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Via email only: 2014_interim_guidance@uspto.gov

Ms. Michelle Lee
Undersecretary of the Department of Commerce and
Director of the USPTO

Dear Undersecretary Lee:

In response to the USPTO's request for comments concerning the July 15, 2015 Guidance on Section 101 (the "Guidance"), please consider the comments below. The views expressed represent those of Borson Law Group, PC.

1. The key Supreme Court cases cited in the Guidance are (1) *Bilski v. Kappos*, (2) *Mayo v. Prometheus*, (3) *Alice v. CLS Bank*, (4) *AMP v. Myriad*, and (5) *Diamond v. Diehr*. Other than *Diamond v. Diehr*, these Supreme Court Decisions provided no workable, objective standards for determining patent eligibility. In *Mayo*, for a claim drawn to a relationship between a drug metabolite and the need to adjust the dose of administered drug (considered a "natural law"), the Court required "substantially more," "markedly different," or "inventive concept" than the "natural law."

In the more recent *Alice* decision, the Court further promulgated the same vague standards for eligibility of what are termed "Abstract Ideas." However, the Court provided no definition of the term "Abstract Ideas." The USPTO has followed suit, requiring the same subjective, vague standards to meet patent eligibility. In contrast to *Mayo* and *Alice*, the *Diehr* court held the application of a law of nature to be patent eligible because it was "new and useful." The USPTO has departed from the relatively well known "new and useful" standard in favor of the subjective analysis articulated by the Supreme Court. Because the meanings of those standards are difficult to ascertain, the Guidance provides little objective understanding of the law, and leaves patent applicants and patentees without sufficient, usable guidance for either prosecuting applications or defending against PTAB post grant proceedings.

In *Mayo*, the Court stressed that the judicial exceptions should be applied rarely and narrowly. More recent decisions by the Federal Circuit and district courts have expanded the "narrow application" of section 101 to exclude wide areas of innovation (e.g., *Ariosa v. Sequenom*). We believe this trend to be highly detrimental to the essential purposes of the Patent Statute, "to promote the useful arts." In particular, some of the most significant advances in medicine involve determining whether particular patients might be harmed by a particular therapy, and in other cases, whether certain patients would benefit from a particular therapy. That is, these advances are in the burgeoning field known as "personalized medicine." Although many of the advances in personalized medicine have involved analysis of patient specific biological properties, patent claims, including those in the *Sequenom* and *Prometheus* patents considered to be "directed to" laws of nature have either failed to issue or been invalidated.

These newer decisions represent a trend towards denying patent eligibility for "discoveries." This trend is difficult to understand, given the Constitutional provision in Article I. Section 8, Clause 8,

that permits patents to be granted in the "useful arts to inventors for their ... discoveries." We believe that in 1789, the definition of "discovery" was the same as today, to mean to "uncover," or "reveal." Denying patent eligibility broadly undercuts the economic value of applications of discoveries, particularly related to health care.

In *Bilski*, *Mayo*, *AMP* and *Alice*, the Court simply held that the claims at issue were ineligible because they were "directed to" Abstract ideas (*Bilski* and *Alice*), or to "Laws of Nature" (*Mayo* and *AMP*), and the claims did not provide "significantly more," were not "markedly different," or included an "inventive concept" in addition to the allegedly ineligible subject matter. The USPTO has not defined what is meant by the term "directed to," and apparently is denying patent eligibility for any claim that recites or "includes" a judicial exception.

The claims at issue in *Bilski*, *Mayo*, *AMP* and *Alice*, were not "close." In both *Bilski* and *Alice*, the Court noted the claimed process to be previously widely used, and therefore, the claims could have been invalidated under 35 U.S.C. Sections 102 or 103 either as not novel or as obvious. Similarly, in *Mayo*, the Court noted the claimed process had been previously carried out by medical practitioners, and that the claim held invalid was only directed to certain "threshold amounts" of the drug metabolite being measured. Interestingly, the *Mayo* Court did not address an important question 'if the Prometheus claim is a "natural law" (namely the particular thresholds claimed), how could it be that Mayo's different thresholds were not also 'natural laws'. This leads us to wonder, "which of these 'laws' is the 'true' Natural Law?"

In *AMP*, the Court held 'isolated human genes' to be ineligible 'products of nature', but that complementary DNA (cDNA) was not ineligible because cDNA is an eligible, synthetic 'manufacture'.

In each of these cases, the Supreme Court cautioned that these holdings were narrow, and based 'on the claim at issue', and any consideration of a judicial exception to patent eligibility should not be over-applied.

In *Diamond v. Diehr*, the Court held the claim eligible because the claim was directed to a 'new and useful' process. This 'new and useful' standard is currently incorporated into 35 U.S.C. Section 101 as renewed in 2011 without amendment by Congress in the America Invents Act.

For the claims held ineligible under Section 101, the Court's recent decisions did not follow *Diehr's* standard of 'new and useful' but rather applied an indefinite and poorly articulated set of analytical tools. Lower courts have been reluctant to clarify what is meant by the phrases 'significantly more', 'markedly different', 'inventive concept', and 'routine, conventional and well-known', leaving the USPTO, patent applicants and patentees with little guidance.

We believe the lower courts and the USPTO have overemphasized the judicial exceptions to the point of holding any invention 'involving a judicial exception' to be *per se* ineligible. The approach urged in the recent USPTO Guidance, to provide Examiners with the authority to assert subject matter ineligible without making a *prima facie* case based on evidence. In our view, this approach represents a significant expansion of USPTO power, and may represent substantive rulemaking, which may be in violation of the Administrative Procedures Act (APA).

The *Diehr* standard has not been overturned or declared unconstitutional by the Supreme Court. Quite the contrary, in subsequent cases (e.g., *Mayo*, *Alice*, *AMP*), the Court cited *Diehr* for the proposition that use of an abstract idea (e.g., the Arrhenius equation) did not automatically render the claim ineligible. It was the use of other manufacturing methods (cure time in a rubber mold, and automatically opening the mold when the rubber was cured) that demonstrated an 'inventive concept'

sufficient to impart patent eligibility to the claims. In *Diehr*, the Court did not "dissect" the claim into the "exception" and "everything else," but rather considered the claim as a whole. It is unclear if the Supreme Court would have reached the same decision if it had dissected out the Abstract Idea and considered only the remaining elements. We believe that the mold, compositions of rubber, temperature and other features of the claim may not have been patentable, based on prior art, independently of the Arrhenius equation.

Because the Constitution recites the same standard in Article 1 Section 8 Clause 8, we believe it would be very difficult for the Supreme Court now to explicitly declare *Diehr* unconstitutional. Accordingly, the decisions (*Mayo, Alice*) by the Supreme Court would appear to be in conflict with Diehr. These conflicts remain.

This conflict should be resolved through patent cases coming up from the USPTO, and through district courts and the Court of Appeals for the Federal Circuit. We encourage the USPTO to grant patents that could present close questions of 101 patent eligibility.

The reliance upon 'pre-emption' has been over stressed. The Supreme Court held it to be impermissible to 'pre-empt the entire field' [of the judicial exception]. However, according to the Patent Act, any valid patent claim pre-empts others from making, using, selling, offering for sale, or importing the claimed invention. Therefore, the scope of 'pre-emption' is properly analyzed under 35 U.S.C. §§112(a), 112(b) and 112(f). If a claim is 'over broad', vague, or insufficiently supported under any of those sections, it can be invalidated under §112. Because every patent claim 'preempts' others from practicing the proper scope of the claim, any argument about preemption should be couched in terms of §112.

Attempts to circumvent §112 through an *a priori* conclusion of 'preemption' are, in our opinion, not helpful. Some cases from the Federal Circuit have applied §101 to avoid having to consider other portions of the Patent Statute. Although this approach may appear to conserve scarce judicial resources, it is, misplaced and does not contribute to clarification of patent eligibility. We believe it to be better for courts to carefully consider all aspects of the Patent Statute in determination of claim eligibility and validity.

2. The "Guidance" documents prepared by the USPTO have made some limited strides towards predictable standards. Unfortunately, the revised Guidance remains overreaching, and still does not provide sufficiently clear standards. The use of examples of claims considered by the USPTO to be 'eligible' is helpful, but does not go far enough to clearly distinguish 'eligible' from 'ineligible' subject matter, especially in close cases.

Reliance upon the vague standards articulated in the Supreme Court decisions does not provide the needed clarity. In particular, the USPTO's reliance upon the phrases 'inventive concept', 'significantly more', 'markedly different,' 'conventional, routine, and well-known' adds little clarity. Further, the USPTO apparently does not acknowledge that 'inventive concept' is intimately related to obviousness under Section 103 of the Patent Act.

We believe focusing upon an undefined 'inventive concept' as a test for patent eligibility is similar to the older, now discarded concepts of 'flash of genius', and 'gist of the invention'. Those standards were appropriately discarded, at least in part, because it was (and still is) impossible to identify what is a 'flash of genius' or 'gist'. It was difficult to use those standards because they were not subject to supporting evidence. The United States court system and Patent Statute have evolved to apply 'rules of law', and 'evidence'.

The July 2015 Guidance appears to overturn "evidence-based" analysis and permits an Examiner to reject a patent claim for 'ineligibility' without providing evidence sufficient to make a *prima facie* case. The initial guidance of 2014 instructed an Examiner to make a valid *prima facie* case for ineligibility. The reasons for the apparent change in the new Guidance is unclear.

We urge the USPTO to retain a requirement for Examiners to present a complete *prima facie* case for patent ineligibility, and including sufficient evidentiary support. An evidence based conclusion is founded in the Patent Act itself. Section 102 begins with the phrase, "a person is entitled to a patent unless..." We believe this phrase places an initial burden on the USPTO to provide evidence that a claim is ineligible. Making a non-evidence based rejection improperly shifts the burden on the patent applicant to refute or rebut the rejection with evidence. We believe such a shift of burden is not proper under the Patent Act.

The USPTO should not train Examiners to reject a claim without evidence based on a simple allegation of ineligibility. We are concerned that the absence of a requirement for the Examiner to make a *prima facie* case for ineligibility coupled with any attempt to move examination of 'inventive concept' (obviousness) into 101 instead of its proper place under 103 will be used as a fast track for rejection of inventions simply based on an Examiner subjective belief of a lack of 'inventive concept'.

Further, permitting the USPTO to reject a claim without making a *prima facie* case for ineligibility may violate the APA. The APA permits agencies to promulgate 'procedural rules', but not 'substantive rules'. The Courts are able to provide 'Chevron deference' to agency rulemaking if the rulemaking is procedural. We believe the Guidance to be either substantive rulemaking or too close to the line distinguishing procedural from substantive rulemaking. If the Guidance represents substantive rulemaking, actions by Examiners may invoke challenges based on the APA resulting in protracted litigation. All parties would agree that this is not in the best interests of the USPTO or the patent community. Recent experience with the 'Claims and Continuation' rules demonstrates some of the problems that may arise.

The Guidance should clearly adhere to the *Diehr* standard requiring the 'claim as a whole' to be considered, instead of the claim limitations being considered 'individually or in ordered combination'. Under *Diehr*, it is impermissible to separate the 'exception' from the remainder of the claim and then to require the remainder to be not only patent eligible, but also to be patentable. Parsing out the 'exception' vitiates the claim. There is ample case law disparaging claim vitiation. All words of a claim are deemed important.

3. Examples provided by the USPTO are helpful, and the new Appendices provide some workable suggestions for addressing Abstract Ideas and Products of Nature. We urge the USPTO to stress the importance in the Guidance to provide examples (hypothetical or real) of cases in which claims including a 'Natural Law' would be held eligible. It is especially useful to provide examples that identify the 'thresholds' for eligibility. The USPTO is to be complemented on this process, and it should continue to refine the standard illustrated by such examples.

4. As an Executive agency, the USPTO should not try to 'divine' the underlying standards as articulated by vague language from the Supreme Court. Rather, the USPTO may use its authority as part of the Executive branch of Government, to issue patents that could be close 101 cases, and not to try to 'out-do' the courts, by rejecting all cases 'involving a judicial exception.' Without relatively close cases being brought forward, the courts will have little opportunity to clarify standards for patent eligibility.

5. With the passage of the America Invents Act (AIA), a new complexity was introduced as 'Post Grant Opposition' ('PGO'), 'Inter partes Review' ('IPR'), and 'Covered Business Methods' ('CBM'). Use of these 'Board Trials' has altered the presumption of validity and the standards for patentability. In court proceedings, claims are presumed to be valid, and can be invalidated only upon a showing of 'clear and convincing evidence'. In court proceedings, claim interpretation is addressed through a claim construction process and a Markman hearing. Under current court standards (e.g., according to *Markman v. Westview* and *Phillips v. AWH*), claim interpretation is carried out based on the evidence in the record and extrinsic evidence if needed.

In contrast with a court's claim construction, the USPTO has replaced the 'clear and convincing evidence' standard to invalidate a claim with the patent examination standard of a 'preponderance of evidence' standard. Further the USPTO applies the patent prosecution standard of 'broadest reasonable interpretation' of a claim. These trends have, in our opinion, undercut the expectations of patent holders and applicants. Even in a litigation context, an accused infringer is permitted to submit a Petition for Inter partes Review to effectively remove issues of claim construction and validity from the court setting to the USPTO. Although those provisions of the AIA were intended to provide an alternative to protracted and expensive litigation, the differences between court litigation and Board Trials has, and will continue to create uncertainty among stakeholders. This change renders a validly issued Ribbon Patent to be merely another prosecution document, and the public loses its ability to rely upon the patent rights granted.

The impact of Board Trials on CBM patents is now clear. According to some commentators, if review under the CBM procedure is authorized by the Director, the probability of a CBM patent being held invalid is very high, possible as high as 90% or event 100%. Many of those cases were invalidated under Section 101, using the USPTO's interpretation of patent eligibility, and the USPTO 'preponderance'standard.

6. The Supreme Court has invited lower courts to further 'refine' standards for eligibility. The USPTO can contribute to this process through ongoing efforts to further refine Guidance, to proffer useable definitions of 'substantially more,' 'inventive concept,' 'markedly different,' and 'conventional, routine, and well-known.' We urge the USPTO to narrowly apply court decisions, and to allow patents, especially in close cases.

7. The impact of the emphasis on patent eligibility on industry and innovation are substantial. Without predictable standards for patenting, innovators are turning away from the patent system altogether, and will instead, rely upon trade secrecy to protect their innovations. This trend is diametrically opposed to one of the key goals of the patent system, to grant patentees with limited rights to exclude others in exchange for a full and complete disclosure of inventions. For certain industries, including those in diagnostics, pharmaceuticals, and biotechnology, the inability to obtain patents will stifle investment, and slow progress in some of the most important human endeavors: to maintain health and to treat or prevent disease.

These adverse consequences of overzealous rejections of 'new and useful' innovations are especially harmful in the diagnostic realm. With improved diagnostic and evaluative methods, necessary innovations include being able to determine whether a particular patient would likely benefit from a particular treatment, or whether such treatment should be avoided due to predicted adverse side effects. These advances in ability to predict outcomes are especially important to 'personalized medicine'. Such advances will help eliminate costly adverse side effects of unnecessary treatments, and will help keep medical costs down by not instituting expensive, unnecessary treatments. These advances will also increase the ability of the medical community to more effectively treat those diseases that cause the highest morbidity and mortality, including cancer.

8. It is for these reasons we urge the USPTO to do the following:

A. Refrain from training Examiner to make arbitrary, capricious or subjective rejections without proper evidentiary and legal support.

B. Train Examiners to provide an evidence-based *prima facie* case of patent ineligibility, including requiring a valid *prima facie* case to be made.

C. Train Examiners to apply patent ineligibility "rarely."

D. Train Examiners to avoid making assertions of ineligibility for lack of 'inventive concept', 'well-known, routine, and conventional' without providing sufficient supporting evidence to permit a patent applicant to provide either 'refuting' or 'rebuttal evidence'.

E. Continue to use its authority and powers to help foster a more viable, predictable guidance for analysis of patent claims under section 101.

F. Apply the Supreme Court's 'new and useful' standard as exemplified by *Diamond v. Diehr*.

G. Train Examiners to analyze claims 'as a whole' and to avoid considering patent eligibility based upon 'individual or ordered combinations of elements'. Train Examiners to avoid claim vitiation.

H. Provide additional examples in its Examiner training materials that address close cases for eligibility for Abstract Ideas, Laws of Nature, and Natural Phenomena.

I. Train Examiners to avoid overreaching application of judicial exceptions.

J. Confirm patent eligibility in close cases.

Reasons for these recommendations are easy to understand. Without an issued patent or final rejection to consider, no court will:

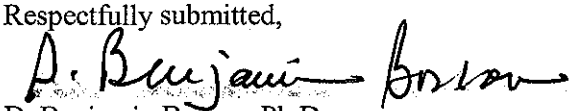
1. have an opportunity to consider validity or infringement;

2. be in a position to clarify standards of patent eligibility; or

3. be in a position to determine the proper meaning and scope of the phrases 'well-known, routine, and conventional', 'inventive concept', 'significantly more', 'Abstract Idea', or 'Law of Nature'. Without further guidance from the courts, the USPTO will have only limited information necessary to properly apply patent eligibility standards.

We thank you for the opportunity to contribute to the USPTO's ongoing efforts to provide clarity on this important issue. We also look forward to further guidance from the USPTO to assist stakeholders of the patent system to 'promote the useful arts.'

Respectfully submitted,



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