup>45</sup> As will be discussed in the coming Sections of this Article, subsequent holdings related to the judicial exception for natural phenomena have required more than merely a manmade contribution for a patent drawn to biotechnology to withstand § 101 scrutiny.

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<sup>41</sup> *Id.* at 307.

<sup>42</sup> 35 U.S.C. § 101 (2018) ("Whoever invents or discovers *any* new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." (emphasis added)).

<sup>43</sup> *Chakrabarty*, 447 U.S. at 303, 310.

<sup>44</sup> *Id.* at 310.

<sup>45</sup> See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (holding cDNA fragments to be patentable subject matter as cDNA does not exist in nature); see also *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (holding claims for process of producing hepatocytes patent-eligible as they had properties which did not exist naturally).

*B. Modern Supreme Court § 101 Jurisprudence*

A massive shift in the Court's § 101 jurisprudence first began in 2010 when the Court issued its decision in *Bilski*, finding a patent directed to a computer-implemented method of hedging risk to be invalid under § 101.<sup>46</sup> *Bilski* is less notable for its central holding, which alone was not a significant deviation from the Court's prior § 101 jurisprudence, but is significant for initiating the Court's modern § 101 decisions: it signaled the beginning of the end for business method patents and was the first time the Court used § 101 to invalidate a patent that basically implemented a preexisting idea on modern computers.<sup>47</sup> This was the first decision involving § 101 that the Court had issued in many years, and prior to this, § 101 issues rarely came up in practice.<sup>48</sup>

Following *Bilski*, the Court's subsequent decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* in 2012, *Alice* in 2014, and *Association for Molecular Pathology v. Myriad Genetics, Inc.* in 2013 significantly upended § 101 jurisprudence with each decision finding previously eligible patent claims to be invalid under § 101.<sup>49</sup>

In *Mayo*, the Court held claims to a method for determining an effective dose of a pharmaceutical based upon metabolite levels invalid under § 101 because it fell under the law of nature exclusion: the Court placed the patent into the exclusion because the method used the natural metabolic rates of thiopurine drugs in the human body to estimate proper drug dosage and the patent otherwise lacked novelty.<sup>50</sup> This decision was significant because it created a strong presumption against any method using natural properties of living

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<sup>46</sup> *Bilski v. Kappos*, 561 U.S. 593, 609 (2010).

<sup>47</sup> See, e.g., *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

<sup>48</sup> See, e.g., *Berman*, *supra* note 3; *Crouch*, *supra* note 6.

<sup>49</sup> *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012).

<sup>50</sup> *Mayo*, 566 U.S. at 72.

organisms as a part of the method, and it has been applied to severely limit the patentability of diagnostic methods.<sup>51</sup>

In *Alice*, the Court held claims to a computer-readable medium for mediating settlement risk in electronically based bank transactions invalid under § 101 as an abstract idea.<sup>52</sup> There, the Court found that the patent did no more than implement a conventional process on a computer, even though the method (which involved maintaining an extensive list of “shadow records”) was something that was impracticable to do in the absence of a computer, and despite the fact that settlement risk was not ordinarily mitigated in this way.<sup>53</sup> *Alice* is also significant as it announced the Court’s current test for § 101 eligibility and expanded upon *Bilski* in severely limiting the patentability of computer-implemented business method patents.

In *Myriad*, the Court held claims to gene segments of isolated naturally occurring human DNA to be invalid under § 101 as a natural phenomenon, finding that the gene segments occurred naturally in the human body (even though they did not exist in any manner which could be utilized or altered outside of the human body) and were produced by manmade techniques.<sup>54</sup> *Myriad* is also significant for its holding that claims to non-naturally occurring cDNA fragments were valid because the gene segments did not exist in spliced cDNA form in nature, though they were nearly identical to protein coding regions (exon segments) of the natural forms of RNA transcribed from the base DNA fragments.<sup>55</sup>

Collectively, these three decisions created great uncertainty in patent law because they appeared to indicate that familiar claim types directed to treatment methods, gene segments, and computer-readable media were *per se* patent-ineligible subject matter,

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<sup>51</sup> See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

<sup>52</sup> *Alice*, 573 U.S. at 225.

<sup>53</sup> *Id.*

<sup>54</sup> *Myriad*, 569 U.S. at 580. The Court found claims to non-naturally occurring cDNA fragments to be valid because the gene segments did not exist in spliced cDNA form in nature, but only as DNA and RNA segments with both exon and intron segments.

<sup>55</sup> *Id.* at 580, 594–95.

particularly in view of *Alice*'s vague § 101 eligibility test, discussed below.<sup>56</sup> While this conclusion was not exactly accurate, these decisions did have the effect of retroactively invalidating many issued patents.<sup>57</sup>

#### i. The *Alice* Test

The Court's current test for § 101 subject matter eligibility was generally set forth in *Alice* and refined by *Mayo*.<sup>58</sup> The current test has two steps. Step 1 asks whether the claims are drawn to one of the three judicial exceptions for abstract ideas, natural phenomena, or laws of nature, so as to trigger § 101 scrutiny.<sup>59</sup> Step 2 asks whether there is "something more" that is sufficient to transform the claims from a patent-ineligible judicial exception into patentable subject matter.<sup>60</sup>

The *Alice* test represented a significant shift in § 101 jurisprudence because it formally changed the standard for subject matter eligibility to require "something more" and has been used frequently to strike down all manners of invention as claiming ineligible subject matter, unlike the Court's prior decisions.<sup>61</sup> Further, because *Alice* specifically pertained to a computer-implemented business method that embodied abstract ideas, it has been frequently applied in the context of computer-implemented methods that embody abstract ideas, as well as to business method patents.<sup>62</sup>

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<sup>56</sup> See, e.g., *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (applying *Alice* and holding claims for "mathematical calculations" directed to an abstract idea); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (applying *Myriad* and holding claims to a diagnostic method utilizing naturally occurring cfDNA to be invalid).

<sup>57</sup> See, e.g., *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014).

<sup>58</sup> *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73 (2012).

<sup>59</sup> *Alice*, 573 U.S. at 217.

<sup>60</sup> *Id.*; *Mayo*, 566 U.S. at 72.

<sup>61</sup> See, e.g., *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018).

<sup>62</sup> See *id.*



The Court's current test is quite vague, largely because the Court did not clarify what was the "something more" required for § 101 eligibility beyond the somewhat specific circumstances of the instant cases.<sup>63</sup> Step 1 of the test was left rather unclear: the Court stated that it "need not labor to delimit the precise contours of the 'abstract ideas' category in [*Alice*]" and did not delineate those contours subsequently.<sup>64</sup> However, what became clear from the *Alice* and *Mayo* decisions is that patents directed to computer-implemented methods and diagnostics would be subject to additional scrutiny.<sup>65</sup> This was not necessarily clear before these decisions because of the infrequency with which patent applications and litigations were disposed of on the basis of the Court's prior § 101 holdings, and because of earlier jurisprudence's uncertain application to technologies utilizing modern computers. In particular, we now know that patents related to computer-implemented methods, as well as claims to computer-readable media which facilitate execution of the methods on a computer, are invalid if they do no more than what could be done using the method without a computer—notwithstanding the impracticability of completing and repeating calculations by hand, or the technical challenge posed by programing and executing such methods on a computer.<sup>66</sup> As it relates to biotechnology and gene segments, the test is somewhat less problematic as *Myriad* more clearly sets forth that "something more" is something artificial or manmade that does not exist in nature.<sup>67</sup> *Myriad* accomplished this by holding that claims to non-naturally occurring cDNA fragments were patentable because the gene segments did not exist in spliced cDNA form in nature (though the gene did naturally occur), presenting a standard

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<sup>63</sup> See Guy Gosnell & Jim Carroll, CLS Bank Int'l v. Alice Corporation Provides Little Guidance from Federal Circuit on 101 Eligibility of Method, Computer Readable Medium, and Computer System Patents, 130 BANKING L.J. 720, 728 (2013).

<sup>64</sup> *Alice*, 573 U.S. at 221.

<sup>65</sup> See *id.* at 217.

<sup>66</sup> See *id.* at 219–21.

<sup>67</sup> See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593 (2013).

that is easier to follow as compared to a general call for “something more.”

Diagnostic methods are a type of patent claim which is, unfortunately, faced with persistent general hostility.<sup>68</sup> Current § 101 jurisprudence does not establish what, if anything, is “something more” as it relates to the field of diagnostics.<sup>69</sup> This is unfortunate because it means that patent law currently provides no incentive to invest in the development of new diagnostic technologies, a technological field that has practical applications in diagnosing diseases—whether that be early diagnosis of cancer or screening for novel diseases like COVID-19, it has the potential to save many lives. The lack of guidance in this area is problematic as most patents for diagnostic methods are struck down under current jurisprudence.<sup>70</sup>

The vagueness of the Court’s *Alice* test and the question of what exactly constitutes “something more” have been the subject of many subsequent Federal Circuit decisions,<sup>71</sup> as the test notably changed § 101 jurisprudence in its requirement of “something more” in subject matter eligibility determinations, and in its use to strike down all manners of invention as claiming ineligible subject matter.<sup>72</sup> The 2019 Guidance primarily drew its rules from post-*Alice* Federal Circuit decisions. It is due in part to the vagueness of the Court’s *Alice* test that the 2019 Guidance, which modifies its application in view of Federal Circuit precedent, can be considered compliant with *Alice*.<sup>73</sup> As will be discussed, the 2019 Guidance is supported by Supreme Court precedent unproblematically, largely

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<sup>68</sup> See, e.g., *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018).

<sup>69</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 754 (Fed. Cir. 2019).

<sup>70</sup> See, e.g., *Cleveland Clinic*, 859 F.3d at 1361.

<sup>71</sup> See, e.g., *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015).

<sup>72</sup> See, e.g., *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018).

<sup>73</sup> See *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014).

because of the Court's unspecific and undemanding presentation of the test in *Alice*.

### C. Federal Circuit § 101 Jurisprudence

This Section discusses the Federal Circuit's modifications to the Supreme Court's modern § 101 jurisprudence. It begins by discussing cases that have refined and expanded upon *Alice* Step 1, which asks whether claims are directed to a judicial exception. It then discusses cases that have refined and expanded upon *Alice* Step 2, which seeks to define "something more." The discussion of what is "something more" is split into two parts: first the judicial exception for abstract ideas is covered, and then the exceptions for laws of nature and natural phenomena are discussed together.

#### i. Refining *Alice* Step 1; Claims "Directed To" a Judicial Exception

Since the Court's decisions in *Alice*, *Mayo*, and *Myriad*, the Federal Circuit has issued numerous opinions that have made findings as to what sorts of technologies are directed to abstract ideas, laws of nature, and natural phenomena within the meaning of *Alice* Step 1.<sup>74</sup> These decisions have clarified application of *Alice* Step 1 by providing specific examples of what can be considered judicial exceptions sufficient to trigger § 101 scrutiny.

Application of *Alice* Step 1 has been especially challenging as it relates to the abstract idea exception, primarily due to the breadth of this exception and the many different technologies that have been found to be directed to abstract ideas.<sup>75</sup> The types of technologies

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<sup>74</sup> See *SAP Am., Inc.*, 898 F.3d at 1163 (holding claims for "mathematical calculations" were directed to an abstract idea); *Cleveland Clinic*, 859 F.3d at 1362 (holding claims for diagnostic technology were directed to a law of nature); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (holding claims for diagnostic technology were directed to natural phenomena).

<sup>75</sup> See *SAP Am., Inc.*, 898 F.3d at 1163 (holding system and methods claims for performing certain statistical analyses of investment information were directed to an abstract idea); *Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*, 876 F.3d 1372, 1378 (Fed. Cir. 2017) (holding claims for system for local payment processing for goods purchased remotely to be directed to an abstract idea);

that are typically considered to be directed to abstract ideas are those that operate based upon mathematical concepts, equations, formulas, or calculations; facilitate methods of organizing human activity; or facilitate a mental process performed in the human mind.<sup>76</sup>

Considering the broad application of the abstract idea exception, an important question facing patent applicants is what constitutes a patent-ineligible abstract idea, so they at least know what sort of technologies for which they should not even attempt to seek patent protection. In *DDR Holdings, LLC v. Hotels.com*, the Federal Circuit found system claims directed to emulating the look and feel of a website to be patent-eligible subject matter, notwithstanding the claims being drawn to an abstract idea or their nature as a business practice.<sup>77</sup> In reaching this decision, the Federal Circuit began by acknowledging the relative ambiguity of Step 1 of the *Alice* test and noting that the abstract idea present in the instant case was “not as straightforward as in *Alice* or some of [the Federal Circuit’s] other

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*Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1324 (Fed. Cir. 2016) (holding anonymous mortgage loan shopping over the internet to be an abstract idea); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1280 (Fed. Cir. 2012) (finding managing life insurance policies by performing calculations to be an abstract idea).

<sup>76</sup> 2019 Guidance, *supra* note 8, at 51. For a case involving mathematical concepts, equations, formulas, or calculations, see *SAP Am., Inc.*, 898 F.3d at 1163 (holding claims for “mathematical calculations” directed to an abstract idea). For a case involving methods of organizing human activity, see *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) (holding claims for organizing information by using “mathematical correlations” directed to an abstract idea). See generally *Inventor Holdings*, 876 F.3d at 1378–79 (finding local payment processing for goods purchased remotely to be a fundamental economic practice); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) (finding offer-based price optimization to be an abstract idea); *Bancorp Servs.*, 687 F.3d at 1280 (finding managing life insurance policies by performing calculations to be an abstract idea). For cases involving mental processes performed in the human mind, see *Mortg. Grader*, 811 F.3d at 1324 (holding anonymous mortgage loan shopping over the internet to be an abstract idea); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375, 1372 (Fed. Cir. 2011) (holding incidental use of a computer does not make a process which can be performed by a person more than a patent-ineligible abstract idea).

<sup>77</sup> *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1256 (Fed. Cir. 2014).

recent abstract idea cases.”<sup>78</sup> The claims in *DDR Holdings* were found not to be a patent-ineligible abstract idea because the claims did not “merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet,” *i.e.*, claims which would presumably be patent-ineligible abstract ideas.<sup>79</sup> Rather, the claims were “necessarily rooted in computer technology” to overcome the problem of retaining website visitors “specifically arising in the realm of computer networks.”<sup>80</sup> *DDR Holdings* is notable because it indicates that the Federal Circuit does not intend to place a categorical prohibition on inventions involving computer-implemented methods, which tend to dominate abstract idea jurisprudence.<sup>81</sup> Instead, it shows that the Federal Circuit, at least in part, views the abstract idea exception as a way of keeping old ideas out of the realm of newly issued patents as to prevent a repeat of *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,<sup>82</sup> per the Supreme Court’s decision in *Bilski*.<sup>83</sup> In *State Street Bank & Trust Co.*, the Federal Circuit upheld a patent for a computerized accounting system used to manage a mutual fund investment structure, holding it was not an “[u]npatentable mathematical algorithm” and that there was no “business method” exception to patentability.<sup>84</sup> This decision was viewed as problematic, both because it opened the door for many business method patents over the course of the next decade until the Court’s decision in *Bilski*, and because it allowed what were fundamentally old ideas (such as estimating share prices in a mutual fund) to become patentable simply because they were implemented on a computer. *Bilski* is thus

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<sup>78</sup> *Id.* at 1257.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *See id.*

<sup>82</sup> *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (finding a machine that transformed data by a series of mathematical calculations to a final share price to be patent-eligible).

<sup>83</sup> *See Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

<sup>84</sup> *State St. Bank & Trust Co.*, 149 F.3d at 1373, *abrogated by In re Bilski*, 545 F.3d at 943.

significant, not only for being the first § 101 case the Court had decided in many years, but also because it was the first time the Court had used § 101 to invalidate a patent on a preexisting idea as it had been implemented using modern computers. As such, using the abstract idea exception to keep old practices out of the realm of newly issued patents is an important consideration for the Federal Circuit.

However, in some cases, the Federal Circuit has taken this policy consideration too far when holding patents invalid on § 101 grounds. In *ChargePoint, Inc. v. SemaConnect, Inc.*, the court disposed of a patent on § 101 grounds in an unusual manner, deciding the case on § 101 grounds despite the recitation of many structural elements and other limitations in the claims.<sup>85</sup> This was significant because, ordinarily, the presence of many structural elements and other limitations in the claims when combined with a practical application (such as facilitating the function of an electronic vehicle (“EV”) charging network) is sufficient to present patentable subject matter under *Alice*. In applying Step 1 of the *Alice* inquiry, the Federal Circuit elected not to engage in claim construction to determine if the claims were directed to an abstract idea, instead relying upon the patent’s specification to support the finding that the claims were directed to an abstract idea—here “communication over a network.”<sup>86</sup> The Federal Circuit’s application of *Alice* Step 1 was very unusual in that it first looked outside of the claims to determine if the claims were directed to an abstract idea, and in that it used the specification to make this determination despite not engaging in claim construction.<sup>87</sup> Contrary to the court’s application of *Alice* Step 1, the many structural elements and other limitations in the claims suggested that the claims were not actually directed to an abstract idea within the meaning of *Alice* Step 1. The structural

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<sup>85</sup> *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 767–70 (Fed. Cir. 2019) (holding patents relating to networked electric vehicle charging station technology were directed to patent-ineligible abstract idea of communication over a network for interacting with network-attached devices).

<sup>86</sup> *Id.* at 766–67.

<sup>87</sup> Ordinarily, such an analysis of the specification is only done when the court is engaging in claim construction and would usually be done at *Alice* Step 2 where the court is seeking to determine if there is “something more” than claims to an unpatentable abstract idea.

elements and other limitations in the claims included a control device modifying charge transfer based upon electricity demand and power grid load data, transceiver, electrical coupler, remote servers, current measuring device, and electrical supply, among other limitations.<sup>88</sup> Despite these limitations, the court stated that the reason for finding the patent invalid on § 101 grounds was that the claim language would preempt the idea of “communication over a network” as it related to EV chargers and noted that communication over a network is a “building block of the modern economy.”<sup>89</sup>

While these policy reasons were soundly grounded in the policy behind § 101 jurisprudence (that is, keeping old ideas out of the realm of newly issued patents), the application of the abstract idea exception to the claims in this case was likely improper because all the structural elements and other limitations in the claims indicated that the patent was more than an attempt to monopolize the idea of communication over a network as it related to EV chargers. Put differently, the many structural elements and other limitations narrowing the scope of the claims to the claimed embodiment show that the claims were not directed to an abstract idea within the meaning of *Alice* Step 1, or, alternatively, that they added “something more” within the meaning of *Alice* Step 2. If claims lack ingenuity because the only novel component of the claims is the application of an abstract idea, but there are limitations that narrow the scope of the claims such that it is not an attempt to monopolize every application of the idea, it is improper to find the patent invalid on § 101 grounds; the court should instead dispose of the patent on § 103<sup>90</sup> grounds for obviousness.<sup>91</sup> *ChargePoint* suggests that there is still significant uncertainty in how courts will apply *Alice* Step 1 to abstract ideas and that determining whether claims are directed to

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<sup>88</sup> *ChargePoint*, 920 F.3d at 766, 771.

<sup>89</sup> *Id.* at 773.

<sup>90</sup> Section 103 of 35 U.S.C. requires that all newly issued patents be nonobvious in view of all cited prior art considered by the USPTO at the time of examination. 35 U.S.C. § 103 (2018).

<sup>91</sup> See Russell Silfer, *The Federal Circuit Just ‘Swallowed All of Patent Law’* in *ChargePoint v. SemaConnect*, IP WATCHDOG (Apr. 2, 2019), <https://www.ipwatchdog.com/2019/04/02/federal-circuit-just-swallowed-patent-law-chargepoint-v-semaconnect/id=107917/>.

an abstract idea may not always be straightforward, if such a determination is applicable in the context of the present invention.

However, when considering application of *Alice* Step 1 with respect to natural phenomena and laws of nature, there is less difficulty involved in determining whether the claims are “directed to” these exceptions.<sup>92</sup> This difference is likely due to the significant breadth of the abstract idea exception, which covers many technological arts, as opposed to the natural phenomenon and law of nature exceptions, which tend to be limited to chemical arts, medicine, and biotechnology. For instance, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the court required no more than the mention of cell-free fetal DNA (“cffDNA”) in a claim, and a description of cffDNA in the specification stating that it can be found in maternal serum, to support a finding that the claim was directed to a natural phenomenon.<sup>93</sup> Similarly, in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, the court found a method of treating cardiovascular disease to be directed to a law of nature, reasoning that the method involved nothing more than “‘seeing’ MPO already present in a bodily sample and correlating that to cardiovascular disease.”<sup>94</sup> In some cases, the patentee does not even dispute that their claims are directed to a natural phenomenon or law of nature.<sup>95</sup> Because many biotechnologies inherently operate based upon the presence of naturally occurring compounds, and because of the manner in which these particles interact with their environments and the human body, there is less room for argument that they are not directed to a judicial exception within the meaning of *Alice* Step 1.<sup>96</sup>

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<sup>92</sup> See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

<sup>93</sup> *Id.* (“[T]he asserted claims of the ’540 patent are directed to a multistep method that starts with cffDNA taken from a sample of maternal plasma or serum—a naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman . . . . The written description supports the conclusion that the claims of the ’540 patent are directed to a naturally occurring thing or natural phenomenon.”).

<sup>94</sup> *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018).

<sup>95</sup> *Ariosa Diagnostics*, 788 F.3d at 1376.

<sup>96</sup> See *id.*; *Cleveland Clinic*, 859 F.3d at 1361.



However, claims for applications of biotechnology have also been found not to be directed to a law of nature or natural phenomenon, and such claims have either involved novel manipulation of the natural phenomenon in a manner that does not occur in nature<sup>97</sup> or have involved narrowly claimed treatment methods that do not preempt the use of laws of nature and which address significant variations of a natural law within a target patient population.<sup>98</sup> Though these cases are somewhat narrow examples, they are significant in that they show it is possible for applications of biotechnology to not be directed to a law of nature or natural phenomenon at *Alice* Step 1.

In *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, claims for “a method of producing a desired preparation of multicryopreserved hepatocytes” (liver cells) by using multiple freeze-thaw cycles were found not to be directed to a law of nature or natural phenomenon.<sup>99</sup> The court reasoned that the claims were “not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims [were] directed to a new and useful method of preserving hepatocyte cells.”<sup>100</sup> In other words, the patentee had developed a novel laboratory technique which involved manipulation of a natural phenomenon (liver cells) in an unnatural way to achieve a result that did not occur in nature (a population of hepatocytes with high viability upon a final thawing).<sup>101</sup>

In *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, claims for a “method for treating a patient with iloperidone, wherein the patient [was] suffering from schizophrenia,” were held not to be directed to a law of nature or natural phenomenon because the steps of carrying out a dosage regimen based on the results of genetic testing instead directed the

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<sup>97</sup> See *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

<sup>98</sup> See, e.g., *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347, 1353 (Fed. Cir. 2019); *Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018).

<sup>99</sup> *CellzDirect*, 827 F.3d at 1048.

<sup>100</sup> *Id.*

<sup>101</sup> See *id.* at 1049–50.

claims to “a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.”<sup>102</sup> The inventors “recognized the relationships” between iloperidone and natural phenomena like the enzymes the drug affected in the human body, but the court highlighted that the inventors did not claim such relationships; they instead claimed a very specific application of such a relationship.<sup>103</sup> Similarly, in *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, claims for a “method of using oxymorphone or a pharmaceutically acceptable salt thereof to treat pain in a renally impaired patient” were held to not be directed to a law of nature or natural phenomenon by the court, reasoning that the steps of carrying out a dosage regimen based on the results of kidney function were “a new treatment for an ailment, albeit using a natural law or phenomenon,” and that the claims were “legally indistinguishable” from those in *Vanda Pharmaceuticals*.<sup>104</sup> Of note in both of these decisions was the court’s discussion distinguishing *Mayo*, finding preemption to not be a concern because the claims did not “tie up the doctor’s subsequent treatment decision” in either case.<sup>105</sup>

Though difficult in applications of biotechnology and in pharmaceutical treatment methods, these cases show that it is possible to avoid such inventions being “directed to” a judicial exception at *Alice* Step 1. As such, if patent applicants are seeking to avoid *Alice* at Step 1, it is important they seek claims that are narrowly tailored to the novel inventive application and which do not limit a doctor’s subsequent treatment decisions where applicable.

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<sup>102</sup> *Vanda Pharm.*, 887 F.3d at 1134–36 (holding patent method of treating schizophrenia patients with iloperidone wherein the dosage range was based on the patient’s genotype to present patent-eligible subject matter).

<sup>103</sup> *Id.* at 1135.

<sup>104</sup> *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347, 1353–54, 1357 (Fed. Cir. 2019) (holding patent covering a method of using oxymorphone to treat pain in patients with impaired kidney function to present patent-eligible subject matter).

<sup>105</sup> *Vanda Pharm.*, 887 F.3d at 1135 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 86 (2012)); see *Endo Pharm.*, 919 F.3d at 1354 (quoting *Mayo*, 566 U.S. at 86).

ii. Refining Step 2 with Respect to the Abstract Idea Exception; What Is “Something More”?

Step 2 of the *Alice* inquiry asks whether there is “something more” to the claims that is sufficient to transform them from a patent-ineligible judicial exception into patentable subject matter.<sup>106</sup> The *Alice* test, and Step 2 in particular, represented a significant shift in § 101 jurisprudence because it formally changed the standard for subject matter eligibility to require “something more,” which is a vague standard that can reasonably be interpreted in different ways by people of ordinary skill in the art. Prior to *Alice* was *Mayo*, whose reasoning laid the foundation for *Alice* and which has been used to support applying the *Alice* test to the field of medicine and diagnostics using the natural phenomena exception. Following *Alice* was *Myriad*, which formally extended application of the *Alice/Mayo* test to the field of biotechnology using the natural phenomena exception. The combined *Alice/Mayo* test, which is merely referred to as the *Alice* test in this Article, has been used frequently to strike down all manners of invention as claiming ineligible subject matter, unlike the Supreme Court’s § 101 decisions that preceded *Alice* and *Mayo*.<sup>107</sup>

Since the Court’s decisions in *Alice*, *Mayo*, and *Myriad*, the Federal Circuit has also issued numerous opinions finding what sorts of technologies qualify as abstract ideas and yet provide “something more” under Step 2 of the *Alice* test.<sup>108</sup> Similar to how the decisions regarding *Alice* Step 1 have provided some guidance through examples, the Federal Circuit has offered some clarity as to

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<sup>106</sup> *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (distinguishing “between patents that claim the buildin[g] block[s] of human ingenuity, which are ineligible for patent protection, and those that integrate the building blocks into something more, thereby transform[ing] them into a patent-eligible invention” (internal quotations omitted) (citing *Mayo*, 566 U.S. at 89)).

<sup>107</sup> *See, e.g.*, *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018).

<sup>108</sup> *See, e.g.*, *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1257 (Fed. Cir. 2014) (providing an example of what is enough to qualify as “something more” in the context of an abstract idea); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715–16 (Fed. Cir. 2014) (providing an example of what is not enough to qualify as “something more” in the context of an abstract idea).

*Alice* Step 2 through its decisions on a series of specific examples of what can be considered “something more.”<sup>109</sup>

*DDR Holdings* is again relevant because of the court’s findings with respect to Step 2 of the *Alice* test. There, the court considered the appellant’s characterizations of the “abstract idea” at issue, and it found that “under any of [its] characterizations of the abstract idea, the ’399 patent’s claims satisf[ied] *Mayo/Alice* step two.”<sup>110</sup> The patent-eligible abstract ideas were characterized as “making two web pages look the same,” promoting “syndicated commerce on the computer using the Internet,” and “making two e-commerce web pages look alike by using licensed trademarks, logos, color schemes and layouts.”<sup>111</sup> The abstract ideas sufficiently added “something more” within the meaning of *Alice* Step 2 because they did not “merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet. Instead, the claimed solution [was] necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.”<sup>112</sup> Accordingly, what can be considered “something more” as applied to an abstract idea includes improvements to a technology that overcomes a problem in a novel manner, regardless of whether the improvement is purely digital in nature.<sup>113</sup>

But this is not to say that all claims purporting to address internet or computer-based problems are eligible for patent protection merely because they solve a problem that now presents itself in electronic form. For example, in *Ultramercial, Inc. v. Hulu, LLC*, the Federal Circuit found claims that were directed to a method of electronic advertisements displayed over the internet as a currency to be patent-ineligible because they merely recited the abstract idea of “offering media content in exchange for viewing an

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<sup>109</sup> *Supra* preceding note.

<sup>110</sup> *See DDR Holdings*, 773 F.3d at 1257.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 1257–58 (“We caution, however, that not all claims purporting to address Internet-centric challenges are eligible for patent.”).

<sup>113</sup> *Id.* at 1259.

advertisement” along with “routine additional steps.”<sup>114</sup> This refines application of *Alice* Step 2 because it clarifies that “something more” does not include solving digital variations of basic economic problems, even if the identical problem was not previously presented in a non-electronic medium.<sup>115</sup> “Something more” in an abstract idea does not include simply applying a routine process to an electronic medium, especially if it is claimed in a manner which would preempt every application of the idea in electronic form.<sup>116</sup>

In sum, there is still significant difficulty surrounding the judicial exception for abstract ideas, an exception whose breadth covers electronically implemented methods, software, and internet-based features of inventions, among many other fields. Because of the somewhat conflicting decisions in this area, particularly as they revolve around e-commerce and internet-based applications of inventions, the court’s decisions are at times arbitrary and unpredictable. As such, it is difficult for patent applicants to navigate § 101 jurisprudence as to the abstract idea exception, and it is this difficulty with the abstract idea exception, among others, that the 2019 Guidance seeks to address.

iii. Refining Step 2 as to Laws of Nature and Natural Phenomena; What Is “Something More”?

Ever since the Supreme Court’s decision in *Mayo* invalidated a patent for a method of determining the proper dosage of a drug by analyzing metabolite levels in a patient’s blood as a patent-ineligible law of nature, there has been a strong bias in the courts against

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<sup>114</sup> *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715–16 (Fed. Cir. 2014) (holding patent for a method of using ads as a digital currency to be an ineligible abstract idea).

<sup>115</sup> *See id.*

<sup>116</sup> *See id.*; *see also* *U. of Fla. Research Found. v. Gen. Electric Co.*, 916 F.3d 1363, 1367 (Fed. Cir. 2019) (holding claims to a method of integrating physiological patient treatment data to universal format to be an invalid abstract idea, finding it to be a mere replacement of pen and paper methodologies); *DDR Holdings*, 773 F.3d at 1257 (holding patents relating to an e-commerce system and method providing hosts with transparent, context-sensitive e-commerce-supported pages patent-eligible).

diagnostic patents which operate based upon laws of nature as they occur within the human body.<sup>117</sup>

In *Ariosa Diagnostics*, claims for determining fetal characteristics based upon paternally inherited cffDNA circulating in the blood of pregnant women were found invalid by the district court because cffDNA was a naturally occurring phenomenon, and the other steps of the method “were well-understood, conventional and routine.”<sup>118</sup> In the Federal Circuit’s opinion affirming the invalidity, all the patent did was instruct one skilled in the art to use “routine, conventional techniques when seeking to detect [the] cffDNA.”<sup>119</sup> The court further stated that the method claims added nothing novel to the art other than a naturally occurring compound and that, therefore, the claims failed Step 2 of the *Alice* inquiry—they failed to add “something more.”<sup>120</sup> While this characterization may have been correct with respect to some of the patentee’s broader claims for merely detecting cffDNA, even claims that limited their scope to the specific embodiments of using cffDNA to determine certain fetal characteristics (such as gender) were found invalid.<sup>121</sup> This decision was reached notwithstanding the meaningful limitations incorporated into some of the dependent claims that would have prevented a monopoly on the law of nature and notwithstanding the clear practical application of being able to use a simple blood test to determine fetal characteristics like gender.<sup>122</sup>

In *CellzDirect*, § 101 eligibility of laboratory techniques involving laws of nature as they affect the human body took a step

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<sup>117</sup> See, e.g., *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 754 (Fed. Cir. 2019) (holding patent for method of diagnosing neurological disorders by detecting antibodies to MuSK protein invalid); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1359 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018) (holding patents for methods of treating cardiovascular disease by testing for myeloperoxidase invalid); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015) (holding patent for detecting paternally inherited cell-free fetal DNA circulating in blood of pregnant women invalid).

<sup>118</sup> *Ariosa Diagnostics*, 788 F.3d at 1377.

<sup>119</sup> *Id.*

<sup>120</sup> See *id.*

<sup>121</sup> *Id.* at 1373, 1377.

<sup>122</sup> See *id.*

forward when a patent for producing multi-cryopreserved hepatocytes was held patent-eligible.<sup>123</sup> In this case, liver cells (hepatocytes) were twice frozen and thawed in order to create a hepatocyte population with increased viability.<sup>124</sup> While the ability of some liver cells to survive multiple freeze and thaw cycles was considered to be “natural,” the process of repeating the freeze and thaw cycle a second time was “far from . . . conventional” as the prior art taught away from the practice, indicating it would decrease viability.<sup>125</sup> For these reasons, even though the method involved a natural phenomenon, it added “something more.”<sup>126</sup>

In *Cleveland Clinic*, patents for methods of treating cardiovascular disease by testing for myeloperoxidase were held invalid as patent-ineligible natural phenomena.<sup>127</sup> Though the prior art had not produced a viable method of detecting myeloperoxidase levels such that it could be correlated to risk of cardiovascular disease, the claims were held to be invalid because they used “well-known techniques” to carry out their method.<sup>128</sup> The Federal Circuit distinguished *CellzDirect* by indicating that the patentee in *Cleveland Clinic* had “not created a new laboratory technique” and used only conventional laboratory techniques to carry out the method.<sup>129</sup> This decision is notable because the Federal Circuit appeared to fault the patentee for not inventing a new laboratory technique in a § 101 inquiry, which has never been the standard for patent-eligible subject matter.<sup>130</sup> The method at issue clearly did have a practical application in treatment of cardiovascular disease, as evidenced by the failure of others to solve the problem of correlating myeloperoxidase levels to a risk of cardiovascular

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<sup>123</sup> *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050–51 (Fed. Cir. 2016).

<sup>124</sup> *Id.* at 1051.

<sup>125</sup> *Id.*

<sup>126</sup> *See id.*

<sup>127</sup> *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018).

<sup>128</sup> *Id.* at 1361.

<sup>129</sup> *Id.*

<sup>130</sup> *See id.*

disease, but appears to have received heightened scrutiny because it involved a natural phenomenon occurring within the human body.<sup>131</sup>

In *Athena Diagnostics*, the Federal Circuit further restricted § 101 eligibility for natural phenomena and laws of nature as they relate to diagnostic methods when a patent for diagnosing neurological disorders by detecting antibodies to the MuSK protein was held invalid.<sup>132</sup> While the MuSK protein was naturally occurring, an element of the method claims called for using a modified version of the MuSK protein, 125I-labeled MuSK.<sup>133</sup> This compound was artificially created by using the radioactive isotope of iodine I-125 to iodinate the MuSK protein.<sup>134</sup> The disease could then be detected based upon the binding of antibodies to this artificially 125I-labeled MuSK.<sup>135</sup> Notwithstanding the use of an artificial, manmade molecule in the claims of the diagnostic method, the patent was still held to be invalid.<sup>136</sup> This holding is problematic because the Supreme Court’s prior holding in *Myriad* indicates that manmade compositions of matter are not directed to natural phenomena, even if they are closely related to a naturally occurring composition of matter.<sup>137</sup> For at least this reason, the *Athena Diagnostics* decision appears to be in conflict with *Myriad*, as 125I-labeled MuSK should not have been found to be directed to a natural phenomenon at *Alice* Step 1, or at least should have been found to add “something more” at *Alice* Step 2.<sup>138</sup>

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<sup>131</sup> See *id.*; cf. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

<sup>132</sup> *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 754 (Fed. Cir. 2019) (holding patent for diagnostic methods for diagnosing neurological disorders by detecting antibodies to the MuSK protein invalid).

<sup>133</sup> *Id.* at 748.

<sup>134</sup> *Id.* at 747.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.* at 754–55.

<sup>137</sup> See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589, 595 (2013) (holding claims to cDNA sequences, which produce the same proteins as their corresponding, naturally occurring mRNA sequences, to be § 101-eligible).

<sup>138</sup> See *Athena Diagnostics*, 915 F.3d at 754 (holding patent for diagnostic methods for diagnosing neurological disorders by detecting antibodies to the MuSK protein invalid); cf. *Myriad*, 569 U.S. at 589, 595 (holding that claims to



In sum, patents on technologies directed to biotechnology involving laws of nature and natural phenomena, particularly as they occur within the human body, are likely to be held invalid absent the development of a novel laboratory technique or other non-conventional aspect of the process—even if such technologies utilize manmade compounds or limit the scope of the claims to narrow practical applications with meaningful limitations. In this way, Federal Circuit § 101 jurisprudence as it relates to natural phenomena and laws of nature may be in conflict with the Supreme Court’s decision in *Myriad*.<sup>139</sup> These Federal Circuit decisions were likely driven by similarities between the ineligible diagnostic method in *Mayo* and the diagnostic methods at issue in these cases, as they all concerned different diagnostic methods that inherently operated based upon natural laws and natural phenomena as they occur in the human body.<sup>140</sup>

For this reason, among others, the 2019 Guidance is necessary in order to promote the consistent and correct application of § 101 jurisprudence at the USPTO, as patent examiners, as well as patent applicants and their representatives, can reasonably apply these conflicting decisions in different ways. This can lead to an inconsistent application of § 101 at the USPTO, to the detriment of both patent applicants and the public.

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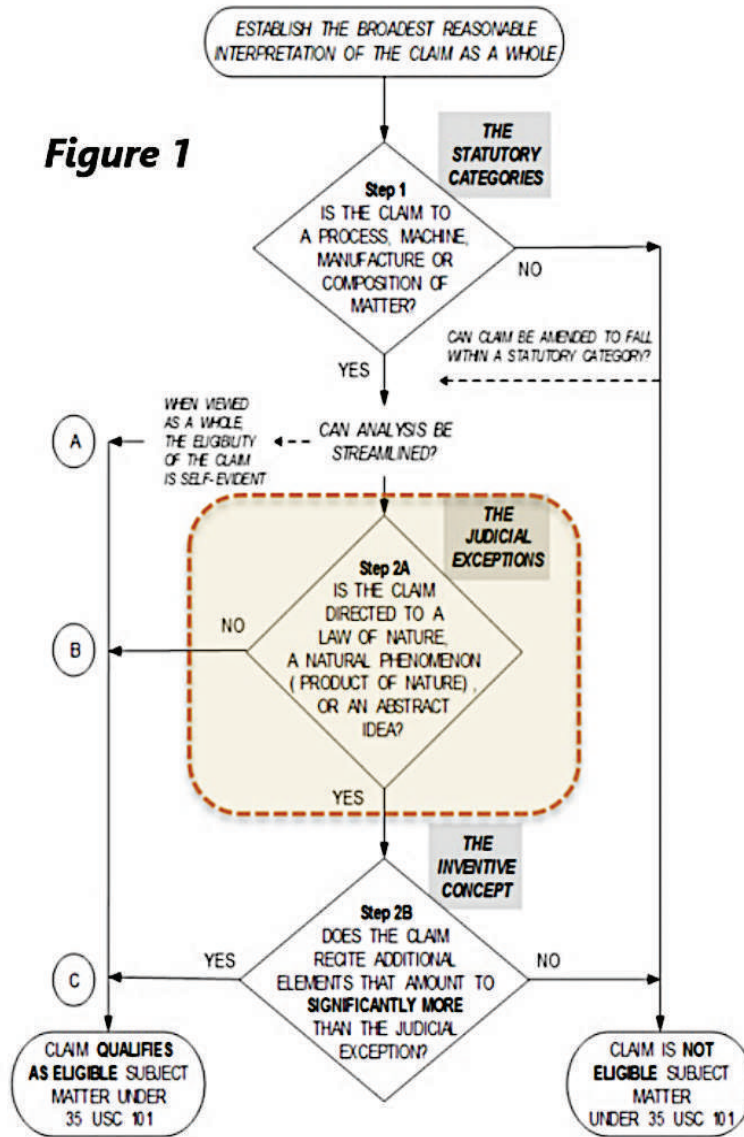
cDNA sequences, which produce the same proteins as their corresponding, naturally occurring mRNA sequences, to be § 101-eligible).

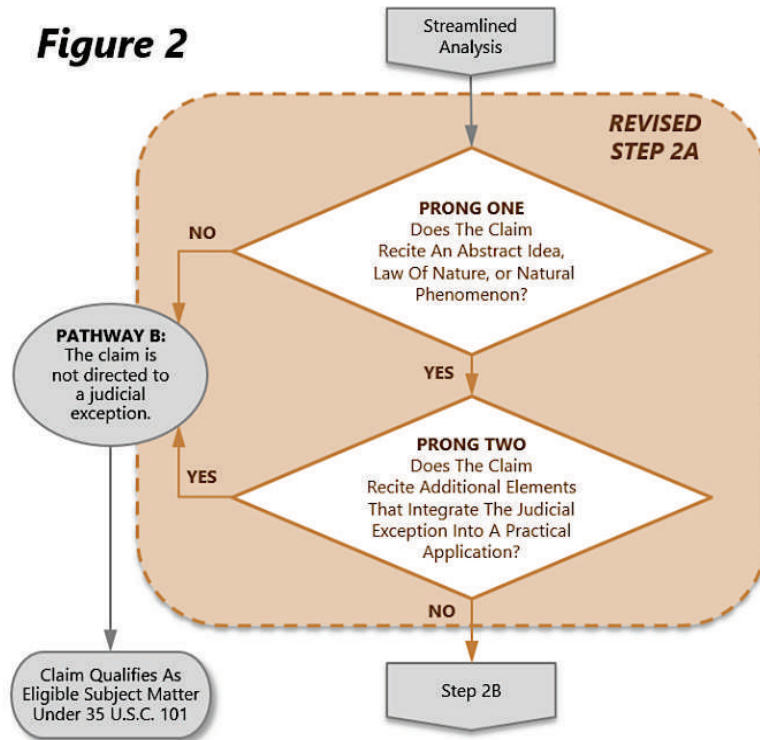
<sup>139</sup> *Myriad*, 569 U.S. at 589, 595.

<sup>140</sup> See *Athena Diagnostics*, 915 F.3d at 754; *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015).

## II. SUMMARY OF 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE

**Figure 1**



**Figure 2**

The 2019 Guidance refines the *Alice Corporation Pty. v. CLS Bank International* test by providing clear direction on and specific examples of how to apply its Steps 1 and 2.<sup>141</sup> The Guidance is rooted in Federal Circuit precedent setting forth the proper application of the *Alice* test.<sup>142</sup> The 2019 Guidance is separated in four parts by the review procedure, which includes: USPTO Step 1, USPTO Step 2A Prong 1, USPTO Step 2A Prong 2, and USPTO Step 2B.<sup>143</sup> As the 2019 Guidance relates to the *Alice* test, USPTO Step 1 applies *Alice* Step 1; USPTO Step 2A Prong 1 further applies *Alice* Step 1; USPTO Step 2A Prong 2 fulfills the requirements of *Alice* Step 2; and USPTO Step 2B further applies *Alice* Step 2 in the event the preceding steps were insufficient to reach a determination

<sup>141</sup> 2019 Guidance, *supra* note 8.

<sup>142</sup> See, e.g., *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016); *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1256–57 (Fed. Cir. 2014).

<sup>143</sup> 2019 Guidance, *supra* note 8, at 51.

as to § 101 eligibility.<sup>144</sup> The preceding figures are drawn from the USPTO’s October Update to the 2019 Guidance, discussed in Section III.E.<sup>145</sup>

*A. USPTO Step 1: Are the Claims Drawn to One of the Four Traditional Statutory Categories?*

USPTO Step 1<sup>146</sup> directs examiners to first determine whether the “claimed subject matter falls within the four statutory categories of patentable subject matter”<sup>147</sup> which include “any new and useful process, machine, manufacture, or composition of matter.”<sup>148</sup> Regardless of whether the examiner finds the claims are directed to one of the four standard statutory categories of patent-eligible subject matter, the 2019 Guidance directs examiners to proceed to USPTO Step 2A.<sup>149</sup>

*B. USPTO Step 2A (2-Prong)*

USPTO Step 2A refines Step 1 of the *Alice* test in that it provides additional avenues by which an applicant can show their invention is not directed to a judicial exception.<sup>150</sup> The primary objective of USPTO Step 2A is to determine whether the claims are in fact directed to a judicial exception.<sup>151</sup> It represents a significant change with respect to the USPTO’s procedure of identifying abstract ideas by providing that any claim which integrates the judicial exception

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<sup>144</sup> *Id.*

<sup>145</sup> See U.S. PATENT & TRADEMARK OFFICE, OCTOBER 2019 UPDATE: SUBJECT MATTER ELIGIBILITY (2019), [https://www.uspto.gov/sites/default/files/documents/peg\\_oct\\_2019\\_update.pdf](https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf).

<sup>146</sup> See generally 2019 Guidance, *supra* note 8. The 2019 Guidance confusingly also refers to the first step of its analysis as “Step 1,” making it likely to be mistaken for *Alice* Step 1 by an unwary reader.

<sup>147</sup> 2019 Guidance, *supra* note 8, at 53–54.

<sup>148</sup> 35 U.S.C. § 101 (2018).

<sup>149</sup> 2019 Guidance, *supra* note 8, at 53–54.

<sup>150</sup> *Id.* at 54.

<sup>151</sup> *Id.* at 56.

into a practical application in an appropriate manner is not directed to the judicial exception within the meaning of Step 1 of *Alice*.<sup>152</sup>

i. Prong 1

In Prong 1 of USPTO Step 2A, examiners are directed to “evaluate whether the claim recites a judicial exception, *i.e.*, an abstract idea, a law of nature, or a natural phenomenon.”<sup>153</sup> If the examiner determines that the “the claim does not recite a judicial exception, it is not directed to a judicial exception ([USPTO] Step 2A: NO) and is eligible,” concluding the § 101 eligibility analysis.<sup>154</sup> If, on the other hand, the examiner determines the claims *do* recite a judicial exception, then the examiner should proceed to apply Prong 2.<sup>155</sup>

A special procedure exists with regard to abstract ideas under Prong 1 to determine whether claims are directed to a judicial exception. The 2019 Guidance provides a list of categories of activity that have been held by the Federal Circuit and Supreme Court to be abstract ideas, and these categories broadly include technologies which operate based upon mathematical concepts, equations, formulas, or calculations; facilitate methods of organizing human activity; or facilitate a mental process which is performed in the human mind.<sup>156</sup> “[M]ethods of organizing human activity [include] fundamental economic principles[,] . . . commercial and legal interactions[,] . . . [and systems of] managing personal behavior or relationships or interactions between people.”<sup>157</sup> If the claims are not directed to one of these categories, then the claims in most cases should not be found to be directed to an abstract idea, rendering them patent-eligible on § 101 grounds.<sup>158</sup> However, the 2019 Guidance also

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<sup>152</sup> An “appropriate manner” is a practical application that does not prevent others from making use of the underlying judicial exception in other inventions.

<sup>153</sup> 2019 Guidance, *supra* note 8, at 54.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at 52.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* at 53.

provides for an exception in the “rare circumstance” that an examiner is of the position that a claim recites an abstract idea but is not included within one of the provided categories, in which case the examiner should proceed to apply Prong 2.<sup>159</sup> Prong 1 represents a change for the USPTO’s previous handling of § 101 abstract idea rejections only, which was previously limited to the convoluted “something more” analysis of the *Alice* test.<sup>160</sup>

## ii. Prong 2

In Prong 2, examiners “evaluate whether the claim recites additional elements that integrate the exception into a practical application of that exception.”<sup>161</sup> The Guidance provides that a “claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.”<sup>162</sup> If it is found the exception is integrated into a practical application by meaningful limitations in the claims, the claim is patent-eligible on § 101 grounds, concluding the § 101 eligibility analysis.<sup>163</sup> If it is found the judicial exception is not integrated into a practical application, then the examiner is directed to proceed to apply USPTO Step 2B of the 2019 Guidance.<sup>164</sup> USPTO Step 2A Prong 2 represents a change from prior USPTO procedure with respect to all claims drawn to a judicial exception, now applying the “practical application” standard.<sup>165</sup>

In the context of determining what is a practical application of a judicial exception, the 2019 Guidance provides certain exemplary considerations drawn from Federal Circuit and Supreme Court precedent which may indicate the combination of elements that has

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<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 54.

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

integrated the judicial exception into a practical application. These comprise additional elements which may include an application that:

reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field; . . . applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition; . . . [uses the] judicial exception . . . in conjunction with[] a particular machine or manufacture; . . . effects a transformation or reduction of a particular article to a different state or thing; . . . [or] applies or uses the judicial exception in some other meaningful way, . . . such that the claim as a whole is more than a drafting effort designed to monopolize the exception.<sup>166</sup>

The 2019 Guidance notes that the list is not exhaustive,<sup>167</sup> but it makes clear with several examples what will not constitute a practical application, as in the case of an additional element that merely recites the words “apply it;” something which adds “insignificant extra-solution activity;” or something that does no more than generally link the exception to a particular technological environment.<sup>168</sup>

### C. USPTO Step 2B

USPTO Step 2B of the 2019 Guidance is modelled like *Alice* Step 2. USPTO Step 2B provides that a judicial exception recited in the claims may nonetheless be patent-eligible if reevaluation of the claim elements indicates that the combination of elements is unconventional enough to represent an “inventive concept” and therefore provides “something more.”<sup>169</sup> Because of the breadth of USPTO Step 2A and the fact that most patent applications are in fact integrated into a practical application of the core idea, it is unlikely that most applications will proceed to USPTO Step 2B because they

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<sup>166</sup> *Id.* at 55.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.* at 56.

will be deemed patent-eligible at Step 2A, necessitating no further analysis.

When reevaluating the claim elements under USPTO Step 2B, the 2019 Guidance directs examiners to consider whether the combination of claim elements adds a limitation that is “not well-understood, routine, [or] conventional” (indicating that an inventive concept may be present), or whether it “simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality to the judicial exception,” indicating that an inventive concept may not be present.<sup>170</sup> If the examiner finds that the combination of claim elements is unconventional enough to represent an “inventive concept” and therefore provides “something more,” the claims are patent-eligible under § 101.<sup>171</sup>

### III. ANALYSIS OF 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE

The following Part sets forth an analysis of the 2019 Guidance. It highlights why it is consistent with Supreme Court and Federal Circuit precedent and represents sound policy on the part of the USPTO. It begins by discussing how the limitations on what qualifies as an “abstract idea” based on the lists provided in the 2019 Guidance are supported by specific examples from judicial precedent. It then discusses why the “practical application” standard introduced by the 2019 Guidance is supported by precedent and meets the “something more” requirement of *Alice*. Next, it explains why it is consistent with precedent and good policy to dispose of most § 101 inquiries at *Alice* Step 1 using USPTO Step 2A, which embodies the “something more” requirement of *Alice* Step 2. Following this is an explanation of the “inventive concept” exception introduced in the 2019 Guidance from Federal Circuit precedent and an examination of why it is good policy and supported by existing case law. Lastly, this Part addresses the October Update

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<sup>170</sup> *Id.* at 55.

<sup>171</sup> *Id.*



to the 2019 Guidance issued by the USPTO following the initial publication of the 2019 Guidance in the Federal Register.

*A. The PTO's Limitations on What Qualifies as an "Abstract Idea" Are Supported by Precedent*

Among the most significant changes to the USPTO's § 101 procedures in the 2019 Guidance is the introduction of the list of abstract ideas at USPTO Step 2A Prong 1.<sup>172</sup> The 2019 Guidance provides that if the claims are not found to be directed to a category described on the list, then the claims are not directed to an abstract idea. The types of technologies that are typically considered to embody abstract ideas are those that operate based upon mathematical concepts, equations, formulas, or calculations; facilitate methods of organizing human activity; or facilitate a mental process performed in the human mind.<sup>173</sup> Because all of these categories of abstract ideas are supported by both Supreme Court and Federal Circuit precedent, this aspect of the 2019 Guidance represents a lawful application of § 101 jurisprudence, as the many cases decided by the Federal Circuit following the Supreme Court's decisions in *Bilski v. Kappos* and *Alice Corporation Pty. v. CLS Bank International* have enabled the USPTO to propagate the list of abstract ideas categories in the 2019 Guidance.<sup>174</sup> The result of this list is that many § 101 inquiries as to abstract ideas will terminate at this stage.

A number of cases have held claims drawn to mathematical concepts, equations, formulas, or calculations to be directed to abstract ideas. In *Parker v. Flook*, a method of updating alarm limits based upon a mathematical formula was found to be directed to an abstract idea and was ineligible.<sup>175</sup> In *Diamond v. Diehr*, a method of producing rubber using the Arrhenius equation was held to be

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<sup>172</sup> Prior to the 2019 Guidance, there was no formal list of technologies integrated into practical application that were clearly denoted as being abstract ideas or not.

<sup>173</sup> See *supra* notes 12, 15, 18, 23.

<sup>174</sup> 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 53 nn.12–14, 54 nn.15–19 (Jan. 4, 2019).

<sup>175</sup> *Parker v. Flook*, 437 U.S. 584, 590 (1978).

directed to an abstract idea, but it was eligible.<sup>176</sup> In *SAP America, Inc. v. InvestPic, LLC*, a method for performing an analysis of statistical information using “mathematical calculations” was held to be directed to an abstract idea.<sup>177</sup> In *Digitech Image Technologies, LLC v. Electronics for Imaging, Inc.*, a method of improving the quality of a digital image when transferring it between devices was held to be directed to an abstract idea.<sup>178</sup>

There are also many cases which have held claims that facilitate methods of organizing human activity to be directed to abstract ideas. Methods of organizing human activity have been found to include fundamental economic principles, commercial and legal interactions, and methods of managing personal behavior or relationships between people.<sup>179</sup> Perhaps the most famous example is that of *Bilski* (where a patent for a method of hedging risk electronically was held to be directed to an abstract idea, finding it to be a fundamental economic principle), as it was the first § 101 case the Supreme Court had decided in decades, and because it abrogated *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* in finding most business method patents to be ineligible abstract ideas.<sup>180</sup> Additionally, a number of cases that followed *Bilski* also support the fundamental economic principle category.<sup>181</sup>

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<sup>176</sup> See *Diamond v. Diehr*, 450 U.S. 175, 184–85 (1981).

<sup>177</sup> *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018).

<sup>178</sup> *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014).

<sup>179</sup> 2019 Guidance, *supra* note 8, at 52.

<sup>180</sup> *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

<sup>181</sup> *Voter Verified, Inc. v. Election Sys. & Software, LLC*, 887 F.3d 1376, 1385 (Fed. Cir. 2018) (finding the concept of voting, verification, and tabulation ineligible); *Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*, 876 F.3d 1372, 1378–79 (Fed. Cir. 2017) (holding a method of local payment processing for remotely purchased goods to be directed to an abstract idea, again finding it to be an economic principle); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) (holding a method of pricing an item for sale based upon offer-based price optimization was directed to an abstract idea, once again finding the method to be an economic principle); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (holding that the concept of “creating a contractual relationship—a ‘transaction performance guaranty’”—is an abstract idea); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1280 (Fed. Cir. 2012) (holding a method of managing life insurance policies

There are also several cases that have held claims that facilitate mental processes that could be performed in the human mind to be directed to abstract ideas. The category of mental processes includes concepts performed in the human mind generically implemented on a computer, as well as tasks that involve observation, evaluation, and judgement.<sup>182</sup> In the case *In re BRCA1 & BRCA2-Based Hereditary Cancer Test Patent Litigation*, a patent for a method of diagnosing mutations in DNA sequences by comparing gene sequences was held to be directed to an abstract idea, finding it was an “abstract mental process,” supporting this classification.<sup>183</sup>

The many cases decided by the Federal Circuit following the Supreme Court’s decisions in *Alice* and *Bilski* have enabled the USPTO to propagate the list of abstract ideas categories in the 2019 Guidance.<sup>184</sup> Because the categories of mathematical concepts, equations, formulas, or calculations; methods of organizing human activity; and mental processes which are performed in the human mind are all drawn directly from the Federal Circuit’s post-*Bilski* and *Alice* decisions, the list represents a lawful application of patent

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through performance of calculations was directed to an abstract idea, finding it to be an economic principle).

<sup>181</sup> *In re Comiskey*, 554 F.3d 967, 981 (Fed. Cir. 2009) (holding that claims directed to “resolving a legal dispute between two parties by the decision of a human arbitrator” are ineligible).

<sup>182</sup> 2019 Guidance, *supra* note 8, at 52; *see, e.g.*, *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1324 (Fed. Cir. 2016) (holding a system that facilitated anonymous loan shopping over the internet to be directed to an abstract idea, finding it was an activity that could be performed by people without a computer and was only generically implemented on a computer); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1318 (Fed. Cir. 2016) (holding a method of screening e-mail to be directed to an abstract idea, finding it could be done by a person and had only generic computer-implemented steps); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372, 1375 (Fed. Cir. 2011) (holding a method of preventing credit card fraud for transactions over the internet was directed to an abstract idea, finding the method could be performed by a person alone, without a computer).

<sup>183</sup> *In re BRCA1 & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014) (concluding that the concept of “comparing BRCA sequences and determining the existence of alterations” is an “abstract mental process”).

<sup>184</sup> *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014); *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

law and Step 1 of the *Alice* test.<sup>185</sup> Further, the list represents a logical application of patent law because the abstract idea exception generally is a very broad and somewhat vague category which can encompass many different technologies. Because the abstract idea exception is so broad, many examiners have improperly applied the exception. Different technology centers applied the exception in either over-inclusive or under-inclusive manners, which led to inconsistent application of § 101 within the USPTO.<sup>186</sup> By providing a list of abstract ideas, the 2019 Guidance easily enables examiners to bypass § 101 scrutiny for those inventions not drawn to the sorts of concepts which the Court (and subsequently the Federal Circuit) has held to be directed to abstract ideas.<sup>187</sup> This, in turn, benefits both examiners and applicants in the prosecution process by clarifying from the beginning what sorts of technologies are not drawn to abstract ideas and those which are likely to present § 101 issues.

*B. The PTO's "Practical Application" Standard Is Supported by Precedent and Meets the "Something More" Requirement of Alice Step 2*

The next biggest addition to § 101 procedures at the USPTO, after the listing of abstract ideas, is the “practical application” standard which terminates the § 101 inquiry upon a finding that a claim directed to a judicial exception embodies a practical application constrained by meaningful claim limitations.<sup>188</sup> The practical application standard of the 2019 Guidance is the equivalent of the “something more” judicial inquiry of *Alice* Step 2 and therefore also represents a lawful application of patent jurisprudence.<sup>189</sup> Many of the cases that considered technologies drawn to judicial exceptions and found them § 101-eligible did in

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<sup>185</sup> See, e.g., *Mortg. Grader*, 811 F.3d at 1324.

<sup>186</sup> 2019 Guidance, *supra* note 8, at 52.

<sup>187</sup> *Id.*

<sup>188</sup> Claims that recite a practical application of a judicial exception are considered not “directed to” a judicial exception. *Id.* at 53.

<sup>189</sup> The USPTO 2019 Guidance uses the “practical application” standard as a way of fulfilling the “something more” requirement of *Alice* Step 2. *Id.*

fact embody the judicial exception in a practical application constrained by meaningful limitations: take, for example, the method of preparing hepatocytes of *Rapid Litigation Management Ltd. v. CellzDirect*,<sup>190</sup> the system for producing websites that appear similar of *DDR Holdings, LLC v. Hotels.com*,<sup>191</sup> and the treatment methods of *Endo Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*<sup>192</sup> All are examples of practical applications of § 101 concepts which were held to have met the “something more” standard of *Alice* Step 2.

The position of the USPTO is that the “practical application” standard of USPTO Step 2A Prong 2 is supported by Supreme Court precedent.<sup>193</sup> This position is strong upon consideration of § 101 cases which the Court has considered. For instance, in *Diehr*, the Court held the rubber-making process to be patent-eligible, finding the Arrhenius equation was integrated into the rubber-making process as a whole—no doubt a practical application.<sup>194</sup> Or in *Diamond v. Chakrabarty*, a bacterium genetically modified to break down oil was held to be patent-eligible—a very practical application.<sup>195</sup>

However, when considering the full range of § 101 cases decided by the Supreme Court, the Court’s focus seems to land more on preventing preemption of the fundamental tools of scientific discovery as opposed to focusing on the final practical applications of the methods at issue. For example, in *Bilski*, a computer-implemented method of hedging risk was found to be ineligible, largely due to the preemptive effect that allowing the patent to stand would have had on the financial industry, notwithstanding the practical application of using a computer to estimate risk and

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<sup>190</sup> *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

<sup>191</sup> *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1257 (Fed. Cir. 2014).

<sup>192</sup> *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347, 1353 (Fed. Cir. 2019) (involving a method of using oxymorphone to treat pain in patients with impaired kidney function).

<sup>193</sup> 2019 Guidance, *supra* note 8, at 53.

<sup>194</sup> *See Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

<sup>195</sup> *See Diamond v. Chakrabarty*, 447 U.S. 303, 304 (1980).

provide recommendations.<sup>196</sup> Similarly in *Alice*, a computer-implemented method of mitigating settlement risk was held to be ineligible due to concerns of preemption of a basic economic practice, notwithstanding the practical application of using a computer to automatically avoid paying money in deals that were unlikely to close.<sup>197</sup> Or in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, treatment methods based upon metabolite levels and human metabolic rates were held to be patent-ineligible because of a concern about preempting the use of these metabolic rates (natural laws) in other areas of medicine, notwithstanding the practical application of being able to tailor doses of medication to individual patients.<sup>198</sup>

Despite the incongruency between § 101-ineligible inventions which had practical applications and the policy reasons which appear to be driving the Supreme Court’s § 101 jurisprudence, the practical application standard is likely in compliance with § 101 jurisprudence because (1) the requirement that the claims contain meaningful limitations serves to prevent preemption of basic ideas, and (2) the “something more” requirement of *Alice* Step 2 is embodied in the practical application standard of USPTO Step 2A Prong 2.<sup>199</sup>

With respect to the abstract idea exception, it is likely that the practical application with meaningful limitations standard will work very well, leading examiners to the same outcome a court would come to in an application of *Alice* Step 2. Considering the standard as it would have been applied to *DDR Holdings*, where the subject matter at issue was a system for producing a similar-looking website, we recall that such system was constrained by numerous limitations such as:

- (a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually

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<sup>196</sup> See *Bilski v. Kappos*, 561 U.S. 593, 612 (2010).

<sup>197</sup> See *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 225 (2014).

<sup>198</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012).

<sup>199</sup> 2019 Guidance, *supra* note 8, at 54–55.

perceptible elements correspond to the plurality of first web pages;

- (i) wherein each of the first web pages belongs to one of a plurality of web page owners;
  - (ii) wherein each of the first web pages displays at least one active link associated with a commerce object associated with a buying opportunity of a selected one of a plurality of merchants; and
  - (iii) wherein the selected merchant, the outsource provider, and the owner of the first web page displaying the associated link are each third parties with respect to one other;
- (b) a computer server at the outsource provider, which computer server is coupled to the computer store and programmed to:
- (i) receive from the web browser of a computer user a signal indicating activation of one of the links displayed by one of the first web pages;
  - (ii) automatically identify as the source page the one of the first web pages on which the link has been activated;
  - (iii) in response to identification of the source page, automatically retrieve the stored data corresponding to the source page; and
  - (iv) using the data retrieved, automatically generate and transmit to the web browser a second web page that displays:
    - (A) information associated with the commerce object associated with the link that has been activated, and
    - (B) the plurality of visually perceptible elements visually corresponding to the source page.<sup>200</sup>

Not only are the claims directed to the practical application of producing two websites which appear similar, but the claim

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<sup>200</sup> See *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1249–50 (Fed. Cir. 2014).

limitations are meaningful enough that allowing the patent to stand does not preempt every way in which someone could copy a webpage. For instance, one does not necessarily need to determine if a link on a web page they are copying had been previously activated to copy a website. Applying the practical application standard to *DDR Holdings*, the same result of patent eligibility can be reached.<sup>201</sup>

Considering the practical application standard as it may have been applied in *Enfish, LLC v. Microsoft Corporation*,<sup>202</sup> the same result of patent eligibility can be reached based upon the practical application standard of the 2019 Guidance. In *Enfish*, claims for improvements to a data storage and retrieval system for computer memory were held to be § 101-eligible, finding the claims were not directed to an abstract idea because they were instead directed to a specific improvement in the way computers operate.<sup>203</sup> The patent in *Enfish* disclosed a logical model of data in computer databases that was “[c]ontrary to conventional . . . models” because it enabled databases to be self-referential.<sup>204</sup> The logical model in *Enfish* could store all entity types in a single table and could define the table’s columns by rows in that same table, improving memory function by consolidating what would usually be several files in different locations into a single table in one location.<sup>205</sup> This model decreased the amount of time, number of commands, and processing power required to store and retrieve data, improving the function of the

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<sup>201</sup> *Id.* at 1257–59 (holding a patent § 101-eligible where the abstract ideas it embodied were characterized as “making two web pages look the same,” promoting “syndicated commerce on the computer using the Internet,” and “making two e-commerce web pages look alike by using licensed trademarks, logos, color schemes and layouts” and reasoning that the system was something more within the meaning of *Alice* Step 2).

<sup>202</sup> *See Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016) (holding claims for improvements to a data storage and retrieval system for computer memory to be § 101-eligible and not directed to an abstract idea, reasoning they were instead directed to an improvement in the way computers operate).

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 1330.

<sup>205</sup> *See id.* at 1332.



computer.<sup>206</sup> This would qualify as a practical application sufficient to meet § 101 scrutiny under the Guidance.

Next we turn to the *Enfish* claim limitations to ensure the claim contains meaningful limitations. The claim language provides:

A data storage and retrieval system for a computer memory, comprising:

means for configuring said memory according to a logical table, said logical table including:

a plurality of logical rows, each said logical row including an object identification number (OID) to identify each said logical row, each said logical row corresponding to a record of information; a plurality of logical columns intersecting said plurality of logical rows to define a plurality of logical cells, each said logical column including an OID to identify each said logical column; and means for indexing data stored in said table.<sup>207</sup>

Here, that “the plain focus of the claims [was] on an improvement to computer functionality itself[ and] not on economic or other tasks for which a computer is used in its ordinary capacity” shows a necessary limitation because the claims did not prevent others from improving the function of a computer memory by monopolizing a basic concept.<sup>208</sup> Instead, they were narrowly drawn to the specific practical application that was the subject of the patent, here the unique “search and retrieval system[] . . . [that] employ[ed] a flexible, self-referential table to store data,” a logical model which stored data as a class instead of in many individual file paths.<sup>209</sup> For these reasons, the patent of *Enfish* likely would have met § 101 scrutiny under the 2019 Guidance.

The portion of the 2019 Guidance calling for the claims to be constrained by “meaningful limitations” such that the patent is more

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<sup>206</sup> See *id.* at 1333.

<sup>207</sup> *Id.* at 1336.

<sup>208</sup> See *id.* (“[T]he claims are not simply directed to *any* form of storing tabular data, but instead are specifically directed to a *self-referential* table for a computer database.”).

<sup>209</sup> See *id.* at 1337 (citation omitted).

than an attempt to monopolize the judicial exception is an important qualification upon the practical application standard because it is necessary to reconcile the 2019 Guidance with some of the Federal Circuit’s more problematic decisions, namely those which have found technologies drawn to judicial exceptions ineligible, even though they probably added “something more.” For instance, in *ChargePoint, Inc. v. SemaConnect, Inc.*, the following claim language was found to be invalid under § 101:

1. An apparatus, comprising:
  - a control device to control application of charge transfer for an electric vehicle; a transceiver to communicate with a remote server via a data control unit that is connected to the remote server through a wide area network and receive communications from the remote server, wherein the received communications include communications as part of a demand response system; and a controller, coupled with the control device and the transceiver, to cause the control device to modify the application of charge transfer based on the communications received as part of the demand response system.

...

8. The apparatus of claim 1, wherein the communications received as part of the demand response system include power grid load data, and wherein the controller is further to manage charge transfer based on the received power grid load data.<sup>210</sup>

The Federal Circuit’s primary concern with respect to the § 101 eligibility of these claims was the “breadth of the claim language.”<sup>211</sup> The court was of the position that the claim limitations were so broad that allowing the patent to stand would have

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<sup>210</sup> See *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 770–71 (Fed. Cir. 2019).

<sup>211</sup> *Id.* at 769.

effectively prevented any other party from utilizing the principle of “communication over a network” in building a network of EV chargers.<sup>212</sup> Because the policy rationale behind almost all modern § 101 jurisprudence is preventing the preemption of the basic tools of technological advancement, this case comports well with the judicial policy behind § 101.

However, if the patentee in *ChargePoint* had followed the direction of the 2019 Guidance and placed meaningful limitations in the claims that were narrowly drawn to the specific practical application of facilitating communication between a network of EV chargers, a central network location, and end users on their smartphone apps, the claims likely would have met § 101 scrutiny. The application in *ChargePoint* of facilitating communication of a network of EV chargers is indeed a practical application, but the claims were so broad as to raise the preemption issues that drive § 101 jurisprudence. Had the claims not raised these preemption issues, it is unlikely the court would have had issues with the claims under § 101.<sup>213</sup> In this way, the portion of the 2019 Guidance calling for claims to be constrained by “meaningful limitations” such that the patent is more than an attempt to monopolize the judicial exception is an important part of making the 2019 Guidance consistent with existing case law.<sup>214</sup>

This aspect of the 2019 Guidance, however, does present a challenge for applicants: how does one claim an invention in a constrained manner sufficient to pass § 101 scrutiny while leaving the claims broad enough to give the patent some exclusive value? This is an area wherein a talented patent prosecutor can offer significant value to a client by building a client’s IP portfolio in these difficult technological fields. Working with technologies involving judicial exceptions will require a skilled patent prosecutor to navigate the 2019 Guidance and convoluted § 101 jurisprudence to obtain claims with good coverage likely to hold up during infringement litigation. This specialty in patent prosecution has

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<sup>212</sup> See *id.* at 768, 770–74.

<sup>213</sup> See *id.*

<sup>214</sup> See, e.g., *id.* at 766–71 (reasoning that the risk of creating a monopoly in facilitating communication over an EV charging network warranted invalidation on § 101 grounds).

evolved significantly within the past few years as a result of the Supreme Court's § 101 decisions.<sup>215</sup>

One area where the 2019 Guidance may not lead to results consistent with § 101 jurisprudence is in the technological field of diagnostics. In general, following the Supreme Court's decision in *Mayo* (holding that a patent for a method of determining the proper dosage of a drug by analyzing metabolite levels in a patient's blood was ineligible subject matter under the law of nature exception),<sup>216</sup> the Federal Circuit has invalidated many patents for diagnostic methods, continually finding them to be invalid on § 101 grounds. Exemplary cases include *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, and *Athena Diagnostics, Inc. v. Mayo Collaborative Services*, where patents drawn to diagnostic methods were all found to be invalid as claims drawn to laws of nature.<sup>217</sup> There is little doubt that the methods of determining fetal characteristics (such as gender) by detecting paternally inherited cfDNA circulating in the blood of pregnant women of *Ariosa Diagnostics*;<sup>218</sup> that the methods of treating cardiovascular disease by testing for myeloperoxidase of *Cleveland Clinic*;<sup>219</sup> and that the methods of diagnosing neurological disorders by detecting antibodies to the MuSK protein of *Athena Diagnostics* were practical applications.<sup>220</sup> *Ariosa Diagnostics* and *Cleveland Clinic* can partially be distinguished because some of the broader claims from their respective patents may have lacked meaningful limitations sufficient to prevent

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<sup>215</sup> See, e.g., *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

<sup>216</sup> *Mayo Collaborative Servs.*, 566 U.S. at 72.

<sup>217</sup> See *supra* notes 51, 68, 69.

<sup>218</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375–76 (Fed. Cir. 2015).

<sup>219</sup> *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1355–58 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018).

<sup>220</sup> *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746 (Fed. Cir. 2019).

preemption of the underlying natural law—something the Supreme Court has cautioned against.<sup>221</sup>

What is by far the most problematic case of the trio is *Athena Diagnostics*, where the patentee developed an artificial version of the MuSK protein by using a radioactive isotope of iodine (I-125) to iodinate the MuSK protein in order to facilitate the diagnostic method.<sup>222</sup> It is the most problematic case of the three due to the presence of a manmade molecule as a meaningful limitation in the claims, which were nonetheless held invalid under § 101. While in *Mayo* the Supreme Court found claims to a treatment method that utilized human metabolic rates to tailor the dosage of thiopurine drugs invalid under § 101 because it found the claims amounted to no more than an instruction manual on how to read the laws of nature (human metabolic rates), the Court's decision in *Myriad* appropriately set out the standard for subject matter eligibility of biotechnology as it should have been applied in *Athena Diagnostics*.<sup>223</sup>

Applying the standard for the § 101 eligibility of biotechnology as set forth in *Myriad*,<sup>224</sup> these claims should have met § 101 scrutiny because of the presence of a manmade molecule in the claims which elevated them beyond unpatentable natural phenomena and laws of nature.<sup>225</sup> The fact that the claims in *Athena Diagnostics* were method claims as opposed to product claims is irrelevant, as the method was still constrained by the meaningful limitation requiring the presence of the artificial I-125 MuSK molecule.<sup>226</sup> While claims to the correlation between the naturally occurring MuSK protein and the disease alone would properly constitute an unpatentable law of nature, utilizing this natural correlation by creating an artificial molecule to facilitate the

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<sup>221</sup> See *supra* Sections I.A–B.

<sup>222</sup> See *Athena Diagnostics*, 915 F.3d at 747–48.

<sup>223</sup> See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

<sup>224</sup> *Myriad*, 569 U.S. at 589–90.

<sup>225</sup> See *id.*

<sup>226</sup> See *Athena Diagnostics*, 915 F.3d at 747.

diagnostic method constitutes more than claims to the law of nature within the meaning of *Alice*.

This decision potentially creates a conflict with the 2019 Guidance because application of the Guidance seems to suggest that the claims of *Athena Diagnostics* would be § 101-eligible due to the claims being integrated into a practical application constrained by meaningful claim limitations—a diagnostic method facilitated by the presence of a manmade molecule. The claims were drawn to the practical application of diagnosing neurological disorders, and they were constrained by the meaningful limitations of detecting antibodies to the MuSK protein using the manmade molecule I-125 to iodinate MuSK.<sup>227</sup> The presence of a manmade molecule in the claims clearly indicates the claims were more than an attempt to monopolize a law of nature, and, as such, application of the 2019 Guidance suggests a finding of eligibility under § 101 would be appropriate, even though the manner in which the I-125 MuSK was produced was conventional.<sup>228</sup> If the court’s issue with the patentability of the claims were about whether the method was “conventional,” then the proper way to dispose of the patent would have been through obviousness under § 103, not subject matter eligibility under § 101. Disposal under § 101 improperly indicated that diagnostic methods do not present patentable subject matter, when the issue the court actually seemed to have with the method is that it was merely conventional—or rather obvious.<sup>229</sup> The medical community, the rapidly aging population of the United States, and the rest of the world which relies upon medical advancements developed in the United States can only hope that the Supreme Court will address these issues in its § 101 jurisprudence as it relates to diagnostic methods because, as it currently stands, patent law provides limited incentive to invest in the development of new diagnostic methods, as current jurisprudence indicates that most new diagnostic methods will not present patent-eligible subject matter.<sup>230</sup> Unfortunately, there is little that can be done on the part

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<sup>227</sup> See *id.*

<sup>228</sup> See 2019 Guidance, *supra* note 8.

<sup>229</sup> See *id.*

<sup>230</sup> See, e.g., *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015).

of the USPTO to remedy this problem—patents to diagnostic methods as they have issued are regularly struck down by the Federal Circuit on appeal, and the problem lies with the Federal Circuit’s interpretation of the Supreme Court’s § 101 jurisprudence.<sup>231</sup> An improvement to the Supreme Court’s § 101 jurisprudence as it relates to application of the law of nature and natural phenomena exceptions when applied to diagnostic technologies is therefore required.<sup>232</sup>

Overall, the “practical application” standard of the 2019 Guidance is a consistent application of § 101 jurisprudence because it fulfills the requirements of *Alice* Step 2 calling for “something more,” notwithstanding some potential conflict with the current state of case law as it relates to diagnostics.<sup>233</sup> The requirement for “meaningful limitations” to resolve § 101 preemption issues is another important aspect of the 2019 Guidance which ensures consistency with precedent.<sup>234</sup> The 2019 Guidance is, in fact, a logical application of § 101 jurisprudence because it communicates the relevant legal standards to examiners at the USPTO in an effective manner which leads them to the same conclusion as if they had applied the *Alice* inquiry directly, while also factoring in the Federal Circuit’s § 101 jurisprudence.

*C. It Is Lawful and Logical to Dispose of Most § 101  
Inquiries at Alice Step 1 as the 2019 Guidance  
Recommends*

The practical effect of the 2019 Guidance will be to dispose of most § 101 inquiries at *Alice* Step 1, the inquiry as to whether the claims are “directed to” a judicial exception. This is because the 2019 Guidance provides that the inquiry terminates at *Alice* Step 1 and not Step 2 when applying USPTO Step 2A at either prong.<sup>235</sup>

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<sup>231</sup> See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015).

<sup>232</sup> See *id.*

<sup>233</sup> See 2019 Guidance, *supra* note 8; *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014).

<sup>234</sup> See 2019 Guidance, *supra* note 8, at 54–55.

<sup>235</sup> See *id.*

With respect to USPTO Step 2A Prong 2, it provides that any claims which integrate the judicial exception into a practical application through meaningful limitations are not “directed to” a judicial exception (encapsulating *Alice* Step 1).<sup>236</sup> Therefore, the vast majority of § 101 inquiries will be terminated at this stage, as most applicants do in fact have practical applications in mind for their ideas when applying for patents.

It is logical to dispose of most § 101 inquiries at *Alice* Step 1 because Step 2, calling for an inquiry into “something more,” is a vague standard that is not workable for most examiners. Most patent examiners are not attorneys; they are non-attorney employees of the USPTO trained in patent law with the technical backgrounds necessary to understand the relevant technologies. While most patent examiners are technically strong, they lack formal legal training and may struggle when attempting to integrate vague legal standards into the patent prosecution process. One of the stated reasons for the 2019 Guidance’s promulgation is to provide examiners with a workable standard to apply in patent prosecution.<sup>237</sup> For many examiners, engaging in a detailed analysis of what exactly “something more” is in the context of every new application potentially involving a judicial exception would be burdensome and impractical. This is generally what examiners have been forced to do up to this point, and it has led to inconsistent application of patent law within and across many of the USPTO’s technology centers.<sup>238</sup> By allowing examiners to dispose of most § 101 inquiries at *Alice* Step 1 via the practical application standard, the guidelines spare them from having to formally engage in the convoluted “something more” analysis of *Alice* Step 2.<sup>239</sup> This will generally benefit examiners and the prosecution process as most examiners will be better able to apply the practical application standard of the 2019 Guidance than the “something more” standard of *Alice* Step 2. Since the practical application standard meets the

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<sup>236</sup> See *id.* at 57.

<sup>237</sup> See *id.* at 50.

<sup>238</sup> See *id.* at 50–51.

<sup>239</sup> See *id.* at 57.



requirements of *Alice* Step 2, this practice is consistent with Supreme Court and Federal Circuit precedent.<sup>240</sup>

It is also more logical for the USPTO to direct examiners to reach a decision at *Alice* Step 1 through the 2019 Guidance because it will simplify issues on appeal. An application file history filled with a patent examiner attempting to apply the *Alice* test is more likely to include misapplication of law because most examiners are not attorneys. In addition to being more difficult to understand, applying *Alice*'s Step 2 would make examiners more likely to be reversed at the Patent Trial and Appeal Board and Federal Circuit. Since patent examiners have a better technical understanding of the technology and more experience reviewing similar technologies than administrative law judges, district court judges, or appellate judges, they are likely in the best position to determine whether particular claim language would effectively amount to a monopoly on a basic technological principle, preventing others from doing the same thing in a different way. Said differently, examiners are in the best position to protect the public when they can do their job well. It is therefore logical to provide examiners with a workable standard that they can interpret and apply correctly in order to reduce the likelihood they will be reversed on appeal, to the detriment of the public.

It is consistent with precedent to dispose of most § 101 inquiries at *Alice* Step 1 because once it has been found that claims are not “directed to” a judicial exception, there is no need to continue the § 101 inquiry.<sup>241</sup> However, many of the § 101 cases to have come out of the Federal Circuit have proceeded to *Alice* Step 2, even those

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<sup>240</sup> See *supra* Section III.B.

<sup>241</sup> See *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018) (“If the claims are not directed to a patent ineligible concept at step one, we need not address *step two* of the inquiry.”); see also *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (finding that the claimed invention was patent-eligible because it was not directed to a patent-ineligible concept under *Alice* Step 1, or was an inventive application of the patent-ineligible concept under *Alice* Step 2); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016) (finding that § 101 eligibility determinations can be reached if the claims are not directed to an abstract idea under *Alice* Step 1 or upon recitation of concrete improvements under *Alice* Step 2).

which state that the inquiry need not go beyond *Alice* Step 1.<sup>242</sup> This is somewhat unsurprising, as cases on appeal at the Federal Circuit tend to be the tougher cases, and since “there is considerable overlap between step one and step two.”<sup>243</sup> But this does raise the issue of whether the 2019 Guidance is improperly circumventing *Alice* Step 2 in most cases. For the reasons set forth above, the 2019 Guidance does not amount to an improper circumvention of *Alice* Step 2 as the “practical application” standard fulfills the “something more” requirement of *Alice* Step 2 and will lead examiners to the same conclusion as would a formal and proper application of the *Alice* test.<sup>244</sup> Further, since there is overlap between *Alice* Step 1 and Step 2, it would be redundant to force examiners to proceed to *Alice* Step 2 in every application when they have already applied the practical application standard, which fulfills the requirements of *Alice* Step 2. Therefore, the Guidance represents both a logical and consistent application of § 101 jurisprudence.

*D. The Investigation into “Inventive Concept” Is Within the Scope of Alice’s “Something More” Standard and Is Supported by Precedent*

The final step of the 2019 Guidance, Step 2B, calls for an inquiry into “inventive concept” after finding that claims do not represent a practical application.<sup>245</sup> This final step of the 2019 Guidance calls for a reevaluation of claim elements to determine if the combination of elements is unconventional enough to represent an “inventive concept” and therefore provide “something more” under *Alice* Step 2.<sup>246</sup> Because the inquiry into “inventive concept” is rooted in *Alice*

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<sup>242</sup> See *Vanda Pharm.*, 887 F.3d at 1134; *Enfish*, 822 F.3d at 1334; *CellzDirect*, 827 F.3d at 1050.

<sup>243</sup> *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016).

<sup>244</sup> See *supra* Section III.B.

<sup>245</sup> See 2019 Guidance, *supra* note 8, at 54, 56.

<sup>246</sup> *Id.* at 56.

Step 2, it represents an appropriate application of § 101 jurisprudence.<sup>247</sup>

In general, the Supreme Court's *Alice* test is quite vague and leaves significant room for interpretation as to exactly what fits into the category of "something more."<sup>248</sup> While *Alice* provided some insight into the subject matter eligibility of computer-implemented methods at issue in the instant case, very little was specified as to what exactly would qualify as something more in other applications.<sup>249</sup> Rather, the Court spent most of its opinion reviewing its prior § 101 cases and delineating a few narrow circumstances as to what was not "something more."<sup>250</sup> Because of the void left in the opinion which leaves significant room for interpretation of exactly what qualifies as "something more," the *Alice* test is broad enough to lawfully encompass an inquiry into "inventive concept" as is required by the 2019 Guidance.<sup>251</sup>

The inquiry into "inventive concept" is also notable in that the Supreme Court's pre-2010 jurisprudence used inventive concept as the standard for assessing subject matter eligibility under § 101.<sup>252</sup> In this way, the inquiry into inventive concept is not only supported by *Alice* Step 2, but is also supported by earlier Supreme Court precedent, which applies the same standard, using the same language.<sup>253</sup> Further, following the Supreme Court's decision in *Alice*, the Federal Circuit has incorporated the language and standard of "inventive concept" into its own § 101 jurisprudence when applying *Alice* Step 2.<sup>254</sup> Because of the heavy reliance upon

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<sup>247</sup> See *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 221 (2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 82–83 (2012)).

<sup>248</sup> See discussion *supra* Section I.B.i.

<sup>249</sup> See *Alice*, 573 U.S. at 217.

<sup>250</sup> See *id.* at 221–27.

<sup>251</sup> See *id.*

<sup>252</sup> See *Parker v. Flook*, 437 U.S. 584, 594 (1978) ("[T]he discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.").

<sup>253</sup> See *id.*

<sup>254</sup> See, e.g., *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1262 (Fed. Cir. 2016) ("We find no 'inventive concept' that transforms the abstract idea of out-of-region delivery of regional broadcasting into a patent-eligible application of that abstract idea.").

the language and standard of “inventive concept” by the Federal Circuit, there is a strong basis for finding the inquiry into inventive concept, as called for by the 2019 Guidance, to be consistent with existing precedent.<sup>255</sup>

The inquiry into “inventive concept” is also a logical application of § 101 jurisprudence because it allows for flexibility in application of the 2019 Guidance. As has been set forth above, patent examiners are in the best position to reach determinations as to whether particular claim language would effectively amount to a monopoly on a basic technological principle, due to their strong technical understanding of the technology which they are examining and experience in reviewing many similar technologies.<sup>256</sup> One of the primary policy goals of patent law is to promote innovation by providing an incentive to invest in new technologies. Just as patent examiners are in the best position to make determinations as to whether claims amount to innovation stifling monopolies, patent examiners are also in the best position to make determinations as to whether an invention represents a novel and nonobvious contribution to an art as to merit a patent. Though it is unlikely, there will undoubtedly be some inventions which represent significant improvements to a technological field which may not yet amount to a “practical application.” By allowing for an inquiry into “inventive concept,” the 2019 Guidance allows for flexibility in its application, as to best serve the chief underlying policy goal of patent law—promoting innovation. However, the USPTO must be cautious to ensure this exception to the 2019 Guidance is applied sparingly and appropriately, as this exception has the potential to be misapplied and could swallow the entire Guidance procedure if it is applied in an imprudent and wanton manner. This part of the 2019 Guidance is riskier than its other portions: while it is unlikely that inventions not already incorporated into a practical application will offer “something more” within the meaning of *Alice*, this exception serves as a catchall with the potential to find that any patent application presents eligible subject matter, notwithstanding a lack of a practical application.

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<sup>255</sup> See *id.*

<sup>256</sup> See *supra* Section III.C.

Both the Supreme Court and Federal Circuit's § 101 jurisprudence supports an inquiry into "inventive concept," and such an inquiry is therefore consistent with precedent.<sup>257</sup> Further, the "inventive concept" inquiry is logical as it allows for flexibility in application of the 2019 Guidance as to best promote the underlying policy goals of patent law.

*E. The October Update to the 2019 Guidance Reaffirms the Guidance Procedures, Consistent with the Conclusions Reached in This Analysis*

On October 17, 2019, the USPTO released an update to its 2019 Guidance procedures (the "October Update").<sup>258</sup> The October Update supplements the 2019 Guidance by requiring that all examiners of the USPTO follow the 2019 Guidance procedures; qualifying what it means to "recite" a judicial exception in a claim; providing further support for its groupings of abstract ideas; further elaborating on the practical application standard of USPTO Step 2A; and explicitly stating the *prima facie* case for § 101 rejections.<sup>259</sup> The October Update does not deviate from the procedures originally set forth in the 2019 Guidance and serves to reaffirm the existing procedures with further support from additional Federal Circuit decisions. In accordance with the conclusions reached in this Article, the October Update indicates that the USPTO considers the 2019 Guidance a success in that it sets forth a logical procedure for addressing subject matter eligibility issues, consistent with § 101 jurisprudence.

What is likely the most significant part of the October Update to the 2019 Guidance is the requirement that "USPTO personnel are expected to follow it."<sup>260</sup> The lack of any such requirement in the original 2019 Guidance procedures indicates that application of the

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<sup>257</sup> See *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed. Cir. 2018), *cert. denied*, No. 18-415, 2020 WL 129532 (U.S. Jan. 13, 2020) (finding claims 4–7 to "contain limitations directed to the arguably unconventional inventive concept described in the specification" and thus to be § 101-eligible).

<sup>258</sup> U.S. PATENT & TRADEMARK OFFICE, *supra* note 145, at 2.

<sup>259</sup> *Id.* at 1.

<sup>260</sup> *Id.* at 17 ("it" being the 2019 Guidance).

2019 Guidance was left to the discretion of examiners of the USPTO.<sup>261</sup> While this may have been appropriate at first while the USPTO evaluated the 2019 Guidance, it makes sense for the USPTO to now require that examiners follow the 2019 Guidance as it has been well received by the inventive community and works well for facilitating the timely resolution of § 101 issues. The October Update further indicates that the examining corps of the USPTO has completed training in the 2019 Guidance and that the USPTO is in the process of ascertaining what further training is appropriate.<sup>262</sup>

The October Update also defines what it means to “recite” a judicial exception within the meaning of § 101. It states that a claim “recites” a judicial exception if the exception is “set forth” or “described” in the claim.<sup>263</sup> While the terms “set forth” and “describe” are both encompassed within the meaning of “recite,” the October Update clarifies that the different language is intended to indicate that there are two ways in which an exception can be recited.<sup>264</sup> “For instance, the claims in [*Diehr*] clearly stated a mathematical equation” which when used in the claims was deemed to have “‘set forth’ an identifiable judicial exception, but the claims in [*Alice*] ‘described’ the concept of intermediated settlement without ever explicitly using the words ‘intermediated’ or ‘settlement.’”<sup>265</sup> In other words, a claim “sets forth” a judicial exception when it is literally included in the claims, while a claim “describes” a judicial exception when the literal words used to define an embodiment of a judicial exception are not actually used in the claims, but the claim language is nonetheless sufficient to encompass the judicial exception. However, this difference is largely semantic: regardless of whether a claim “sets forth” or “describes” an exception, it is still deemed to “recite” the exception, and the same procedure is followed when assessing the subject matter eligibility of the claim. This portion of the October Update

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<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.* at 1.

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

also clarifies that it is possible for “[a] claim [to] recite more than one judicial exception.”<sup>266</sup>

What is probably the next most important part of the October Update is the USPTO’s reaffirmation of its groupings of abstract ideas embodied in USPTO Step 2A Prong 1. The October Update clarifies that “the Office has shifted its approach from the case-comparison approach” to a “test that distills the relevant case law to aid in examination” as set forth in the 2019 Guidance.<sup>267</sup> Consistent with the conclusions reached in Section III.A of this Article, the October Update states that “[t]he enumerated groupings are firmly rooted in Supreme Court precedent as well as Federal Circuit decisions interpreting that precedent.”<sup>268</sup> The October Update indicates that the grouping of abstract ideas is good policy because it shifts examiner focus from individual cases to a more general application of § 101 case law spanning all technologies and claim types.<sup>269</sup> While there is room for argument as to whether this will always lead to correct § 101 determinations (such as when there is a case directly on point), in general, the use of a uniform standard will benefit the public, as examiners are better able to interpret and correctly apply the standard of the 2019 Guidance (as opposed to them having to interpret specific § 101 cases which may or may not be directly applicable).<sup>270</sup> The October Update goes on to further support its groupings of abstract ideas by providing additional examples of cases falling within the categories and further explanations of why these cases are abstract ideas that fall within a specified category.<sup>271</sup> The USPTO’s strong reaffirmation of its categories of abstract ideas at USPTO Step 2A Prong 1 indicates that this portion of the 2019 Guidance is something that has worked well for the Office following its release in January of 2019 and that it is a procedure it will continue to utilize for the foreseeable future.

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<sup>266</sup> *Id.* at 2.

<sup>267</sup> *Id.*

<sup>268</sup> *Id.*; see also *supra* Section III.A (finding the listing of abstract ideas to be a logical application of § 101 jurisprudence consistent with Supreme Court and Federal Circuit precedent).

<sup>269</sup> U.S. PATENT & TRADEMARK OFFICE, *supra* note 145, at 2.

<sup>270</sup> See *supra* Section III.C.

<sup>271</sup> U.S. PATENT & TRADEMARK OFFICE, *supra* note 145, at 3–9.

Other additions provided by the October Update include updates on what it means for a judicial exception to be integrated into a practical application under USPTO Step 2B, the inclusion of a flow chart, and additional elaboration on some of the specific categories provided in the 2019 Guidance which indicate that a judicial exception has been integrated into a practical application and is therefore § 101-eligible.<sup>272</sup> These additional procedures do not represent any substantive change in the 2019 Guidance but simply offer further direction to examiners on how to apply the preexisting 2019 Guidance procedures.

The October Update then goes on to state the requirements of a *prima facie* case for a § 101 rejection under the 2019 Guidance. In order to set forth a *prima facie* case for a § 101 rejection, an examiner must: (1) under USPTO Step 2A Prong 1, identify the judicial exception and explain why it is considered to be a judicial exception; (2) under USPTO Step 2A Prong 2, identify any additional elements recited in the claim beyond the judicial exception and evaluate if the judicial exception has been integrated into a practical application when considering the claim as a whole; and (3) under USPTO Step 2B, explain why the additional elements, when taken individually and in combination, do not result in the claim, as a whole, amounting to significantly more than the judicial exception.<sup>273</sup> The October Update does not change what is required to establish a *prima facie* case of ineligible subject matter under the

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<sup>272</sup> The considerations which were elaborated upon in the October Update included whether the claimed invention improves the functioning of a computer or other technology; whether the claimed invention uses the judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition; whether the treatment or prophylaxis limitation has more than a nominal or insignificant relationship to the exception; and whether the additional limitations merely constitute extra-solution activity or a field-of-use. *Id.* at 10–15. The October Update also included clarification that the improvement to a technology consideration “applies equally whether it is a computer implemented invention, an invention in the life sciences, or any other technology,” that “there is no requirement for the judicial exception to provide the improvement,” and that the “improvement can be provided by one or more additional elements,” either alone or in combination with the judicial exception. *Id.* It also clarified that when applying the treatment or prophylaxis consideration, examiners should further consider the particularity or generality of the treatment or prophylaxis. *Id.*

<sup>273</sup> *Id.* at 16.



2019 Guidance; it merely sets forth exactly what is required to establish a *prima facie* case for the convenience of patent examiners and applicants.

The October Update to the 2019 Guidance can largely be considered a reaffirmation of the 2019 Guidance procedures, as it makes no substantive changes to the 2019 Guidance, provides further support for the 2019 Guidance, and explicitly directs all examiners to follow the 2019 Guidance. In particular, the additional examples and explanations provided as to the categories of abstract ideas in the 2019 Guidance indicate that this portion of the 2019 Guidance is something which the Office strongly supports. In sum, the October Update shows that the USPTO is satisfied with the 2019 Guidance and that the 2019 Guidance will likely remain a part of examination procedures at the Office for the foreseeable future.

#### CONCLUSION

The USPTO's 2019 Subject Matter Eligibility Guidance for inventions drawn to judicial exceptions represents a lawful and logical application of § 101 jurisprudence. Its listing of abstract ideas is drawn directly from Supreme Court and Federal Circuit precedent and is an efficient way to establish what technologies are likely to present § 101 issues. The practical application standard of the 2019 Guidance embodies the requirements of the *Alice Corporation Pty. v. CLS Bank International* test and is easy for examiners to understand and apply. Sparing examiners from having to engage in a formal *Alice* Step 2 analysis is permissible because the practical application standard already embodies the requirements of *Alice* Step 2. Further, the inquiry into inventive concept is appropriate, so long as it is applied sensibly.

When considering the post-*Alice* uncertainty as to the subject matter eligibility of many inventions and the inconsistent application of § 101 jurisprudence at the USPTO, direction as to the subject matter eligibility of inventions drawn to judicial exceptions was needed. The USPTO's 2019 Guidance does an excellent job of providing the needed direction to both patent examiners and patent applicants in a logical manner consistent with Supreme Court and Federal Circuit precedent. As such, the 2019 Guidance is likely to accomplish its stated goal of facilitating the correct and consistent

application of patent law to § 101 inquiries. This will further the underlying policy goals of patent law as to the promotion of innovation by allowing the inventive community to assess the subject matter eligibility of inventions at an early stage of development, thereby providing an incentive to invest in the development of new technologies which are eligible for patent protection. In sum, the 2019 Guidance is a well-thought-out application of patent law likely to benefit the USPTO, patent applicants, and the public.