

**Comments on New USPTO Guidance of 4 March 2014 for  
Patent Eligibility of Claims Drawn to “Laws of Nature”**

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**April 29, 2014**

**Disclaimer**

The author is a scientist and patent attorney registered by the United States Patent and Trademark Office (USPTO), and represents inventors and companies in the life sciences. The comments that follow are those of the author and do not necessarily represent the views of any other entity or person.

**Introduction**

The purposes of the Guidance as presented in Mr. Andrew Hershfeld’s memorandum of 4 March 2014 (the “Guidance”) and slide set are to train examiners in analysis of patent eligibility under 35 U.S.C. §101. However, the Guidance will become the “de-facto” standards for determining patent eligibility for most innovators and patent applicants. The Guidance and slide set are purportedly intended to implement the Supreme Court’s recent decisions in *Mayo v. Prometheus* (“*Mayo*”) and *AMP v. USPTO and Myriad Genetics* (“*AMP*”).

The goals reflected in these Supreme Court decisions are intended to ensure that patent claims drawn to Natural Laws do not “preempt the entire field” and impose “meaningful limits” to claim scope. Those goals have traditionally been met with the use of prior art under 35 U.S.C. §§102 and 103, requirements for sufficient disclosure under 112(a), specificity of claim terms under §112(b), and the relationship between the claim and the specification as filed under §112. Case law since enactment of 35 U.S.C. has refined these standards to require that Written Description and Enablement be for the full scope of the claim. Under these well-understood standards, problems of over-reaching: “preempting the entire field” and “providing meaningful limits to claim scope” are to be resolved by analysis of the claim and the specification. If a claim is overbroad or indefinite, it can be rejected by the USPTO and binding amendments to the claims can be entered into the application prior to allowance and issue. If an overbroad or indefinite claim is subject to litigation, the court may hold such a claim to be invalid under §112(a).

**Summary**

The new Guidance represents a substantial expansion of and departure from these well-known, well-litigated standards of utility, novelty, non-obviousness and disclosure. Additionally, the Guidance goes well beyond the Supreme Court’s decisions on patent eligibility under §101. Therefore the Guidance goes beyond the Supreme Court standards, and may represent “substantive rulemaking” by the USPTO in contravention of the Administrative Procedures Act (APA). The APA limits agency rulemaking to “procedural” rules, and excludes “substantive rulemaking,” which is left to the Congress. The departure from

§101 as defined by the Court is troubling, and is likely to stifle open and complete disclosure of inventions.

The Supreme Court's decisions, as interpreted by the USPTO to underlie the Guidance represent policy-driven results that change the ways in which patent claims are analyzed but without sufficient consideration of legal precedent. By focusing on patent eligibility as a threshold matter, the Court's decisions and USPTO's proposed Guidance ignore the well-studied precedential opinions by the Supreme Court on §101 and other sections of the Statute. Although the Guidance is purported to implement the Supreme Court decisions, the Guidance goes well beyond Supreme Court decisions, and therefore has substantial problems that should be remedied before they are implemented.

### **General Comments**

1. First, the Guidance does not place analysis of patent eligibility under §101 within the context of prior Supreme Court decisions, particularly *Diamond v. Chakrabarty* and *Diamond v. Diehr*. *Chakrabarty* held that to be eligible subject matter, the creation must have a "substantial different characteristic" compared to the Natural Phenomenon. The Court's use of the word "characteristic" is very different and significantly broader than the Guidance's "substantially different structure." Therefore, the Guidance has ignored the true scope of *Chakrabarty*, and therefore represents a new, substantive change in patent law.

2. The Guidance does not take advantage of or apply the well-used, relatively well-understood framework of §§ 102, 103 and 112 in determining whether claims preempt the entire field and provide meaningful limits on claim scope. By not taking this advantage, the Guidance may lead Examiners to ignore those portions of the statute.

3. The standards articulated by the Supreme Court in *Mayo* and *AMP* are poorly understood and inadequately explained. Many of the Court's comments, especially in *Mayo*, use unusual and vague language, such as "apply it," "integrated," and "insignificant post-solution activity." These terms were not defined by the Court, yet form a substantial basis for the Guidance. Without proper definitions of these and similar terms, the Guidance appears to simply restate the vague terms from the Court, and fails to provide proper guidance for training examiners.

Without clear, consistent training, based on well-articulated eligibility standards, there will be wide variations in application of the Guidance, and result in unpredictable results. The inclusion of examples in the Guidance is helpful, but without more examples, especially those that are close the boundary between what is considered eligible and what is considered ineligible, it is likely that Examiners will simply use their own subjective judgment and are likely to reject many claims under §101 that would, in fact, be eligible. To remedy this likely consequence, I encourage the USPTO to provide examples on both sides of the close issues of patent eligibility.

4. If implemented, the standards proposed will significantly and adversely affect the biotechnology, pharmaceutical, diagnostics industries and are likely to stifle the major purposes of the patent system, namely, to provide limited legal rights to exclude others in exchange for

complete disclosures of inventions. The proposed standards will create more uncertainty and are likely to encourage innovators to rely more upon trade secrecy and not on patents, thus depriving the public of important information.

5. Section 101 is a very “blunt tool” and is not needed to implement the purposes for which the Guidance is intended. The USPTO is tasked with examination of claims of an application, and determining the proper scope and detail needed for patentability. These tasks are carried out by understanding the broadest reasonable interpretation (BRI) of a claim as a whole, searching the prior art, analyzing the claims in light of the prior art and the Statute, and preparing and filing Office Actions, setting forth grounds for patentability or unpatentability. USPTO Examiners are technically skilled and trained to carry out these tasks of searching, analysis of prior art, and applying the claims to the prior art. Examiners are trained on analyzing utility under §101, but have not been trained adequately on patent eligibility under §101.

6. The Guidance is inadequate to address the policy-driven holdings of the Court and providing meaningful training about the vague terms used by the Court. The Guidance articulates a hybrid of both on Supreme Court decisions and USPTO policies. If the underlying policies of the Supreme Court are the sole drivers for the Guidance, then the USPTO would not have expanded the standards beyond the Supreme Court decisions in *Chakrabarty* and *Diehr*.

The key elements of the new standards in the guidance are not defined. The terms “markedly different” and “substantially different structure” (referring to differences between the claimed invention and the Natural Law) are completely undefined and do not instruct Examiners how to use them. Rather, the Guidance merely instructs Examiners to read the Guidance, and “apply it.” This will lead to inconsistency within and between examiners, and will result in increased uncertainty, decreased faith in the patent system, and is likely to produce undesirable and unpredictable responses from innovators.

In *AMP*, the Court held that claims drawn to isolated genomic DNA are ineligible for patenting if the mere fact of isolation defined the invention. The Court’s reasoning rested to a degree on the information content of the genomic DNA, and if the utility of the sequence information was due to the function of the DNA, then the claim would not be patent eligible. In the case of the Myriad patents, the relationship between the existence of mutant BRCA1 and BRCA2 genes was well understood: mutations in those genes are directly related to tumorigenesis.

However, there are many uses of knowledge of genomic DNA and mRNA that are not directly related to the function of the DNA sequence. For example, certain aspects of personalized medicine rely upon the ability to diagnose disease and to predict disease progression through the use of one or more “genetic markers.” In many cases, the markers can be highly useful as diagnostic or predictive tools, even if the functions of the markers is unknown or unrelated to the disease itself.

7. Based on the new Guidance, it may be easy for Examiners to take an “easy way out” of proper and complete examination by simply creating a “threshold” rejection that the claim is ineligible for patenting, and not go through a complete search of prior art and apply §§102, 103,

and 112. If this were to occur, it would represent substantial departure from the long-held precept espoused by the USPTO of “compact prosecution.” This would also not serve the goals of examination, which limit the scope of the claims to only those claims that are novel, not obvious, adequately described, and clear.

8. The standards in the Guidance also represent a departure from Congressional intent in the 1952 Patent Act and the AIA. The statute specifically incorporates the Constitutional power granted to Congress to “promote science and the useful arts” (Article I, Section 8, Clause 8), which permits patents to be granted on both “inventions” and “discoveries.” If the discovery meets all requirements of the Act, it should remain patentable. Although the Supreme Court has apparently ignored this portion of the Statute, in creating “judicial exceptions” to patent eligibility, the legal basis for these exceptions is not based on the Supreme Court’s traditional role of determining whether a Statute or portion of a Statute is in conflict with the US Constitution and therefore is unconstitutional.

To my knowledge, the Supreme Court has never held that any portion of Section 101 of the Patent Act is unconstitutional. Additionally, with the passage of the AIA in 2013, Congress did not amend Section 101 although it had the opportunity to do so. Because Congress did not amend §101, it is uncontroverted that Congress intended to continue its support for patent eligibility of discoveries. It is also uncontroverted that Congress intended to tighten other sections of 35 U.S.C. By amending §102, Congress intended to have the USPTO and the courts apply prior art from additional sources, including foreign disclosures and disclosures made “otherwise available to the public.”

9. These new standards in the Guidance also appear to be in conflict with those of other industrial countries, and are likely to increase the conflicts between the U.S. and other jurisdictions, and may lead to decreased filing of US patents by innovators throughout the World.

### **Specific Comments**

10. The slide set is likely to confuse the public and innovators by being vague about the “integration” of an Abstract Idea or Natural Law into an “application” of the Idea or Law. On the one hand, Supreme Court Precedent (*Diamond v. Diehr*) instructs us that it is necessary to consider the “claim as a whole” and it is not appropriate to dissect the claim into separate parts for claim construction. Similarly, in *Mayo v. Prometheus*, the Supreme Court required that the judicial exception be “integrated” into a practical implementation of the Law, with “meaningful limits” to the scope of the claims. However, the Court’s decision rested in part on a new claim analysis. The Court instructed that patent claims could be dissected into elements, and if one element is drawn to a Law of Nature, and the remaining elements represent “mere post-solution activity,” or were “well known,” or “routine,” then the claim must fail patent eligibility. In *Mayo*, the Court simply held that the other limitations of the claim were well-known and routine, and did not sufficiently “integrate” the Law to be patent eligible.

11. Because many methods used in science are based on known principles, such a dissection of a claim into the “Law of Nature” and “everything else” could easily result in an ineligible claim. In contrast to this view, the Supreme Court in *Diamond v. Diehr* explicitly repudiated

dissection of a claim into individual elements, and instead instructed courts to consider the "claim as a whole." In contrast to Supreme Court precedent, the Guidance may provide Examiners with the authority to hold a claim ineligible if the examiner opines that one feature or limitation of the claim is ineligible as a Law of Nature or Natural Phenomenon.

12. The Guidance fails to adequately implement the differences between a "Natural Law" and its application. The USPTO is currently rejecting claims under §101 as ineligible, merely if the claim contains a limitation to a genetic marker. The rationale is that the relation between the genetic marker and disease is a Natural Law. However, the USPTO is not currently analyzing the use of the law in its analysis. In many examples, a claim is drawn to the meaning of the relation between the Natural Law and its application. The purpose of the Myriad patents is not to simply claim the Natural Law, but rather to provide important health care information for health care providers and patients. If a patient becomes aware of a risk to health or life through use of an application of a Law of Nature, then one critical policy is fulfilled. By limiting the scope of patent eligibility to mere structural differences, the Guidance will frustrate this important public policy.

This aspect of the guidance may reflect the standard described in the briefing to the Supreme Court in *AMP v. USPTO and Myriad*, in which the Office proposed use of a "magic microscope" to allegedly "see" the sequence of a naturally occurring gene. This concept would rely upon the arguments made in the District Court of New York, in which even a cDNA was considered ineligible because it contained the sequence of the gene. This argument was repudiated by the Supreme Court in its decision in *AMP*, in which Justice Thomas held that cDNA was a synthetic molecule, not occurring in nature, and therefore was eligible for patenting.

13. The reliance on "marked difference" in structure of a compound or composition appears to ignore not only the Court's decision in *Chakrabarty*, but also ignores functionally important features. For example, Slide 53 discusses "primers" (for use in polymerase chain reactions, "PCR") and instructs examiners only to ask if the sequence of the primer is markedly different from the sequence of the naturally occurring nucleic acid. It is well known that the efficacy of primers to amplify oligonucleic acids is based on the ability of the primer to bind to complementary portions of the oligonucleotide to be amplified. Without amplification, it is highly unlikely that analysis of genetic information would be possible. The invention of PCR led to the awarding of a Nobel Prize in Chemistry to the inventor, thus demonstrating its high degree of value and utility.

Under the Guidance, process claims drawn to use of PCR to serve the crucial goal of assisting in diagnosis and prediction would be ineligible for patenting, regardless of the desirability of the process claim. A limited way in which a process claim using PCR would be eligible is if the primer is directed to a portion of the oligonucleotide that crosses an exon boundary (with the intron removed). This distinction apparently ignores the fact that PCR primers are not isolated but are actually synthetic molecules. Because Justice Thomas concluded that cDNA is patent eligible because it is synthetic, other synthetic molecules, including all PCR primers and probes should also be eligible under §101. This should not be limited to DNA, but should include purely synthetic molecules, even if the structure is the same as a natural product.

The Guidance would be markedly improved if any synthetic molecule is considered eligible under §101. This would comport with Justice Thomas' decision in *AMP*.

### **Recommendations**

14. Given the great uncertainty about the meaning of the Court's decisions, and the vagueness of the standards in the Guidance, it is premature to propose such a sweeping change in USPTO training or examination. I suggest waiting until reviewing bodies (PTAB, Court of Appeals, and Supreme Court) clarify the meaning of the Supreme Court's decisions. Thus, I believe that the Guidance should be withdrawn in favor of the well-understood patentability rubric. The policy goals of avoiding complete preemption of the Natural Law and providing meaningful limits on claim scope should still be based on the traditional criteria for patentability embodied in §§102, 103, and 112. Until the courts have refined the meaning of the decisions in *Mayo* and *AMP*, the USPTO should maintain the current standards for patentability and not expand them into uncharted territory.

15. Apply the standard of *Chakrabarty* and examine the differences in "characteristics" of the "Natural Phenomenon" and not simply analyze the structure of a molecule. Explicitly state that all synthetic molecules are patent eligible.

16. Provide additional examples that will provide meaningful guidance to Examiners to ensure consistent, predictable application of patent eligibility. These examples should be carefully drawn to illustrate the distinction between ineligible and eligible claims. The example of claims to gunpowder could provide a model for such an analysis. Although the components of gunpowder were individually known, it is the combination of them in particular proportions that render the product valuable, and deserving of patent eligibility. It would be helpful for the USPTO to carefully craft the facts into two different illustrative claims, one that would be eligible and another that would not. Additional examples of claims that would be held eligible will be especially useful and will provide clarity.

17. As part of the AIA, Congress instructed the USPTO to carry out a study of Genetic Testing, in light of the controversies surrounding the Myriad patents. This requirement has led to several public roundtable discussions, and a Draft Report. However, no Report has been published, and to my knowledge, Congress has received the Report. Finish and publish the Study on Genetic Testing as required by Congress in the AIA.

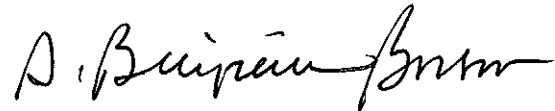
18. Be cautious about embarking on substantive rulemaking. Recall the lessons of the notorious "Claims and Continuations" rules promulgated by the USPTO and avoid making substantive changes to the law. Do not expand upon the Court's rulings in *Chakrabarty*, *Diehr*, *Mayo* and *AMP*.

19. Make all comments submitted related to the Guidance available to the public on the USPTO website and advertise where on the website the comments can be viewed by the public.

20. Increase goodwill among all stakeholders, especially innovators. Consider their comments seriously during the upcoming Roundtable meetings, and incorporate the suggestions into any further Guidance or Rulemaking. The public deserves to have any further Guidance be based on the rule of law, supported by precedent, and not based on subjective impressions of Examiners or incomplete training.

Thank you for the opportunity to voice my comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D. Benjamin Borson". The signature is fluid and cursive, with a long horizontal stroke at the end.

D. Benjamin Borson  
April 29, 2014