



October 28, 2015

The Honorable Michelle Lee  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22313

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

**RE: July 2015 Update on Subject Matter Eligibility**

Dear Director Lee,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to submit comments on the United States Patent and Trademark Office's (USPTO) July 2015 Update on Subject Matter Eligibility (Guidance).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members—many of which are small, emerging companies—are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO's members continue to be concerned about the state of subject matter eligibility in the United States, and few areas of substantive patent law have received more discussion within our membership.

**Introduction**

BIO appreciates the USPTO's continuing dialogue with the patent user community on the topic of patent-eligible subject matter, and the thorough consideration the Office has given to this important issue. However, we continue to be concerned with the recent judicial and administrative expansion of nonstatutory patent law governing the patent-eligibility of certain classes of biotechnology inventions in the United States. And we continue to believe that the USPTO's interpretation of § 101 case law, as embodied in the Guidance, rests upon an overly broad and invalid interpretation of recent Supreme Court decisions.

Notwithstanding these concerns, BIO commends the USPTO on the progress it has made in revising the Guidance to better reflect § 101 case law. In particular, we agree with the Office's approach to Step 2A, which now correctly acknowledges that the "markedly different characteristics" analysis can be satisfied by multiple rationales that have been recognized in the body of § 101 case law. We also agree with the

remarks of other commentators that additional rationales, such as “enlarges the range of utility”<sup>1</sup> and “distinctive name, character and use”<sup>2</sup>, are appropriate—and, indeed, required—additions to the Office’s evolving § 101 framework.

We also encourage the USPTO to continue to revise the Guidance to better reflect the § 101 case law pertaining to Step 2B. A specific example where Step 2B could be improved is with respect to the “well-understood, routine and conventional” rationale. In *Mayo*, the Supreme Court held that “simply appending conventional steps, *specified at a high level of generality*, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”<sup>3</sup> The Federal Circuit’s formulation of this rationale in *Ariosa* was similar: “appending routine, conventional steps to a natural phenomenon, *specified at a high level of generality*, is not enough to supply an inventive concept.”<sup>4</sup>

What necessarily follows from these holdings is that some claims remain patent-eligible even when reciting additional elements that are “well-understood, routine and conventional,” so long as such elements are specified to a sufficient degree of detail. For example, in claims reciting “conventional” methods, the addition of steps or elements that optimize or perfect the conventional method for some specific purpose should always be patent-eligible for purposes of satisfying Step 2B of the § 101 analysis. Accordingly, the USPTO should consider providing examples of claims to nature-based products where otherwise “well-understood, routine and conventional” activity has been specified with enough detail to render the claim patent-eligible.

## **I. The § 101 Analysis Is a Question of Law with Underlying Factual Issues**

The Guidance asserts that the § 101 analysis is a pure question of law, and thus invites Examiners to reach ultimate legal conclusions on eligibility without actually making any factual findings.<sup>5</sup> As discussed below, this is wrong as a matter of law. But it is also wrong as a matter of institutional policy. As an agency with unparalleled scientific and technical expertise, the USPTO should embrace its institutional role as the patent system’s supreme fact-finder and should strive to develop a thorough, well-supported administrative record for use on appeal. This role is especially critical in the present context, where the contours of § 101 jurisprudence continue to evolve through developments in the common law.

### **A. Courts Have Acknowledged That the § 101 Analysis Involves Factual Determinations**

The Federal Circuit has recognized that the § 101 analysis involves factual determinations. In *Ultramercial*, the court acknowledged that the § 101 analysis “while ultimately a legal determination, is rife with underlying factual issues.”<sup>6</sup> As the court explained, “factual issues may underlie determining whether the patent embraces a [judicial exception]” (Step 2A), and “factual inquiries” may be required

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<sup>1</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (“The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility.”).

<sup>2</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (The “claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’ ” (citing *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)); see also *id.* at 310 (another suitable rationale is the “potential for significant utility”).

<sup>3</sup> *Mayo Collaborative Serv. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1300 (2012).

<sup>4</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015).

<sup>5</sup> USPTO, July 2015 Update: Subject Matter Eligibility 6 (Jul. 30, 2015) [hereinafter *July 2015 Update*], <http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf> (“The courts consider the determination of whether a claim is eligible . . . to be a question of law.”).

<sup>6</sup> *Ultramercial, Inc. v. HULU, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013).

when analyzing whether an element is “routine, well-understood, or conventional” (Step 2B).<sup>7</sup> Similarly, in *In re Comiskey*, the court acknowledged that “there may be cases in which the legal question as to patentable subject matter may turn on subsidiary factual issues . . . that must be resolved in order to address the patentability of the subject matter of [the] application.”<sup>8</sup>

Indeed, a survey of recent § 101 decisions demonstrates that both the Supreme Court and the Federal Circuit have considered factual findings when making subject matter eligibility determinations. In *Bilski* and *Alice Corp.*, the Supreme Court cited authoritative documentary evidence to demonstrate that the claimed subject matter was an abstract idea and thus not patent-eligible (Step 2A).<sup>9</sup> And in *Ariosa* the Federal Circuit concluded that a method for amplifying and detecting DNA was “well-understood, routine, and conventional” after considering deposition testimony and a declaration filed during prosecution (Step 2B).<sup>10</sup> Thus, where the issue has been in dispute, both the Supreme Court and the Federal Circuit have considered findings of fact when resolving § 101 issues.

## **B. Subsidiary Factual Findings Are Inherent in the Guidance’s § 101 Framework**

The framework set forth in the Guidance inherently requires certain factual determinations to be made. However, the specific content of such determinations differs somewhat depending on which rationale is selected to reject (or to support) the claim. Here, the Guidance’s use of the “well-understood, routine, and conventional” rationale in Step 2B is instructive. To properly apply this rationale, the fact-finder—whether that be the USPTO or a court—must consider the following basic factual inquiries:

First, the fact-finder must determine whether the additional element in question was “well-understood, routine and conventional” *at the time of the claimed invention*. This consideration was apparent in *Ariosa* where the Federal Circuit assessed whether a claimed method was “well-understood, routine and conventional” *in 1997*—i.e., the time period surrounding the date of invention.<sup>11</sup> Thus, similar to the § 103 analysis, the Guidance should instruct Examiners to consider how a “person of ordinary skill in the art” would have viewed the element at the time of the claimed invention, and it should caution Examiners against committing the error of hindsight bias.

Second, the fact-finder must determine whether the additional element was “well-understood, routine and conventional” (at the time of the claimed invention) in the specific technological context of the claim (i.e., in the claim’s field of art). As the Supreme Court held in *Mayo*, a claim is not patent-eligible when it merely involves “well-understood, routine and conventional activity *previously engaged in by researchers in the field*.”<sup>12</sup> Thus, an element that is “well-understood, routine and conventional” (at the time of the claimed invention) in one field of technology is not necessarily patent-ineligible in other technological contexts.

Upon making these underlying factual determinations, the fact-finder must then proceed to consider the § 101 analysis as a question of law. That is, the USPTO (or the court) must then undertake a legal analysis to determine whether the additional element is “well-understood, routine and conventional” *in the specific*

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<sup>7</sup> *Id.*

<sup>8</sup> *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009).

<sup>9</sup> See, e.g., *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (citing three textbooks to demonstrate that a concept was an “abstract idea”); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. \_\_\_, 34 S. Ct. 2347, 2356 (2014) (citing several authoritative references to demonstrate that a concept was an “abstract idea.”).

<sup>10</sup> *Ariosa*, 788 F.3d at 1377.

<sup>11</sup> *Id.*

<sup>12</sup> *Mayo*, 132 S. Ct. at 1294 (2012); see also *id.* at 1298 (“Thus, this step tells doctors to engage in well-understood, routine, conventional activity *previously engaged in by scientists who work in the field*. (emphasis added)).

*context of the patent claim at issue.* This is especially necessary in the § 101 analysis where subject matter eligibility is determined by considering the “claim as a whole.”<sup>13</sup>

Last, the Guidance should acknowledge that a *single* report of an activity being used in a particular field of art is never a sufficient basis for concluding that an additional element is “well-understood, routine and conventional.” The Supreme Court’s choice of words indicates that such elements must be so abundantly and pervasively practiced in the prior art that their status as “well-understood, routine, and conventional” is basically self-evident. This is a far cry from instances where a claim element may have been practiced or reported in the prior art on isolated occasions, or where the practice of such elements in the prior art was not well-understood or not routine.

Accordingly, BIO does not believe, for example, that a finding of “well-understood, routine, and conventional” can be supported by the same quantum of proof that would be sufficient for a rejection under § 102 or § 103, where one or two relevant references may indeed be dispositive of the issue. For this reason, the Guidance should require Examiners to support any § 101 rejection based on the “well-understood, routine and conventional” rationale with sufficient documentary evidence to demonstrate that the element in question not only merely exists in the prior art, but was truly “routine” or “conventional” to a person of ordinary skill in the art at the time of the claimed invention.

### **C. Factual Findings by the USPTO Must Be Supported by Substantial Evidence**

The USPTO is subject to the constraints of the Administrative Procedure Act (APA).<sup>14</sup> Under the APA, factual findings made by the USPTO, such as those inherent in the § 101 analysis, must be supported by substantial evidence in order to survive judicial review.<sup>15</sup> In *In re Zurko*, the Federal Circuit concluded that “with respect to core factual findings in a determination of patentability” the USPTO “cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense.”<sup>16</sup> Rather, the USPTO “must point to some concrete evidence in the record in support of these findings.”<sup>17</sup>

For this reason, the USPTO must strike all suggestion in the Guidance that it is proper for Examiners to reach ultimate legal conclusions on subject matter eligibility by merely relying on conclusory statements based on their personal knowledge of the art. To be sure, as scientific and technical subject matter experts, the opinions of Examiners as to underlying factual issues should be afforded some weight. But this is only proper where such opinions are corroborated by sufficient documentary evidence. Mere conclusory statements as to the merits of key premises are never sufficient to support a § 101 rejection.<sup>18</sup>

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<sup>13</sup> 2014 *Interim Guidance on Patent Subject Matter Eligibility*, 79 Fed. Reg. 74618, 74624 (Dec. 16, 2014) [hereinafter *2014 Interim Eligibility Guidance*] (“A claim directed to a judicial exception must be analyzed to determine whether the elements of the claim, considered both individually and as an ordered combination, are sufficient to ensure that the *claim as a whole* amounts to significantly more than the exception itself . . .” (emphasis added)).

<sup>14</sup> See *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999).

<sup>15</sup> See *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

<sup>16</sup> *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

<sup>17</sup> *Id.*; see also *In re Sang-Su Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002) (“Judicial review of a [USPTO] decision denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency’s reasoning in reaching its conclusions.”).

<sup>18</sup> See, e.g., *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (“Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’”).

When revising the Guidance, the USPTO should consider aligning the § 101 analysis with the Office’s current framework for analyzing § 103. The “functional approach” adopted by the Supreme Court to resolve § 103 issues in *Graham*<sup>19</sup> is consistent with the Court’s view in *Bilski* that there is no single test for subject matter eligibility in the § 101 analysis.<sup>20</sup> It is also consistent with the Guidance’s own acknowledgement that Step 2 of the framework can be satisfied using any of the rationales recognized in the body of § 101 case law.

Under the modified § 101 analysis, the Guidance should instruct Examiners to clearly set forth in the first Office action all basic factual findings underlying the particular rationale selected to support the § 101 rejection. Such an initial showing by the examiner then provides Applicants with a fair opportunity to either attack the legal sufficiency of the rejection, or to effectively rebut the substance of the Office’s findings with evidence and argument. This procedure ensures that any factual disputes are well-developed at the point of the second Office action.

## **II. The Requirements of a Prima Facie Case Set Forth in the Guidance Are Inconsistent with the USPTO’s Stated Examination Practices**

The *prima facie* case is a procedural tool of patent examination, which enables the burden of production to be shifted between Examiner and Applicant.<sup>21</sup> The USPTO should embrace its authority to govern the conduct of this procedure by ensuring that the *prima facie* case for establishing subject matter eligibility is efficient—in terms of time and cost—for both Applicants and the Office.<sup>22</sup> Moreover, the USPTO should remain mindful that even procedural matters can have substantive consequences, especially where Applicants are not afforded fair notice of their application’s deficiencies or are deprived of an effective opportunity to timely present evidence and argument. Accordingly, the USPTO should review the Guidance to determine whether the right of Applicants to a fair and effective examination procedure is adequately preserved in the current § 101 framework and whether the Guidance is consistent with the Office’s own model examination practices.

### **A. Compact Prosecution**

In sharp contrast to the USPTO’s own policy of compact prosecution, the Guidance permits—even encourages—Examiners to issue § 101 rejections supported solely by conclusory statements as to whether the claimed subject matter satisfies the requirements of Steps 2A and 2B. This practice puts Applicants at a disadvantage because it forces them to rebut an unsupported conclusion, rather than providing them with an opportunity to rebut the factual substance of the rejection. Moreover, Examiners are permitted to issue a final rejection in a second Office action following a conclusory rejection even if the examiner decides to supplement the record with a reference, so long as the reference is “added only as directly corresponding evidence” to support the prior rejection.<sup>23</sup> Although options are available for Applicants wishing to continue prosecution, these options make prosecution more expensive and time-consuming, which are outcomes that run counter to the Office’s goal of promoting examination “efficiency.”<sup>24</sup>

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<sup>19</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966) (“The Hotchkiss formulation, however, lies not in any label, but in its functional approach to questions of patentability.”).

<sup>20</sup> *Bilski*, 130 S. Ct. at 3259 (“The machine-or-transformation test is thus an important example of how a court can determine patentability under § 101, but the Federal Circuit erred in this case by treating it as the *exclusive test*.” (emphasis in original)).

<sup>21</sup> See *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

<sup>22</sup> 35 U.S.C. § 2(b)(2) (USPTO has authority to “establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office . . . [and to] facilitate and expedite the processing of applications.”)

<sup>23</sup> MPEP § 2144.03(D).

<sup>24</sup> *2014 Interim Eligibility Guidance*, 79 Fed. Reg. at 74620 (stating that one objective of the Guidance is to “promote[] examination efficiency”).

For these reasons, the Guidance should be improved by making it more consistent with the USPTO's own practice of compact prosecution. As stated in MPEP § 706, "The goal of examination is to clearly articulate any rejection *early* in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply *completely* at the *earliest* opportunity."<sup>25</sup> In the context of the § 101 analysis, this means that Examiners should support any § 101 rejections with sufficient documentary evidence during the first Office action.

Further, the USPTO should recognize that there is a difference between supporting a *single* ground of a rejection with adequate evidence (the approach suggested here) and issuing multiple, cumulative grounds for the same rejection. In fact, as previously discussed in Part I.B., certain factual determinations underlying the § 101 analysis, such as whether an element is "well-understood, routine, or conventional," may necessarily require the production of multiple types of documentary evidence in order to demonstrate that an element was truly "routine" to a "particular industry" at the "time of invention."

## **B. Official Notice**

The Guidance states that the examiner's burden of production may be satisfied by providing a reasoned rationale for why the claimed invention is not eligible and that this rationale may rely "on the knowledge generally available to those in the art."<sup>26</sup> As such, it may be particularly tempting for Examiners to use this rationale in the context of Step 2B, where the Guidance instructs them to "rely on what . . . *those in the art* would recognize, as elements that are well-understood, routine and conventional."<sup>27</sup> Indeed, the Guidance expects that Examiners will rely "on [their] expertise in the art" when determining whether an additional element amounts to "significantly more."<sup>28</sup> In essence, the Guidance encourages Examiners to take "official notice" of dispositive factual issues underlying the § 101 analysis. This instruction, however, is rooted in the faulty premise that no court has relied upon underlying factual findings when determining whether an additional element was "well-understood, routine and conventional" and, thus, that the factual determinations inherent in Step 2B are matters "appropriate for judicial notice."<sup>29</sup> As previously discussed in Part I.A., this premise fails to pass muster in light of past § 101 decisions issued by the Supreme Court and the Federal Circuit.

In addition, the instructions in the Guidance are at odds vis-à-vis USPTO's own examination practices. In 2002, the USPTO issued a memorandum clarifying the circumstances in which it is appropriate to take "official notice of facts by relying on common knowledge in the art without a reference."<sup>30</sup> This policy is now embodied in MPEP § 2144.03, which states that "official notice without documentary evidence" is proper *only* where the "facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." That is, official notice is *never* proper in a situation where an examiner is unable to readily locate multiple pieces of documentary evidence to support the rejection. The fact that a search for supporting evidence is difficult or time-consuming should be a strong indication that the asserted facts are not "well-known" or "common knowledge in the art."

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<sup>25</sup> MPEP § 706 (emphasis added).

<sup>26</sup> *July 2015 Update*, at 6.

<sup>27</sup> *Id.* at 7 (emphasis added).

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

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

<sup>30</sup> USPTO, Procedures for Relying on Facts Which are Not of Record as Common Knowledge or for Taking Official Notice 1 (Feb. 21, 2002), <http://www.uspto.gov/web/offices/pac/dapp/opla/documents/offnotice.pdf>.

Further, the USPTO's own examination practices dictate that it is "*never* appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the *principal* evidence upon which a rejection was based."<sup>31</sup> This policy derives from the Federal Circuit's decision in *In re Zurko*, where the court explained that the USPTO "clearly has expertise in the subject matter over which it exercises jurisdiction" but that such "expertise may provide sufficient support for conclusions [only] as to *peripheral* issues."<sup>32</sup> Thus, according to the USPTO's own practices, it is *never* proper to take official notice of a factual matter that is dispositive as to the ultimate legal conclusion concerning the eligibility of a claim.

### C. Use of Legal Precedent

The Guidance also states that an examiner's initial burden of production may be met by providing a reasoned rationale for why the claimed invention is not eligible and that this rationale may rely "on case law precedent."<sup>33</sup> Specifically, the Guidance encourages Examiners to identify judicial exceptions in Step 2A by relying "solely on comparisons to concepts found to be exceptions in past [court] opinions."<sup>34</sup> And for Step 2B, it instructs examiners to "rely on what the courts have recognized . . . as elements that are well-understood, routine and conventional."<sup>35</sup> This use of legal precedent in the Guidance is in conflict with the USPTO's own examination practices.

The USPTO's examination practices permit Examiners to use legal precedent as a repository of rationales to support certain claim rejections, such as those under § 103.<sup>36</sup> According to MPEP § 2144(III), an examiner "may use the *rationale* used by the court" but only if "the *facts* in a prior legal decision are *sufficiently similar* to those in [the] application under examination."<sup>37</sup> But the Guidance's use of legal precedent is at odds with this practice because it encourages Examiners to issue § 101 rejections by analogizing to the *holdings* of prior legal decisions, not to the rationale. Moreover, even in situations where relying on the rationale of a prior legal decision might be proper, Examiners must still clearly set forth the basis for their conclusion that the *facts* of the prior legal decision are "sufficiently similar" to the *facts* in application being examined. This is especially the case in the context of the § 101 analysis, which requires subject matter eligibility to be determined on the basis of the "claim as a whole."<sup>38</sup>

### Conclusion

Finally, it is fair to restate that there was cautious optimism and a sense of improvement among BIO's members when the USPTO promulgated its Interim Eligibility Guidance on December 16 of last year, and the July 2015 updates thereto. Unfortunately, such optimism is tempered by the expectation that the USPTO's efforts to bring stability to this area of patent law could easily be undone by ongoing or future developments in the United States courts, whose precedential decisions the USPTO is bound to follow. We are concerned that our members will be prosecuting patent applications on a shifting slate for some time to come, and going forward a more stable solution is needed.

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<sup>31</sup> MPEP § 2144.03(A) (emphasis added).

<sup>32</sup> *In re Zurko*, 258 F.3d at 1385 (emphasis added).

<sup>33</sup> *July 2015 Update*, at 6.

<sup>34</sup> *Id.* at 7.

<sup>35</sup> *Id.*

<sup>36</sup> See, e.g., MPEP § 2144 ("In keeping with the flexible approach to obviousness . . . Office personnel may invoke legal precedent as a source of supporting rationale when warranted and appropriately supported.").

<sup>37</sup> *Id.* § 2144(III) (emphasis added); see also *id.* § 2144 (noting that "rationales should not be treated as per se rules, but rather must be explained and shown to apply to the facts at hand").

<sup>38</sup> See, e.g., *2014 Interim Eligibility Guidance*, 79 Fed. Reg. at 74624.

Moreover, no policy reason has been articulated for singling out important segments of socially beneficial biotechnologies for disfavored treatment under the patent law. Likewise, there has been no discussion about whether rejecting patent applications on antibiotics, vaccines, industrial enzymes and similar products makes good sense as a matter of industrial or innovation policy. Indeed, policymakers in the United States have been surprisingly uninvolved in this issue, and the expansion of extrastatutory patent law in this area seems to be driven largely by judges and private litigants. Yet, the state of § 101 jurisprudence, even just in the biotechnology space, is ripe for a policy dialogue outside the forum of the courts. We encourage the USPTO to open such a dialogue and to explore options for bringing lasting stability to this area of U.S. patent law.

Respectfully submitted,

