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Sent: Monday, July 28, 2014 1:53 PM
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Subject: Comments in Response to Guidance

Dear Deputy Commissioner Hirshfeld

Please consider the comments in the attached file in response to the *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)*.

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

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The following comments are submitted in reply to the Office's request for public commentary on the *Guidance* issued March 4, 2014 under cover of the memorandum by Mr. Andrew H. Hirshfeld, Deputy Commissioner.

Summary

The analysis detailed in the *Guidance* improperly includes elements of "patentability" analysis under sections 102 and 103 as part of a "subject matter eligibility" analysis under section 101.

In describing and applying its methodology, the *Guidance* mischaracterizes and over-generalizes the principles of analysis set forth in *Myriad*, *Mayo*, and *Chakrabarty*, which are based upon narrow fact specific scenarios and which themselves includes patentability considerations beyond subject matter eligibility.

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.

Suggested changes to the "factors" are presented.

Comments

Paragraph 2 of the cover letter states, "The new procedure set forth in the *Guidance* will assist examiners in determining whether a claim reflects a significant difference from what exists in nature and thus is eligible, or whether a claim is effectively drawn to something that is naturally occurring, like the claims found ineligible by the Supreme Court in *Myriad*."

Comment: This opening statement already misses the point that the analysis in *Myriad* included aspects of analysis under sections 101, 102 and 103.

Accordingly, any guidance derived from *Myriad* cannot be over generalized as being only related to a section 101 analysis.

The *Guidance* instructs examiners as follows: "Examiners are reminded that §101 is not the sole tool for determining patentability; where a claim encompasses a judicial expression such as a natural product, sections 102, 103 and 112 will provide additional tool for ensuring that the claim meets the

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conditions for patentability.” The *Guidance*, is entitled “Guidance For Determining Subject Matter Eligibility...”

Comment: Regardless of the fact that examiners are obliged to consider all sections of the Patent statutes when determining patentability, such instruction immediately confuses the basis of the *Guidance*, which is only to determine whether or not a claim covers patent eligible subject matter. This confusion is present throughout the *Guidance*.

The *Guidance* (pg 2) characterizes the subject matter eligibility related principles set forth in *Myriad*, *Mayo*, and *Chakrabarty*; however, those principles are not properly reflected in the ensuing method of analysis for subject matter eligibility.

The flowchart (Section I., pg 3) provides a framework for the proposed three-step analysis for determining whether or not claimed subject matter is patent-eligible.

Step 1 (Section I.1) asks whether or not “the claimed invention is directed to one of the four statutory patent-eligible subject matter categories.

Comment: It is proper to consider whether or not a claim is “directed to” one of these statutory categories under section 101. However, the flowchart immediately confuses the issue at hand.

It is important to understand the differences between the statutory classes. In the most basic sense, 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.

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.

Accordingly, the statutes clearly identify processes and tangible products as being subject matter eligible. If a claimed invention is “directed to” a “tangible” product, then there is no need for further analysis as to subject matter eligibility. Any further analysis of the patent eligible subject matter should turn to the remaining statutes. If a claimed invention is directed to a process, it should be further analyzed to see if it is subject matter eligible.

For example, a chemical compound or mixture of compounds is a composition of matter, is a tangible product and is thus necessarily subject matter eligible. However, a determination of patentability still remains, and one of the many considerations under that determination is whether or not the composition is anticipated or rendered obvious by a natural product. The fact that a claimed

compound is the same as a natural product renders the claimed compound unpatentable as being anticipated not as being subject matter ineligible according to the statutes. It is poor jurisprudence that has led to the generalized conclusion that a natural product is not subject matter eligible.

A composition cannot *per se* incorporate a law of nature or a natural principle as a tangible part of the composition. A law of nature can be thought of as a “stated regularity in the relations or order of phenomena in the world that holds, under a stipulated set of conditions, either universally or in a stated proportion of instances”,² or “an empirical truth of great generality, conceived of as a physical (but not a logical) necessity”.³ A principle is a “basic truth”; therefore a natural principle is a basic truth of nature.

In other words, laws and principles are intangible, not tangible. They exist regardless of whether or not they have been recognized by humanity or memorialized by some human expression, e.g. a mathematical formula or written expression. This means that inclusion of a natural principle as an element in a claim “directed to” a “machine”, “manufacture” and “composition of matter” does not change the essence of the claim from tangible product to intangible product. The claim remains directed to the tangible product and thus remains subject matter eligible, even though it is still subject to a determination of patentability under the remaining statutes. Consider that a physical property of a compound is arguably a natural principle of that compound.

As a first example, 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.

A claim to a medical method of treatment, such as a method of treating cancer, is in its broadest sense also intangible before it is executed, because it too is merely a set of instructions on how to treat cancer, i.e. the mere existence of those instructions is not sufficient to treat the cancer. However, the method must be embodied in a tangible way (it must include at least one tangible step) in order to produce the tangible result: treatment of cancer. Since a method of treatment must be embodied in a tangible way and must produce a tangible result, there is no question that the method is subject matter eligible, even though it is still subject to a determination of patentability under the remaining statutes. In other words, there is no need to determine whether or not a method of treatment includes a law of nature or a natural principle or an abstract idea if the method as claimed also includes within it tangible steps.

² Encyclopedia Britannica

³ Collins English Dictionary

Step 2 (Section I.2) asks whether or not “the claim recites or involves one or more judicial exceptions”, which include “abstract ideas, laws of nature/natural principles, natural phenomena and natural products”.

Comment: In view of the above comments, a machine, manufacture or composition should not be subject to this consideration, since each is already a tangible product and cannot be an abstract idea, law of nature, or natural principle.

One of the problems the USPTO faces and attempts to address with this question is how to handle examination of a natural product in view of the judicial exception created by poor jurisprudence. As noted above, a natural product is clearly a composition of matter, which is clearly statutorily subject matter eligible (albeit not necessarily patentable). It does not matter that a claim directed to and specifying a natural product also includes some recitation of an abstract idea, law of nature, natural principle or natural phenomena. The fact that the claim is directed to a composition, which may already exist in nature, is sufficient to render it subject matter eligible. Again, the composition as claimed must still be novel and nonobvious over all art including materials that already exist in nature.

The only subject matter that should be considered for subject matter eligibility in this step of the analysis is a process, because a process can conceivably be completely intangible and can provide intangible and/or tangible results. Accordingly, an additional part of this consideration should be whether or not the claimed process incorporates a tangible step and/or provides a tangible result. The scenarios resulting from such analysis would be as follows:

Scenario 1: The claimed process only comprises intangible steps. The process is not subject matter eligible.

Scenario 2: The claimed process provides a tangible result. The process is subject matter eligible.

Scenario 3: The claimed process comprises at least one tangible step and provides tangible and/or intangible results. The process is subject matter eligible.

Finally, step 3 (Section I.3) asks whether “the claim as a whole recites something significantly different than the judicial exception(s)”.

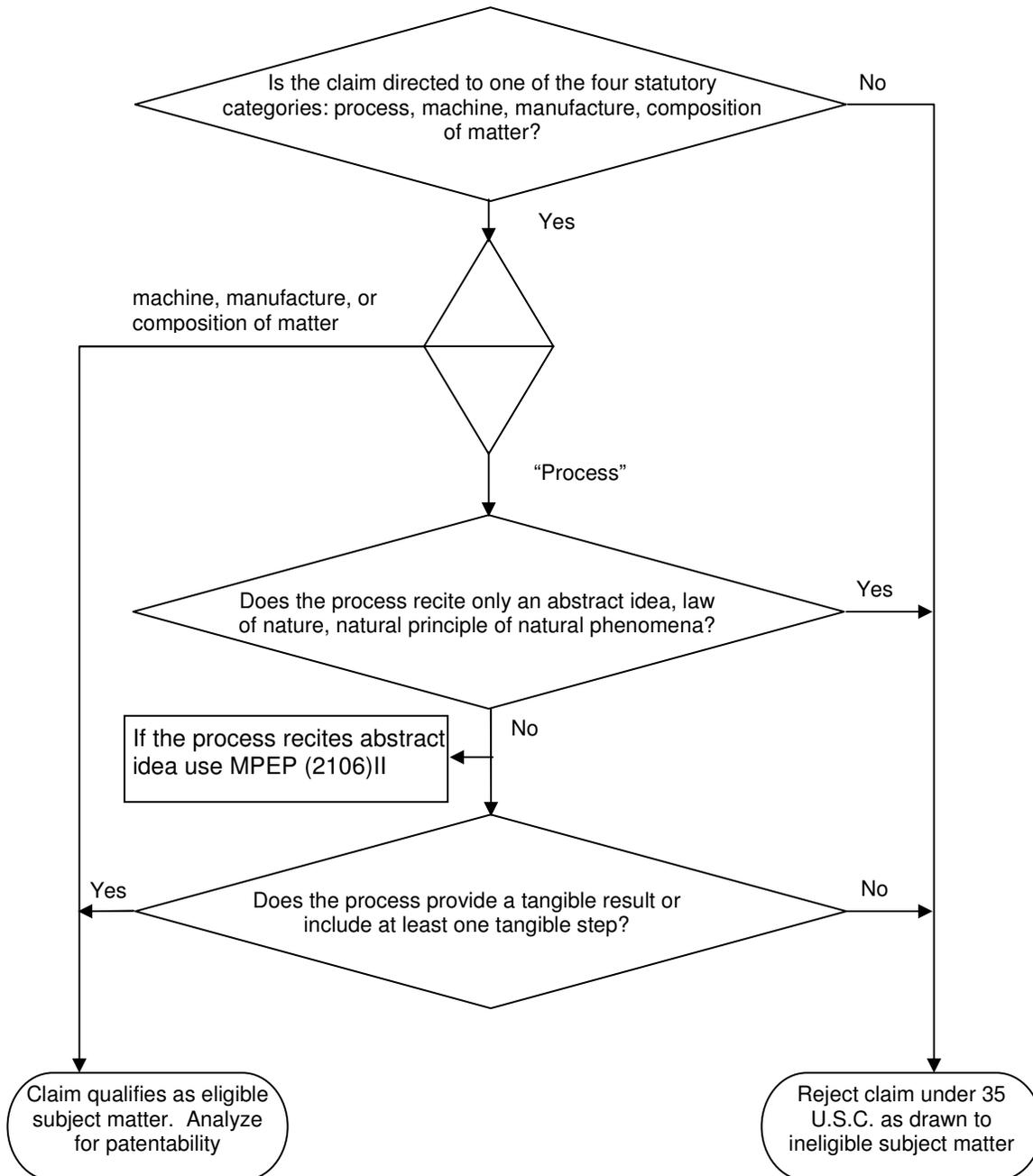
Comment: If one follows the above reasoning for Steps 1 and 2, then this question does not merit further consideration. It is already addressed in the questions above. Consider the following.

A claim cannot be “directed to” a “machine”, “manufacture” or “composition of matter” and still be “directed to” an “abstract idea”, “law of nature”, or “natural principle”. By being “directed to” a “machine”, “manufacture” or “composition of matter”, the claim is necessarily directed to a tangible product (object, article), regardless of whether or not that the claim also includes some recitation of an intangible aspect such as “abstract idea”, “law of nature”, or “natural principle”.

Following the Office’s reasoning, a physical property of a composition of matter might well be considered a “natural principle”. After all, the physical properties of a composition of matter are necessarily the result of the nature of the

composition. If that is the case, then a novel crystalline form of a compound, wherein the compound is characterized in a claim according to its X-ray powder diffraction pattern, would be considered subject matter ineligible even though the product is novel. Surely, that is not the intent of the Patent statutes.

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



To test the feasibility and merits of the proposed flowchart, the subject matter eligibility of the claims set forth in the example of the *Guidance* (Section III) was determined and the findings summarized as follows:

Ex.	Claim	Subject Matter Eligibility	Patentability
A	1	Y- composition of matter	N- exists in nature
A	2	Y- composition of matter	Y- does not exist in nature or prior art
B	1	Y- composition of matter	N- exists in nature
B	2	Y- composition of matter	Y- does not exist in nature or prior art
B	3	Y- process with tangible step and tangible result	Y- does not exist in nature or prior art
C	1	Y- composition of matter	Y- does not exist in nature or prior art
D	1	Y- composition of matter	*Y- claim directed to an "inoculant" comprising "selected" strains. The Court in <i>Funk</i> was wrong: analysis was based upon eligibility rather than obviousness. An inoculant is a composition of matter. Prior art provides basis for unexpected result from the combination of "selected" strains. No evidence that the combination of "selected" strains existed in nature.
E	1	Y- composition of matter	N- as claimed, exists in nature
E	2	Y- process with tangible step and tangible result	Y- does not exist in nature or prior art
F	1	Y- process with tangible step and tangible result	Y- does not exist in nature or prior art
G	1	Y- process with tangible step and tangible result	N- exists in nature
G	2	Y- process with tangible step and tangible result	N- exists in nature
G	3	Y- process with tangible step and tangible result	Y- does not exist in nature or prior art
H	1	N- process with only intangible steps and intangible result	N/A

Comments Regarding the Factors

In its instruction on “How to analyze ‘significantly different’” (Section II) the *Guidance* states, “A significant difference can be shown in multiple ways, such as: (1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g. by adding significantly more to the judicial exception; and/or (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature (and thus not a judicial exception).

Comment: Such direction is incorrect. In *Myriad*, the determination of “significantly different” is based upon a determination of what is “markedly different”. Determination of the inclusion of “elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way” is the very determination that “markedly different” makes.

Regardless, the comments above concerning Step 2 of the *Guidance* provide clear rationale as to why a claim directed to subject matter that can be categorized as a “machine”, “manufacture” and “composition of matter” necessarily meets the requirements of subject matter eligibility under 101, because the claim covers a tangible product.

The *Guidance* generally describes the proposed weighting system, wherein examiners are instructed to determine whether or not the “factors that weigh toward eligibility” (Factors a) through f), pg 5) outweigh the “factors that weigh against eligibility” (Factors g) through l), pgs 5-6).

Comment: Even though the *Guidance* instructs examiners to follow the *Wands* factor-based analysis, such instruction is almost meaningless as there is no case precedent to establish which of the individual factors (a) through g)) would be considered of greater value/merit/weight in terms of subject matter eligibility. How can an examiner or applicant balance without knowing the value (weight) of the factors? There is no way for examiners or applicants to understand the relative importance of the different factors, so there is no way to develop proper rejection and response strategies, respectively.

The Factors in the *Guidance* fail to address the substantial differences and incongruence between natural products and laws of nature/natural principles in particular as they relate to the statutory classes of subject matter: process, machine, manufacture or composition of matter. The *Guidance* confuses the requirements of analysis under sections 101 and 102.

Comment: For example, how can a composition of matter that has been “manufactured” be considered a “natural product”? The term “manufactured” infers a direct or indirect product of willful human activity for the purpose of preparing a specific composition. In other words, in the purest sense of their definitions, a single-compound composition of matter that has been “manufactured” cannot be considered a “natural product”. A product that is a “manufactured” single compound should necessarily be “subject matter eligible” without judicial exception regardless of whether the “manufactured” product is exactly the same as another compound already present in nature. That is not to say that the “manufactured” product would be “patentable”. In fact, such a

“manufactured” product would not be patentable, because is it anticipated by the product in nature. In other words, having satisfied the subject matter eligibility criteria, the manufactured product remains unpatentable as being anticipated.

As another example, one should not be able to obtain a claim to “ascorbic acid” that has been manufactured and is in every way the same as ascorbic acid as found in nature not because the so-manufactured ascorbic acid is a natural product but because the manufactured ascorbic acid is anticipated (section 102) by the ascorbic acid present in nature. Yet, the flowchart direct examiners to provide the wrong reason for unpatentability. By providing the wrong reasoning and logic, the Office is merely propagating poor jurisprudence.

Consider a process, such as “a method of preventing Vitamin C deficiency comprising administering an orange to a subject”. Such a process has existed in nature *per se* since the first time a human ever consumed an orange. Unpatentability arises not from the fact that eating is a process of nature, nor from the fact that oranges inherently contain Vitamin C, nor from the fact that oranges and Vitamin C are products that exist in nature. Eating as a process falls within a statutory category, and each the orange and Vitamin C as compositions of matter fall within a statutory class. In other words, all aspects of the “invention” are subject matter eligible; however, the process remains unpatentable as being anticipated (section 102).

Factors a) and g) are direct opposites and concern whether or not the claimed subject matter is “markedly different in structure” from naturally occurring products.

Comment: There are major problems with factors a) and g).

First, by including determination of “markedly different” in factors a) and g), there is no need to proceed with the determinations under factors c), d), e), f), h), j), k) and l). The a) versus g) determination is the whole of the determination under “significantly different” as proposed by *Myriad*. The factors c), d), e), f), h), j), k) and l) should be considered a subset of the a) versus g) determination.

Second, by reducing the determination of “markedly different” to differences in “structure”, the analysis fails to consider physical property, performance changes, new utilities and other features that may occur as a result of the claimed form of the product. For example, an aqueous extract containing plural pharmacologically active products isolated from a plant, animal or microbial source arguably only contains natural products, yet when that extract exhibits substantially higher levels of efficacy or exhibits synergistic levels of efficacy as compared to the individually isolated products or as compared to the products as they exist in nature, which themselves might not be subject matter eligible, there is no question that the extract is markedly different than the natural product, and the extract should be deemed markedly different, subject matter eligible and patentable. The “extract” includes a small subset of the compounds present in the original source in concentrations and ratios that are necessarily different than what is present in the original source, and the extract exhibits properties not exhibited by and provides utility not available from by the original source.

Third, a product-by-process derives its novelty from the product; however, the product, though structurally similar (at least as far as current analytical methodology can elucidate) to a product made by a different process, may possess characteristics, features or advantages that result due to the process by which it was made. Thus, even though current chemical structure analytical methodology may not have evolved to the level necessary to structurally differentiate the products of the two different processes, the new product-by-process is deemed markedly different because of the difference in property.

For example, consider cold-water gellable versus hot-water gellable starch. Each is starch (a recognized natural product) and each was initially obtained from a plant source; however, the processes used to produce each resulted in grades of starch that are substantially different. Untreated starch obtained directly from the plant requires heat to thicken or gelatinize; however, pre-cooking the starch and drying it results in a grade of starch (pre-gelatinized starch) that thickens instantly in cold water. Without consideration of differences in property and with only consideration of structure as proposed by the *Guidance*, the pre-gelatinized starch would be deemed subject matter ineligible *per se*.

Factors c) and k) concern whether or not a claim recites elements/steps in addition to the judicial exception(s) that “relate to the judicial exception in a significant way, i.e. the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s)” or that are “insignificant extra-solution activity... merely appended to the judicial exceptions”.

Comment: How is one supposed to determine whether something is “nominally, insignificantly, or tangentially related to the judicial exception(s)”?

Factor d) concerns whether or not a “claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).

Comment: There is a substantial difference between application of a natural product for a particular use and application of a law of nature/natural principle or natural phenomena for a particular use. There is no doubt that a claim reading as follows has historically been and should remain subject matter eligible: “A method of treating a bacterial infection by administration of [specific natural product]”. However, Factor d) would improperly render similar new claims subject matter ineligible and similar granted claims invalid, because the instruction to administer is general. Such a consideration regarding “generality”, however, is more akin to a lack of written description analysis under section 112 not a subject matter eligibility analysis under 101.

The above scenario is completely different than the following claim which would be properly deemed subject matter ineligible: “A method of reacting monomers to form a polymer comprising using the Arrhenius equation to correlate reaction temperature to reaction rate.” This latter claim is subject matter ineligible, because it simply instructs use of a natural principle. The claim is also unpatentable, because use of the Arrhenius equation in that manner is anticipated.

The conclusion regarding subject matter eligibility would be different if the above claim had instead read as follows, but the conclusion regarding unpatentability would still remain the same: “A method of reacting monomers to form a polymer comprising: a) heating a mixture of monomers; and b) using the Arrhenius equation to correlate reaction temperature to reaction rate.” By recitation of the “heating” step, the claim as a whole is now subject matter eligible under section 101 because heating is a tangible step; however, the claim remains unpatentable as being anticipated or obvious under section 102 or 103, since the heating step and use of the Arrhenius equation is well-known in the art of polymer production.

Factor e) concerns whether or not a “claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) and integrates the judicial exception(s) into a particular practical application”.

Comment: This is a key aspect of the analysis under *Mayo v Prometheus* even though its importance is downplayed in the decision. Prometheus’ claims include the steps of “administering” a drug and “determining” the level of corresponding metabolite in the blood. Prometheus’ claims also specified two data points that “indicate a need for” an increase or decrease in dose. However, Prometheus’ claims failed to specify any affirmative action step carried out in response to knowledge of the data points. In other words, Prometheus’ claims failed to include a transformation that integrates the judicial exception into a particular practical application. The holding of invalidity (as being drawn to ineligible subject matter) in *Prometheus*, however, incorrectly focused on an analysis under sections 102 and 103.

The Court found that the “administering” and “determining” steps were already known and that Prometheus’ only contribution to the art was identification of two data points which were also already known in or suggested by the art but the importance of which had not been realized. As a result, the Court turned its analysis to the data points and found those data points as being subject matter ineligible because they expressed a principle of nature. The Court then held that the claim as a whole was subject matter ineligible. Simply put, the Court’s reasoning and conclusion regarding subject matter ineligibility in *Prometheus* was incorrect.

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*. Using the flowchart in the *Guidance* (not the proposed flowchart) the Court’s reasoning should have been as follows:

- a) Does the invention fall within a statutory class? Yes- a method
- b) Does the invention recite or involve a judicial exception? Yes- a natural principle or abstract idea (the data points)
- c) Does the claim as a whole recite something significantly different than the judicial exception? Yes- it includes the steps of “administering” and “determining”, both of which are not inconsequential in the pharmaceutical industry and both of which require human intervention.

- d) **First finding:** the claim is subject matter eligible. This is where the Court erred.
- e) Is the claim as a whole patentable under sections 102 and 103? No- the steps of “administering” and “determining” were already known in the art, and the correlation between drug dose and plasma concentration of metabolite were already known. Prometheus recognized the importance of the two data points but did not affirmatively recite any significant step that is conducted as a result of one having identified the data point. As a result, recitation of the data points does not “integrate the judicial exception(s) into a particular practical application” of the judicial exception.
- f) **Second finding:** the claim as a whole is unpatentable.

Accordingly, the Court should have found Prometheus’ claims subject matter eligible but unpatentable and thus still invalid.

It is worth noting that the claims of Prometheus would more likely have been found subject matter eligible and perhaps even valid if they had affirmatively recited the steps of “increasing the amount of drug administered when the level of 6-thioguanine is less than about 230 pmol per 8×10^8 red blood cells” or “decreasing the amount of drug administered when the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells”, of course, provided that clinicians at the time were not already inherently practicing such dose escalation or de-escalation steps.

Factors f) and j) concern whether or not the “claim recites one or more elements/ steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.”

Comment: There are at least two major problems with these factors.

First, subject matter eligibility considerations differ substantially when considering a natural product versus a law of nature or natural principle as discussed above. A claim directed to a composition of matter is statutorily subject matter eligible under section 101. The only relevant question to ask then is whether or not the composition of matter is patentable under the remaining statutes. A law of nature or natural principle is not necessarily subject matter eligible specifically because the law or principle. The importance of this distinction is discussed above as part of the basis for proposed flowchart.

Second, this determination falls squarely within the “patentability” considerations of sections 102 and 103. It is not properly part of a 101 analysis, because it considers the relative level of understanding in the prior art, i.e. “a feature that is more than well-understood, purely conventional or routine in the relevant field”. Inclusion of this factor within the *Guidance* for determination of “subject matter eligibility” is improper and merely propagates the confusion that has arisen due to generalization of the various different concepts put forth by the Court in *Myriad* and *Mayo v Prometheus*. The question of whether or not a feature in the claim is “more than well-understood, purely conventional or routine in the relevant field” is a question arising out of a 102/103 analysis not out of a subject matter eligibility analysis.

Finally, the *Guidance* is missing factors directed specifically to a method/process claim, for example as factor a) is directed to product claim. If the factors and flowchart proponed in the *Guidance* are to be maintained, albeit with some modification, they should provide a fork early in the subject matter eligibility determination such that a process is considered differently than a machine, manufacture or composition of matter.

Additional Comments

The *Guidance* fails to provide any useful instruction on determination of the statutory category. While it may seem a trivial determination, it is important to make a determination that is commensurate with both the literal language of the statute and the legislative intent.

How does one determine what a claim as a whole is “directed to”?

What are the metes and bounds of the terms “process, machine, manufacture, composition of matter”?

What is the purported lack of clarity in these terms that somehow justifies the need for judicial exceptions?