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kira.alvarez@americanbar.org

AMERICAN BAR ASSOCIATION

March 7, 2019

Hon. Andrei Iancu
Undersecretary of Commerce for Intellectual Property and
Director
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Via email: Eligibility2019@uspto.gov

**Re: Request for Comments on 2019 Revised Patent Subject Matter
Eligibility Guidance**

Dear Director Iancu:

I write on behalf of the American Bar Association Section of Intellectual Property Law (“Section”) to provide comments on the “2019 Revised Patent Subject Matter Eligibility Guidance” (“Guidelines”) in response to the request of the United States Patent and Trademark Office (the “USPTO”) 84 *Federal Register* 50 (January 7, 2019). The views expressed herein are presented on behalf of the Section of Intellectual Property Law. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

The Section appreciates your efforts to bring increased clarity, certainty and predictability to the patent system and sees these revised Guidelines as an important step in achieving those goals. Specifically, the Section believes that these Guidelines provide a sound basis for applying recent U.S. Supreme Court jurisprudence to the patent examination process at the USPTO.¹ We support the general approach that the USPTO has taken in determining whether a patent claim is “directed to” a judicial exception by focusing on whether a practical application is claimed as that approach is consistent with the historical concerns of the Supreme Court’s jurisprudence, that is, whether a claim is written in a way

¹ See *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1296-97 (2012).

that precludes or pre-empts the judicial exception itself.² As you are aware, the Section’s recognition of the Supreme Court’s pre-emption concerns, which can be found in virtually all Supreme Court precedent since the adoption of section 101 in the 1952 Patent Act, is an important aspect to the Section’s legislative proposal to amend 35 U.S.C. §101 to rectify the uncertainty and lack of predictability in current subject matter eligibility jurisprudence.³

More specifically, we provide comments about a few particular provisions in the Guidelines, including (1) the identification of three groupings of abstract ideas; (2) the lack of a clear statement as to the supporting evidence required to sustain an examiner’s contention, across any of the three groupings used to define the scope of abstract ideas, that the claim limitations at issue cover an abstract idea, including whether the supporting evidence must specifically comply with 37 CFR 1.104(d)(2); (3) the notion that a practical application must impose a “meaningful limit on the judicial exception”⁴; (4) lack of clarity with respect to the differences between steps 2A and 2B in performing the USPTO’s Subject Matter Eligibility Guidance (including the use of the “significantly more” test); and (5) unclear instructions to examiners as to whether they need to apply the claim language itself (as a whole) or only elements or combinations thereof (which might allow for a subjective recharacterization of the claim into more general “elements”), in making the subject matter eligibility determination..

(1) Groupings of Abstract Ideas

The Section appreciates that the Guidelines present an improvement in subject matter eligibility procedure by helping to define the subject matter that falls within a judicial exception, particularly the “proper scope and application of the ‘abstract idea’ exception.”⁵ The Section supports the Guidelines’ establishment of groupings of subject matter that fall into the “abstract idea” judicial exception. This structure provides useful direction to examiners as to how to analyze claims in an area that has become a barrier to patent eligibility for many inventions. The creation of these “groupings” is also an elegant manner with which to implement the Federal Circuit’s case law that seeks to interpret the Supreme Court’s “abstract idea” exception.⁶ However, while the groupings

² See, e.g. *O’Reilly v. Morse*, 56 U.S. 62 (1853).

³ Included as an attachment.

⁴ 84 Fed. Reg. 50, 53 (Jan.7, 2019).

⁵ *Id.* at 50.

⁶ E.g. *SAP America, Inc. v. Invest Pic, LLC*, 891 F.3d 1161 (Fed. Cir. 2018); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 785 F.3d 1344 (Fed. Cir. 2014); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F. 3d 1266 (Fed. Cir. 2012); *Inventor Holdings, LLC v. Bed, Bath & Beyond, Inc.*, 876 F. 3d 1372 (Fed. Cir. 2017); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 967 (Fed. Cir. 2009); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014); *In re Ferguson*, 558 F.3d 1359

in Section I of the Guidelines are a good start toward clarification of what constitutes an abstract idea under current case law, as the USPTO no doubt appreciates some of the listings within the groupings are subject to their own risks of ambiguity and subjective evaluation (such as the list of “methods of organizing human activity”). These risks are largely a creation of current case law for which it is unlikely any Guidance from the USPTO can provide an effective remedy. However, as the USPTO gains practical experience in applying these groupings, we recommend that the expression of these groupings over time be subject to the iterative process for refining these Guidelines as referenced on page 51 in the Guidelines. We agree that these groupings, in particular, will require refinement over time.

(2) Lack of a clear statement as to the supporting evidence required to sustain an examiner’s contention, across any of the three groupings used to define the scope of abstract ideas, that the claim limitations at issue cover an abstract idea

As noted above, the Section generally supports the addition of the three groupings in Section I of the Guidelines that are intended to provide clarity to the concept of “abstract” ideas. In order to further increase clarity, it is important that examiners follow existing regulatory requirements such as 37 CFR 1.104(d)(2), which requires that actions by the Office be as specific as possible and supportable by an examiner’s affidavit (or equivalent).⁷ In that regard, we urge the USPTO to require that an examiner specifically identify the claim limitations that the examiner contends recite an abstract idea that falls under one of the groupings of Section I (including specifically stating that applicable grouping), and further state what the examiner contends the abstract idea is. We also urge the USPTO to include in the Guidelines an express requirement that, in making abstract idea rejections, examiners must follow 37 CFR 1.104(d)(2). While compliance with this CFR might include the citation of evidentiary support to justify an

(Fed. Cir. 2009); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307 (Fed. Cir. 2016); *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314 (Fed. Cir. 2016); *Versadata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306 (Fed. Cir. 2015); *CyberSource Corp. v. Retail Decisions, Inc.* 654 F.3d 1366 (Fed. Cir. 2011); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F. 3d 1138 (Fed. Cir. 2016); *In re BRCA1 & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014).

⁷ 37 CFR 1.104(d)2: “When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.”

examiner's contention,⁸ the Section is cognizant of the need to avoid turning the 101 examination into a prior art investigation that would be more appropriate for an analysis of 102 and 103. Nevertheless, it is important for the USPTO to be prepared to back up abstract idea contentions at least to the extent required by current CFRs such as 1.104(d)(2).

(3) Imposing a “meaningful limit on the judicial exception”

The Guideline's instruction that “a claim is not ‘directed to’ a judicial exception, and thus is patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of the exception”⁹ is a welcome recognition by the USPTO of the important distinction between an ineligible judicial exception and an eligible practical application of the exception. The Guidelines then set out how examiners evaluate whether the claim provides a meaningful limit on the judicial exception (*i.e.*, the claim integrates the exception into a practical application of that exception) with reference to additional elements.¹⁰

While we appreciate that Section III (A)(2) of the Guidelines provide “exemplary considerations” and particular examples where courts have found application of these principles, we remain concerned that this test remains incomplete and as a result too unpredictable. The test is incomplete because the critical consideration under Supreme Court precedent is whether a claim is written in a way that pre-empts the judicial exception.¹¹ However, even though the courts have consistently stated that the philosophical basis for its patent eligibility jurisprudence is the concern about pre-emption, we recognize that the courts have not yet adopted that basis as the test for patent eligibility. Thus, we further recognize that the Office may be of the view that it is

⁸ In fact, the Supreme Court, in both *Alice*, 573 U.S. 208, 219-220 (2014) and *Bilski v. Kappos*, 561 U.S. 593, 611 (2010), provided evidentiary support by citing to textbooks to sustain the contention that the claims at issue embodied “fundamental economic principle[s]”.

⁹ 84 Fed. Reg. 50, 53.

¹⁰ *Id.* at 54-55. (“Examiners evaluate integration into a practical application by: (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application, using one or more of the considerations laid out by the Supreme Court and the Federal Circuit, for example those listed below.”)

¹¹ The Section's legislative proposal, which is also rooted in this concept, proposes that “a claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility ... under this section ... on the ground that ***the scope of the exclusive rights under such a claim would pre-empt the use by others of all practical applications*** of a law of nature, natural phenomenon, or abstract idea.” *See attached proposal.*

constrained by case law in how it expresses the practical application test of Step 2A. Nonetheless, the test remains subject to the risks of incompleteness and unpredictability.

Respectfully, we continue to believe that the proper question to be asked under Step 2A when assessing whether a meaningful limit on the judicial exception exists is whether the claim as a whole, including the judicial exception and any additional elements, pre-empts the use of the exception in all practical applications. If all uses of the exception are pre-empted, then the additional claim elements are not meaningful limitations.¹² The use of preemption as an initial test will make the assessment under Step 2A more complete and lessen the risk of subjective application of this step. If a claim passes the initial preemption test, any further analysis under Step 2A as provided in the Guidelines could be subject to a presumption that the claim is patent eligible unless one of the examples in the Guidelines of non-integration of a judicial exception into a practical application is directly applicable.

In this regard, the Office should consider referencing specifically the use of functional claim language that incorporates the judicial exception in a way that may result in a claim pre-empting the use of the judicial exception in all applications.¹³ In our view, it is likely that a wholly functional claim integrating a judicial exception may be invalid under *O'Reilly v. Morse* and *Halliburton*, unless section 112(f) is applicable to limit the functional language to disclosed structure plus equivalents (practical applications to specific application of the judicial exception).¹⁴

(4) Lack of clarity with respect to the differences between steps 2A and 2B in performing the USPTO's Subject Matter Eligibility Guidance

In addition, while we are supportive and welcome the Guidance on how examiners will perform the Step 2A analysis to determine whether a claim is directed to a judicial exception, Step 2B provides a less objective analysis than Prong Two of Step 2A. While the subsequent application of Step 2B provides another opportunity for a claim to

¹² As noted in the Guidance, examples of additional elements that would not meaningfully limit the scope of the claim, include “apply it”, perform on a computer, or other insignificant extra solution. 84 Fed. Reg. 50, 55.

¹³ For example, the judicial exception in *Mayo* was the natural correlation between the blood metabolite 6-thioguanine and efficacy. Notably, the drug was defined functionally by its ability to generate the natural metabolite, 6-thioguanine (“a drug providing 6-thioguanine”), such that the claim sought to pre-empt any thiopurine drug that might be used. *Mayo*, 566 U.S. at 74-75. In contrast, the claims in *Vanda* are directed to a specific drug, iloperieon, to treat schizophrenia. The dose of the drug is a specific, practical application of the natural CYP2D6 metabolism. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1135.

¹⁴ *O'Reilly v. Morse*, 56 U.S. 62 (1853); *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

avoid a finding of ineligibility in those instances where a claim does not pass the Step 2A analysis, it does so with an ambiguous subjective “significantly more” test for an inventive concept. However, we recognize that, despite the ambiguity of Step 2B, Step 2B may be required simply because current case law calls for the use of this test in the manner generally set forth by the USPTO. For that reason we are reluctantly supportive of the need to keep Step 2B to address the (hopefully rare) circumstances for which it may be necessary.

(5) Ambiguity regarding the need to review the claim language itself (as a whole) or only elements or combinations thereof

We are concerned that as currently structured it is not clear that examiners must look at the claim language itself (as a whole) in making the step 2A determination. While the Guidelines affirmatively instruct examiners to evaluate “whether the claim as a whole integrates the recited judicial exception in a practical application,”¹⁵ and in fact, footnote 24 states that “whether an additional element or combination of elements integrate the exception into a practical application should be evaluated on the claim as a whole,”¹⁶ the Guidelines create potential confusion by further providing additional considerations for the step 2A determination. Namely, instead of just focusing on claim language itself the Guidelines provide that “an additional element (or combination of elements) may have integrated the exception into a practical application.”¹⁷ This creates ambiguity as to whether the examiner should be reviewing the words of the claim or only “elements” of it. The latter creates the risk that examiners are being invited to subjectively recharacterize parts of the claim as elements rather than strictly applying the language of the claims. We urge the USPTO to make clear that the Step 2A determination must be made based on the claim language itself as a whole.

Overall, the Guidelines are a significant improvement in the examination of patent eligibility by providing a greater degree of certainty and increased predictability in subject matter eligibility determinations at the USPTO. We understand that these Guidelines, however, do not constitute substantive rulemaking and thus do not “have the force and effect of law.”¹⁸ While the day may come when substantive rulemaking may be appropriate, the nature of the jurisprudence on patent eligibility is such that it is difficult to predict whether that day may ever arrive. This is why the Section strongly supports efforts to enact a legislative amendment to section 101 that resolves the

¹⁵ 84 Fed. Reg. 50,54 (emphasis added).

¹⁶ *Id.* at 55 (emphasis added).

¹⁷ *Id.* at 55 (emphasis added and footnote omitted).

¹⁸ *Id.* at 51.

ambiguity and confusion that has been injected into the eligibility determination by Supreme Court and lower court jurisprudence. Legislative reform is needed to restore predictability to the patent system and maintain incentives to invest in future technologies and discoveries.

Lastly, while as noted above the Section appreciates the clarifications that the Guidelines provide as to the scope and meaning of the “abstract idea” judicial exception, the revisions to the Guidelines do not clarify the scope and meaning of the judicial exceptions applicable to the life sciences industry (laws of nature and natural phenomena). Specifically, the Section urges the Office to consider developing groupings or categories that help define subject matter that falls within the “laws of nature” and “natural phenomena” exceptions. Likewise, when employing these groupings to make a rejection, examiners should be required to identify the judicial exception, to identify the claim limitation(s) that recite the exception, and to back up ineligibility assertions at least to the extent required by the current regulations. Finally, throughout the Guidance the Office should consider increasing the number of examples that focus on life sciences inventions. In general, the Section urges the Office to develop guidelines that increase clarity, certainty and predictability for all of the judicial exceptions and across all impacted industries.

As always, the Section appreciates the opportunity to comment on important developments, and thanks the USPTO for the invitation to submit these comments. We would be pleased to further discuss these comments with you and others as appropriate.

Very truly yours,

A handwritten signature in black ink that reads "Mark K. Dickson". The signature is written in a cursive, slightly slanted style.

Mark K. Dickson
Chair, ABA Section of Intellectual Property Law

Attachment

Current Statutory Language:

§101. Inventions patentable

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.

ABA IPL Section Proposal:

§ 101. Conditions for patentability: eligible subject matter.

(a) Eligible Subject Matter.- Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.

(b) Exception. - A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.