

Comments on the 2014 Interim Guidance on Patent Subject Matter Eligibility

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The following comments are submitted in reply to the Office's request for public commentary on the *Guidance* issued Dec. 16, 2014 (79 FR 74618) and Jan, 1, 2015 (1410 Off. Gaz. Pat. Office 50). These comments are supplementary to those provided July 28, 2014 by the above-named respondent.

Summary

The Subject Matter Eligibility Test (the Test) for Products and Processes fails to properly consider whether the claimed product or process is tangible, includes a tangible step or provides a tangible result.

The Test continues to improperly consider the simple and widely accepted definitions for terms naming the four statutory classes of patent eligible subject matter.

Step 2A of the two-step analysis fails to properly consider the materiality of the preamble of a claim when determining its subject matter eligibility.

Step 2A of the two-step analysis fails to properly consider the claimed subject matter as a whole when determining whether or not the claimed invention falls within a Judicial Exception or one of the four statutory classes of patent eligible subject matter.

The analysis continues to improperly rely upon patentability considerations under 102 and 103 when making subject matter eligibility determinations under 101.

An amended flowchart for determination of subject matter eligibility under section 101 is proposed. The determination of subject matter eligibility for a process is necessarily different than it is for a machine, manufacture or composition of matter. Reasoning establishing this assertion is presented.

Comments on the *Guidance*

Opening comments in the *Guidance* properly state "... the claimed invention (Step 1) 'must be directed to one of the four statutory categories' and (Step 2) 'must not be wholly directed to subject matter encompassing a judicially recognized exception.'"

It is important to note that the *Guidance* uses the term "wholly", yet the Test does not consistently consider the claimed invention as a whole and instead dissects the claim into individual elements in different parts of the analysis.

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Step 1 asks “Is the claim to a process, machine, manufacture, or composition of matter?”

Comment: Presumably the Office intended to state, “Is the claim directed to a process, machine, manufacture, or composition of matter?” This nuance is important as the term “directed to” follows the *Guidance*’s introductory comments and properly focuses on the entirety of the claim. In other words, this is a determination as to the “spirit” (for lack of a better term) of the claimed invention.

A “**machine**”, “**manufacture**” and “**composition of matter**” are tangible products whose existence ultimately result from a process, be it simple or complex or a process by man and/or of nature. A tangible product is capable of being touched or discernible by touch or more broadly “sensed” by a human; whereas an intangible product is not. It is important to note that an intangible product does not fall within any statutory category in section 101.

Proper and simplistic application of this initial analysis is key. An invention directed to a **manufacture or machine** is necessarily subject matter eligible regardless of whether or not the claim includes a specific limitation including a law of nature, natural phenomenon, abstract idea or judicial exception. The reason is simple: a “manufacture” refers to a tangible product manufactured (prepared) by man (with or without the use of machinery) and a machine refers to an apparatus or piece(s) of equipment that contains one or more parts and does work. A manufacture and machine both result from human ingenuity and effort and are necessarily incapable of being a law of nature, natural phenomenon, abstract idea (each of the three is intangible) or even a Judicial Exception (a natural product necessarily exists in nature and not as a result of human ingenuity and effort). Accordingly, it is not proper to further consider the subject matter eligibility of an invention if it falls within the category of machine or manufacture.

Although it is tempting, and indeed the courts have improperly done so, it is improper to consider novelty and obviousness considerations concerning patentability when making a determination under eligibility. Even if a claimed “manufacture” is the same as a “natural product”, the “manufacture” is necessarily subject matter eligible because it is the product of human intervention. That is not to say that it should be patentable, because the “manufacture”, which is the same as a natural product, would be properly anticipated by and unpatentable over the natural product. Notice there is no need for application of Judicial Exception to a manufacture.

A “**composition of matter**” (COM) is necessarily tangible. It might or might not result from human ingenuity and effort. It necessarily is incapable of being a law of nature, natural phenomenon or abstract idea, since each of those is intangible. Regardless of whether or not a claimed COM includes a limitation concerning a law of nature, natural phenomenon or abstract, the claim is still directed to something that is tangible. A COM, however, might still fall within the Judicial Exception of “natural product”. Accordingly, it is proper to consider whether or not the claimed COM is nothing more than a “natural product”. If the claimed COM is merely a “natural product”, then the claimed product is not subject matter

eligible. It should be understood that a “natural product” is a product of nature without the requirement of human intervention, ingenuity or effort.

A “**process**” might or might not include a tangible step and might or might not provide a tangible result. A “process” is a way of doing something. It is a sum of “actions” that ultimately produces a tangible or intangible product. A process is realized, or placed into existence, when it is executed or reduced to practice; otherwise, it is merely a set of instructions with an intent to use. In other words, one can only infringe a process claim by executing the process, not merely by thinking about the process or memorializing the process on some media. Upon execution, a process can comprise intangible steps, tangible steps or a combination thereof. Accordingly, it is proper to further consider the tangible aspects of the process in determining whether or not it is subject matter eligible. If the process includes no tangible steps and provides no tangible result, it is not subject matter eligible. If the process includes a tangible step and provides a tangible result, it is subject matter eligible.

Considering software, it is merely a compilation of instructions and, in some cases, information relied upon by the instructions in order to render the instructions operational. Software that merely executes calculations, manipulates data in a database and/or provides the mathematical results of calculations is necessarily subject matter ineligible, because each of those results can be the product of human thought (abstract ideas). However, a method that incorporates software to provide a tangible result is subject matter eligible.

Step 2A asks, “Is the claim directed to a law of nature, natural phenomenon, or an abstract idea (judicially recognized exceptions)?”

Comment: In view of the above comments, a machine or manufacture should not be subject to this consideration, since each is already a tangible product and cannot be law of nature, natural phenomenon, or abstract idea (judicially recognized exception).

Although it might seem an unimportant nuance, the phrase “is the claim directed to” should be amended to “does the claim specify”. The former phrase goes to the entirety of the claim (proper for classification of claims into categories) and the latter to the individual elements thereof (proper for consideration of scope).

One of the problems the USPTO faces and attempts to address with this question is how to handle examination of a composition of matter that might be considered a natural product. It does not matter that a claim directed to and specifying a composition of matter also includes some recitation of an abstract idea, law of nature, natural principle or natural phenomena. The only relevant question is whether or not the composition of matter is a natural product. If so, it is not subject matter eligible due to judicial exception.

It is proper to ask this question as regards a process, because a process can include tangible and/or intangible steps and can provide tangible and/or

intangible results. If the process claim does not specify a law of nature, natural phenomenon..., then it need not be considered under Step 2B.

Step 2B asks, “Does the claim recite additional elements that amount to more than the judicial exception?”

Comment: It is proper to ask this question as regards a process, because a process can include tangible and/or intangible steps and can provide tangible and/or intangible results.

The Guidance (I.A.3. Nature-based Products) uses the terms “nature-based product” and “product of nature” in a confusing manner. The Guidance states, “Nature-based products, as used herein, include both eligible and ineligible products and merely refer to the types of products subject to the markedly different characteristics analysis used to identify “product of nature” exceptions... To determine whether a claim that includes a nature-based product limitation recites a ‘product of nature’ exception, use the markedly different characteristics analysis to evaluate the nature-based product limitation.”

Comment: By adding the term “nature-based product” to the already confusing considerations under the judicial exception of “product of nature”, the Guidance merely further confuses the analysis. There is no need to develop additional terminology. The definition for “nature-based product” provides little clarity. The Guidance should merely instruct the examiner to consider the claimed subject matter as a whole to determine whether or not the subject matter as a whole claims a “product of nature”. (See additional comments below.)

The Guidance correctly instructs the examiner: “Care should be taken not to overly extend the markedly different characteristics analysis to products that when viewed as a whole are not nature-based...” However, it then incorrectly instructs the examiner: “The markedly different characteristics analysis should be applied only to the nature-based product limitations in the claim to determine whether the nature-based products are ‘product of nature’ exceptions...”

Comment: It is proper to consider the claim as a whole in determining whether the claimed subject matter is markedly different than a nature-based product and is thus subject matter eligible. It is improper, and even contrary to the Guidance’s earlier instruction and comments, to dissect a claim into its elements and then consider the subject matter eligibility of the individual elements and use that determination as a subject matter eligibility determination of the claim as a whole.

The markedly different analysis is properly applied to the claimed subject matter as a whole and not to the individual elements of the claim.

Consider the Guidance’s example of “a probiotic composition comprising a mixture of Lactobacillus and milk in a container”. Such a combination of elements simply does not exist in nature. The container, which is presumably a carton, for example, puts the composition into the realm of a “manufacture”,

which necessarily cannot be a “product of nature”. The subject matter as a whole is simply not a product of nature. Again, use of the term “nature-based” merely confuses the analysis. The Guidance should acknowledge subject matter eligibility of the claimed subject matter as a whole and then instruct the examiner to further consider patentability under 102 and 103, which might very likely result in a finding of unpatentability.

The *Guidance* (I.B) is headed “(Part 2 **Mayo** test)- Determine whether any element of combination of elements in the claim is sufficient to ensure the claim amounts to significantly more than the judicial exception”. It then instructs the examiner, “A claim directed to a judicial exception must be analyzed to determine whether the elements of the claim, considered both individually and as an ordered combination, are sufficient to ensure that the claim as a whole amounts to significantly more than the exception itself- this has been termed a search for an ‘inventive concept’.³³ ... It is important to consider the claim as a whole... Individual elements viewed on their own may not appear to add significantly to the claim, but when combined may amount to significantly more than the exception.” Further in this same section, the Guidance states, “Limitations that may be enough to qualify as “significantly more” when recited in a claim with a judicial exception include:...” In the following text, the Guidance cites **Alice**, **Bilski**, **Diehr**, and **Mayo**.

Comment: The Office’s citation of **Alice** (cited as “33”) when addressing **Mayo** and reliance upon **Alice**, **Bilski**, **Diehr**, and **Mayo** in the determination of “significantly more” is unfortunately symptomatic of key problems with the Guidance. The Office improperly combines the findings of completely different fact scenarios dealing with completely different technologies to arrive at a mutated Test that inaccurately reflects and improperly generalizes prior decisions based upon very specific fact scenarios.

The Guidance states, “A claim directed to a judicial exception...” However, the Guidance does not instruct how an examiner is to determine whether a claim is “directed to” a judicial exception. Is it by consideration of just the preamble, an individual element of a claim or the claim as a whole? This lack of instruction is not inconsequential, because it is the key inferential decision an examiner undertakes early in the analysis under the Test. It would be a marked improvement to include within the Guidance examples of how to determine what a claim is “directed to”.

A determination of what a claim is “directed to” should be considered equivalent to a determination of the “spirit” of the claim. The spirit of a claim is determined by consideration of the claim as a whole, meaning consideration of the preamble and body of the claim. Greater weight should be placed on the preamble, since it immediately indicates the field for examination, i.e. an article/object (machine, manufacture, composition of matter) versus a method (process). Inclusion of a judicial exception in a claim element does not override the preamble in determining what a claim is “directed to”. For example, a claim to “a process for breaking stones, the process comprising breaking stones by using the force of gravity.” Such a claim is directed to the tangible process of breaking stones and

is thus subject matter eligible (101), but the claim remains unpatentable as being anticipated (102) by occurrences in natures and prior man-made processes.

By clarifying this determination, examiners will be able to more clearly determine whether or not the claimed subject matter as a whole even requires further analysis as to subject matter eligibility.

Additional Comments on the Cited Case Law

The *Guidance* summarizes case law concerning determination of subject matter eligibility. Unfortunately, there has been poor jurisprudence.

In key precedential decisions, the Courts have been incapable of separating the issue of subject matter eligibility under 101 from the issues of novelty under 102 and obviousness under 103. They have rendered incorrect decisions on subject matter eligibility (101) based upon argumentations of novelty (102) and obviousness (103).

In *Myriad*, the Court incorrectly concluded that the isolated DNA of claim 1 was subject matter ineligible under 101. The Court correctly recognized the existence of structural differences between the natural and isolated DNA; however, the Court erroneously concluded that it was “not different enough”. Having admitted that the natural and isolated DNA are structurally different, the Court should have acknowledged subject matter eligibility (the isolated DNA is/was a “manufacture”) and should instead have concluded that the isolated DNA was unpatentable under 103, because although it was not a product of nature (thus it was subject matter eligible under 101) and it was different (thus not anticipated under 102) from the natural product, it was not different enough (obvious under 103) from the natural DNA, because isolated DNA is well known and the BRCA1 gene is merely another isolated DNA. So even though the Court likely correctly concluded that the isolated DNA was unpatentable, it incorrectly concluded that it was subject matter ineligible. Had the Court used this reasoning, it would have followed long-standing precedential case law and would not have obfuscated patent law by improperly relying upon obviousness considerations in a subject matter eligibility analysis.

In *Mayo*, the Court incorrectly concluded that the method of optimizing therapeutic efficacy was subject matter ineligible under 101. The Court incorrectly gave virtually no weight to the fact that the two steps recited in the claim are tangible steps, each requiring human intervention; moreover, the claim provides a tangible result (method of optimizing). The Court simply completely missed the boat and developed incorrect tangential argumentation as regards the materiality of the steps toward subject matter eligibility. The Court properly observed that the “wherein” clause merely provided information but then incorrectly argued that the information in the wherein clause simply tells a doctor about the relevant natural laws. Nature does not indicate to a physician that a certain concentration of 6-thioguanine (6TG) “indicates a need to increase [or decrease] the amount of said drug subsequently administered to said subject”. It takes human intervention to determine the level of 6TG (step (b) of the claimed process), and a human decides what to do with that information. The Court should have acknowledged subject matter eligibility and should have instead

concluded that the invention was not patentable under 102 (and 103), because the prior art already taught the very same steps of “administering” and “determining”. The information in the wherein clause was simply not acted upon in any meaningful way. In other words, Prometheus’ claims failed to include a transformation that integrates the judicial exception into a particular practical application. Although the Court’s ultimate holding of invalidity (unpatentability) was correct, its reasoning was incorrect and has thus added to the confusion within which the USPTO finds itself, as evidenced by the *Guidance*. It should be noted that the claim would likely have been deemed subject matter eligible and perhaps even novel and non-obvious if the patentee had included within the claim an additional administration step making substantive use of the information.

Additional Comments

The Office is the expert of Patent Law, yet the Office seems completely willing to acquiesce to the Courts, which are necessarily full of generalists of the law as opposed to experts in Patent Law. It is understandable that the Office would make a concerted and diligent effort to harmonize examination procedures with precedential case law; however, the Office cannot and should not attempt to harmonize its procedures with case law that is evidently in a state of flux or that is contradictory and even contrary to U.S. Patent Law.

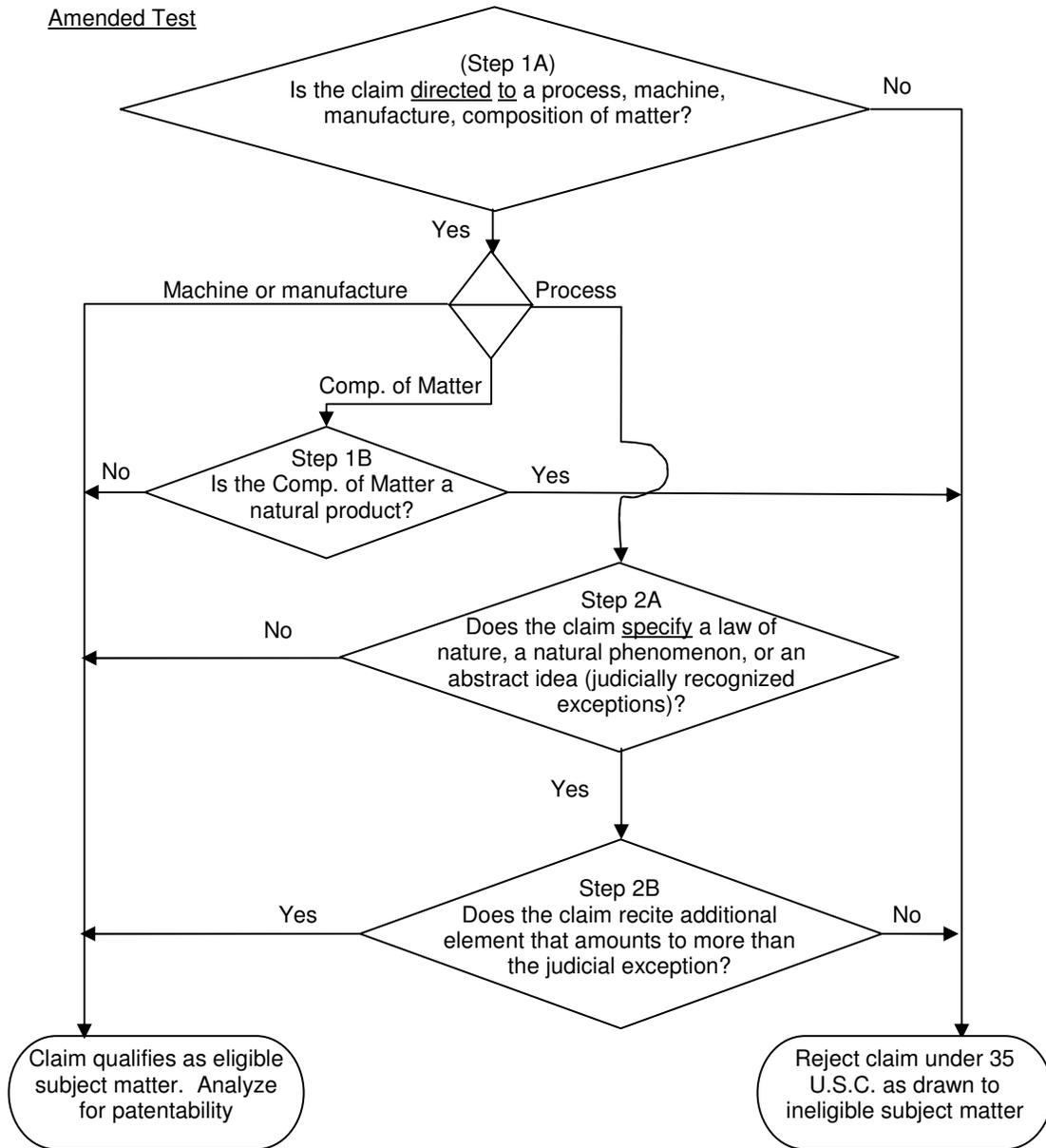
Moreover, the Office cannot try to oversimplify and generalize complicated case law, which in most cases is applicable to very narrow and specific fact scenarios. The fact that the Courts are seemingly unable to sever the requirements of a 101 analysis from those of 102 and 103 analyses cannot justify the Office doing the same. The Office should, instead, place greater effort at legislative clarity by amending Law as needed to keep pace with evermore complex technologies of today.

It is imperative that the Office provide clear direction to the Examining Corp as to the difference between a determination of subject matter eligibility and a determination of patentability under the remaining statutes. A determination of subject matter eligibility is merely a determination as to whether or not it is appropriate to further consider the patentability of the subject matter under the remaining statutes. In other words, subject matter eligibility is merely an entryway into further patentability examination.

Proposed Amended Test

In view of the above comments, it is proposed that the flowchart depicted in the *Guidance* be modified as follows:

Amended Test



We can evaluate the rigor, applicability and utility of the above Amended Test by analyzing specific examples.

Ex. 1: A claim directed to a chemical compound or mixture of compounds. A chemical compound or mixture of compounds is a composition of matter and is a tangible product. If the compound or mixture of compound is a **manufacture**, it is necessarily subject matter eligible; however, the compound or mixture of compounds would need to be analyzed under 102 and 103 for patentability, since it might still be anticipated by another manufacture, composition of matter or even a natural product. If the compound or mixture of compound is a not a **manufacture**, it would need to be analyzed further to determine if it is a natural product, which is not subject matter eligible as being judicially excluded.

Ex. 2: A plant extract comprising at least one specified component, wherein the extract exhibits at least one property not provided by the plant alone. Considering the claim as a whole, the extract is subject matter eligible because it is a manufacture (the term “extract” necessarily implies human intervention), and as a result of its manufacture, it provides a property not exhibited by the plant.

Ex. 3: A dosage form containing a therapeutically effective amount of acetylsalicylic acid (aspirin). Aspirin is, in fact, present in the bark of the willow; however, the claim is not directed merely to aspirin. It is directed to a dosage form containing a therapeutically effective amount of aspirin. The dosage form is subject matter eligible, because the bark of the willow is not a dosage form and cannot contain a therapeutically effective amount of aspirin in a form that is administrable as a dosage form.

Ex. 4 A claim directed to ipecac. Ipecac is an alcohol-based extract derived from rhizomes and roots of the ipecacuanha plant. Even though it is derived from a natural product, it is not a natural product, because nature does not form or provide an alcohol-based extract of the ipecacuanha plant. Moreover, the root of the plant is poisonous, so inclusion of the plant contents in the form of an extract renders it non-lethal and therapeutically useful. Accordingly, ipecac is subject matter eligible.

Ex. 5: A claim directed to process for the manufacture of a chemical product. The process necessarily provides a tangible product and should be considered subject matter eligible.

Ex. 6: A claim directed to process for the manufacture of a chemical product, wherein the process requires calculation (intangible step) of an optimal operating temperature for the process and then conducting (tangible step) of the process at that optimal temperature to provide the chemical product (tangible product). Regardless of the fact that the process requires a calculation, the process uses the calculated optimal temperature in a meaningful way (a tangible step) and provides a tangible product and should be considered subject matter eligible.

Ex. 7: A claim directed to a method of treating obesity to affect weight loss comprising administering an emetic. The method includes a tangible step

(administering) and provides a tangible result (weight loss) and is thus subject matter eligible.

Software, in its truest sense, is merely information, since it only contains a set of instructions. Software can be embodied in a series of intangible steps to produce an intangible result. As such, it is an intangible process, the product of which can be tangible or intangible depending upon whether or not the software controls devices that produce a tangible product or affect. Since software is intangible and may comprise purely intangible steps and can produce both tangible and intangible products/affects, it is proper then to further consider its subject matter eligibility (abstract idea analysis, law of nature, natural principle) as well as to consider its patentability under the remaining statutes

Ex. 8: A claim directed to software that controls one or more components of a display to produce a particular visual affect on a display. The software is not a manufacture, machine or composition of matter. It is a process that produces a tangible result (the visual affect). The software should be considered subject matter eligible.

Ex. 9: A claim directed to software that calculates (predicts) the future value of stock based upon a known dataset. The software merely provides the results of one or more calculations (mental processes) and does not produce a tangible result. The software should be considered subject matter ineligible.

Ex. 10: A claim directed to software that calculates (predicts) the future value of stock based upon a known dataset and then affects purchase or sale of stock at a particular price. Although the software conducts one or more calculations to predict future stock value, it then uses that information to conduct the tangible step of purchasing or selling stock at a particular price. The software should be considered subject matter eligible.

It is important to keep in mind, that further analysis under the remaining statutes must be conducted in order to determine patentability.