AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

July 31, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314 *Via Email: myriad-mayo_2014@uspto.gov*

RE: Comments on "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products"

Dear Deputy Under Secretary Lee:

The American Intellectual Property Law Association (AIPLA) is pleased to have this opportunity to present its views to the U.S. Patent and Trademark Office with respect to the "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products" ("Guidance"). These written comments supplement the testimony that AIPLA provided at the Office Subject Matter Eligibility Forum on May 9, 2014.

AIPLA is a national bar association with approximately 15,000 members engaged in private and corporate practice, in government service, and in academia. AIPLA members represent a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, copyright and trademark law, as well as other fields of law affecting intellectual property. Our members are concerned with the interests of both owners and users of intellectual property.

Introduction

AIPLA believes that it was appropriate for the Office to issue guidance to its Examiners in light of the Supreme Court's decision in *AMP v. Myriad*, 569 U.S. __ (2013), 133 S. Ct. 2107 ("*Myriad*"). However, AIPLA believes that the Guidance's factor-weighing approach to determine whether a "claim as a whole recites something *significantly different* than the judicial exceptions" unnecessarily extends well beyond what Supreme Court precedent requires for both composition claims and process claims. Moreover, the Guidance's approach also extends well beyond what would be reasonable during examination to ensure that patents are not granted on ineligible subject matter.

Decision in *Myriad*

Writing for a unanimous Court, Justice Thomas in *Myriad* concluded that the subject matter of the patent claim was ineligible by applying settled principles of law, not by introducing new rules of analysis. The Court found that the claims were directed to the statutory category of "composition

of matter"—DNA sequences—but that they were also subject to the "products of nature" exclusion implied in the statute. The Court further concluded that the importance of "discovering" the location of the claimed genetic sequences was not enough to warrant tying up basic tools of science and inhibiting future innovation.[1]

Specifically, the *Myriad* Court stated that the patent eligibility of the claims were not saved by the fact that isolating DNA from the human genome severs chemical bonds to create a nonnaturally occurring molecule. Upon close examination, according to the Court, the claims were not expressed as a chemical composition and did not rely on chemical changes resulting from the isolation of claimed genes.[2] Instead, they focused on the genetic information encoded in the claimed sequences, Justice Thomas pointed out. He added the following:

> If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

Id. at 2118. The fact-intensive nature of the decision is also revealed in the conclusion that cDNA, consisting of exons-only molecules, is not naturally occurring and thus is patent eligible. The Court was not persuaded by the argument that the cDNA structure "is dictated by nature," even if it may not be found in nature. Justice Thomas observed that the lab technician "unquestionably creates something new" when cDNA is made.[3]

It is evident from this discussion that the Court reached its decision in *Myriad* without introducing any new rules on patentable subject matter. Instead, it looked closely at the language of the patent and found that the claimed chemical composition amounted to a claim of exclusive rights to the information imparted by a product of nature. While the *Myriad* opinion reached into various past Supreme Court decisions for its analytical structure of patentable subject matter, it nowhere suggests that the analytical approaches of those precedents were being displaced. In fact, Justice Thomas recited and affirmed the important maxims from those decisions.

Importantly, the opinion concludes with an express disclaimer of any implication of the decision for other patent issues.[4] Justice Thomas pointed out that there are no method claims before the Court, and no "new applications of knowledge" about the claimed genes. Nor is there any patentability question as to DNA whose naturally occurring nucleotides have been re-ordered.

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[1] *Id.* 2117.
[2] *Id.* 2118.
[3] *Id.* 2119.
[4] *Id.* 2119-2120.

"We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material," he concluded.[5]

By contrast, the Office's Guidance on applying the *Myriad* decision is a unilateral expansion of the rules that reads all of the limiting language out of the opinion. In doing so, it threatens to exclude from eligibility important subject matter in the biotechnology and chemical arts, which are critical to the energy, chemical, food, animal health, diagnostics, and pharmaceutical industry sectors of the United States economy. If the method of determining subject matter eligibility is implemented as set forth in the Guidance, the costs of prosecution will rise due to prolonged prosecution (with the effect of pricing some smaller entities out of the patent system), an already back-logged PTAB will be further burdened, and the grant of critical, legitimate patent rights will be needlessly delayed.

Congress used simple, direct, and expansive language in 35 U.S.C. § 101. Judge-made exceptions must be narrowly construed and limited to very similar factual situations, even during examination. As the Supreme Court has repeatedly noted, including in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___ , 132 S. Ct. 1289 (2012) ("*Mayo*") and *Myriad*, "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law." *Myriad*, 569 U.S. at ___, 133 S. Ct. at 2116 (*quoting Mayo*, 566 U.S. at ___, 132 S. Ct. at 1293). When assessing whether a product reflects human ingenuity or a process recites more than a judicial exception, the Supreme Court has cautioned that patent eligibility must be determined by considering the claim as whole, not by dissecting the claim into its elements. *Alice Corp. v. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. ___ (2014) (slip op. at 7, n.3); *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

AIPLA recognizes the challenge to achieve this delicate balance and proposes that the Guidance can be appropriately tailored to account for both the breadth of the statutory language and the narrowness of the judicial exceptions. Adjusting the Guidance as proposed herein would promote greater clarity, certainty, and consistency in the application of 35 U.S.C. § 101 to both product claims and to process claims during prosecution.

Proposed Changes

AIPLA respectfully requests that the Office modify the Guidance in the specific ways summarized below in order to improve the Guidance for Examiners and for Applicants:

1. *Use distinct analytical approaches for product claims and process claims.* The Guidance sets forth a single approach on "How to Analyze 'Significantly Different'" for both product and process claims.[6] This approach deviates from Supreme Court precedent by combining

[5] *Id.* 2119-2120.
[6] The term "product" in reference to a claim will refer to things that are in the statutory categories of compositions of matter, machines, and articles of manufacture. The term "process" will refer to processes and methods.

considerations that are only applicable to product claims with considerations only applicable to process claims. Such an approach is not supported by precedent; the Supreme Court decisions maintain an analytically separate approach for process claims and product claims. Further, using a hybrid list of factors poses significant risk that the analysis will be confused and inappropriately applied. AIPLA suggests that the Office amend the Guidance to provide distinct analyses for product claims and process claims, as proposed below (Figure 1).

AIPLA submits that the Supreme Court's eligibility analysis for product claims relies on a distinct set of standards or considerations that significantly differ from standards or considerations the Court has used for process claims. For product claims, the key question is whether the claimed product as a whole possesses markedly different characteristics from naturally-occurring products.[7] In contrast, the key determinant of eligibility for a process claim is whether the claim contains elements other than or in addition to the judicial exceptions that are sufficient to ensure that the claimed invention in practice amounts to significantly more than a claim to the exception itself, foreclosing any use of the exception by others.[8] As the Court recently explained in the *CLS Bank* decision involving a computer-implemented method for mitigating settlement risk, "the concern that drives this exclusionary principle [is] one of pre-emption" and the related "'concern that patent law not inhibit further discovery by improperly tying up future use of' these building blocks of human ingenuity." *CLS Bank*, 573 U.S. at ___ (slip. op. at 5) (*quoting Mayo, supra*, at ___ (slip op. at 16).

The distinct analytical approaches for process claims and product claims are clearly set forth in the "process" and "product" lines of Supreme Court cases. With very few cross-references across the lines, the process line of cases includes *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); *Diehr*, *supra*; *Bilski v. Kappos*, 561 U.S. 593 (2010); and *Mayo, supra*. The product line includes *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); and *Myriad*, *supra*

In *Myriad*'s consideration of the product claims in that case, the Court made no substantive reference to any of its cases dealing with process claims. In particular, the Court made no reference to *Benson*, *Flook*, *Diehr*, or *Bilski* at all, and it referred to *Mayo* only for general propositions.[9] The limited holding of *Myriad* was that a naturally occurring product does not become patent eligible when isolated, and none of the process patent precedents played any role in that decision. In light of this, it was not surprising that the Federal Circuit did not change its analysis of the product claims at issue in *Myriad* on remand after the Supreme Court's decision in *Mayo*.

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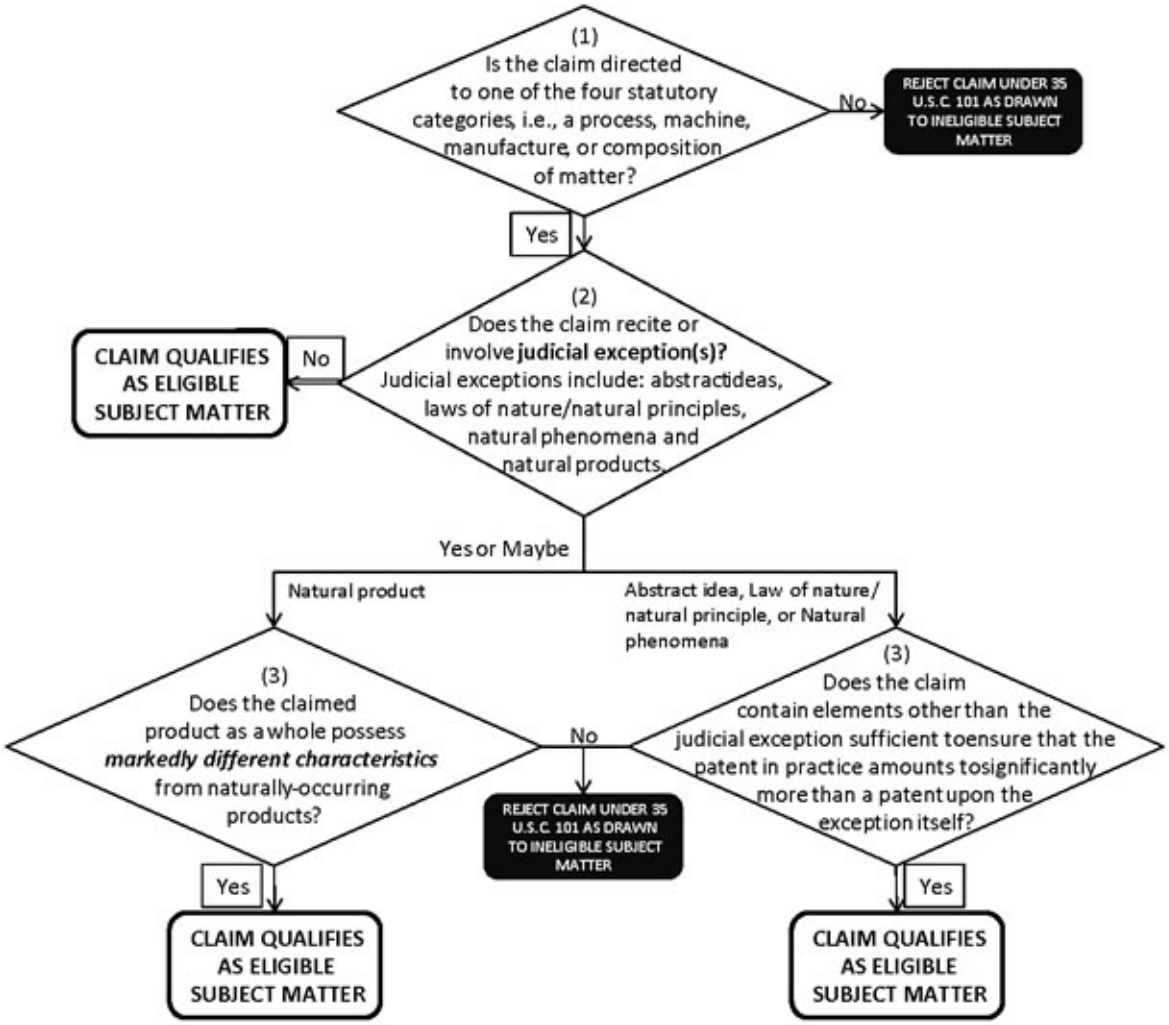
[7] *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980); *see also Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. ___ (2013) (slip op. at 12).
[8] *Mayo*, *supra*, at ___ (slip op. at 3, 8, 10, 11, 12, 16, 18, and 21).
[9] *Myriad*, *supra*, at ___ (slip op. at 11) (referring to the mention in *Mayo* of the implicit exception in 35 U.S.C. § 101 for laws of nature, natural phenomena, and abstract ideas, which are the basic tools of scientific and technological work that lie beyond the domain of patent protection, without which there would be considerable danger that the grant of patents would inhibit future innovation).

Likewise in *Mayo*, the Court made no substantive reference to any of its cases dealing with product claims.[10] As such, AIPLA urges that the inquiry of Step 3 set forth in the Guidance should be modified to properly instruct Examiners about the Court's distinct inquiries and analytical procedures for product claims and process claims.

Figure 1. Proposed distinct analyses for product claims and process claims.



[10] *Mayo*, *supra*, at ___ (slip op. at 1) (stating that the Court has long held that section 101 contains an exception for laws of nature, natural phenomena, and abstract ideas and citing *Diamond v. Chakrabarty*, *supra*, and other cases not involving products).

2. *A single inquiry for product claims*. The Guidance poses two considerations for products: (1) Is the claimed product non-naturally occurring? and (2) Is the claimed product markedly different in structure from naturally occurring products?[11]

   However, there is no need to assess whether the claimed subject matter is "non-naturally occurring" because, even if it is non-naturally occurring, the entire analysis turns on whether the claimed product has been changed by disclosed human action to be markedly different as a whole from naturally-occurring products. Furthermore, Supreme Court precedent does not confine the inquiry to structural or compositional differences, considering differences in function or use as well (see below). Thus, the sole inquiry for products is:

   > Does the claimed product as a whole possess markedly different characteristics from naturally-occurring products?

   If the answer to this question is "Yes" then the subject matter of the claim is statutory and the claim should not be rejected under section 101.

   The Supreme Court precedent involving the question of patent eligibility for products has considered more than structural differences between the claimed product and naturally-occurring products. In *Myriad*, the rationale for holding that mere isolation was insufficient for eligibility of genetic DNA included both similarity in structure and also the identity of function as compared with naturally-occurring genetic DNA.[12] In *Chakrabarty*, the Court stated that the subject matter at issue, which was determined to be patent-eligible, was new "*with markedly different characteristics from any found in nature*," which was due to the additional plasmids and resultant "capacity for degrading oil." 447 U. S. at 310 (emphasis added). *See also Myriad*, *supra* at ___ (slip op. at 10).[13] Finally, the Court in *Funk Brothers* focused predominantly on function in deciding that the compositions at issue were not eligible for patenting. 333 U.S. at 131 ("Each of the species of root nodule bacteria contained in the

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[11] These two questions are inferred from the construction of factors a) and g) in the Guidance.

[12] *Myriad*, *supra* at ___ (slip op. at 11-12) ("It is undisputed that Myriad did not create or alter any of the *genetic information encoded in the BRCA1 and BRCA2 genes*. (emphasis added)); *id*. at 14-15 ("Instead, the claims understandably focus on the *genetic information encoded in the BRCA1 and BRCA2 genes*. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because *its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule*." (emphasis added)); *id*. at 18 ("We merely hold that genes *and the information they encode* are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material." (emphasis added).

[13] *Chakrabarty*, 447 U.S. at 310 ("Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for *significant utility*." (emphasis added); *id.* at 309-10 ("Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity '*having a distinctive name, character [and] use.*'" (emphasis added)) (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 121 U. S. 615 (1887)).

package *infects the same group* of leguminous plants which it always infected. *No species acquires a different use*. The combination of species produces no new bacteria, no change in the six species of bacteria, and *no enlargement of the range of their utility*. Each species has the *same effect it always had*. The bacteria perform in their natural way. Their use in combination does not improve in any way *their natural functioning*." (emphases added)).

In summary, Supreme Court precedent provides no support or justification for the Guidance's narrow focus on structure alone. The entire line of the Court's product eligibility cases considers structure and other properties, such as function and use, in deciding whether *markedly different characteristics* exist as compared with naturally-occurring products. The Office should take an approach that is consistent with the Court's entire line of precedent and it should advise Examiners to consider all relevant properties when they are assessing whether there are "markedly different characteristics" between a claimed product and things that exist in nature.

3. *Indicia of "markedly different characteristics" for products*. The Guidance's mechanical scorecard of factors "for" and "against" eligibility fails to capture the nuances of the precedent. The absence of one factor should not "weigh against" patent eligibility or necessarily negate the presence of any factor indicating patent-eligibility. The Office should replace the factors relating to product with the following indicia of "markedly different characteristics" for product claims.

    a. The claimed product is compositionally different from naturally-occurring products or it has a functional characteristic that does not exist in compositionally-similar, naturally-occurring products as they exist in nature; ***or***

    b. The claimed product is compositionally different from naturally-occurring products or it has a functional characteristic markedly different in use or degree (such as efficacy or efficiency) as compared with compositionally-similar, naturally-occurring product as they exist in nature; ***or***

    c. The claimed product is a combination of elements comprised of one or more naturally-occurring products and the combination has compositional and functional characteristics that do not exist in nature.

    A product claim that has any one of the indicia is properly drawn to patent-eligible subject matter and the claim should not be rejected under section 101. Nothing in the *Myriad* decision conflicts with this approach. Indeed, an important obstacle to patent eligibility cited by the *Myriad* Court for the broad product claims in that case was that they focused on genetic information encoded in the BRCA1 and BRCA2 genes and were not expressed in terms of chemical compositions. By contrast, the Court held that claims to cDNA containing the same information were patentable because the subject matter had a different structure and use as compared to the naturally occurring genetic information.

As the Examiners have been applying the Guidance, claims directed to (a) and (b) are being rejected as ineligible subject matter. For example, an epitope isolated from its native protein can acquire a different or enhanced utility and efficacy that does not exist when the epitope resides within its natural, unisolated form. Such an isolated epitope has markedly different structural and functional characteristics that create useful vaccine compositions not found in nature. It is well known in the field of protein chemistry that a peptide can take on different structure and function than a larger protein or polypeptide containing the identical sequence of amino acid residues within it. Thus, examination of each claim should take into account the structure and use of the claimed subject matter.

4. *A single inquiry for process claims*. The Guidance should be amended to include instruction to Examiners that the ultimate eligibility standard for process claims is stated in the question below:

> Does the claim contain an element or elements other than or in addition to a judicial exception sufficient to ensure that the claim as a whole in practice is not insignificantly different from a patent upon the exception itself so that the claim does not foreclose use of the exception by others?

Mayo, *supra* at __ (slip op. at 3, 8, 10, 11, 12, 16, 17, 18, and 21).[14] If Examiners are not clear about the ultimate question, then weighing the various factors is an exercise with no clear objective.

Moreover, this inquiry is consistent with and underscores the importance of the longstanding principle articulated in *Diehr* that patent-eligibility must be determined by considering the claim as a whole, not by dissecting the claim into its elements. After all, it has long been recognized that inventions are simply new combinations of old elements. This principle is easily lost in the factor-based test set forth in the Guidance. While the details of a claim must be examined to identify its constituent elements, no individual element may be deemed dispositive, but instead must be considered in the context of all the elements of the claim as a whole. This is wholly consistent with the recent *CLS Bank* decision in which the Supreme Court underscored that the analysis involves consideration of each element of the claim

[14] "And they [*Morse, Benson,* and *Flook*] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, *supra* at ___ (slip op. at 3) (referring to *Flook* at 594 and *Bilski*, slip op. at 14). "The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?" *Id*. at 8. "And so the patentees [in *Diehr*] did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Id*. at 12. "And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. *Id*. at 17.

individually and "as an ordered combination" "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *CLS Bank*, *supra* at ___ (slip op. at 7).

5. *Flexible, totality of the circumstances analysis for process claims.* AIPLA proposes that the Office instruct Examiners to use a flexible, totality of the circumstances approach which would permit consideration of any and all relevant information, not the factors laid out in the Guidance, in reaching a conclusion with respect to the ultimate question as posed above in Item No. 4. If the Office continues to follow a factor-based approach, an approach that AIPLA believes runs counter to Supreme Court precedent, AIPLA submits that the Guidance should state that no weighing of factors is necessary for the types of claims that the Court has already recognized are confined to a particular application of natural laws, such as claims to new drugs and claims to new ways of using drugs.[15]

   A process claim may recite a series of steps, each of which may be considered "routine and conventional" when viewed separately, but which are applied together in a manner that is neither routine nor conventional. Such a claim, when viewed as a whole, may recite an application of a natural principle that differs from a claim that forecloses use of the judicial exception by others. This type of analysis can be applied to claims that recite, for example, a diagnostic method that involves assays for detection of one or more known markers that have been routinely applied in other contexts, but are not routinely applied in the recited combination or in the recited context (e.g., for detection of colon cancer versus for assessment of glucose tolerance). This latter example would be more analogous to the process recited in the claims found patent-eligible in *Diehr* than to the method claims found ineligible in *Mayo*. Many diagnostic method claims fall within this latter category, yet are not addressed by the Guidance, leading to inconsistent treatment between patent examiners.

6. *Provide case citations for the language in each analysis.* In its proposed analysis set forth above, AIPLA requests that the Guidance provide case citations for the language of the process and product inquiries, as well as the indicia that examiners may consider. In the current Guidance, there are some instances where the precedential basis of the language used in the factors is clear; in others, that precedential basis is unclear. Whether the Office maintains the Guidance analysis in its current form or revises it, it might improve the various stakeholders' acceptance of the Office's approach to have clear disclosure of the precedential basis for each aspect of the Office's analytical approach. AIPLA recommends that the Office provide a footnoted version of the Guidance with point citations and quotations to the governing Supreme Court case law.

7. *Include a reminder to Examiners that after a response by the Applicant, the entire analysis must be performed again considering all evidence, amendment, and argument.* The Guidance does not make it clear enough that the Applicant is entitled to respond to a rejection made on

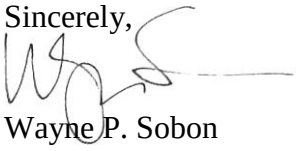
[15] "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws." *Id*. at 18.

the basis of the procedure in the Guidance with evidence, amendment, and argument. The Applicant can directly challenge the propriety of the *prima facie* rejection, amend rejected claims or rebut the rejection with evidence or argument. The Guidance should be updated to remind Examiners that when the Applicant responds with evidence, amendment, or argument, the Examiner must conduct the analysis again considering all the evidence, any amendment, and the Applicant's arguments.

Conclusion

AIPLA thanks the Office for the opportunity to provide these written comments on this important issue. AIPLA urges the Office to adopt the modifications suggested herein, and also respectfully requests the Office provide updated Guidance only after careful consideration of all submitted comments. AIPLA also welcomes the opportunity to work closely with the Office in improving the Guidance in a way that better reflects statutory requirements, legislative intent and judicial approaches to 35 U.S.C. § 101 for both product claims and method/process claims, respectively. Finally, AIPLA welcomes the opportunity to address any questions relating to the substance of these comments.

Sincerely,



Wayne P. Sobon
President
American Intellectual Property Law Association