July 31, 2014

Via myriad-mayo_2014@uspto.gov
Mr. Andrew Hirshfeld
Deputy Commissioner for Patent Examination Policy
United States Patent and Trademark Office

Re: USPTO 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products published March 4, 2014.

The Animal Health Institute (AHI) submits these comments to the USPTO 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products published March 4, 2014 (the "Guidance"). AHI is the US national trade association for research-based manufacturers of animal health products – the pharmaceuticals, biologicals, and pesticides used to keep pets and livestock healthy and in modern food production. Our members represent the vast majority of animal health products used in the United States, as well as serving a significant segment of the global market. They hold numerous patents relative to the products they develop and market. As such, we have a tremendous interest in the development of this new policy.

The Guidance is intended to advise examiners of the factors for determining whether an invention satisfies the U.S. Supreme Court's interpretation of 35 U.S.C. §101, as applied to patent-eligibility. *See Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107 (2013) ("*Myriad*") and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289 (2012) ("*Prometheus*"). The Guidance advises examiners to apply the *Myriad* and *Prometheus* holdings to any subject matter that could be characterized as a "judicial exception" to patent eligibility: a law of nature; a natural principle; a natural phenomenon, or a natural product.

In *Myriad*, the Court held that isolated genomic DNA molecules were products of nature and therefore not patent eligible subject matter. The decision made it clear that what is patentable subject matter must be "made different by the hand of man". *Myriad* relied on *Diamond v Chakrabarty*, 447 U.S. 303 (1980) ("*Chakrabarty*") as central to the eligibility requirement, and reaffirmed the Office's reliance on *Chakrabarty*'s criterion for eligibility of natural products – whether the claimed product is a non-naturally occurring product of human invention that is markedly different from naturally occurring products. Through *Myriad* it was also clarified that not every change to a product will result in a marked difference, and that the recitation of particular words ("isolated" or "recombinant") in the claims does not confer eligibility

Two sets of guidelines were issued to assist the Examining Corp after the June 2013 *Myriad* Supreme Court decision. In the first memo, the Examiners were directed to examine pending claims in light of the *Myriad* decision based solely towards claims involving DNA. However, in March of 2014 new guidelines were issued which vastly expanded the reach of the USPTO to include any subject matter

considered to be a "natural product" that fit under the judicial exception criteria. While *Myriad* had already taken that step that for "isolated" in the context of "genes and the information they encode," the USPTO's expanded reach, as stated in the new Guidance, is directed towards any claims "reciting or involving natural products," is more than a "*reminder"* that those claims "should be examined for a marked difference under *Chakrabarty*." The Guidance makes clear that the Office has adopted an overly expansive view of the Myriad decision and will be examining claims directed to anything that can be considered a natural product under a "significantly different" standard. We strongly feel that this position should be reconsidered.

Patent Eligible vs. Patentable

As an overarching observation, the USPTO is confusing "patent eligible" with "patentable." It is one thing to say that what is claimed is found in nature, but quite another to say that something that doesn't appear in nature requires a significant difference, rather than the *Prometheus* standard of something "more" than what is found in nature. Each of the examples applies only the factors described in Section II, which suggests a closed list, rather than an open list. The issue with this analysis is that the factors tend to incorrectly weigh patent eligibility using patentability standards.

Section I – Overall Process for Subject Matter Eligibility Under 35 U.S.C. 101

Section 1 of the Guidance addresses the Overall Process for Subject Matter Eligibility Under 35 U.S.C. 101. The process is outlined in a flowchart and three questions.

Question 1: Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?

Whether the claim meets the requirements of §101 must always be asked.

Question 2: Does the claim recite or involve one or more judicial exceptions?

This question is reasonable, provided the public, including practitioners, are provided with a clear definition for each of these judicial exceptions, and how the USPTO's definition thereof is specifically pronounced by Supreme Court holdings. The Guidance for comment does not accomplish this task. The question is overly inclusive, with the discussion stating: "If there is any doubt as to whether the claim recites a judicial exception [] the claim requires further analysis under Question 3." This "catch-all" sends a laundry list of claims into the Question 3 analysis: laws of nature, physical phenomena, natural phenomena, products of nature, natural products, naturally occurring things, "something similar to a natural product," scientific principles, disembodied concepts, and their combinations. The problem is that the subsequent "Significantly Different" test in Question 3 does not reflect Supreme Court pronouncements. Accordingly, the USPTO appears to have ignored or side-stepped the *Myriad* Court's explicit caution against extending its holding.

Question 3: Does the claim as a whole recite something significantly different than the judicial exception(s)?

On its face, this question seems reasonable. However, the USPTO appears to have unilaterally limited "markedly different" to "markedly *structurally* different." This appears to be based upon the

Myriad Court's holding that merely breaking the bonds to release a naturally-occurring sequence of DNA failed to sufficiently alter the structure of the "natural product" to render it patent eligible. According to June Cohan (USPTO Office of Patent Legal Administration), the "significantly different" test is a combination of the "markedly different" requirement of *Myriad* and the "significantly more" requirement of *Mayo*, *Gottschalk v. Benson*, 409 U.S. 63 (1972) ("*Benson*"), and *Parker v. Flook*, 437 U.S. 584 (1978) ("*Flook")*. Accordingly, neither the "substantially different" test nor the "balancing of factors" in the Guidance is expressly pronounced by any of the Supreme Court's holdings. Instead, the Guidelines reflect the USPTO's consolidation of many past "eligibility factors." Finally, the USPTO's interpretation runs counter to the Supreme Court's holdings in *Chakrabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) ("*Funk Brothers*"), which support the proposition that "functional" differences between the claimed article/composition and the corresponding natural product may be a factor favoring patent eligibility.

From the perspective of the animal health products industry, a major issue with the Guidance could be distilled to a question of whether a claimed invention that is a natural product includes chemicals derived from natural sources such as antibiotics and proteins. If so, the impact to the animal health industry will be tremendous, as a very high percentage of drugs and biologics approved over the past 30 years include derivatives of natural products. *See e.g.* Newman and Craig, "*Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010*, J. Nat. Prod. 2012 March 23, 75(3): 311–335. The authors of this article have categorized approved human drugs as biological ("B"), natural product ("N"), natural product (botanical) ("NB"), derived from a natural product (usually a semi-synthetic modification) ("ND"), totally synthetic ("S"), made by total synthesis but of a natural product (S) and a vaccine ("V). Their results, spanning 1981-2010, show that 1355 new human drugs were approved [15% B, 4% N, 22% ND, 29% S, 13% S, and 6% V]. Under the USPTO's §101 guidelines, the majority of approved drugs would not qualify for patent protection. And if the rejections our members have received are any indication, the office will reject most applications having claims reciting biological compositions, which tend to contain at least some portion of "natural products." These compositions will still qualify for patent protection in the majority of the industrialized nations. Accordingly, instead of aligning the US Patent Law with the rest of the industrialized Nations, Congress' stated intention in passing the America Invents Act, the USPTO's Guidelines have increased the divide to an unprecedented distance.

Even if two-thirds of approved drugs that were derived from natural products were determined to be "markedly different" from their corresponding natural versions, the guidelines would render 390 drugs ineligible for patent protection. Pharmaceutical and Biotechnology companies, particularly small ones, rely heavily upon patents and patent applications to secure funding to fuel their R&D efforts. Accordingly, companies will be dissuaded from developing natural products (or derivatives thereof) into useful medicines and/or vaccines. Even those not skilled in the biological and chemical arts are familiar with a host of medically important products of nature: aspirin, vitamin B, insulin, Taxol (from the Pacific Yew tree), adrenaline, penicillins, other antimicrobial compounds, etc. The Guidelines remove the ability to secure protection from many of these items, and will have a profound chilling effect on innovation.

Section II – How To Analyze "Significantly Different"

The Guidance's overly expansive view of *Myriad* will result in claims directed to anything that can be considered a natural product to be examined under a "significantly different" standard. For determining whether such a difference exists, the guidelines list twelve factors, six of which indicate the presence of something "significantly different" from nature and thus support eligibility, and six that do not. The Guidance states: "The Examiner's analysis should carefully consider every relevant factor and related evidence before making a conclusion. The determination of eligibility is not a single, simple determination, but is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts of the application." The twelve factors significantly confuse patent eligibility and patentability standards, and in the end the standard amounts to little more than "we know it when we see it," which will lead to inconsistent application of the standard across the Examining Corps and seemingly arbitrary results for applicants.

The Office compares the multi-factorial, open ended inquiry into "significantly different" to the analysis set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)("*Wands*") used to assess enablement. The Office's comparison misses the mark on at least two accounts. First, patentable subject matter is a threshold matter that should be easily assessed by all parties. Second, and very importantly and relatedly, when judging enablement under section 112, the Office bears an initial burden to provide a supported, factual basis for asserting it would take undue experimentation to practice the claimed invention. The application of the section 101 threshold, by comparison, places no such burden on the Office. The framework is open to the Examiners reaching conclusory, unsubstantiated results, placing applicants at a significant disadvantage.

Input on the twelve factors is below:

Factors that weigh toward eligibility (significantly different):

a) Product appears to be a natural product but turns out to be non-naturally occurring and "markedly different in structure" from natural products;

The product is either the same as the natural product or different. "Markedly" would suggest an analysis under section 103. This is a patentability factor.

b) Claim meaningfully limits scope of method so that others are not substantially foreclosed from using an exception;

The analysis of whether a claim is meaningfully limited in scope is a patentability factor.

c) Claimed elements are more than nominally, insignificantly, or tangentially related to an exception;

This relates to patentability. The analysis of whether a claim adds in a "significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially" related is more appropriate to analysis under Section 102 or Section 103.

d) Claims do more than describe exception with general instructions to apply or use it;

e) A machine or transformation of matter implements or integrates an exception, but the claim recites additional elements or steps;

f) Something more than well-understood, purely conventional or routine is added to the exception.

Evaluation of whether something is added "that is more than well-understood, purely conventional or routine in the relevant field" relates to patentability and analysis under Section 103

Factors that weigh against eligibility (not significantly different):

g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.

The product is either the same as the natural product or different. "Markedly" would suggest an analysis under section 103. This is a patentability factor.

h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.

The inquiry of whether a claim is so general that "substantially all practical applications" are covered is a patentability issue, not a patent eligibility issue.

i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).

We do not understand the analysis that this factor is intended to cover. It is vague and should be rewritten to convey the type of analysis suggested.

j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.

Again, the analysis relates to patentability, not patent eligibility. The inquiry as to whether a claim recites something "that is more than well-understood, purely conventional or routine in the relevant field" relates to an analysis under Section 103.

k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, *e.g.*, are merely appended to the judicial exception(s).

This relates to an analysis under Section 103, and not to patent eligibility.

l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.

If the use is inventive, why isn't it patent eligible? This factor appears to be directed at inherency, but we do not see how this is relevant to the issue of patent eligibility.

Section III – Examples

The difficulty in applying the Office's would-be guidance is evident from the uneven and at times contradictory statements and analysis that are set out in the Examples. For example, Question 3 of the Guidance asks, "Does the claim as a whole recite something significantly different than the judicial exception(s)." The analysis given in Example A applies Question 3 correctly. Under Example A, claim 2 is directed to a "bacterium from the genus Pseudomonas" containing "at least two stable energy-generating plasmids." In seeking to address whether claim 2 recites something significantly different from the judicial exception(s), the Guidance states, "in claim 2 the recited 'something different that initially appears to be a natural product' that is analyzed...is the bacterium containing the plasmids, and not the bacterium alone or the plasmids alone." The analysis here adheres to the well-settled proposition (reiterated in the Guidance) that patentability is measured against the claim as whole.

In other Examples the Office strays far from the notion that patentability is measured by the claim as a whole. In Example C, for example, the analyzed claim is directed to a "fountain style firework." The analysis, however, parses out the individual claim elements of calcium chloride and gunpowder, rather than focusing on the claim as a whole. In Example B, the Office parses claim 2 to "Purified 5-methyl amazonic acid" even more finely. According to the Office's analysis, claim 2 recites or may recite a judicial exception because "amazonic acid is a naturally occurring chemical found in the leaves of Amazonian cherry trees." The analysis, however, misses the forest for the trees. Quite simply, the compound 5-methyl amazonic acid is not a natural product and should thus not be subject to the Guidance.

A. Composition/Manufacture Claim Reciting A Natural Product

Claim 1: **A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway.**

Claim 2: **A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.**

The USPTO considers claim 1 to be patent ineligible because the plasmid is naturally occurring. The Examiner is supposed to review the specification to determine if the plasmid is a natural product. However, what is "significantly different" than what exists in nature? If, by isolating or purifying the plasmid, there are changes, what would be considered "significant"? The Guidance document assumes that there are no structural changes from the natural product. This example conflates eligibility with obviousness since the Examiner is to determine what "significant differences" mean to determine eligibility. Arguably, it would make more sense to lower the eligibility bar and reject the claim based on art disclosing naturally occurring plasmids. This claim appears to fall within the scope of *Myriad* in that it is naturally occurring and that the functional language adds nothing patentable because there are naturally occurring plasmids that have this function. The open question, however, is if there are

changes when isolating or purifying the material, does that make it patent eligible? Would modifying the material to avoid the "natural product" issue, but where there are no functional differences between the naturally occurring product and the modified product, render the modified product ineligible?

Claim 2 is one of the claims in *Chakrabarty*. The claim is considered to be patent eligible and follows the reasoning of *Chakrabarty* because the bacterium was modified and the bacterium's function was different from what occurs in nature. However, the modification of the bacterium alone justifies patent eligibility, and thus, this Example unduly confuses the criteria for making the determination of patent eligibility.

B. Composition vs. Method Claims, Each Reciting A Natural Product

Claim 1. **Purified amazonic acid.**
Claim 2. **Purified 5-methyl amazonic acid.**
Claim 3. **A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.**

As in Example A, claim 1, this claim is patent ineligible because amazonic acid is a naturally occurring product.

Claim 2 is patent eligible because it is structurally different from the naturally occurring amazonic acid. In addition, in the specification, there is a showing that it has additional functional properties. However, since the naturally occurring amazonic acid differs from the modified structure, that alone should support eligibility. It appears because a method is added to amazonic acid, the product is no longer natural. However, there is discussion of different functional qualities along with the structural difference. Modification of a naturally occurring product alone is enough to ensure eligibility.

Unfortunately, the Guidance conflates patentability under section 101 with obviousness under section 103. Thus, the Guidance states, "While a functional difference is not necessary in order to find a marked difference, the presence of a functional difference resulting from the structural difference makes a stronger case that the structural difference is a marked difference." The Office, however, fails to provide any rationale as to why this is the case. (This statement is reminiscent of the three-way "function/way/result" test used to determine whether claim elements are not "substantially different" under the doctrine of equivalents.) The Office's statement drives home that much of the determination of whether a product or process is "significantly different" is best left to an analysis under section 103. In the end, as stated above, the compound 5-methyl amazonic acid is not a natural product and should thus not be subject to the Guidance.

Claim 3 is patent eligible and it is because the claim is narrow in scope (specific dosage for a defined period of time). There is commentary that with respect to factor h), that the administering step is not general. Does this mean that language like "administering an effective amount of purified amazonic acid to a patient in need of said treatment" would not pass eligibility muster? Again, this is a conflation of eligibility vs. Section 112.

It is also clear that a naturally occurring product can be part of a method or process claim. However, determining eligibility based on the scope of the claim (*e.g.*, narrow is eligible, broad is not eligible) should be performed during examination under Sections such as 112, 102, and 103 and not here.

C. Manufacture Claim Reciting Natural Products

Claim: **A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.**

The Guidance considers this to fall within a *Myriad* analysis because calcium chloride and gunpowder are naturally occurring. But this claim is patent eligible because there are additional elements that amount to a practical application of natural products. While the outcome appears correct, the analysis focuses too much on the individual claim elements of calcium chloride and gunpowder, rather than focusing on the claim as a whole.

D. Composition Claim Reciting Multiple Natural Products

Claim: **An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.**

This is the *Funk Brothers* claim and was determined to be patent ineligible. The claim is a combination of naturally occurring strains. The Supreme Court recognized there was discovery in that the mixture wouldn't be harmful (*e.g.*, quality of non-inhibition when in combination) but considered it to be a newly discovered natural principle. Thus, claiming the combination of naturally occurring products, without more is patent ineligible. However, adding functional language of unexpected properties should render the claim patent eligible (*e.g.*, synergistic effect).

E. Composition vs. Method Claims, Each Reciting Two Natural Products

Claim 1. **A pair of primers, the first primer having the sequence of SEQ ID NO: 1 and the second primer having the sequence of SEQ ID NO: 2.**

Claim 2. **A method of amplifying a target DNA sequence comprising:**
providing a reaction mixture comprising a double-stranded target DNA, the pair of primers of claim 1 wherein the first primer is complementary to a sequence on the first strand of the target DNA and the second primer is complementary to a sequence on the second strand of the target DNA, Taq polymerase, and a plurality of free nucleotides comprising adenine, thymine, cytosine and guanine; heating the reaction mixture to a first predetermined temperature for a first predetermined time to separate the strands of the target DNA from each other; cooling the reaction mixture to a second predetermined temperature for a second predetermined time under conditions to allow the first and second primers to hybridize with their

complementary sequences on the first and second strands of the target DNA, and to allow the Taq polymerase to extend the primers; and repeating steps (b) and (c) at least 20 times.

The first part of this example indicates that the "minor structural differences" involved in generating isolated nucleic acid fragments are not sufficient to render the nucleic acids patent eligible, especially in the absence of "any functional difference." This example does not define what characteristics would distinguish a "minor structural difference" from something more. However, since "***any*** functional difference" (emphasis added) would render the isolated nucleic acid patent eligible, there may be a low bar for the introduction of a change sufficient for patent eligibility of a composition of matter. This should be clarified. However, as repeatedly stressed, the Office is incorrectly importing an obvious standard into its analysis of patent eligibility.

The second part of this example relates to methods employing isolated nucleic acids. Simple heating and cooling (i.e. thermocycling) appears sufficient for patent eligibility, as natural DNA replication occurs at a relatively steady temperature. Apparently this thermocycling is a "more than insignificant or tangential" use of the nucleic acids, although, again, the terms "insignificant" and "tangential" are not further defined and appear to meet an obviousness threshold rather than a patent eligible threshold.

F. Process Claim Involving A Natural Principle And Reciting Natural Products

Claim: **A method for determining whether a human patient has degenerative disease X, comprising: obtaining a blood sample from a human patient; determining whether misfolded protein ABC is present in the blood sample, wherein said determining is performed by contacting the blood sample with antibody XYZ and detecting whether binding occurs between misfolded protein ABC and antibody XYZ using flow cytometry, wherein antibody XYZ binds to an epitope that is present on misfolded protein ABC but not on normal protein ABC; and diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.**

This example discussed a diagnostic method. Unlike the claim in *Prometheus*, this claim is patent eligible because it is narrow in scope. In other words, the limitations of the claim do not foreclose other methods of detecting or measuring a particular biomarker.

The novelty of the antibody recited in this example appears to be influential in the determination of patent eligibility. However, this appears to confuse obviousness and anticipation with patent eligible subject matter. In particular, factors f, j, k, and l of the Guidance document contribute to this confusion. In addition, whereas a rejection based on Sections 102 and 103 would require an examiner to cite specific pieces of prior art, incorporating an obviousness-like or novelty-like factor into Section 101 would allow an examiner to make conclusory statements that are not based on prior art and thus are more difficult for an applicant to rebut. It is inappropriate to have this analysis take place under Section 101.

G. Process Claims Involving A Natural Principle

Claim 1. **A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: exposing the patient to sunlight, wherein the exposure to sunlight alters the neuronal activity in the patient's brain and mitigates the mood disorder.**

Claim 2. **A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: exposing the patient to a synthetic source of white light, wherein the exposure to white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.**

Claim 3. **A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: providing a light source that emits white light; filtering the ultra-violet (UV) rays from the white light; and positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the patient's brain to the filtered white light, wherein the exposure to the filtered white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.**

As above in Example F, claim 3 of this example is patent eligible because it contains sufficient limitations. Whether or not all of the limitations recited in the claim are necessary for patent eligibility is unclear. Additional Guidance is requested.

H. Process Claim Reciting An Abstract Idea And A Natural Product

Claim: **A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.**

This example uses the *Myriad* claim as a sample of patent ineligible subject matter. Interestingly, the Guidance does not apply the twelve factors to analyze the claim, nor does it give suggestions of what elements or limitations may have made the claim patent eligible. For example, if the claim had recited a particular method of comparing the sequences of normal and mutant BRCA2, would the claim have been limited enough to be patent eligible? The Office should provide this additional guidance for this example, as it would be very helpful.

Conclusion

Moving forward it is difficult to know how the USPTO will treat claims to proteins, fusion-proteins, fragments of proteins, and antibodies, synthesized DNAs, primers that are within coding regions that do not overlapping splicing regions, vaccines, antibiotics (isolated from bacteria, fungi or soil samples), insulin, human growth hormones and a vast array of industrially or therapeutically useful enzymes. The lack of predictability, uncertainty and inconsistent application of the standard across the Examining Corps will be a clear detriment for the biotechnology sector and the innovations that ultimately lead to therapies used to improve the health of patients.

In summary, the Guidance provided by the Office fails to mitigate the uncertainty that arises when judicial exceptions to patentability under section 101 are applied widely. The judicial exceptions should be narrowly tailored to exclude natural products, laws of nature and natural phenomena from patentability. Subject matter that falls outside these narrow exceptions should meet the threshold for eligibility under section 101. Application of open-ended inquiries to patentability such as those set out in the Guidance are better suited to determining patentability under other sections of the Patent Laws, such as sections 102, 103 and 112. The Guidance should be substantially revised to focus on the patent eligibility criteria, rather than mixing in the other criteria for patentability under other sections of the statute.