March 12, 2015

The Honorable Michelle Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
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via e-mail: 2014_interim_guidance@uspto.gov

Dear Director Lee,


The Section thanks the Office for involving stakeholders as the Office prepares examination guidance, and encourages the Office to continue its outreach. The Section welcomes opportunities to provide further assistance to the Office at future roundtables or other meetings.

The Section supports the Office’s revised test for patent eligibility to determine whether a claim would preempt the use of a judicial exception (“JE”). The Section further agrees with the Interim Guidance that the Supreme Court did not create any per se excluded category to eligibility. However, the Section is concerned that the improper application of the test disproportionately affects certain technology centers, such as those involving business methods and medical diagnostics. Indeed, the unintended application of a “presumed guilty” (or “presumed abstract”) approach to computer-implemented, software, and/or business method processes, where the invention is initially viewed as an abstract idea unless proven otherwise, threatens continued innovation in a variety of technical fields. Moreover, the complete omission of hypotheticals relating to diagnostic discoveries needs to be remedied.
I. Congress Intended § 101 to Be a Broad Grant of Eligibility

The Supreme Court recognized that Congress intended 35 U.S.C. § 101 to be a broad statutory grant. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).”) Instead of rejecting nearly 100% of applications in certain art units, the Office should “tread carefully in construing this exclusionary principle lest it swallow all of patent law.” Therefore, the two-part patent eligibility test must be carefully applied without a view to finding that every computer-implemented, software, diagnostic, and/or business method claim is “directed to” a judicial exception. Indeed, the Supreme Court has explicitly stated that business methods, living organisms, and applications of natural correlations can be patent-eligible.

As has been held (and referred to in *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)), “[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” *Le Roy v. Tatham*, 14 How. 156, 175. However, as recognized by the Office in the Interim Guidance, “…at some level all inventions embody, use, reflect, rest upon, or apply a law of nature, natural phenomenon, or abstract idea.” (emphasis added). Interim Guidance at 74622. The Supreme Court continues to recognize this important notion. See, e.g., *Alice Corp.*, 134 S. Ct. at 2354. As discussed below, the difficulty lies in identifying the JE in the claim, assessing how it is expressed, and having examiners making consistent, objective assessments.

II. Difference between “Recites” and “Directed to” a Judicial Exception (JE)

The Office seems to intend some distinction between “recites” and “is directed to” a judicial exception (JE). Interim Guidance at 11. If the Office intends some difference, it should not use the word “recites” in the definition of “directed to.” The Interim Guidance also seems to equate the two terms in the box below the flowchart and in § I.A.1. The problem is the statement in the Guidance: “A claim is directed to a judicial exception when the [JE] is recited (i.e., set forth or described) in the claim.” (Emphasis added). If the Office means that a claim that recites a JE has to be further considered but upon further consideration finds that the claim is not “directed to” the JE because it does not tie up the JE, then this should be made more clear.

Whether a claim “recites” a JE should be a threshold question for whether further analysis is required to determine whether the claim is “directed to” a JE, because only a claim directed to a JE runs the risk the it will “tie up” the JE. The Guidance should instead say that a claim is directed to a JE if it is the JE itself that is being claimed, as opposed to the use of the JE. For example, a claim that recites the word “sun” certainly recites a judicial exception. However, the risk that the claim will tie up that JE is virtually non-existent because the claim likely involves some use of information about the sun rather than claiming the sun *per se*. The only way that a patent can “tie up” a JE is if the claims recite nothing more than the JE itself.

However, the Supreme Court in *Mayo* now requires that the claim include “significantly more” than the JE itself, referring to *Diamond v. Diehr*, 450 U.S. 175, 191-192 (1981). Notwithstanding that a “significantly more” requirement is not the same as merely excluding “insignificant post-
solution activity,” the Section encourages the Office to remain focused on the true intent of Congress and the long-held principles of the Supreme Court—avoiding granting patents on “…the basic tools of scientific and technological work” (Benson, 409 U.S. at 67), i.e., one cannot patent “a fundamental truth; an original cause; a motive”.

III. The United States Might Be in Violation of an International Treaty

The United States ratified the Trade-Related Aspects of Intellectual Property Rights (TRIPS) as required to be a member of the World Trade Organization (WTO). Article 27 of TRIPS (titled “patentable subject matter”) corresponds with 35 U.S.C. § 101 (“inventions patentable”) and states the following:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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

3. Members may also exclude from patentability:
   
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   
   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

(Emphasis added). Importantly, this treaty requires WTO members to issue patents to processes “in all fields of technology,” subject to certain optional exclusions. These exclusions focus on life-science-related inventions where action is taken “on a human or animal,” such as methods of “diagnostic, therapeutic and surgical methods.” TRIPS does not allow for exclusion of all diagnostic, therapeutic and surgical methods—only those that are “for the treatment humans or animals.” TRIPS also does not allow for exclusion computer-implemented business methods, and indeed the Supreme Court did not categorically exclude such inventions from patent eligibility. Bilski v. Kappos, 130 S. Ct. 3218, 3228 (“Section 101 similarly precludes the broad contention that the term ‘process’ categorically excludes business methods.”) The Section recommends that the Office make clear to examiners that business and diagnostic methods are patent eligible, as required by both TRIPS and Supreme Court precedent.
IV. Presidential and Legislative Mandates for Advances in Personalized Medicine May Be in Conflict with the Judiciary’s and the USPTO’s Interpretation of Case Law Involving 35 U.S.C. §101

On January 30, 2015, President Obama released details on his “Precision Medicine Initiative” (“Initiative”), touted as a “bold new research effort to revolutionize how we improve health and treat disease.” vii The President’s 2016 Budget allocates $215 million toward this personalized medicine Initiative to “pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients.” Id. The Initiative makes explicit that “public-private partnerships” will be encouraged to “lay the foundation for this effort.” Id.

Similarly, in December 2013, lawmakers introduced H.R. 3742, the Antibiotic Development to Advance Patient Treatment Act of 2013 (“ADAPT Act”), to provide additional incentives to encourage research and development of drugs and diagnostics for unmet needs. The director of the FDA’s Center for Drug Evaluation and Research advised a Congressional subcommittee that the ADAPT Act is needed because a robust pipeline of new antibiotics does not exist due to lack of commercial incentives to develop those drugs.

The Interim Guidance fails to address the fate of inventions relating to personalized medicine—not one example or comment in the Interim Guidance involves a diagnostic and/or a genetic or biologic marker, which are at the heart of all personalized medicine. Personalized medicine begins with an understanding of the individual patient’s biomarkers, without which treatments cannot be tailored.

Moreover, it is unclear from the Interim Guidance whether the USPTO would consider a claim to a new antibiotic, for example, to be patent eligible, where the new antibiotic is a natural product present in a host bacterium, but when present in that bacteria is unsuitable for administration to humans. The purification of the antibiotic from its natural host allows for an improved and therapeutically useful drug.

At the same time that the President and Congress are calling for incentives to personalized medicine innovators, the Interim Guidance and the Courts are placing burdens on these same innovators by broadly interpreting 35 U.S.C. § 101. The USPTO should revise existing, or provide additional, guidance that encourages patentability and continued investment in this technology, in keeping with President Obama’s focus and the clear importance of personalized medicine-related discoveries.

We urge the Office to take a leadership role in working with the legislative and executive branches of government to communicate the potential problem caused by the recent Supreme and Federal Court decisions relating to abstract ideas, natural phenomena, and laws of nature. That is: How can personalized medicine be fast-tracked when the patents protecting the discoveries are neither granted nor enforceable? How can the Obama administration deem personalized medicine as so important as to “lay the foundation for a new generation of lifesaving discoveries,” when, at the same time, the uncertain patentability of such inventions has
decreased the incentive for the pharmaceutical industry to invest in this field? The same is true for antibiotics.

Without the Office narrowly interpreting the case law relating to §101 with respect to personalized medicine and antibiotics, personalized medicine and new antibiotics are in danger, which is in direct contrast to President Obama’s and Congress’ mandate to focus energy and resources in these areas.

V. The Office Should Narrowly Interpret the Case Law

Alice, Myriad, and Mayo were narrow decisions, and the Office should allow the courts to incrementally determine, over time, what should not be patent-eligible subject matter, rather than attempting to affirmatively delineate the scope of patent-eligible subject matter, thereby risking excluding whole classes of inventions, including prospectively excluding deserving but yet-to-be discovered technology. The Section fears that the Office may be improperly excluding from patent-eligibility many important diagnostic, nature-based products, computer-implemented, software, and/or business method inventions, which would otherwise allow many new businesses to flourish.

The Section lauds the Office’s efforts to revise its guidance in view of ever publishing case law. For instance, the Office included DDR Holdings, LLC, v. Hotels.com in the Interim Guidance and only incurred a minor delay. The Office should continue to make future guidance flexible to implement changes in the law as to the law will surely continue to evolve.

VI. The Basis of Rejecting a “Fundamental Economic Practice” Should Be Its Long and Prevalent Use

Rejections from the Office must rely on substantial evidence as per the Administrative Procedure Act. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000), and 5 U.S.C. § 556(d). The Board may not take official notice that an alleged abstract idea is “common knowledge” or “a fundamental economic practice” without citing to documentary evidence in the record and providing appropriate reasoning. Relying on subjective determinations of what has been in long and prevalent use will cause inconsistency due to what examiners might think is abstract, unless they identify objective evidence. Again, an abstract idea is “a fundamental truth; an original cause; a motive,” not just common knowledge or known business or transactional practices. Indeed, even considering the use of “official notice” leads more to an analysis under 35 U.S.C. §§ 102 and/or 103 with respect to patentability, not patent eligibility.

The Supreme Court cited documentary evidence of the long and prevalent use of abstract ideas in both Bilski and Alice. The case law does not support the Office taking official notice that a claim recites a fundamental economic practice. Many rejections issuing now provide no support for a determination that a claim is directed to or recites a fundamental economic practice. Claim 7 of the January 2015 example claims posted by the Office is representative. While potentially reaching the correct result, the analysis makes the following conclusory, subjective statement: “This describes the creation of a contractual relationship, which is a commercial arrangement involving contractual relations similar to the fundamental economic practices found by the courts to be abstract ideas (e.g., hedging in Bilski).” As previously explained, the Supreme Court did
not permit the Office to reject claims simply because they are similar to fundamental economic practices. To reject a fundamental economic practice as not patent eligible, the Office must demonstrate that the alleged abstract idea is a fundamental truth; an original cause; a motive. Simply stating a process has been long known is not the same as rejecting the claim as being “directed to” a fundamental truth.

The Office should construe past precedent narrowly and consider each claim on its own merit. Of course, while past precedent guides us in determining whether a claim might be patent eligible, simply analogizing a claim to a court-canceled claim is insufficient. Therefore, once again, the Office must provide substantial evidence that claims are not patent eligible, and their similarity or dissimilarity to court-canceled claims, while potentially assisting in the analysis, is not dispositive on the issue of patent eligibility.

The Section is concerned that, while useful, examiners may reject claims simply because they are similar to claims previously canceled by courts. Example claim 5 recently published by the Office is representative. This claim recites, “capturing, transforming or rendering an image” by using a series of mathematical algorithms for processing data, such as “measured chromatic stimuli.” Humans, by themselves, cannot perform this claim. The specification expressly states, that the recited “digital image reproduction system” is computer implemented. The fact that the claim uses a mathematical algorithm or whether it is similar to the claims in Benson is not dispositive. The claim comes from the case Digitech Image Tech., LLC v. Electronics for Imaging, Inc. 758 F.3d 1344 (Fed. Cir. 2014). In that case the rationale for canceling the claim included that the claim was not tied to a machine, and therefore recited a mathematical algorithm per se, and was therefore ineligible. The Office should make clear that the claim was not tied to a machine. The court did not reach the issue of whether positively reciting hardware would have then made the claim patent eligible. Example claim 2 is quite similar to example claim 5, except that example claim 2 positively recites a processor and memory. Therefore, the Office should emphasize the requirement for positively reciting hardware in its analysis of example claim 5.

VII. Claims Reciting Computer-Implemented Methods without Non-Computer Analogs Are Patent Eligible

DDR v. Hotels.com held that a claim is patent eligible if “the claimed solution is necessarily rooted in computer technology to overcome a problem specifically arising in the realm of computer networks.” Slip op. at 20. The court further stated, “[a]lthough the claims address a business challenge (retaining website visitors), it is a challenge particular to the Internet.” Id. at 19. Therefore, claims directed to processes focused on a technological problem with a technological solution, such as “retaining website visitors that, if adhering to the routine, conventional functioning of Internet hyperlink protocol, would be instantly transported away from a host's website after ‘clicking’ on an advertisement and activating a hyperlink,” should be patent eligible. Id. at 20.

As with other § 101 cases, examiners should not rest their analysis solely on a comparison between claims under examination and the claims at issue in DDR; however, DDR nonetheless provides important clues as to which claims are patent eligible. For instance, DDR held that claims are patent eligible if “they do 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…”
as such an application may be considered “insignificant post-solution activity.” Id. Even though
the invention relied on conventional computer equipment, as the dissent pointed out, the claims
were still patent-eligible. Id. dissent at 3 and 5. Therefore, generic computer equipment may be
used to implement what is unconventional and not routine.

The case law on patent eligibility is changing rapidly, and, unfortunately, the balance of cases
currently skews towards ineligibility. It appears that the identification of an abstract idea,
whether the claim is directed to the abstract idea, and whether “significantly more” is included in
the claim naturally leads to the easiest, although potentially incorrect, conclusion that the claim is
not patent eligible. DDR is the only case from the Federal Circuit finding a claim to be patent
eligible after Alice. As such, until we receive further guidance, the Office should focus on its
holding to resolve the current impasse that patent applicants and examiners face. A well-
functioning patent system is one in which all stakeholders understand the law and disagreements
can be minimized. The Office should rely on DDR to instruct examiners, as discussed above, that
a claim is patent eligible if “the claimed solution is necessarily rooted in computer technology to
overcome a problem specifically arising in the realm of computer networks.” Id. at 20.

VIII. The Examiner Has a Burden to Establish a Rational Underpinning for a Prima
Facia Case, Evidence of Novelty and Non-Obviousness Strongly Supports Patent-
Eligibility

Examiners should not issue boilerplate rejections that a claim simply recites an abstract idea and
does not recite anything significantly more than the abstract idea. Examiners should specifically
identify the type of ineligible subject matter of the claim, e.g.,

- mathematical algorithms, including those executed on a generic computer. Benson, 409
  U.S. at 64.

- fundamental economic and conventional business practices. See Bilski, 130 S. Ct. at 3231
  (finding the “fundamental economic practice” of hedging to be patent ineligible); Alice,
  134 S. Ct. at 2356 (same for intermediated settlement).

- using a computer to send and receive information over a network in order to implement
  the abstract idea of creating a “transaction performance guaranty.” buySAFE, Inc. v.
  Google, Inc., 765 F.3d 1350, 1355 (Fed. Cir. 2014).

- “generalized software components arranged to implement an abstract concept [of
  generating insurance-policy-related tasks based on rules to be completed upon the
  occurrence of an event] on a computer.” In Accenture Global Servs., GmbH v. Guidewire
  Software, Inc., 728 F.3d 1336, 1344–45 (Fed. Cir. 2013)

- use of a computer “employed only for its most basic function, the performance of
  repetitive calculations,” to implement the abstract idea of managing a stable-value
  (U.S.), 687 F.3d 1266, 1278 (Fed. Cir. 2012).
Examiners should identify express claim language in their rejections to demonstrate that the claim is indeed directed to an abstract idea. The examiner must also analyze the claim as a whole by specifically addressing each claim limitation and whether it adds something “significantly more” than simply claiming the patent-ineligible concept.

Furthermore, if an examiner determines that a claim is directed to a fundamental economic practice that is long prevalent in use, the examiner should identify corresponding evidence of the long and prevalent use, as the Supreme Court did in Bilski and Alice. Bilski, 130 S. Ct. at 3231 and Alice, 134 S. Ct. at 2356. The Section recommended that the Office require such evidence in its comments on the preliminary guidance on Alice, and maintains that as a best practice as required by the Administrative Procedure Act. 5 U.S.C. § 556(d).

Examiners must consider applicant’s rebuttal evidence, and should recommend claim language that can be added to overcome a § 101 rejection. For instance, if the applicant can amend the claims to remove any semblance of a “brick and mortar” embodiment, the claim might then become patent eligible. DDR, slip. op. at 21. Applicants can similarly rebut a rejection under § 101 if they are able to demonstrate that the claims are inapplicable to a “brick and mortar” context, which must be more than simply reciting a computer.

IX. Computer-Implemented Example

A. Data Encryption

Background

The method recites encrypting data sent from a computer using a bandwidth optimizer. The method uses the AES key wrap algorithm, but is capable of performing the algorithm at a faster rate than previously possible due to the bandwidth optimizer. The AES key wrap specification can be found at this link: http://csrc.nist.gov/groups/ST/toolkit/documents/kms/key-wrap.pdf and is illustrated below:

![AES Key Wrap Specification at 3, (2001).](image-url)
Embodiments of the claims include performing bandwidth optimization before performing the AES Key Wrap algorithm. Bandwidth optimization includes, for example, dropping packets targeting unapproved websites, such as social media websites or shopping websites. Businesses may choose to block such websites because they are not business-related. The method can be performed entirely in software or can be implemented in application specific hardware. The embodiments can perform encryption more quickly because they drop a sufficient number of packets that they do not have to perform the encryption algorithm on each packet.

Claim

1. A method of securing network communication at a high speed comprising:
   receiving packets at a router;
   decoding, at the router, the packets to determine a destination address for each packet;
   comparing, at the router, the destination address of each packet to a table of destination addresses;
   dropping, at the router, each of the packets that has a destination address that matches a destination address of the table;
   forwarding, at the router, each of the packets that does not have a destination address that matches a destination address of the table to an AES key wrap module;
   encrypting, at the AES key wrap module, each of the forwarded packets at an AES key wrap encryption algorithm; and
   transmitting the encrypted packets.

Analysis

Claim 1: Eligible

The claim is directed to a method of securing network communication at a high speed. Thus, the claim is directed to a process, which is one of the statutory categories of invention. (Step 1: YES).

The claim is then analyzed to determine whether it is directed to any judicial exception. In that regard, the claimed invention relates to software technology for dropping packets destined for predetermined websites. But, such action does not match an abstract concept, or a concept similar to those found by the courts to be abstract, such as a fundamental economic practice, a method of organizing human activity, an idea itself (standing alone), or a mathematical relationship. Even assuming the claim recites abstract ideas of comparing destination addresses and performing an encryption algorithm, all of which can be performed without a computer or software, the invention does not preempt any abstract ideas because it requires improves the technology of routing and encrypting network packets on a computer using software. Humans
are capable of performing the comparing and encrypting algorithms using pen and paper; however, it would be impractical and not useful to have humans perform this method as they would be inefficient. Furthermore, the claim is expressly tied to a specific machine, and therefore humans can perform this method without infringing the claims. Accordingly, the claim is not directed to any judicial exception (Step 2A: NO).

X. The Interim Guidance Completely Lacks a Discussion of Diagnostic-Type Discoveries

The Section encourages the Office to provide further guidance containing examples relating to diagnostic-type claims. There is not one example in the Interim Guidance, or the January 2015 materials, relating to diagnostic discoveries, despite this being one of the most impacted sectors of the life sciences community.

The Section supports that a new and useful process is not patent ineligible solely because it is based upon one or more scientific principles or natural phenomena. The Office should provide further guidance making clear that methods for diagnosing diseases are not excluded as a class from patent eligibility.

For example, methods for diagnosing disease using specific reagents that do not prevent the public from all uses of the judicial exception are patent eligible. For instance, the Office should consider whether a method for diagnosing a disease using specific reagents is patent eligible, possibly under the streamlined analysis for eligibility, where including the specific reagent in the claim makes it clear that the claim does not “tie up” all uses of the judicial exception. See, for example, the following hypothetical claim:

Hypothetical Claim: A method for diagnosing a patient as having degenerative disease X, comprising testing [or “ordering a test”] for the presence of misfolded protein P in a sample from said patient by contacting said sample with reagent R, and diagnosing the patient as having degenerative disease X if misfolded protein P reacts with reagent R.

One possible analysis of this claim is that the natural phenomenon is the correlation between misfolded protein P and disease X. The inclusion of reagent R in the claim makes clear that the claim does not “tie up” the entirety of the judicial exception because others could detect the correlation any number of ways except in the limited circumstance of using reagent R. The claim is thus patent eligible under the streamlined analysis for eligibility.

Likewise, the Office is encouraged to provide further guidance making clear that methods for diagnosing diseases and treating such diseases do not tie up the entirety of the judicial exception, and are therefore patent eligible. For example, consider the following hypothetical claim X.

Hypothetical Claim X: A method for diagnosing and treating a patient as having degenerative disease X, comprising testing [or “ordering a test”] for the presence of misfolded protein P in a sample from said patient, diagnosing the patient as having degenerative disease X if misfolded protein P is determined to be present in the sample, and treating the patient with compound C.
One possible analysis of this claim falls under the “streamlined analysis for eligibility.” The natural phenomenon provided in this claim is the correlation between misfolded protein P and disease X. The claim clearly does not tie up all uses of the judicial exception, because it provides a further treatment step – others are free to take advantage of the natural phenomenon to diagnose the disease, the claim being limited by the additional step of treating the diagnosed patient. The administration step is an application of the correlation. Note that this claim differs from the fact pattern on Mayo v. Prometheus, where there was no recited step of administering a treatment post-diagnosis.

If it were determined that this claim is not eligible for the “streamlined analysis,” the claim would still be deemed patent eligible. Under step 2B of the Interim Guidance, the administration step, when viewed in the context of the entire claim (as is required), amounts to significantly more than the judicial exception, which does not contemplate treatment. Indeed, the treatment is a patentable application of the knowledge gained from assessing the correlation of misfolded protein P and disease X.

XI. Conclusion

The ABA welcomes the opportunity to work with the USPTO and the Office of Policy and International Affairs in its development of advice to the executive branch related to patent eligibility. These comments focus on the Office’s Interim Guidance, but the Section is working in parallel to develop recommendations on what, if anything, Congress should do to clarify the law on patent eligibility.

Sincerely,

Lisa A. Dunner
Section Chair
American Bar Association
Section of Intellectual Property Law

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ii Post-Alice Exam Stats In Software Art Units: A Bleaker Road, Kate Gaudry, Law360 (October 3, 2014).
ixi Bilski, 130 S. Ct. at 3231 and Alice, 134 S. Ct. at 2356.
ixiii Bilski, 130 S. Ct. at 3231 and Alice, 134 S. Ct. at 2356.